THE PRINCIPLE OF GENERIC CONSISTENCY AS THE SUPREME PRINCIPLE OF HUMAN RIGHTS AND THE INTERPRETATION OF ORDRE PUBLIC AND MORALITY IN EU PATENT LAW

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THE PRINCIPLE OF GENERIC CONSISTENCY AS THE SUPREME PRINCIPLE OF HUMAN RIGHTS AND THE INTERPRETATION OF *ORDRE PUBLIC* AND MORALITY IN EU PATENT LAW

Submitted for the Degree of Doctor of Philosophy

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2016

ABSTRACT

This research explores how the Court of Justice of the European Union and European Patent Office should interpret the immorality exclusions to patentability, particularly of biotechnological inventions, through the lens of EU constitutional law. After analysing the application of previous and current balancing tests in hypothetical patent cases and historical decisions made by the organs of the European Patent Organization (EPO) and the Court of Justice of the European Union, the thesis proposes a concept-theoretic position for balancing competing rights under EU patent law. This framework is built around Alan Gewirth's Principle of Generic Consistency (PGC). The thesis seeks to defend this framework by showing that it is not only applicable to current judicial decisions, but that it does no violence to the provisions of the European Patent Convention, the EU Biotechnology Directive and the European Convention on Human Rights, and is, indeed, applicable in any legal system committed to the universal principles of human rights. The framework is particularly useful in having the capacity to adjudicate conflicting rights. Apart from this adjudication, in line with a broad concept of morality, a co-operative model of the relationship between morality and patentability built upon the key idea that, although the two sets of values can come into conflict, they can also support each other. The thesis applies the concept-theoretic position to three separate contexts: the European patent system, the United States patent system, and on hypothetical cases which were never brought to the court. Using the 'criterion of degree of needfulness for action', the thesis successfully analyses balancing rights scenarios in a way which results in consistent and rational decisions.

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DECLARATION

I hereby declare that no portion of the work that appears in this study has been used in support of an application of another degree in qualification to this or any other university or institutions of learning.

STATEMENT OF COPYRIGHT

ACKNOWLEDGMENTS

My thanks are due to all who facilitated the completion of this PhD. I would like to express my appreciation and thanks to Professor Deryck Beyleveld for his insightful interim supervision. Deryck's expert guidance, knowledge, support and enthusiasm have been invaluable and, without him, this thesis would not have been possible. I would also like to thank my secondary supervisor, Dr Mike Adcock, who has given his time and guidance. His understanding, kindness, and support were invaluable.

My examiners assisted me generously and provided constructive comments at the viva. My special gratitude goes to Professor Richard Goldberg of Durham University and to Professor Stuart Toddington of Huddersfield University. Academically, this work is a product of the richness my encounters with several fields of thought. I thank all those who have been my colleagues and intellectual interlocutors. I am especially grateful to my colleagues at the Durham Centre for Ethics and Law in the Life Sciences for inspiring and thought-provoking academic events. I extend thanks to the members of 'Gewirth Fan Club', particularly Joshua Jowitt and Clayton O'Neil, for sharing their thoughts and words, for their generous advice, and for their insightful suggestions.

On a more personal note, I want to thank my family. I thank my loving parents and my sister for their unconditional love and care. I am also grateful to my husband for his unwavering support, the generosity of his love, and his encouragement. I would not have made it this far without them.

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U.S.

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UK

Human Fertilisation and Embryology Act 1990

LIST OF ABBREVIATIONS

ASA Argument from the Sufficiency of Agency

Biotechnology Directive/Directive European Parliament and Council Directive on the egal protection of biotechnological inventions

CJEU the Court of Justice of European Union

ECJ European Court of Justice

ECHR European Convention on Human Rights and Fundamental Freedom

ECtHR European Court of Human Rights

EPC European Patent Convention

EPO European Patent Organisation

EU European Union

GCA Generic Conditions of Agency

HRA Human Rights Act 1998

ICCPR International Covenant on Civil and Political Rights

ICESC International Covenant on Economic Social and Cultural Rights

LPU Principle of Universalisability

NIH National Institute of Health

PGC Principle of Generic Consistency

TEU Treaty on European Union

TFEU Treaty on the Functioning of the European Union

TRIPs Trade Related Aspects of Intellectual Property Rights

UDHR Universal Declaration of Human Rights

UK United Kingdom

USA United States of America

hESC Human Embryonic Stem Cell Research

CHAPTER I

THE PROBLEM OF MORALITY EXCLUSIONS WITHIN BIOTECHNOLOGY PATENTS

1.1 Introduction

This thesis aims to conceptualise and apply a framework for the interpretation of morality exclusions in EU patent law. This chapter provides brief background information on the topic of the dissertation, surveys the relevant literature, states the aims of the dissertation, explains its methodology and provides an overview of the dissertation's structure.

The thesis consists of two main parts. The first part formulates, explains, and provides a justification for a normative framework for the interpretation of morality. In the second part, the framework is applied to the activities, judgments, statutes, cases, problems and issues within the European Union, and to some extent in the United States, in relation to patenting of biotechnological inventions. In addition to examining real life judgments, statutes, cases and problems, the thesis examines hypothetical cases which have not been considered in the European Patent Office or the CJEU. The thesis applies the concept-theoretic framework to see whether the law complies with the PGC and makes a comparison between decisions made or likely to be made on the basis of precedents,

and/or the objections and opposition raised in each case AND what these institutions ought to do, according to the requirements of the theoretical framework.

1.2 Research Background

In recent decades, different fields of genomics, molecular biology, biotechnology and molecular medicine have advanced considerably. These advances have had considerable impact on the commercial activities of pharmaceutical firms and those generally seeking to market healthcare. Patenting products for medical treatment and healthcare is viewed as crucial for the exploitation of scientific advances. However, the unfettered patenting of biotechnological inventions is challenged by legal limitation and prohibitions, which include prohibitions on the ground of being contrary to *ordre public* and morality. European patent law is driven by the combination of the European Patent Convention 1973 (EPC) and the 1998 EU Directive on the Legal Protection of Biotechnological Inventions (Biotechnology Directive)[1]and its implementation, together with relevant EU and EPO cases. Before starting the main arguments, the use of the term 'European patent system' in this dissertation needs to be clarified. It is used to refer to a combination of the European Union and European Patent Office position. It therefore may include analysis of the content of European Patent Convention, European Patent Office cases and decisions, EU Biotechnology Directive and the Court of Justice of the European Union's preliminary rulings.

Morality exclusion provisions are contained in European patent law, but are not explicit in United States (U.S.) patent law. These provisions are contained mainly in Article 53a of the EPC 1973, covering patents generally and now in Directive 98/44 EC, which is

[1]Directive 98/44/ECof the European Parliament and the Council of 6 July 1998 on legal protection of biotechnological inventions [1998] OJ L213/13 (Biotechnology Directive).

confined to patents for biotechnological inventions. The principal provisions of the EU Directive are Articles 5 and 6. Article 5 begins with clarification on the patentability status of the human body, 'The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.' It further provides that 'An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.' Finally, it provides that 'the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.' Article 6 provides that 'inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. It later provides a non-exhaustive list of unpatentable inventions including (a) processes for cloning human beings;(b) processes for modifying the germ line genetic identity of human beings;(c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.'

In contrast to the European position, the USA does not make moral permissibility an explicit requirement for the grant of a patent and several biotechnology patents, including for human embryonic stem cells, have been granted so far. In the USA, the key case was the 1980 Supreme Court decision in *Diamond v Chakrabarty*[2]where 'it

[2]*Diamond v Chakrabarty* 447 U.S. Supreme Court 303, 79-136(1980).

was ruled that a "man-made" bacterium able to break down crude oil is patentable subject-matter' thus enabling patents such as the 1988 'Harvard mouse' to be granted (Schutt2004,p.7).

Considering the current European position as explained above, the main area which this thesis will focus on is the interpretation of concepts of *ordre public* and morality in European patent law. Therefore, this thesis seeks to explore challenges towards the interpretation of the concept of morality within patent law. This will assist in evaluating whether there has been a consistent approach in decisions made by European Patent Office and the Court of Justice of the European Union (CJEU) in relevant patent cases, and suggest a concept-theoretic position to solve the problem of interpretation of law and balancing rights.

1.3 The Basic Legal Framework

This section examines arguments on the patentability requirements within European position and United States law. Addressing the European position, two central pieces of European patent law will be analysed: the European Patent Convention and the EU Directive on the Legal Protection of Biotechnological Inventions. I will then relate the relevant provisions to clauses about morality provisions in the Trade Related Aspects of Intellectual Property Rights 1994 (TRIPS) agreement.[3]

1.3.1 The European Position

This section provides a brief background to the structure of the European patent system, and the morality exclusions in two relevant pieces of legislation: the European Patent

[3]Trade Related Aspects of Intellectual Property Rights (TRIPS) 1994 agreement does not include morality provisions, though it permits them.

Convention and the EU Directive on the Legal Protection of Biotechnological Inventions.

In this research, I submit that the European position has incorporated human rights into its law as its fundamental principles, which enshrines the importance of morality in the law. Given that human rights are, by the nature of their concepts, moral rights, the inclusion of morality in European law evidences the clear commitment of this law to human rights. It is also crucial to understand that the EU in particular called for a harmonised system through the implementation of the Biotech Directive. This being the case, there is a requirement that the idea of morality is not different from one society to another. Here we have a clear message that European law must be in conformity with human rights, and the law cannot allow activities which violate the fundamental principles of EU law. This is clearly evident from many EU provisions including Article 6 of the Treaty on European Union (TEU)[4], on the importance of human rights as a fundamental principle in EU, and further, by the incorporation of the European Charter of Fundamental Rights and Freedoms[5] into the EU Constitution. Consequently, as long as these principles maintain as a part of the CJEU decisions, various treaties and the constitution of the EU, they must be complied with. Since the fundamental principles of EU law includes human rights, if the Member States have a law which is not compatible with EU law, that law must be considered void. It follows that failure to give such status to human rights (as moral rights) in EU law means 'to repudiate acceptance of human rights per UDHR or ECHR.'(Adcock & Beyleveld Working Papaer, p.4).

With regard to the concepts of *ordre public*, the fundamental principle of EU law, and respect for human dignity, it is arguable that there is no need to have a legal provision

[4]Consolidated Version of the Treaty on European Union [2008] OJ C115/13.
[5]Charter of Fundamental Rights of The European Union [2012] OJ C 326/391

and/or specific morality exclusions to identify the activities violating the *ordre public* and morality, if one deeply understands the concepts of *ordre public* and morality. The *ordre public* in its French terminology is defined as 'the basic structure of a state governed by the rule of law, or in other words, a proper democratic republic' (Lange *et al*.2007,p.8).However, such a definition is to some extent dissimilar to 'public policy' instances, the English version referred to in the CJEU case law. An alternative definition by Jong (2000, p 204) is the concept of *ordre public* as a means to maintain the sets of values or interests that are considered very crucial and necessary for a particular society or legal system. In fact, such principles constitute a 'system of positive law' that holds superior value and interest for individuals in the society (Schokkenbroek 1986, pp.4-5, 7).Gerhard Van der Schyff (2006, pp.149-150) with reference to Alexandre Kiss's work (1981, p.290)in trying to determine the borders of *ordre public*/public order declares:

> …it is a concept that is not absolute or precise, and cannot be reduced to a rigid formula but must remain a function of time, place and circumstances. In both civil and common law systems, it requires someone of independence and authority to apply it by evaluating the different interests in each case (Van der Schyff 2006, pp.149-150).

Having briefly addressed the terminology of *ordre public*, it is evident that regardless of the definition adopted for this concept, these principles are fundamental principles and moral values that a society has to believe in if it is committed to democracy and the rule of law. Principles of *Ordre public* are moral values that individuals in a society have to embrace when they are committed to democracy and the rule of law. *Ordre public* in a way is a special subset of moral principles; in other words, they are political moral principles. This implies that to offend against *ordre public* is to offend against values

which are necessary for the foundation and existence of a civil society governed by democracy and the rule of law.

Furthermore, for the concept of *ordre public* to have its meaning, it is required to protect the fundamental rights under EU law. These fundamental rights are enshrined in the European Convention on Human Rights (ECHR)[6], and enforced by the European Court of Human Rights (ECtHR) and other organs of the Council of Europe. Fundamental principles of EU law are principles which are categorically binding and form a part of the EU legal order. Therefore, human rights are fundamental principles in EU law. In terms of the relevance of human rights to the notion of morality, the recognition of human rights by EU law is the recognition of moral principles. Human rights are supposed to have characteristics of impartiality, and ought to be categorically binding in relation to humans. These are the characteristics of morality. Therefore, human rights are moral values.

All in all, the European position rightly incorporates both *ordre public* and morality in its patent law to safeguard the fundamental principles of EU law, human rights, and the fundamental principles of rule of law. This would be elaborated further throughout the thesis. In the sections below, a brief background is given on the relevant Articles within European legislation, the European Patent Convention and the Biotechnology Directive.

1.3.1.1 The European Patent Convention

European patent law encompasses a wide range of legislation, including national legislation, the European Patent Convention (EPC) and relevant European Union (EU) directives and regulation, most importantly the European Directive on Legal Protection

[6]Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR) [1950].

of Biotechnological Inventions. International agreements including the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights(TRIPS Agreement), the Patent Law Treaty (2000) and the London Agreement(2000) have a significant role in shaping European patent law. The European Patent Convention was an effort to overcome different problems of the patent system, including the need to file a separate patent application in each country, and the need to translate the text of application into different European languages. The EPC aimed to centralise the prosecution of patents in one language and suspend the cost of translation until the time of the grant, although a translation may still be required after the grant of the patent to validate it in a specific contracting state. In October 1973, the Convention on the Grant of European Patents, known as the European Patent Convention was established as a multilateral treaty that institutionalised the European Patent Organization. This convention empowers the European Patent Office (EPO) to grant or deny a patent.[7]

It is important to bear in mind that the European Patent Office (EPO), as an international organisation established by the European Patent Convention (EPC), is not a European Union or a Council of Europe institution and it has a different system of membership. There are countries like Switzerland, Liechtenstein, Turkey, Monaco, Iceland, Norway, the Republic of Macedonia, San Marino, Albania and Serbia that are members of the EPO but not of the EU (EPO 2015a). Similarly, since the European Union was not a party to the European Patent Convention instituting the European Patent Organisation it is not European Union legislation. However, all Member States of the EU are parties to the EPC.

Article 53 of the European Patent Convention (EPC) excludes from patentability

[7]European Patent Convention, Preamble.

> inventions the commercial exploitation of which would be contrary to *ordre public* or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

To support this Article, Rule 28(c) EPC provides that: "Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following ... uses of human embryos for industrial or commercial purposes." Therefore, under Article 53 EPC, inventions must be excluded from patentability on the ground of morality or *ordre public.*

The opposition procedure in patent law means that even after grant of a patent, its validity can be still challenged in legal proceeding to enforce it. [8] This means A third party, which can be any person except the patent applicant , is entitled to oppose a granted patent which may result in the patent office reconsider the grant of the patent, or the patent revoked, or amended .[9]

Since European patents do not have unitary effect and enforcement proceedings are required to take place in each member state, and protection offered is through the patent law of each Member States and varied in national laws in question, twenty-five EU Member States[10]reached an international agreement[11]to establish a Unified Patent Court (UPC).[12]Two main regulations of the UPC agreement were approved by the European Council in June 2012 and by the in December 2012(European Parliament 2012). The UPC, as a specialised judicial authority, consists of a Court of

[8] The time limit for opposition procedure is within nine months of the grant of the European patent.

[9] Apart from protection through EPO, patent granted by national patents are also available in all European countries and it may be less expensive to apply for several national patents instead of making application for European patent before the EPO (Bossung 1996).

[10] All Member States except Croatia, Poland, and Spain are party to UPC (Chalmers *et al*.2014, p.173).

[12] Agreement on Unified Patent Court [2013]OJ C175/01 (UPC)

First Instance, a Court of Appeal and a Registry.[13] The idea of a European community patent system, with the ultimate aim of creating a patent valid across all European jurisdiction and avoid being at risk of go over challenges in different national courts, has been debated since the 1970s. Unlike the CJEU, which only interpreted EU law, the UPC is given the authority to interpret national law together with international and EU law (Chalmers *et al.* 2014, p.173).Furthermore, it seems that unlike the EPO, the European and Community Patent court (ECPC) would be entitled to refer a question of EU law to the CJEU for a preliminary ruling. The CJEU however declared the new court as illegitimate since it would remove the prerogative of national courts to decide issue of EU law themselves.[14] EU constitutional principles on competency of members states provides that national courts are entrusted and required to deal with interpretation and application of both national and EU law and to delegate their competency to an international tribunal should not be allowed under EU law (Parish 2012, pp. 141-153).

The latest update on enforcement of the agreement shows that Finland, as the ninth Member State[15], completed the ratification stage on January 2016 and this means the completion of the ratification process by two more countries, in addition to the UK and Germany which are the mandatory parties, brings the unified patent system into effect (Von Hertzen 2016). On 12 March 2016,the draft secondary legislation was made (after being approved by both Houses of Parliament)in order to amend the UK Patents Act and to give effect to the UPC Agreement and relevant EU legislations (Bacon 2016). It

[13] UPC art 6(1).
[14] The CJEU in Opinion 1/09 (Unified Patent Litigation System) of 8 March 2011 stated: 'the member States cannot confer the jurisdiction to resolve . . . disputes [about patents] on a court created by an international agreement which would deprive those courts of their task, as 'ordinary' courts within the European Union legal order, to implement European Union law and, thereby, of the power provided for in Article 267 TFEU, or, as the case may be, the obligation, to refer questions for a preliminary ruling in the field concerned. The draft agreement provides for a preliminary ruling mechanism which reserves, within the scope of that agreement, the power to refer questions for a preliminary ruling to the PC while removing that power from national courts. . .The tasks attributed to the national courts and to the Court of Justice respectively are indispensable to the preservation of the very nature of the law established by the Treaties'.
[15] After Austria, Belgium, Denmark, France, Luxembourg, Malta, Portugal and Sweden.

is expected that three months after the deposit of all relevant instruments of ratification, the Unified Patent Court starts working officially (Von Hertzen 2016).

1.3.1.2 The Directive on Legal Protection of Biotechnological Invention

The first draft of the Directive on the Legal Protection of Biotechnological Invention was introduced in 1988.The Directive aims to encourage research and innovation and to improve biotechnological investment in Europe. The Directive can be seen as a response to the patent activity of the USA and Japan between 1981 and 1995 in which 70% of patents granted by EPO belonged to above-mentioned countries. In 1998, the Biotechnology Directive was adopted after 10 years of debate. Although the EPC was already in existence, it was considered that the complex process required to make amendments to the EPC could be circumvented by a Directive. However, implementation of the Directive was not trouble free. Although all members of the EU were required to implement the Directive by the 30th July 2000, only six members had done so by 2002. There are also differences in terms of how long implementation failed. The UK was the first to implement (2000 and 2001), whilst France took 53 months.[16]

Regarding the normative elements of the Directive, in addition to a number of recitals, Articles 5 and 6 of the directive are of special importance. Article 5 mainly concerns requirements for patenting the human body in different stages of its formation and development, elements isolated from the human body and industrial application of a sequence of a gene.Article 6(1) of the directive reads as follows;

> Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however,

[16]European Commission, Communication on development and implications of patent law in the field of biotechnology and genetic engineering, COM (2002) 545 final [Not published in the Official Journal].

exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.[17]

Article 6.2 aims to provide a guide for national courts and patent offices in the interpretation of Article 6.1 by providing some examples of inventions contrary to *ordre public* and morality,[18] which are not an exhaustive according to Recital 38 of the Directive.[19]

The Directive does not copy the EPC; whilst Article 53 of the EPC excludes from patentability inventions the 'publication' or 'commercial exploitation' of which is contrary to *order public* or morality, the Directive excludes inventions only when their 'commercial exploitation' is contrary to *ordre public* and morality. However, the EPC has now been brought substantially in line with the Directive through Rule 28 of EPC, which excludes from patentability "(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes".

Another crucial issue in the Directive's Articles and Recitals is the emphasis given to the concept of 'human dignity' as the foundation of human rights and the Preamble to three constituent instruments: the Universal Declaration on Human Rights (1948), the International Covenant on Civil and Political Rights (1966), and the International Covenant on Economic, Social and Cultural Rights (1966). Specific reference to the concept of human dignity implies that any activity in violation of one's dignity is intrinsically wrong and must be absolutely prohibited. In order to address this, the

[17] Biotechnology Directive art 6.1.
[18] Biotechnology Directive art 6.2 lists a numbers of unpatentable inventions as following:"(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; c. uses of human embryos for industrial or commercial purposes (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes".
[19] Biotechnology Directive Recital 38.

Directive sets a number of specific examples for patentability exclusions. This means that the examples for patentability exclusion are often considered as contrary to *ordre public* and morality. However, we must be vigilant to the possibility of any abuse or misunderstandings resulting from interpretation of morality as there have been warnings about 'the loose cannon of the concept of human dignity' that may result in 'oversimplifying complex questions' and 'encouraging the paternalism' that is not consistent with the essence of 'self-determination' as a basis for the human rights debates (Beyleveld & Brownsword 1998, p. 662).

Living in such a dilemmatic world, the crucial question becomes 'how can we appropriately and accurately define the associated subjects of the moral of society including human dignity?' It is noted that the Directive made changes in the wording of the EPO in terms of exclusions of patentability. Hence, whilst Article 53 of the EPC excludes from patentability, inventions which the publication or commercial exploitation of them is contrary to *ordre public* or morality, the Directive specifies the situations in which the commercial exploitation is likely to be contrary to *ordre public* or morality. Having compared the morality exclusions in the EPC and the Directive, it is evident that the EU Directive is expanded when compared to the general exclusion stated in the EPC. However, claims are regularly made that the specific references to subject matters excluded in the EU Directive are not clearly reasoned.[20]In addition, the cases listed under morality and *ordre public* exclusions in the Directive are in substance, the same as what is stated under Article 52(a) section 1(3).[21]

[20]This will be further discussed in subsequent chapters.

[21]Rule 28 of the EPC excludes from patentability "(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; uses of human embryos for industrial or commercial purpose".

Article 52(a) section 1(3) provides that Paragraph 2 of this art shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

1.3.2 The United States Position

The United States position in the integration of morality and patent rights is dissimilar to the European position. Article 1-section 8.8 of United States Patent Law is one of the clear references to intellectual property rights recognised in the Constitution and it states

Congress shall have the Power:

> To Promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their Writings and Discoveries.

The above statement demonstrates the fact that the patent and copyright laws are identified in the Constitution. Congress legislates on it and federal courts adjudicate the relevant laws. Historically, the current patent system in the U.S. originated in 1449 inspired by the British patent regime. Evidently, this system followed from the British tradition of patents and was transferred to the U.S. through colonialism. Patent Act 1790 was the first patent Act passed by the federal government of the United States. Thomas Jefferson wrote and administered the first Patent Act in 1793 on which the foundation of the current US patent system was laid.[22]The requirements and conditions of a 'Patentable Subject Matter' were eventually developed to cover “Any New or Useful Art, Machine, Manufacture, or Composition of Matter”.[23]The position of the U.S. patent law in relation to morality exclusion is well researched in literature and it is clearly evident that U.S. patent practitioners generally prefer that the U.S. adopts a neutral patent system with no place for morality.

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[22] However, several important changes happened in Patent Act 1836 including the examination of patent applications prior to issuing a patent, recruiting professional patent examiners, and the establishment of a library of prior art to help examiner in examination process.

[23]35 USC. Sec. 101.

It is however necessary to review the United States patent law historically and more in-depth in order to learn about any direct or indirect reference to morality. As a matter of fact, it is crucial to relate the position of the U.S. Constitution to the current patent law, as it is clear that the U.S. Constitution takes hierarchical precedence over federal statutory law, state constitutions, state statutory law, local ordinances, administrative rules and rulings and common law. Furthermore, within the case law, the 'doctrine of moral utility' which has been used in the past to prohibit the granting of patents on medicines with questionable safety, misleading products, and gambling machines, is another matter which questions the morally neutral position of the United States patent law. Finally, there have been examples of unpatentable inventions in US biotechnology patents without using the terms 'morally problematic'. For instance, patenting humans is denied in practice (McCallum 2005). The U.S. law instead relates this to patentability of living subject matters. Thus, the United States Patent and Trademark Office (2012) in Manual of Patent Examining Procedure asserts 'If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under35 U.S.C. 101 must be made', thus indicating that the claimed invention is directed to non-statutory subject matter. Furthermore, the 'claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under 35 U.S.C. 102, 103, or 112 must also be made'.

in later parts of this thesis I will examine whether the European system is a better or worse model to address the patentability question with reference to the concept of morality. Furthermore, it will be argued that the U.S patent system ought to accept and apply the concept-theoretic position in order to adjudicate conflicting rights effectively in its patent system.

1.3.3 International Instruments

This section relates the European provisions to Trade Related Aspects of Intellectual Property Rights (TRIPS), an international agreement by which the World Trade Organization (WTO) attempted to establish minimum standards in different aspects of Intellectual Property (IP) law for WTO members.[24] The idea for this agreement was negotiated in 1994 (Sell 2003). Article 27.1 of TRIPS asserts that patent rights shall be enjoyed without discrimination based on the place of invention, field of technology, and regardless of whether products are imported from another origin or are locally produced. There are, however, a number of requirements for patentability for all inventions, whether products or processes. These general requirements include: being new; involving an inventive step; being capable of industrial application; being disclosed in a sufficiently clear and complete manner for the invention to be carried out by a person skilled in art; and being disclosed in the best manner to indicate the best mode to carry out the invention based on the best knowledge of the inventor at the time of filing or priority date of application. Following this, Article 27.2 and Article 27.3 provide information regarding the field of technology in which patents may be rejected.

Article 27.2 permits (but does not require) members to exclude from patentability "inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality,…."followed by a number of examples for further clarification of the issue.[25]

Part 3 of Article 27, provides specific provisions dealing with biotechnological inventions which allows the exclusion of patentability in a number of specific areas namely;(a) diagnostic, therapeutic and surgical methods for the treatment of humans or

[24]TRIPS Art. 1(3).

[25]TRIPS Art. 27.2. Examples include *"to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law".*

animals; (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.The crucial issue which should be taken into consideration, particularly in relation to the concept of *ordre public* and morality, is that the wording of the provision gives the impression that the risk must be associated to the commercial exploitation of invention, and not to the invention itself. Thus, under TRIPS, this exclusion is not meant to apply to non-commercial uses of the invention including scientific research. However, this is not a sound assumption.

Permitting activities which are in violation of *ordre public* and morality, even for non-commercial purposes, is not compatible with the essence of morality exclusions in law. This is simply because patent laws are about granting patents. Therefore, it is necessary that the laws makes exceptions about the actual patenting. However, this does not mean that activities prior to patenting need not be regulated. Furthermore, it provides that, if to grant a patent would be contrary to *ordre public* and morality, a patent will not be granted. Considering this, the regulatory body has made efforts showing that the concept of morality should be considered in the process of decision making in patent applications. This means that if the patent process at any stage involves any activities in violation of *ordre public* and morality, the patent will not be granted.[26]

[26]In the context of EU law, reviewing the aim of the Biotechnology Directive (particularly reading its Preamble), it is clear that the European Union legislators emphasises the need to exclude from patentability, any invention which affects the respect for human dignity in any way. In addition, the European case law e.g. paragraph 34 CJEU's decision in *Brustle* case provides that: 'the context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of 'human embryo' within the meaning of Article 6(2)(c) of the Directive must be understood in a wide sense'.

1.4 Contribution to the Relevant Literature

This section begins with a brief outline of the problems in judgments or reasoning used in the European Patent Office or the CJEU (section 1.4.1). The section provides a brief introduction to the changes in approaches adopted by the EPO in addressing morality exclusions. This introduction aims to clarify the notion of morality employed within the context of EU patent law. In1.4.2, the section concludes with a brief outline of current research implications, which is that arguments based on 'ethical rationality' can be used to shed light on proposing a framework for permissibility of actions in the patent law. This is adopted later in the thesis, and plays an important role in my argument in justifying the concept-theoretic position.

1.4.1 The Problem with the Current System

The European Patent Office and the Court of Justice of the European Union have dealt with the issues around the interpretation of the concept of morality inconsistently, based on the choice of analysis they have adopted. This research aims to investigate the decisions of examiners in different patent applications in the EPO, and the decision of judges in the CJEU. This is in order to understand their difficulties in following what is so called a 'rational approach' (Beyleveld& Brownsword 1993).

To this end, there has to be a unique framework which provides a guideline for proper interpretation of morality exclusions. This is in order to ensure that the examiners in the Patent Office make their moral judgements, based on the legal instruments within the EU framework, for instance, the European Convention on Human Right as a binding source, and a foundation for legal judgements of the European patent officers (Beyleveld & Brownsword 1993). Problematically, the Convention itself and other human right instruments (e.g. Universal Declaration of Human Right) do not specify

any hierarchy in relation to rights specified in the document in order to enable judges or courts to decide consistently in cases of conflicting rights (Beyleveld and Brownsword 2001, p. 85).

The approach taken regarding interpretation of morality in European patent law has changed. Therefore, a clear difference is recognisable between the initial decisions (e.g. the *Oncomouse* case) to more recent cases (e.g *Brustle*).In the former case the EPO Examining Division claimed that the patent system is not an appropriate scene or the right 'legislative tool' to analyse the morality and *ordre public* related issues,[27]whereas in the latter case the concept of *ordre publ*ic and morality was viewed as an overriding factor. The *Brustle* judgment supports the idea that patent law should be in compliance with these concepts and is not to be considered a morally neutral system of law (Torremans 2009, p.288). [28] However, there have often been disagreements and uncertainty in the EU regarding how the CJEU or EPO ought to make decisions in relation to the interpretation of morality exclusions in patent law, and uncertainties about their reference to a common European concept of morality, and the evaluation of a specific invention based on moral concerns which may appear in a particular Member State about patenting an invention.

1.4.2 The Value of Current Research in Defining the Status of Immorality Exclusions and its Interpretation

There are a number of specific implications which the interpretation of immorality exclusions, the main objective of this research, would contribute to literature in law.

[27]T0019/90 *Oncomouse* [1989] OJEPO 451.

[28]In later chapters of this thesis, it will be further explained how such change occurred in interpretation of exclusions.

Firstly, the research would assist in clarifying the position of immorality exclusions as ineradicable (Adcock & Beyleveld in press, p.6). This means that logically, it should be possible to exclude some activities from patenting, even if the Biotechnology Directive never specifically lists any morality and *ordre public* exclusions. Furthermore, this interpretation helps to identify the proper focus for immorality exclusion. Granting the patent would be prohibited if it is contrary to *ordre public* or morality, including, when commercial exploitation of the invention (independently of consideration of patenting) would be contrary to *ordre public* and morality. This only serves the purposes of the Directive (e.g. preventing violation of human rights). A clear example of mistake in the determination of proper focus of immorality exclusions occurred in the case of *WARF*[29].The courts make a mistake when they do not focus on the question of whether patenting is contrary to *ordre public* and morality. Instead, the court stated that we have to focus on the commercial exploitation of an invention. However, the court ought to ask the question of whether it is contrary to *ordre public* and morality to grant a patent to this invention. Patenting is not contrary to *ordre public* and morality merely because it is patenting. It is only contrary to *ordre public* and morality if the patenting involves activities which renders the grant of patent contrary to *ordre public* and morality.[30]

On the other hand, there is a tendency for the Patent Office to make narrow immorality exclusions operative.[31]The current practice of the Patent Office is to opt for the least

[29]T 1374/04*Use of Embryos/WARF* [2008] OJEPO 31.

[30] The Enlarged Board of Appeal of the European Patent Organisation (EPO) in the WARF Case G0002/06 at 29: 'This Board considers the performing of this invention as commercial exploitation. In this context, it is important to point out that it is not the fact of the patenting itself that is considered to be against *ordre public* or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts.'

[31] For instance, it is reported as made by the applicant *WARF* (in the Appeal against the decision of the Examining Division of the EPO in the Decision of the Board of Appeal T 1374/04, 3 March 2008) that the narrow interpretation of human embryo (a definition that implies a broad concept of morality exclusion) involves the court making a moral value judgment and it is not the role of the courts to make their own moral judgments, but a broad interpretation would not do.

restrictive interpretation, which is appropriate, but to the extent that no fundamental values or rights are involved. Although there are some other implications for conducting research on the interpretation of immorality exclusion provisions, one can see merely from the above issues that it could be concluded that there have been cases in which European Patent Office and/or the CJEU have been fundamentally mistaken about the issues over the morality of patent law and there are still inconsistencies and inadequacies in the interpretation of these exclusions. Considering the above, there is the need for an effective framework to interpret the immorality exclusions in order to ensure the future judgments of courts in relation to interpretation of morality and assessment of rights will be influenced, directed and changed positively.

Furthermore, as discussed previously, the morality provisions have received opposition by patent practitioners and large corporations that rely on patents to recoup their commercial investments. Objections include claims that it is not the concern of patent law to try to regulate immoral activities; this should be done in other areas of law since the concern of patent law is not anything but the granting of a patent. Similarly, there are claims that morality is not the business of the law, as law and morality are conceptually distinct (Gummer 2012).There have even been objection on the basis of judges and patents officers lack competency in the assessment of morality. Morality provisions are also objected on the nature of the concept of morality claiming that what morality consists of is contested and not agreed and these provisions produce uncertainty in the law (Crespi 1997, pp.123-129).These are objections to show that morality exclusions have no place in patent law. The dissertation will address these objections on the basis of a 'concept-theoretic' position outlined by Adcock and Beyleveld (Working Paper, p.1-23).

This position has two principal foundational components. The first is that a commitment to human rights is contained in the legal systems of all European countries and the EU itself has such a commitment enshrined in its constitution. The second is the moral theory of Alan Gewirth. Following Beyleveld (2012) it will be argued that provided that the first stage of Gewirth's argument for the PGC is sound, any person or system of rules that accepts that's there are human rights is bound, on pain of either contradicting that commitment or denying the intelligibility of rules, to accept the PGC.

To sum up, the situation can be improved for the courts if they adopt a unified applicable theoretical framework, which guides them on how to make decisions in relation to morality exclusions and competing rights. Through the next chapters, this thesis will examine how the adoption of a PGC-based framework will benefit the EU patent system in defining and interpreting the concept of morality and the rights under this concept.

1.5 Aims, Objectives, and Research Questions

The way in which the EPO and the Court of Justice of the European Union have dealt with issue of *ordre public* and morality in patent law has evolved from the initial *Oncomouse* case at the EPO to more recent cases like *Brustle* at the CJEU.

This raises a number of questions that frame this dissertation:

I. Must law have moral criteria as criteria of legal validity?

II. If EU law generally makes moral criteria, criteria of legal validity, must patent law have moral criteria?

III. How exactly should morality be interpreted?

In light of the above research questions, the objectives of the research will be the following:

A. Identify the appropriate theoretical framework to address the research questions
B. Analyse the concept of *ordre public and* morality in EU patent law and decisions made in relevant cases (to examine how the European Patent Office or the Court of Justice of European Union have dealt with actual cases with the question of morality)
C. Implement the proposed applicable framework regarding how these concepts ought to be interpreted

The concept-theoretic position implied will be spelled out and applied to evaluate the position taken by patent courts and examiners in relation to biotechnology patents since the early 1980s, and to rebut the critics of the morality provisions. The framework will also be used to examine a selected number of cases, both real and hypothetical, to show how the concept-theoretic provides a rational and workable solution to the issues concerning morality that they pose that other positions are unable to provide.

1.6 Methodology

In order to answer the research questions, the thesis develops a framework that is based on Alan Gewirth's moral theory, according to which the Principle of Generic Consistency (the PGC) is the supreme principle to judge the permissibility of actions (Gewirth 1978).

1.7 Overview of the Dissertation

To respond to the key research questions, this study is structured into 8 chapters including an introductory section as its first chapter. A brief overview of each chapter is provided below.

This thesis will be presented in two parts. The first part provides an introduction to the topic in Chapter I, followed by two further chapters on development and elaboration of the concept-theoretic position. A PGC-complied framework is developed in two main parts. Chapter II specifically aims to spell out and justify the use of the PGC, and Chapter III spells out the implications of PGC in dealing with the concept of agency and rights in the specific context of bioethics, including sections on the concept-theoretic position in dealing with the question of human embryo and foetus and the question of animal rights.

Chapter II provides my reasons for applying the PGC to assess when granting a patent should be regarded as being contrary to morality. Gewirth himself argues that the PGC is a principle that anyone acting for a purpose or implementing a rule categorically ought to comply with merely on the basis of understanding what it is to act (which includes following a rule). I will outline his argument, as this is necessary to explain what the PGC requires. However, rather than rely on this argument, I will argue that the EU is, for as long as it makes human rights fundamental principles of EU law, committed to the PGC as the supreme principle of human rights.[32]I will explain that the framework proposed in this research is built upon a dialectically contingent argument based on the premise of human rights, and not the dialectically necessary argument of

[32] In so doing I follow Deryck Beyleveld (2012) "The Principle of Generic Consistency as the Supreme Principle of Human Rights". *Human Rights Review* 13, pp. 1-18

Gewirth himself (section 2.1 of this piece).[33]The main function of this chapter, however, is to develop an applicable framework based on the Principle of Generic Consistency, in order to apply it to the subsequent chapters of the thesis. This is useful in addressing the problem of interpretation of rights in patent law, and to defending this concept-theoretic position and its philosophical significance against other available options.

To this end, the basic structure of the Gewirthian Principle of Generic Consistency, as the 'supreme rational reference point for judging the permissibility of all action' (Beyleveld 2012, p.2) is discussed in detail. The PGC provides that all agents categorically ought to respect the generic rights of all agents[34]*, subject to the will of the recipient agent* (Beyleveld 2016, p.1).The principle grants rights to the generic condition of agency to all agents [35](section 2.2). Subsequently, the main idea of Gewirth's 'dialectically necessary argument', the fact that 'agents contradict that they are agents unless they accept that the permissibility of all their actions is to be judged by the PGC' (Beyleveld 2012, pp.3-6) will be discussed. It will be argued that if it can be shown that three propositions are true, then the PGC is the categorical imperative (Beyleveld 2016, p.5). The first proposition is that it is dialectically necessary for agents to accept the 'Principle of Hypothetical Imperatives' (PHI).Beyleveld (2013, p.5) explains the 'Principle of Instrumental Reason' or 'Principle of Hypothetical Imperatives' as: 'If doing X (or having) Y is necessary for Albert to pursue/achieve a goal E, then Albert ought to do X (or act to obtain Y) or give up pursuit of E.' The second proposition is that there are Generic Conditions of Agency (GCAs).The generic rights, rights to generic conditions of agency, are necessary for action or successful

[33] Nevertheless, the dialectically necessary argument will be outlined briefly in this chapter, not to defend it in its entirety, but to explain the alternative approach, the dialectically contingent argument and its limitations and force.

[34] This respect includes 'not to interfere with' and, in certain circumstances, to 'protect' the generic condition of agency of all agents(Beyleveld 2016,p.1)

[35] The term 'agent' used here to mean as 'beings that take voluntary steps in pursuit of their freely chosen purposes, which they treat as reasons for their actions' (Beyleveld and Brownsword 2007, p.39).

action. This is because, as Gewirth (1978, pp. 53-54) notes it, interference with such a condition, or depriving agents of possession of these conditions, needs or interests , negatively affects agent's ability to pursue or achieve its purposes whatever these purposes are. Third, dialectically necessary requirements are universal (Beyleveld 2013, p.4).This is how the 'dialectically necessary' argument is spelled out in this thesis (section 2.3).

Later, I discuss the central problems concerning the 'dialectical necessity' argument. This leads to my justification for the adoption of a contingent model of PGC, built upon the premise of recognition of human rights. To apply Gewirth's theory, I use only the first and the least controversial stage of his argument for the Principle of Generic Consistency, which emphasises the first element of his theory, his claim that PHI is an *priori* (dialectically necessary) principle. I will argue, that supposing the first stage is sound and valid, if I accept that there are human rights, and then combine it with the fact that it is dialectically necessary to accept the Principle of Hypothetical Imperatives, this means that I have to accept the Principle of Generic Consistency or I give up the acceptance of the idea that there are human rights , or show that the Principle of Hypothetical Imperatives are not dialectically necessary (Beyleveld 2012, pp. 6-8).Therefore, the PGC should be accepted by any legal system committed to the very principles of human rights, even if the second stage (whether or not it is dialectically necessary for agents to consider that they have generic rights) and third stage (whether or not it is true that it is dialectically necessary for agents to grant generic rights to other agents)are not valid.This is because the idea of human rights is the idea of universal and impartial interests to certain types of entitlements. It is therefore meant to be categorical.

The arguments in this chapter serve to emphasise the importance of adopting the PGC as a supreme principle of human rights. In other words, I will argue that because of

principal presumptions of European law, there is a need to accept equality in human dignity and human rights, which is an established principle under UDHR and the Preamble to the International Covenant on Civil and Political Rights, as well as many other international instruments which results in the acceptance of the PGC (Beyleveld 2012, p.7). Therefore, if a legal system does believe in the very idea that there ought to be commitment to human right, as categorically binding impartial reason for action, it requires that system to believe in the Principle of Generic Consistency as the supreme principle for human rights. This means that this supreme principle governs that legal system (section 2.4). The concept of agency rights within the concept-theoretic position is also discussed. This includes the middle order principles, issues like positive rights as well as negative rights, and the concept of will-theory (Beyleveld & Brownsword 2001, pp.71-72)**.** It justifies and defends the PGC as a moral principle and the generic rights as rights under the will-conception of rights (section 2.5). This will be followed by a section on the interpretation of competing rights and interest through the PGC, which analyses the existing problems in the system and the solution that PGC is capable of offering (section 2.6). The last section in this chapter is allocated to the clarification on the 'added value' of the PGC. An important aspect of the PGC is that it orders the rights according to the criterion of needfulness for action. Thus, it enables conflicts between rights to be adjudicated in a rational manner (section 2.7).The concept-theoretic position, briefly introduced in chapter II is discussed to the effect that if the PGC is the supreme principle, then all permissible actions must be compatible with the requirements of the PGC.

In **Chapter III**, I examine how the PGC deals with the question of rights to apparent agents/non-agents. I present a variety of scenarios in which the concept-theoretic position applies. To address this, the direct and indirect application of the PGC is first

provided (section 3.2). Analysing the significance of the PGC, the criterion for degree of needfulness for action is explained as a key part of the concept-theoretic position. This criterion is specifically useful in the reconciliation of competing interests and rights. Clearly, the conflict may occur in relation to rights or duties. The discussion in this section will be to the effect that the duty to respect agents; having the more necessary goods must be prioritised over respect attributed to other agents having other goods (Gewirth 1978, p.340). However, in direct application of the PGC in relation to the conflict of rights, varied situations may appear. The rights which are in conflict can be from the same or different levels of importance, based on Gewirth's criteria. Dealing with rights which have the same level of importance, 'the criteria for prevention or removal of inconsistency' must be followed. It means that violating the generic rights of a person or group by another person or group follows the 'transactional inconsistency'. This means that the actions, which occur to prevent or remove such inconsistency, may be justified (Gewirth 1978, p.342).

The next section applies the PGC with regard to the question of property and intellectual property. It begins with Gewirth's original view on the right to property followed by Beyleveld and Brownsword's (2001) argument on the 'rule-preclusionary conception of property' and the reasoning for the right to intellectual property (section 3.3). This is followed by an analysis of the circumstances in which the right of animals is at stake or the right of a human non-agent or future agent (one who does not currently physically exist i.e. embryo or foetus) may be violated (section 3.4).

Chapter IV examines the nature of immorality exclusions in intellectual property law to justify a 'co-operative model' as opposed to a 'conflict model' (Beyleveld 2006, p. 156-158) for interpretation of morality or moral rights and intellectual property rights.

First, it briefly analyses cases brought to European patent authorities in order to examine how the approaches of the patent office in relation to interpretation of morality exclusions have changed. Subsequently the narrow conception to morality is analysed which brings a conflict model of relationship between morality (human rights) and patentability (section 4.2) followed by the broad interpretation of morality and a co-operative model (section 4.3). This section includes arguments over 'wide margin of appreciation' for Member States in interpretation of morality exclusions in patent law (section 4.3.3).This section will be completed by a final section to concluding why a co-operative model needs to be adapted within the European system (section 4.3.4).The chapter defends a broad concept of morality in EU patent law and a co-operative model of relationship between morality and patentability. The co-operative model built upon the key idea that, although the two sets of values can come into conflict, they can also support each other.

Chapter V is the starting point of part II of this thesis. This is where I apply the concept-theoretic position on actual EPO and CJEU patent cases**.** Having analysed the content of the concept-theoretic position, I discuss how a system has to operate in order to comply with the PGC. For this reason, the line of analysis that has been used for the interpretation of competing rights and the decisions which have been made by the courts will be examined carefully and thoroughly. Subsequently, various actual cases decided by the European Patent Office and the Court of Justice of the European Union that dealt with the question of morality will be investigated throughout this chapter (section 5.4 to 5.8). I will consider the decisions of the examiners in different patent applications in EPO or comments of the CJEU to understand their difficulties in presenting consistent arguments and reasoning in historical cases.

Based on analysis of the Gewirthian framework discussed mainly in chapters II and III, I structure a sharp application of PGC within the context of rights based on *ordre public* and morality. The chapter considers whether the application of the PGC will enable a better determination of the rights under the concept of human dignity within human rights documents in international (e. g in UDHR) or regional (e. g in ECHR) context. This chapter will focus on the issue of conflicting rights in patent law and interpretations of morality exclusions in order to scrutinise the characteristics of these rights, which may affect the identification of these rights as generic rights.

The rationale for the chapter is based on the problematic nature of the notion of 'proportionality', since logically one may not be capable of making decisions about the level of importance of one right against another right. It seems impractical for less important rights to be overridden by more important rights where there is no solid theory to support the decision, and no criteria to distinguish between the more important and the less important rights. Hence, the problematic issue is that the relevant human right conventions fail to clearly present the criteria for assessment of one right over another. The application of a PGC-compliant framework, however, produces consistent and effective decisions in the process of 'how and why one right can be overridden by another'. This is because the Generic Condition of Agency is actually what an agent's primary rights are and the Generic Conditions of Agency are all ordered within the hierarchy of importance depending on how seriously they affect the 'agency'. Therefore, the discussion of this chapter is mainly about the application of the criteria provided by PGC in order to suggest a rational reconciliation of conflicting rights.

Chapter VI consists of two parts. Part I is specifically on the U.S. patent system and the application of the concept-theoretic position in U.S. cases. This part seeks to analyse the main legal provision and procedures in the United States patent regime (section

6.2).I analyse the concept of morality within the United States Constitution, and the case laws influenced by the 'moral utility doctrine'.

In this part, I will argue that, in spite of the differences between the EU and U.S. systems, the proposed framework will be equally applicable in the U.S system given that the main argument of this framework is based on a common belief in human rights, which both systems are committed to. Even if these fundamental issues are not mentioned explicitly in their law, these principles still have to be implied. Under the same line of analysis, a discussion will be made to the effect that although the patent codes in the U.S. may appear morally neutral, the U.S. Constitution, which is the place for declaring the 'fundamental principles' of the United States, is not morally neutral. The fact that the U.S. patent law managed not to use the particular wording and clear reference to the exclusions of patentability based on morality and *ordre public*, does not affect the position of human rights principles, which of course remain relevant even in United States context of patent law. This will be followed by some discussion on the 'politics' of patents in the U.S. (section 6.3). Finally, the main question of this chapter will be raised, which is whether the PGC is equally workable in balancing right in the U.S. patent system (section 6.4).

Part II of this chapter consists of two historical cases (section 6.5 & 6.6).I will examine the suitability of the concept-theoretic position in such cases and the outcome were this position applied.

Chapter VII analyses the hypothetical cases in patent law. The chapter aims to analyse the suitability of the concept-theoretic position for patent cases in any hypothetical jurisdiction committed to the idea of human rights. The chapter first considers a hypothetical case about a patent recently filed by a Dutch company on the Corona virus.

This is done in order to suggest the possible outcome of the case if it was ever brought to the EPO or if the CJEU requested a preliminary ruling on it. After examining the case, the concept-theoretic position is applied (section 7.2).Another hypothetical case about a recent American patent, 23andme patent, which has never been considered in any court, is also analysed (section 7.3).I will analyse the case on the basis of decisions made in the past and will propose a decision based on the concept-theoretic position.

Chapter VIII concludes on the issues discussed throughout this thesis and makes some recommendations accordingly. This chapter will review the research questions in order to evaluate whether the objectives of the research, identifying an applicable theoretical framework to address the question of interpretation of patentability exclusions (*ordre public* and morality), have been met. Following that, the possible avenue for further research in the field of interpretation of immorality exclusions in patent law will be suggested.

CHAPTER II

DEVELOPING THE APPLICABLE THEORETICAL FRAMEWORK,

THE PRINCIPLE OF GENERIC CONSISTENCY

2.1 Introduction

This chapter presents the theoretical framework for the analysis of immorality exclusions in EU patent law. The suggested framework is built upon the Principle of Generic Consistency which is the moral theory of the North American philosopher, Alan Gewirth. The principle is to the effect that you must *'Act in accord with the generic rights of your recipients as well as of yourself'* (Gewirth 1978, p. 135).

The chapter introduces Gewirth's original 'dialectically necessary argument' [1] that *'*agents contradict that they are agents if they do not accept that the PGC is the supreme principle governing permissibility of actions*'* (Beyleveld 2013, pp. 3-6). This is done in order to underscore the objections, limitations and force of Gewirth's dialectically necessary argument which has been 'greeted with widespread criticism' (Beyleveld 2012) and therefore the thesis adopts only the first and least contested stage. Considering this shortcoming, I will be using a dialectically contingent argument from human rights as opposed to the 'dialectical necessity' argument.

Gewirth's original argument provides that all agents must comply with the requirements of the PGC at all times in relation to the permissibility of actions; otherwise they do not know what it means to be an agent.

The chapter then examines the dialectically contingent argument, which provides that any legal system committed to the very idea of human rights must judge actions, which are in violation of human rights as legally invalid; otherwise, they contradict the

[1] The citation here is taken from Deryck Beyleveld's interpretation of Gewirth's dialectically necessary argument. With regard to all arguments in this thesis taken from Beyleveld instead of Gewirth, I declare here that Beylevelds' interpretation of the PGC has received Gewirth's full endorsement particularly in writing in the in the *forward* to '*The Dialectical Necessity of Morality: An Analysis and Defense of Alan Gewirth's Argument to the Principle of Generic Consistency'* and in footnote of first chapter of Gewirth's '*Community of Rights'.*

recognition of such rights. In other words, I argue that any legal system that recognises human rights must accept the PGC as the supreme criterion of legal validity.

2.2 The Structure of the Principle of Generic Consistency

The approach which Gewirth follows in his argument is best known as 'ethical rationalism', in which a supreme principle, called the 'Principle of Generic Consistency' (hereafter PGC) can be derived logically from the understanding of the idea of 'agency'. The Principle of Generic Consistency claims that 'all agents must act in accordance with his or her own, and all other agents' generic rights to freedom and well-being (Gewirth 1978; Beyleveld 2013, p.2).

The PGC was developed and established by Alan Gewirth. Although the principle was developed earlier than *Reason and Morality* (1978), the fullest statement of the principle is in his *Reason and Morality*. This principle aims to address the ultimate question of introducing a rational foundation for the determination of human rights. According to the PGC, all agents and prospective agents ought to grant 'generic rights' to all other agents, otherwise they contradict that they know what it means to be an agent. All agents must accept PGC as a categorically binding principle and act in compliance with the requirements of the PGC or deny that they are agents. To prove this, Gewirth explains that an agent contradicts that it is an agent if 'it does not consider the sufficient reason why it has the generic rights to be that it is an agent. Consequently, agents deny that they are agents if they do not grant the generic rights equally to all agents (regardless of any of the characteristics they or other agents might contingently possess). So, no additional or stronger generic rights can be conferred on agents by their having characteristics not necessarily possessed by all agents' (Beyleveld 2000, pp. 59-85).

The Agent

According to the Gewirthian moral theory, agents are considered as those who have the capacity to pursue their action to achieve their purposes. Therefore, agents are supposed to be (at least prospectively) capable of undertaking free and purposive actions (Gewirth 1978, pp. 41-43, 52-53).Interestingly, under the Gewirthian theory, which deals with agency rights,[2] being an agent is not conterminous with possessing human life because agent does not necessarily mean biologically human, given that generic features of action may possibly be displayed by androids. Furthermore, we may consider other species which in principle have the relevant capacity to be considered as agents (Beyleveld&Brownsword1998).Furthermore, not all forms of human life (in its biological definition) possess the required capacity.

The Generic Rights

To define the generic rights of agency, Gewirth argues that generic features are called generic, in that the possession of such characteristic is necessary for all agents to act. In other word, 'generic rights are rights to generic needs of agency' (Gewirth 1978, pp. 25-26).Generic need of agency or generic features of agency are those capacities an agent need 'to be able to act at all or with any general chances of success, *whatever its purposes might be'* (Beyleveld and Pattinson 2001,p.39). Based on this definition, Gewirth draws the line in a way that suggests 'action' as being a necessary foundation of morality, and the mentioned generic features as the 'substratum of action'. Through his theory, he developed the idea that a comprehensive analysis of action brings forth a normative structure, accordingly;

[2] Both Deryck Beyleveld (1991:447) and Alan Gewirth(1982:77) acknowledge PGC as a theory of agency rights rather than a theory of human rights (Bielby 2008.p. 68248).

> in that evaluative and deontic judgments on the part of agents are logically implicit in all action; and when these judgments are subjected to certain rational requirements, a certain normative moral principle logically follows from them (Gewirth 1978, p. 26).

Hence, in order to be able to act successfully, all agents require generic conditions of agency which means that the deprivation of such needs or the interference with them will affect the very possibility of acting or acting successfully, *regardless of purposes being pursued.* Gewirth emphasises voluntariness and purposiveness as generic features of action, where the word 'purposive' means that agents must follow an 'end' or 'purpose', which is the 'reason' for their 'action' (Beyleveld & Brownsword 2004). Gewirth in '*the Epistemology of Human Rights' (*Gewirth 1984, p.18) claims that:

> …every agent logically must hold or accept that he has rights to freedom and wellbeing as the necessary conditions of his action, as conditions that he must have; for if he denies that he has these rights, then he must accept that other persons may remove or interfere with his freedom and well-being, so that he may not have them; but this would contradict his belief that he must have them.

Gewirth ordered generic needs of agency hierarchically according to the 'criterion of degree of needfulness for action' which simply means some generic needs are more necessary than others. The first category, 'basic needs' or 'basic goods' are those needs necessary for *the very possibility of acting*. This category includes need to 'life' and capacity involved in making choices and the 'mental equilibrium' on a level that allows the agent to follow the preferences and purposes intended to be achieved and the 'necessary means' to the above mentioned needs. These include food, clothing, shelter, health, and physical and mental integrity. Basic freedom means freedom of the agent to act in accord to the selected purposes and freedom of thought (Gewirth 1978, pp.52-54). Gewirth divides things which are needed for the possibility of successful action into two categories, 'non-subtractive' needs and 'additive' needs. Non-subtractive needs are needed to maintain the agents' ability to act successfully. These needs include

possession of accurate information for agents which relates to the agents 'need to be told the truth, and for others to keep their promises' (Beyleveld & Brownsword 2001, p.71). Interference with non-subtractive needs reduces the agents' chances of achievement of its purposes 'regardless of what the purposes might be'. However, such interference does not diminish the 'possibility of the agent being able to achieve its purposes'.

'Additive needs' are needed to improve the capacity of agents for successful action whatever the purposes are, for instance the need of an agent to access new information and gain special skills (Gewirth 1978, p.56).A common factor between non-subtractive and additive needs is that both classes of needs are needed for 'successful action' rather than action itself.[3]

In order to identify the generic condition of agency an analytical approach is needed and the examples are neither inclusive nor conclusive of Gewirth's argument validity and are set here only to clarify a number of key issues about the abstract idea of generic conditions of agency. Hence, these terms will be elaborated further through the application of the PGC (Beyleveld 2012, p.2).

2.3 The Dialectically Necessary Argument to PGC

Gewirth's 'dialectically necessary' method, as he explains, evolved from judgments and statements that are necessarily applicable to all agents in that they arise from generic features that establish the structure of an action. Therefore, Gewirth asserts his method as a 'dialectically necessary' one as it '*reflects the objectivity and universality reason achieves through the conceptual analysis of action*' (Gewirth1978, pp. 43-44).The

[3]Gewirth in *Reason and Morality*(pp.41-54) defines two categories of the generic needs, generic freedom (referring to procedural needs) and generic wellbeing (referring to substantive needs). I however prefer not to raise this classification at this stage.

reason why the mode is known as 'dialectical' is that the stages of the argument to the PGC, are made from the viewpoint of the agent. Therefore, the steps are not considered independently from the viewpoint of the agent, but are indications of thinking, or implied assertions of the agent. Nonetheless, the argumentation is also considered as 'necessary' since every stage is deduced logically from a premise, which is necessary and inescapable from any agent's perspective (Gewirth 1978).

Gewirth's dialectically necessary argument on morality in many aspects is similar to what Kant has proposed in his argument for moral law (Kant 1785, 4:445).The concept of agent in Gewirthian argument is similar to what Kant calls 'a rational being with a will'(Beyleveld & Brownsword 2001, p.73). Kant states that if morality is considered as a set of categorically binding values, such obligation means that moral law should be proved to be 'connected (completely priori) with the concept of will of a rational being as such'(Kant 1785, 4: 426).Similarly, Gewirth aims to prove the idea of categorically binding principles known as 'morality' which provides that all agents must be treated equally and with same level of respect. According to Gewirth's dialectically necessary argument all agents must accept the permissibility of their action to be judged under PGC, otherwise they contradict their agency.

The next step briefly expounds the 3 main stages of the 'dialectically necessary' argument.[4] It should however be noted that this will not constitute a discussion defending Gewirth's dialectically necessary argument, but to reach the next stage that develops an alternative argument for the application of the PGC which later will be used in context of this thesis by using the first stage of this argument only.

[4]Gewirth's presentation of dialectically necessary was not in this three stage form. Beyleveld established these 3 stages for interpretation of Gewirth's dialectically necessary argument and received full endorsement from him. Here, the outline is adopted from Deryck Beyleveld argument in '*PGC as a Supreme Principle of Human Rights* (2012)'.

According to Beyleveld's interpretation, the essence of Gewirth's argument rests on three premises which mean that the PGC is dialectically necessary for agents if these three premises are true:

First, it is dialectically necessary for agents to accept the Principle of Hypothetical Imperatives.[5]

Second, there are Generic Conditions of Agency.

And third, dialectically necessary considerations are universal.

If all these three propositions are true then the PGC is dialectically necessary. Any of these three propositions is wrong, then it means that PGC is not dialectically necessary (Beyleveld in press, p. 4).

These stages will now be discussed in further detail.

Stage I

The dialectically necessary argument consists of three stages. Stage I contends that any agent (e.g. Marta) contradicts that she is an agent if she does not accept that she generically instrumentally ought to defend her possession (for her purposes) (Beyleveld 2012, p.4).This follows that 'Marta has to accept that generic conditions of agency are a necessary good for her' by which she means that 'this is categorically instrumentally in my interest to pursue this.' In fact, Gewirth does not mean that those categorical instrumental conditions are in my interest. He might want to show that it is necessary

[5] Beyleveld (in press, p.4) interprets it in this way: "If doing Z (or having P) is necessary to pursue or achieve Albert's chosen purpose E, then Albert ought to do Z (or act to secure P) or give up trying to pursue or achieve E."

for me to accept that the possession of GCA is categorically instrumentally in my interest.[6]

The concept of agency does not have to be viewed necessarily as an end itself and PGC does not implicate that Marta contradicts that she is an agent if she refuses (or possibly assume that it is permissible for her to refuse) her agency, or if she knowingly acts in a way that may damage or risk her agency even if she continues up to the stage that she probably end her agency completely. However, in all circumstances she must be aware of the generic negative implication of such actions on her ability to act. Thus, Marta has the necessary obligation only to accept: '*Unless I am willing to accept generic damage to my capacity to act, I categorically ought to defend my possession of the generic conditions of agency'* (Beyleveld in press, p.4).

The conclusion of stage I indicates that it is dialectically necessary for me to accept that I ought to defend my possession of the generic conditions of agency unless I am willing to accept the generic damage to my ability to act.

However, the way this is proved is now important, when it is claimed that it follows from the fact that it is dialectically necessary to accept the PHI and there are generic conditions of agency. In order to prove that PHI is dialectically necessary, and therefore accepting the conclusion of stage I, there is requirement to prove that PHI is dialectically necessary and also prove that there are generic conditions of agency.

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[6] Gewirth aims to show that the PGC is categorically binding and the way in which he does so is by showing that it is dialectically necessary for agents to accept it. There are however, oppositions to this view saying that the fact that it is dialectically necessary for agents to accept it does not make it categorically binding. Therefore, it has been claimed that although it may be true that the PGC is dialectically necessary, that does not prove what Gewirth tries to prove which is that the PGC is categorically binding. Although Beyleveld (e.g. in *Analysis and Defense of Alan Gewirth's Argument to the Principle of Generic Consistency)* provided painstaking replies to such objections, since this Gewirth's original argument is not what this thesis is based on , I do not discuss the justification for Gewirth's view and the relevant replies here.

Stage II

If stage I is correct then it means that: a. PHI is dialectically necessary and b. there are GCAs. This follows that it is dialectically necessary for any agents to accept that they categorically ought to defend *instrumentally* their having the GCAs (Beyleveld in press, p.4). In fact, the second stage of dialectically necessary argument provides that the idea that there are GCAs has to be a coherent idea and contends that 'this is equivalent to me being dialectically necessary to accept that I have generic rights' (Beyleveld 2012, p.5). In other words, Marta believes that: 'Unless I am willing to accept generic damage to my capacity to act, I categorically ought to have the generic conditions of agency whenever this is possible' (Beyleveld 2012, p.5).

Nevertheless, the interference of other agents (e.g. Sam) with the Marta's possession of GCAs or, the refusal to assist Marta when she needs assistance to keep her possession of GCA and she is unable to do so unaided, will harmfully affect Marta's capacity to defend her GCA adequately. This means that it is dialectically necessary for Marta to declare: [Sam] categorically ought not to deprive me of the generic conditions of agency /against my will and categorically ought (when he is able) to assist me to retain these conditions (when I cannot do so by my own unaided efforts) *unless I do not so will'*(Beyleveld 2012, p.5).

Under this line of analysis, Sam can claim that it is necessary for me to have negative and positive rights to generic conditions of agency. [7]

[7] This three stage model is mainly cited (with only minor changes) from Deryck Beyleveld's argument in the Principle of Generic Consistency as a Supreme Principle of Human Rights (2012), pp. 3-6.

Stage III

Stage III follows logically from the fact that it is dialectically necessary for agents to consider that they have generic rights and that they must grant generic rights to all agents. If this follows, then the third proposition is established. The generic conditions of agency are universal which means that the dialectically necessary requirements are universal requirements (Beyleveld in press, p.4).

In fact, the way the above argument is reasoned is through Gewirth's Argument from the Sufficiency of Agency (ASA)(Gewirth 1978, p.110). This stage provides that the dialectically necessary argument needs to be universal, which means that it is dialectically necessary for me to accept that I ought to do X. This implies that it is dialectically necessary for me to accept that you ought to do X, where the fact that you ought to do X is action-guiding for me. In other words '*it is dialectically necessary for me to accept that I have the generic rights because I am an agent'*, which requires me logically to grant the rights to others. Consequently, if it is dialectically necessary for Marta to consider that she has the generic rights, this proposition follows that it is dialectically necessary for her as an agent, '*by virtue of being an agent'*, to have generic rights. In other word, '*it is merely because I am an agent that I have the generic rights'* (Beyleveld & Brownsword 2001, p.75).

As a matter of fact, if Marta wishes to deny the conclusion, it impliedly means that her possession of GCA is due to some specific features not necessarily possessed by all agents. [8] To accept this, Marta should hold that it would be possible for her to be an agent, even without the possession of those features, whereas she may not have the generic rights. Stage II however, does not allow an agent e.g. Marta to imply that she

[8]Gewirth (1978, p.110) gives examples of such characteristics, features like being male; being called Albert; being of a certain age, height, disposition, political party, nationality, creed, hair or eye colour, etc.

would be able to deny some generic rights without contradicting her agency. Therefore, Marta ought to deny that any specific feature is needed to make her an agent entitled to have generic rights, which means that it is dialectically necessary for Marta to accept that 'possession of generic rights' is only as a result of her 'being an agent'. It is noteworthy that at this final stage of Gewirth's argument, generic rights change from 'merely prudential' to 'moral' ones. 'When the original agent now says that all prospective purposive agents have rights to freedom and well-being, he is logically committed to respecting and hence taking favourable account of the interests of all other persons with regard to their also having the necessary goods or conditions of action' (Gewirth 1984, p.17).

With that being said, and 'since all other persons are actual or potential recipients of his action, every agent is logically committed to accept the fact that "I ought to act in accord with the generic rights of my recipients as well as of myself."'(Gewirth 1984, p.17)'I am an agent, therefore I have the generic rights', it follows purely logically that 'all agents have generic rights.' Consequently, it is dialectically necessary for Marta to accept that all other agents e.g. Sam also have generic rights. This means that if Marta denies that Sam is an agent and entitled to generic rights, she contradicts that she herself is an agent in possession of same right. Since it is dialectically necessary for Marta to accept the PGC, by parallel reasoning it is dialectical necessary for all agents to accept the PGC and comply with its requirements (Beyleveld & Brownsword 2001, pp. 74-75), that is '*Act in accord with the generic rights of your recipients as well as of yourself'*(Gewirth 1987, p.135).

2.4Alternative Argument for the PGC: the Dialectical Contingent Argument from the Acceptance of Human Rights

Like any other intellectual debate, Gewirth's dialectically necessary argument for the PGC has attracted both positive comments and harsh objections. Starting with the positive, Hudson (1984) has described the PGC as 'an impressive philosophical venture' which is definitely 'capable of intellectually surviving' even considering the existing criticism. Similarly,Lycan (1969) affirms in support of Gewirth that PGC has a rational basis. After Comparing Gewirth's PGC with the theories developed by Hare (1963) and Singer (1961), Lycanfinds both Hare's and Singers' theories incomplete. Raphael also emphasise on the value of PGC stating that this principle has improved other previous arguments and that such an intelligent attempt 'calls for a congratulation' (Rafael 1984, p.95).

Beside such endorsement and positive comments on PGC, Gewirth's original argument on PGC caused much debate and criticism. In reaction to such appraisal, Gewirth expanded his theory from categorical rule of action, initially termed as the *Principle of Categorical Consistency,* into the categorical rule for the generic features of the action, entitled *the Principle of Generic Consistency*. To address the main critiques about the principle, Gewirth offered a series of detailed replies to the objections. After publishing *Reason and Morality*, more criticisms appeared which called for reply. However, further readings of Gewirth's arguments often reveal that many of the claimed flaws are indeed misunderstandings. In order to address these misunderstandings, Deryck Beyleveld in his painstaking and detailed review of all of the criticisms of Gewirth's theory, *An Analysis and Defense of Alan Gewirth's Argument to the Principle of Generic Consistency,* defended PGC and reformulated Gewirth's

PGC argument. Later, he also introduced a dialectically contingent argument for the acceptance of PGC.

If the application of Gewirth's dialectically necessary argument for PGC was the only option here, I would have discussed the main objections and numerous particular replies here. I however prefer to implement a reformulated version of Gewirth's argument for the PGC presented by Deryck Beyleveld, which is based on a premise of 'acceptance of human rights.' This premise alone widely removes the most thematic or structural criticisms of PGC, which means far less academic resistance; at least within communities with strong belief and commitment to the very idea of human rights.

Commentators' objections to Alan Gewirth's theory of dialectical necessity are generally targeted at stage II or stage III of his argument.[9] Such scepticism is mainly regarding their disagreements with reaching a conclusion on stage II or stage III (or both of them) from stage I. A number of commentators including Richard Brandt (1981, pp. 31-40) are not convinced that agent A has to grant agent B the generic rights unless A ought to treat B's need for the generic conditions of agency as his own. This only happens if A necessarily values B's purposes like his own. Brandt claims that because we cannot assume that all agents value each others' purposes, therefore stage II and III cannot be induced purely logically from stage I.[10]

In addition to this aspect of Gewirth's theory, commentators like Kai Nielsen in *Against Ethical Rationalism* criticised Gewirth's dialectically necessary argument. His aim,

[9]In terms of the number of objections to different stages of Gewirth's theory, it is noted that stage I has been received the smallest number of critiques as opposed to stage II. Although the number of objection to stage III is relatively limited, there have been more commentators which have raised the issues related to this stage. From: Deryck Beyleveld, The Dialectical Necessity of Morality: An Analysis and Defense of Alan Gewirth's Argument to the Principle of Generic Consistency (1991) The University of Chicago press, London. p. 65.

[10]For Beyleveld and Brownsword's reply to Branst objection see their argument in *Justifying the Principle of Generic Consistency* in Human Dignity in Bioethics and Biolaw (2001). Note 16, p. 75.

similar to Kant's approach is 'to get categorically binding moral principles including categorical right-claims from the sheer concept of agency' (Nielsen1984, p.79). Although this aim is shared by many commentators who discussed Gewirth's dialectical necessity arguments, many critics including Golden and Nielsen confessed that the 'level of Gewirth's scholarship' requires us to take his theory seriously. Nielsen (1984, pp.60-83) admits that there is 'thoroughness and philosophical consciousness in Gewirth's defence.'

In order to avoid scepticisms like the above by which a fair consideration of Gewirth's argument would be affected, the need and importance for alternative arguments was noted. This resulted in scholars introducing alternative (dialectically contingent) arguments which could better serve the purpose of the implementation of PGC as the criterion of moral or legal validity with far less resistance.

Although there are objections to second and third stages, the point is the critical step is not even stage II or III. For instance, the commentator may accept stage II but still refuse to accept that stage I will 'universalise'. In other word, it is not acceptable for them to start from the first stage to get to the third stage, unless an assumption of 'impartiality' is made. These opponents of the PGC do not believe that one can prove that dialectically necessary requirements are impartial. Therefore, the main complaint is that even if we accept the first stage, to prove that the PGC is dialectically necessary, one requires to show the dialectical necessary commitments are collectively universal (Beyleveld 2013)

Considering the above, I do not defend Gewirth's argument as a whole; instead, I focus on the alternative argument that builds upon the conclusion of stage I for the

interpretation of human rights.[11] What the alternative argument does is as simply as follows. The whole system of human rights is meant to give effect to the Universal Declaration of Human Rights (1948) and Article 1 and Article 2 in UDHR provide that all human beings are equal in dignity and rights. This notion of equality in dignity and right is a declaration of impartiality. If this declaration of impartiality is combined with stage I of Gewirth's argument, one can simply conclude that 'it is necessary to accept the PGC unless you abandon the idea that all human beings are equal in dignity and rights. This analysis aims to use this impartiality to universalise the first stage of Gewirth's argument. Therefore, stage I still stays there and the categorically instrumental requirements are universalised. It means that de facto rights have to be under the will-conception.

Alternatively, after the first stage it can be argued that if it is accepted that there are human rights merely by realising that there are Generic Conditions of Agency, you would have grant rights to Generic Conditions of Agency; how is it possible to sincerely grant a right to something without granting the right to necessary means to exercise the right? The generic conditions of agency are necessary means to achieve, and in some cases even attempt aright, they would be necessary conditions for agents to exercise the rights, whatever the rights are. Acceptance of the concept of human rights and the concept of generic conditions of agency establishes the 'dialectically contingent argument'. The content one gives to the rights must include the Generic Conditions of Agency. What the first stage of argument does is to demonstrate that the right to grant the Generic Conditions of Agency have to be under the will-conception. This means

[11] The Alternative Argument was first established by Deryck Beyleveld and Roger Brownsword has been spelled out rigorously in their various books and articles e.g. Human Dignity in Bioethics and Biolaw (Beyleveld & Brownsword 2001) and The Principle of Generic Consistency as the Supreme Principle of Human Rights (Beyleveld 2012).

that either you accept it, or deny that you are an agent, or deny that there are human rights which means the conclusion in this alternative argument is not dialectically necessary. The discussion below aims to explain the alternative argument further in detail.

Based on the alternative argument, Stage II and III of the above-mentioned discussions are eliminated, whilst accepting that Stage I of Gewirth's argument is valid and sound. Stage I of the dialectically necessary argument is sound, if I accept that my having the generic needs is good for achieving my purpose, whatever my purposes might be. This follows that I, as a matter of contingent fact, ought to treat other agents with same level of concern and respect as I treat myself. It means that I regard other agents' needs for generic conditions of agency the same as my own need for the GCA in defining what I may do. Marta should value Sam's needs for generic conditions of agency as much as her own. It means that I ought to hold the idea that I categorically ought to treat other agents in a way that supports their generic agency interests (otherwise I either must deny that I am an agent, or contradict this impartiality), unless other agents are willing to damage their capacity to act. It means that I must act in accordance with other agents' generic agency interest, as long as the act is in agreement with their will.

I have generic rights. It means that I ought to accept that all agents (including myself and any other agent) have the generic rights, otherwise, I must deny the facts that either 'I am an agent' or the fact that 'all agents categorically must be treated wholly impartially'. Then it follows that 'all permissible actions must be in accordance with the Principle of Generic Consistency'. All human agents must to be treated equally in dignity and rights. This is undoubtedly the main essence of human rights documents. As

the main evidence for this statement, Article 1 [12] and Article 2 [13] of Universal Declaration of Human Rights emphasis on equality of all human beings in inherent dignity and inalienable rights 'without distinction of any kind'. Acceptance of these human right principles concerning equality in dignity and rights for all human beings means that 'all human *agents* categorically ought to be treated as equal in dignity and rights' (Beyleveld 2012, p.7).

Based on the fact that international human right documents like the UDHR are meant to establish commitment to complete impartiality for all agents, I must accept the UDHR is in accordance with the PGC, unless I refuse in effect, the application of the UDHR to me or any other agent. The impartiality on which the PGC is based ought to be between agents toward the GCA, while the UDHR proclaims this impartiality between humans with regards to the rights mentioned in the Declaration. In order to prove this issue, there are two ways. The first option is to accept that it is dialectically necessary for me to consider that I have generic rights which needs me to accept stage II of the 'dialectically necessary' argument (this however is not accepted in this work).

As discussed earlier, the second argument is to prove that human agents have human rights to generic conditions of agency. In order to be able to exercise any right to act, GCA are required. It follows that if I have the right, I must have access to the means necessary to exercise the right. Therefore, if the concept of the GCA is accepted, it needs those who are committed to human rights conventions, including the UDHR, to accept the fact that human agents have human rights to generic conditions of agency. The human right documents under will-conception ought to be interpreted in terms of

[12] Article 1 of UDHR provides that :'All human beings are born free and equal in dignity and rights They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood'.

[13] Article 2 of UDHR proclaims that:' 'Everyone is entitled to all the rights and freedoms sets forth in this declaration without distinction of any kind.' Beyleveld has argued that the second part of this Article 'They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood' means that 'all human beings are agents'.

the PGC. This is because the rights protected under the UDHR or other international human rights document are more than rights under the GCA. Therefore, PGC provides good criteria for evaluating the legal validity of actions particularly in cases of human rights.

In order for rights to generic conditions of agency to be compatible with the 'dialectical necessity' argument following from stage I, they ought to be assigned as rights under 'will-conception'. This means that if Marta has the right to her generic condition of agency, she can allow Sam to 'not' carry out his correlative duties in relation to Marta's generic rights. It is noteworthy however that if the impartiality of absolute human rights and human dignity with reference to human rights instruments like the UDHR is accepted, then the 'acceptance of the rights granted by PGC per se' should also be accepted (Beyleveld 2012, p.6).

Here, stage II becomes valid by coupling stage I with a commitment to absolute impartiality, according to which Marta ought to grant Sam his generic rights, because she has the same attitude towards other agents' needs e.g. Sam's GCA, as she has in relation to her needs for the generic conditions of agency (based on the whole impartiality idea) (Beyleveld 2012, pp.7-8). If Marta grants the generic rights to Sam with the similar attitude that she has toward her own need for these GCA, then the attitude Marta has toward her need for GCA must be '*equivalent in meaning to or entails'* that she has claimed rights to the generic conditions of agency. It is however noteworthy that the semantic application of the above example has not built upon the idea that Marta is '*actually'* committed to this '*complete impartiality assumption*.' But it is more like an '*attitudinal equivalence*' as a direct implication of the fact that if Marta were to attach the same '*normative attitude'* to Sam's possession of his generic rights as she has for herself, then she ought to grant him the generic rights (Beyleveld 2012, p. 8).

Therefore, an important conclusion is drawn here. If it is true that all human beings must be treated equally and they all are entitled to equal inalienable human rights, and further, that it is true that it is dialectically necessary for Marta to consider that she has generic inalienable rights, then it follows that Marta should accept that Sam (or any other agent) equally has generic rights.

It must be taken into account that the alternative argument will not render the PGC dialectically necessary. However, the point is that it is not aimed here to establish or prove or supposing the dialectical necessity of the PGC by using this argument. The argument does not prove the concept of human rights, but begins with the assumption of human rights. This thesis deals with operating rights based on the concept-theoretic position in the European 'legal system' and the legal system declares that they believe in human rights. The thesis argues if the legal system believes in human rights, they ought to believe in the PGC. From Gewirth's perspective, the argument for human rights is required to first spell out 'what a person has a right to'. Second, it must be 'universally applicable'. And finally, it ought to 'include the principle of equality'. That is why Gewirth asserts that the intuitionist argument made by Thomas Jefferson and by Robert Nozick, simply fails: 'Thus, Thomas Jefferson held it to be 'self-evident' that all humans equally have certain rights, and Robert Nozick has peremptorily asserted that 'individuals have rights' (Gewirth 1984, p.5). Despite its contingent line of reasoning, the ideas of equality and human rights are widely and even deeply accepted among individuals and cultures, especially within the European system. In fact, human rights are fundamental principles of the EU law, and an inseparable part of its legal system.[14]

[14] In *International Handelsgesellschaft v Einfuhr- und Vorratsstelle Getreide* [1970] ECR 1125 Case 11/70 the CJEU held that "Respect for fundamental rights form an integral part of the general principles of law protected by the Court of Justice. The protection of such rights, whilst inspired by the constitutional traditions common to the member states, must be ensured within the framework of the structure and objectives of the Community." Subsequently, in *J Nold v Commission* Case 4/73 the

To conclude, it is dialectically necessary for all those who are committed to the very idea of human rights to interpret the UDHR, the ECHR or other international human right treaties in place in accordance with the PGC, otherwise it contradicts the fact that they are human rights conventions. Consequently, they contradict the idea that all human beings must be treated equally in dignity and rights (Beyleveld & Brownsword 2001, p.82). Clearly this rule applies equally to any legal system which recognises human rights. Therefore, the validity of stage I of the 'dialectically necessary' argument leads us to the acceptance of the PGC as the supreme principle of human rights.

2.5 The Content of Agency Rights within the Concept-theoretic Position

In this section, the implication and interpretive consequences of the 'dialectically necessary' argument is elaborated further which will shed light on the requirements and implications of the alternative argument adopted in this thesis**.**

Positive Rights V Negative Rights

Under the PGC, generic rights are, in principle, positive as well as negative. As it was discussed in Gewirth's argument, the basis for the dialectical necessity argument is the fact that agents have a categorical instrumental need for the generic conditions of agency. Therefore, if an agent is unable to defend its generic conditions of agency by his *own unaided effort,* he/she has a right to be assisted by those agents able to do so

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European Court of Justice reiterated that "human rights are an integral part of the general principles of European Union law and that as such the European Court of Justice was bound to draw inspiration from the constitutional traditions common to the member states. Therefore, the European Court of Justice cannot uphold measures which are incompatible with fundamental rights recognised and protected in the constitutions of member states."

without comparable cost to themselves. This is what positive right to GCA means (Beyleveld& Pattinson 2008, p.47).

In contrast, where the rights are negative, this means that agents have rights to non-interference by other agents with their possession of generic conditions of agency. In other words, the dialectical necessity of PGC requires agents to **positively** assist the agents who need help to maintain their generic conditions of agency, as well as **negatively** not interfere with the requirement of generic conditions of agency of others. However, as discussed above, if Brenda needs help to secure her GCA, Sam has the duty to assist her only if there is no conflict with a comparable or more important GCA of himself. Gewirth (1996, p.59) asserts that in practice, such duties are mainly imposed on institutions and states which are 'representative of collectivities of individuals' instead of being directly imposed on individuals.

In circumstances such as assisted suicide, there is no positive right to such assistance. Therefore, any applicable and effective positive right (to be assisted) must be dependent on a substantive right, otherwise, where there is conflict between their own right to freedom of action and the other agent's right to be assisted, they do not have to assist if they do not wish to do so. The only exception to this rule is when the other agent who is unable to secure his GCA is subjected to 'inhuman or degrading treatment or torture' recognised by Article 3 of the European Convention on Human Rights (Beyleveld 2012).

Rights under the Will-conception Theory

Gewirth considers generic rights under a will-conception theory, which entails that agents are allowed to waive the benefits and protection provided by these rights.

Therefore, the PGC does not impose any duties to human agents to protect or not harm their own generic conditions of agency if they do not wish to. However, this rule is limited to agents' rights constrained by 'real world considerations' including finite resources, the laws of physics and the choices of others (Holm & Coggon 2009, pp. 297-298). This includes moral considerations, which means the situations in which their actions in harming or not protecting themselves, would cause harm to equally important or more important generic rights of other agents.

A choice (will) theory of rights opposes an interest theory. According to choice theories, an agent with at least a minimum capacity to decide has the right to choose, and their decision making authority is protected. This authority includes decision making which may affect their future capacity of decision making(Holm & Coggon 2009, pp. 297-298) This follows that if an agent with a free and informed consent, decides for non-protection of his or her generic interest, this should be allowed and respected and this does not amount to interference with the right related to that interest (Beyleveld 2012). In contrast, an interest theory only values the rights that benefit their holder, not considering what their holders wish. For instance, let us consider a situation where a patient irrationally refuses a blood transfusion. An interest theory does not protect the patients will, in order to prolong his life, whereas under a choice theory the patients right to have his wishes will be respected over any decision to prolong his life.

Sumner (1987, p. 97) in *Moral Foundation of Rights* distinguishes choice and interest theories in the following terms:

> The basic difference between the two conceptions lies in the normative function which they assign to rights. On the interest conception that function is the protection of some aspect or other of the right-holder's welfare. [. . .] There are no internal connections on this model between rights and such values as autonomy, self-determination, and freedom. [. . .] On the choice conception a claim which cannot be alienated in any

> way, thus one which is beyond its holder's normative control cannot count as a right.

The underlying argument in favour of adopting the choice conception theory is therefore built upon two conceptions. Put it in Sumner's word, these two conceptions entail that: 'the concept of a right is sufficiently important to be assigned a distinctive normative function, and that autonomy is sufficiently important to be safeguarded by a distinctive normative concept' (Sumner 1987, p.98)

Now let us assume that a system wishes to give rights to entities with no sufficient capacity to will, for instance embryos, foetuses, neonates, young infants, persons with severe dementia, or people in a permanent vegetative state. Although this may result in the denial of generic rights for these groups, this assumption, of course does not mean that partial, potential, or non-agents are outside of moral concern. Along similar lines, Sumner (1987, p.204) argues that:

> Restricting rights to agents is [. . .] compatible with extending moral standing to a much wider class of creatures—perhaps to all those who have interests, or a welfare, which can be protected by the imposition of moral constraints.

Nevertheless, in such circumstance the real difficulty occurs when a part of society, let us say e.g. Catholics, decide to impose correlative duties on themselves, in order to protect an entity e.g. embryo-foetus (even though it is not dialectically necessary to do so), and then other agents have to undertake such a duty, even against their will, because it is legislated. Although the 'method of consent' involved in the PGC's indirect application prescribes that it is possible to impose 'democratic decisions' to those who do not agree with them,[15] it has its own limits.

[15] On this matter, Beyleveld refers to situations like resolving "disputes on matters that the PGC cannot resolve (e. g., whether to have a law requiring persons to drive on the left or the right-hand side of the

Most importantly, the PGC does not require apparent non-agents (e.g. embryo or foetus) to be granted protection to a level that override the competing generic rights of those agents who do not consent to this (Gewirth 1978, pp. 319-322). The reason is that agents have to be granted generic rights, but to grant the apparent non-agents generic rights is only to granting the protection under the precautionary probability which means to consider it as a form of 'risk'. The harm is not measured against the harm but then with the equal (Pattinson & Beyleveld 2000) Therefore until the informed agent's actions and free will do no harm for other agent's (at least equally important) interests, such actions are permissible even though it is harmful to his/her own generic interest.

2.6 Interpretation of Competing Rights and Interests through the PGC: The Existing Problem and the PGC Solution

Addressing the question of morality, one of the most common and crucial concepts in human rights debates is the utmost respect for human dignity in Article 1 of Charter of Fundamental Rights of the European Union, itself a source of other fundamental rights. But dignity alone cannot solve most of the dilemmas in today's practice of human rights. Bearing this in mind, we need the appeal to human dignity as an overarching principle on the one hand, and the recourse to human rights on the other hand. Yet the problem of conflicting rights exists in legal systems which need to be dealt with. To strike a balance between these conflicting rights, different approaches may be adopted. In the case of the European Court of Human Right, they implement the proportionality test to decide which right should override another. However, in order to evaluate the importance of

road), or which are so complex as to make agreement between even rational and knowledgeable persons practically impossible." See Deryck Beyleveld's the Moral Status of Human Embryo and Fetus, in the Ethics of Genetic and Human Procreation, Aldershot, Ashgate, pp. 215-276.

one right over another, and make it a basis for striking the balance between two categories, there should be a sound, logical and well-reasoned basis to prefer one over another. If it is necessary to protect the less important rights to override the more important one, with no rational defined framework, then it becomes unconvincing. Therefore, there is a need for certain criteria to reconcile the competing rights and interests.

A closer look at the ECHR shows that there are no statements regarding the hierarchy of rights in the document (even though it seems that rights explained in earlier Articles hold greater importance than the rights in later Articles)(Beyleveld and Brownsword 2001, p.85).However, using the PGC enables users to understand how and why they are allowed to act or not act. The generic condition of agency is actually what the primary rights of an agent are, which are all ordered hierarchically according to their importance, depending on how crucial the effect is to an agent's capacity to act. Hence, if an agent loses the requirements for the GCA, then it will no longer be able to act as an agent. It follows that rights that are more important are the rights which are more 'needful for the action per se', and the less important rights are 'needful for the completion of a successful action' (Beyleveld and Brownsword 2001, p.85).This means that the real problem is about how to achieve a balance in cases of conflict. The issue of reconciliation of competing rights and interests develops into more complicated problems when there is no coherent applicable framework to test or deal with those competing rights.

It is noteworthy that the PGC is an absolute principle and there is no exception to the PGC. The reason is that it is either dialectically necessary, or it is absolutely rationally necessary on the basis of the first stage of the argument coupled with the commitment to human rights. Actions are categorically binding, but no actions are categorically

binding on themselves. Actions are categorically binding when they are required by the PGC. Therefore, the PGC is categorically binding on itself. Actions in accordance with the PGC are categorically biding when they are in accordance with the PGC. However, actions might be in accordance with the PGC in some circumstances and not being in accordance with the PGC in other circumstances (Beyleveld 1991, p.32). If requirements of some moral rules under some circumstances are justified to be overridden by requirements of other rules, it does not affect the categoricalness of the PGC or the rules derived from it. For instance, Gewirth's theory is capable of successfully defending the basis on which the alternative options (which have listed first in the sentences below) must yield to the second alternative.

> …when the rule against killing human persons conflicts with the agent's acting in accord with his own generic rights where he is threatened with being killed by someone else; when one person's right to occurrent freedom conflicts with another person's right to basic well-being; when a person's right to occurrent freedom conflicts with his own right to basic well-being, when a person's right to basic well-being conflicts potentially over the long run with his own right to dispositional freedom.'(Gewirth 1978, pp. 341-342)

According to Gewirth, we may face the conflict of duties or the conflict of rights. In terms of conflict of duties, the duty to respect agents having the more necessary goods must be prioritised over respect other agents having other goods (Gewirth 1978, p.340),whereas in direct application of PGC in relation to conflict of rights, different situations may occur. The rights which are in conflict can be from same or different levels of importance, based on Gewirth's criteria. As explained earlier about categories of right, the basic needs are the most necessary and important among all generic needs. Subsequently, regarding the need of agents for successful completion of an action, the non-subtractive needs are more necessary compared to the additive needs. Therefore, Gewirth defines a specific hierarchy of rights for agents based on the generic conditions

needed for action as well as those needed for completion of a successful action (Beyleveld 2001, pp.70-71).

The general criterion is that the violations of the PGC occur when there are 'transactional inconsistency' and applies whether we are dealing with rights are in the same level or different levels. If the people are not treated equally and the generic rights of all agents are not respected equally, it is the violation of the PGC. That is 'transactional inconsistency' when more preference is given to one person's status as the generic rights holder to another person's status as the generic rights holder. It means that in circumstances in which violation of the generic rights of a person or group by another person or group emerge, a 'transactional inconsistency', then the actions that occur to eliminate such inconsistency can be justified (Gewirth 1978, p.340). If we are dealing with Marta's right against Sam's right, Sam could try to protect Marta's right if there is a significant probability that Marta's life is more at risk than Sam's own right. There is 'transactional inconsistency' if the probability of Sam's life at risk is more than probability of Marta's life at risk, and Sam still prefers to protect his life. This is how transactional inconsistency is generated. If using the criterion of needfulness for action, if what is at risk is Sam's life and Marta's privacy, and the preference is given to Marta's privacy, there is 'transactional inconsistency'. Because, right to life is necessary for enjoyment of right to privacy and this means right to life must be order higher hierarchically compared to right to privacy. Right to life is necessary for one's privacy, but the opposite is not fine. From death, Sam will have no privacy, but he still can be alive and have his privacy violated. By doing so, we give effect to the principle of hypothetical imperative, because the 'criterion of needfulness for action' is conceptually linked to the 'Principle of Hypothetical Imperatives'.

‘Transactional consistency’ demands that generic rights are granted consistently and equally to all agents. Transactional inconsistency can occur in a number of different ways, one of which being the violation of ‘criterion of degree of needfulness for action’. This is one of the situations through which transactional inconsistency can arrive.

2.7 The Added Value of PGC

Beyleveld and Brownsword (2001,p.85) in *Human Dignity in Bioethics and Biolaw* assert the fact that no uniform and consistent criterion is employed in the interpretation of ECHR, follows that the requirements of PGC is not at least being contradicted which is mainly due to the silence of the ECtHR, meaning that there is no disagreement with the ‘criterion of degree of needfulness for action’ of the PGC.

To put it in Gewirth’s words, it is based on the idea that the institutional requirements to balance competing rights are relatively comparable to the principle of proportionality (Gewirth 1978, p.344).On the other hand, Precautionary Reasoning asks for minimised risk of violation of the PGC. This is quite similar to the idea of the proportionality principle in the narrow sense. Nonetheless, the next section discusses how the PGC is superior to other similar principles including theories in Utilitarianism.

This section is an attempt to elaborate the added value of the concept-theoretic position. I must emphasise that Gewirth’s theory attempts to address three main questions with regard to the conflict of interests and rights. The first question is what Gewirth terms as an 'authoritative question, ‘why should one be moral’? With respect to this question, we come across debates over necessity of morality. This question is also raised when agents are about making decisions regarding their moral interests that may conflict against others’ rights. Indeed this question is about why we need to consider morality in the

first place in a situation. In answering this question, then the 'distributive' question follows, which is, whose interest should be accommodated, and what are the criteria for this to happen? Then the final question, the 'substantive' one appears to determine which interest must be prioritised based on its importance. In answering this question, the impact of granting or violation of a right on generic condition of agency is being considered which enables us in reconciliation of competing rights (Pattinson 2002, p.10). In defence of the PGC as a supreme moral principle, Robert Montana asserts that "in the tracing of the necessities of moral rightness, wherein from the 'is' of the generic features, the 'ought' of moral principles can be derived, deductive reason becomes the basis by which these features are analysed." Under such line of analysis, the reason is the ultimate justification of the supreme moral principle. In addition, the neutrality of the deductive reason applied to morality means neutrality for the action operating as the content of the supreme moral principle as well. It means that no adherence to any moral normative position is meant through such application, and it is not an effort 'to defend or deduce anything from such' (Montana 2009, p.3).

Adopting a utilitarian approach as a framework for the interpretation of morality can affect the rights and interests of the minority, undesirably similar to what Mills (1859) identifies as a 'tyranny of the majority' and 'prevail of their benefit' and is a crucial concern in some right-based moral theories. A PGC based framework however differs from the utilitarian position, mainly because the Principle of Generic Consistency is the supreme moral principle, contrary to utility maximisation as Gewirth asserts:

> The PGC in contrast [to utilitarianism] focuses on the specific duty owed by the agent to his particular recipient….for the PGC requires that the agent act in accord with the generic rights of his recipients and not all mankind(Gewirth 1978, p.201).

The generic rights based on the 'needs for agency' in the concept-theoretic position, are different in nature from contemporary utilitarian preferences. They are more precise and circumscribed than subjective factors, and the PGC, while dependent on the consequences of actions on the generic rights, should not be confused with the utilitarian consequentialism. According to Gewirth, under the PGC, a generic harm arising from an action against another agent is only acceptable when the action has the capacity to prevent or correct the generic harm, or when it is not possible to avoid the harm by any other means. Therefore, under the concept-theoretic position, views grounded on assumptions such as 'achieving the maximum good' are not convincing at all (Gewirth 1978, p.216). This follows that the assessment of generic rights is made rather objectively for which 'more controversial interpersonal comparison of utility' will not be required (Gewirth 1996, p.50).

Furthermore, Gewirth specifies 'voluntariness' and 'purposiveness' as the two key generic features of action. Therefore in competing right scenarios, if one action is in contravention with the GCA of another right holder, whatever that right is, it must not be permitted. In other words, Gewirth presents practical criteria in balancing rights according to which generic features are thoroughly defined. The procedural aspect of action is investigated under voluntariness, considering the direction as the means according to which the action is operated, whereas both procedural and substantive aspects of the action are involved in the purposiveness and are identified as the ends towards which we supposed to direct our action.

In addition, PGC offers another guidance facility in the adjudication of conflicting rights. This guidance facility is the line that Gerwirth draws between agents and non agents. Gewirth asserts that an agent cannot deny that it is an agent, even if it declines the possession of a property and declines what is defined as what is 'not necessarily

possessed by agents.' The PGC does not treat partial agents completely as agents. Thus, it grants the intrinsic moral status only to full agents (Pattinson 2002, p.21).This criterion enables agents in the assessment of competing rights particularly in cases involving generic rights of both agents and partial agents. The ontology of the PGC however has been modified from the initial version in which Gewirth and Steigleder consider the possibility of a moral status for potential agents. This is a sufficient criterion to qualify agents for enjoyment of full intrinsic moral status Gewirth grounds his argument on the principle of proportionality whereas the concept of potentiality itself is the source of Steigleder's reasoning for derivation of intrinsic moral status for potential agents. In fact, Gewirth believes that partial and/or potential agents must be granted some status but in proportion to how close they are to become an agent.

As discussed in the last section, the application of the PGC may be direct or indirect. Gewirth in *Reason and Morality* (1978, p.200) provides that with regards to the 'direct application' of the PGC, the fact that agents must 'act in accordance with the generic rights of all agents' works on the basis of the 'interpersonal actions of individual persons'(Gewirth 1978, p.200).In such circumstance, the 'criterion of degree of needfulness for action' is applied to reconcile the competing rights. The direct application of PGC is perceived as a deontological consequentialism. Beyleveld and Brownsword in *Consent in Law* regard PGC as consequentialism due to application of a procedure in which the actions are assessed on the basis of their consequences on the generic rights of agents (Gewirth 1978, p.200; also Beyleveld and Brownsword 2007, p.56).

Although PGC consider the consequences of action for the generic condition of agency, it is not regarded as Utilitarian Consequentialism. In other words, a generic harm caused

by an action against another agent is not simply justifiable on the ground that it produces the greatest good. This however can be justified on the basis that in a precautionary sense, the action will prevent occurrence of a generic harm, and it is dependent upon the fact that the harm is not avoidable by any other alternative means (Gewirth 1978, p.216).Therefore, when those very fundamental rights and freedom including voluntariness of action, the right to autonomy and informed consent are at stake, the rights on the lower level may be overridden.[16]

Having discussed the above issues about the PGC, the most important benefit of Gewirth's theory is adopting the criteria of 'degree of needfulness' in dealing with goods with different degrees of importance. Considering the categories of right, the basic needs are the most necessary and important among all generic needs. Subsequently, in relation to the needs of agents for successful completion of an action, the non-subtractive needs are more necessary, compared to the additive needs. The rights under PGC are ranked 'in a hierarchy according to the degree to which they are needful for action per se and for successful action generally' (Beyleveld and Brownsword 2001, pp.70-71). In addition to such hierarchy, there is another hierarchy among and within each level of capabilities of action shaped by the degree of indispensability of the action (Gewirth 1978, p.344).

The application of the PGC and its 'criterion of degree of needfulness for action'lead to more consistency, at least compared to the principle of proportionality. As discussed earlier, it is not clear how accurate and consistent the principle of proportionality define the weight of competing rights, since it lacks specific criteria to develop a hierarchy. If no criteria are designed to deal with conflicting rights, then inconsistencies in the

[16] Arguments on precautionary reasoning and other practical discussions re implementation of PGC will be addressed fully in Chapter III of this thesis.

outcome and judgment are very likely due to individuals' very different parameters, contingencies and situations. Thus, contingent judgment in proportionality balance scale and the lack of a unified criterion, lead to varied inconsistent judgments and consequences. On the contrary what the PGC requires is not dependent on individuals' preferences, circumstances, or happiness, but a criterion relevant to agents' duty to act in accord with generic rights of all agents. Therefore, application of the PGC is more likely to generate rational and consistent analysis and judgments in different circumstances.

As discussed earlier, unlike what the PGC focuses on, the generic need for agency, Utilitarianism mainly values the happiness and lack of happiness. Therefore, under the PGC all agents have rights to their generic interests, only by virtue of being agents. Sam's *prima facie* right to privacy may be overridden by Marta' right to life, but it does not mean that Sam loses his generic rights. Because the right would exist, if not being in conflict with Marta's right, or he would have been able to enjoy it and give effect to it if had not been in conflict with a more necessary right. However, other agent's duty to respect Sam's right to privacy would disappear. Therefore, the PGC is absolute and actions it requires are categorically binding only when the PGC requires them. Whether the PGC requires those actions will depend upon what conflicts are between the various interests, and what the criterion of needfulness for action will require to be done in order to make sure that there is transactional consistency.

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According to the PGC and considering the 'criterion of degree of needfulness for action', the individual's dignity is well respected. Therefore, it is not of importance whether an interest is held by a large number of agents. Thus, if the protection of another right is more needed for action for an agent, then the right can be overridden by the interests of the large number, simply for the sake of their good.

2.8 Chapter Summary

Since the Principle of Generic Consistency, and hence its structure, content, and application, is quite different from those more commonly employed in the adjudication of rights, I began chapter II with a brief discussion of the notion of ethical rationalism, and Gewirth's moral philosophy in particular which underlies the Principle of Generic consistency (section 2.1). The main function of this chapter was however, to develop a concept-theoretic framework to address the problem of conflicting rights, which is to be discussed in the next chapters. And further, to defend this concept-theoretic position and its philosophical significance against other available options.

Spelling out the structure of the Principle of Generic Consistency and focusing on Gewirth's conception of agents and generic rights (section 2.2), first the original dialectical necessary argument explained (section 2.3). Although, the majority of academic objections and resistance to the acceptance of Gewirth's dialectical necessary argument do not appear sufficiently convincing, and do not provide a sound basis

against Gewirth's arguments, I chose to adopt a reformulated version of the PGC, a contingent model built upon the premise of recognition of human rights (section 2.4).

I also provided the content of agency rights within the concept-theoretic position to shed light on the implication and interpretive consequences of the 'dialectically necessary' argument hence the implication of the alternative argument. The Direct and Indirect application of the PGC were discussed, followed by arguments on the generic rights as positive and negative and further information on the PGC as a will-conception theory (section 2.5).

Subsequently, I elaborated further on the interpretation of competing rights and interests through the PGC and discussed the importance of the 'criterion of degree of needfulness for action' in defining a hierarchy to reconcile conflicting rights (section 2.6).

I further discussed the reasons for adoption of the PGC, and why the PGC is capable in the adjudication of rights (2.7). Now, based on the arguments made in this chapter, practical applications of this moral theory to various issues regarding biolaw and medical ethics will be explored in the next chapter.

CHAPTER III

GENERAL PRINCIPLES FOR APPLICATION OF THE PGC WITHIN THE COINCEPT-THEORETIC POSITION

3.1 Introduction

The previous chapter expounded the theoretical framework of this thesis, which is the Principle of Generic Consistency, as the supreme moral principle necessary for all legal systems. I concluded that all legal systems should comply with the requirements of PGC, otherwise their legal validity is lost. Having done the above, what follows is the actual application of the PGC to real life situations. Thus, this chapter is concerned with the application of the PGC. This chapter covers debates such as agency versus human, direct versus indirect application of the PGC, and rights of apparent agents versus non-apparent agent are examined. The application of the PGC to actual world problems is done based on the rules which arise from the PGC. The first part of this chapter aims to develop general principles that have to be followed in applying the PGC framework to questions of practical significance of the action.

The chapter begins with a general discussion over direct and indirect application of the PGC, (section 3.2) and subsequently provides a detailed illustration of the concept-theoretic framework dealing with apparent and non-apparent agents. Issues about PGC dealing with property and intellectual property rights specifically covered under section 3.3. The right of apparent agents over their body parts/tissues is one of the most controversial issues which I discuss in this section. Raising the concept of ownership and commodification of human body parts in this section, the view of opponent and proponents of property rights will be analysed where the former claims to grant agents such right is incompatible with human dignity, whereas the latter put forward the claim that to deny agents these rights is to violate human dignity(Beyleveld &Brownsword 2001).The analysis of Right to Property in this section begins with Gewirth's view

followed by Beyleveld and Brownsword's Rule Preclusionary (2001, p.186-188). The last part in section 3.3 contributes to analysis of intellectual property right.

Apart from PGC dealing with the rights of apparent agents over their organs/tissues, this chapter aims to address the question of PGC dealing with apparent non-agents, that is, beings that do not behave like agents. Section 3.4 specifically analyses the protection given to animals and human embryos under the PGC. I discuss why PGC requires granting them intrinsic status, but not generic rights (Beyleveld, 2000). Therefore, it is necessary to understand how to relate human agents to human beings or apparent agents. This raises a second question which is what the PGC declares (if any thing) about non-apparent agents. This Section initially analyses Gewirth's thoughts on proportionality (3.4.1) followed by Beyleveld and Pattinson's view built upon the precautionary reasoning for the protection of non-apparent agents (Beyleveld & Pattinson 2000) (3.4.2). Finally, it analyses how the concept-theoretic position deals with the rights and duties over animals (section 3.4.3) and human foetus and embryo (3.4.4).

All in all, this chapter addresses certain questions arising from the application of the concept-theoretic framework, before the implementation of these general principles in IP cases in the subsequent chapters.

3.2 Direct and Indirect Application of PGC

Gewirth (1978), in his *Reason and Morality* explains why the PGC's implication for particular actions is not limited to a simple deductive kind. In his book, he put forward the claim that due to the 'varied subject matter of morality' (Gewirth 1978, p.24) and the PGC's own content, its application can either be direct or indirect.

When interpersonal actions between and among individual agents are governed exclusively by the PGC, and without intervening factors, it is direct application of the PGC. However, it is indirect when the PGC is applied 'through the mediation of social rules' that govern multi-person activities and institutions (Gewirth 1978, p.200). Therefore, in the PGC's indirect application, such intervening factors have affected the basis by which decisions are made, and social norms are positioned somewhere between the PGC and the institutions that comply with the requirements of the principle.

In terms of the PGC's indirect application, Gewirth asserts that by placing self-fulfilment for humans within a social context that rewards individual efforts guided by reason, we can approximate it to some extent, although self-fulfilment to a perfect sense may never be attained (Gewirth 1998, p.226). Furthermore, while imposing the requirements of social rules upon individuals, there seems to be some instances of conflict between individual freedom and state mandated actions. Gewirth propounds that in such circumstances, e.g. in the case of forced military conscription, if voluntary military service is not efficiently feasible, then such a recruitment process of the agents can be imposed (Gewirth 1982, p.253). Under indirect application, the optional-procedural, static-instrumental, necessary-procedural, and dynamic-instrumental justifications of social norms are discussed.

Direct application of the PGC establishes a requirement that actions of all agents are 'in conformity with what is morally permissible under the PGC' (Gewirth 1982, p.60; Bielby 2008, p.89). With regard to direct application of the PGC, Gewirth emphasises a number of different issues, most importantly the 'equality of generic rights'. In one of his papers, Human Rights and Prevention of Cancer (1980), Gewirth discussed 'the right of a person not to have cancer inflicted on him' as a human right which means in

order to defend this right, he may have a justification of actions to do so.[1]In addition, he builds his concept of economic rights upon the 'nature of person' and 'not any conseqentialist conditions', which is a different approach to what some other philosophers including Rawls suggested.[2]

Although it is safe to consider the PGC as consequentialist, because under the PGC the actions are assessed according to the consequences they cause for the generic condition of agency, yet it is neither regarded as utilitarian nor teleological. Cummiskey (1996, p.126) in reviewing Gewirth's theory calls him a 'Kantian consequentialist' who has indeed acknowledged his commitment to 'deontological consequentialism' or a form of 'distributive consequentialism', while choosing to 'veil his consequentialism behind a shroud of anti-utilitarian emphasis.'

The reason PGC should not be regarded as utilitarian is because a generic harm caused by an action against another agent is not simply justifiable on the ground that it produces the greatest good. Therefore, even the assessment of consequences is carried out in a distributive manner rather than an aggregated approach (Beyleveld& Brownsword 2008). This however can be justified on the basis that in a precautionary sense, the action will prevent the occurrence of a generic harm and it is dependent upon the fact that the harm is not avoidable by any other alternative means (Gewirth 1978). Beyleveld and Brownsword in *Consent in Law* (2007, p.56) support this view stating that:

[1]Further discussion of direct and indirect application of PGC is provided in Chapter IV.

[2]Gewirth disagree with Rawls where he argued 'transitivity assumptions' which means "if a certain A does not deserve the abilities he gained from conditions of his starting point in life, then he does not deserve the income and wealth proceeding from this – because this would not bring about the greatest benefit to the least advantaged"(Alan Gewirth 1996, pp.189-190).

> Application of the PGC is so strictly distributive that there is no sound justification for holding that one agent may be harmed to avoid this harm to many agents. However bearing in mind the problem of other minds, there is justification for holding that one ostensible[3] agent may be putatively harmed to avoid this same putative harm to many ostensible agents, and this is that (because ostensible agents might not be agent) putative harm to one creates a lower risk of harming an agent than does putative harming to many ostensible agents.

It is emphasised that for prescriptions to be justified indirectly under the PGC, they must not be in contravention with what the PGC prescribes directly, also they should be the 'outcome of decision-making procedures that are justified directly by PGC' (Beyleveld& Brownsword 2008, p. 56). The major circumstances where the PGC must be applied indirectly are where:

I. The PGC has no direct prescription about what ought to be done.

II. The PGC has a right answer for the question but due to complexities in relation to the direct application of the PGC, rational decision makers are less likely to reach a consensus on what the PGC requires directly.

III. The PGC has no requirement or prohibition on some actions or policies, but some agents have preferences for those actions which are not compatible with the competing actions of other agents.

Where we fail to determine a decision which is acceptable for all sides, this may threaten the GCA of agents either directly or indirectly, as they follow 'their side of dispute'. To address this, the PGC requires procedures through which the dispute can be

[3] Deryck Beylveld and Shaun Pattinson in a number of their works including 'Defending Moral Precaution as a Solution to the Problem of Other Minds: A Reply to Holm and Coggon' (2010) have used the terms 'apparent' and 'ostensible' interchangeably. In this thesis, as a matter of consistency, I have tried to use the term 'apparent'. However, in situations like here where the term ostensible 'cited' from their work, it should be read with the same meaning as the term 'apparent.'

resolved. In all the above scenarios the idea that one side must 'accept a decision to which it is opposed' means that the indirect application of the PGC is grounded in the consent of agents (Gewirth 1978, p. 320). Although the 'method of consent' does not ask for the actual consent of agents, it is a requirement that all agents who have the capacity to give their consent should be involved impartially in the decision-making process (Beyleveld& Brownsword 2007).

3.3 PGC dealing with the Questions of Property and Intellectual Property

This section attempts to address the controversial issue of whether human agents have property rights in their body, and possibly a right to control what may happen to their organs and tissue after removal from their body. This is examined particularly from the concept-theoretical framework. Here I need to clarify an important issue. In order to prove that human agents have control over their body parts, it is not necessary to demonstrate that body parts should be considered property. The claim that human agents should have property rights in their body is relevant in order to reach certain conclusion in relation to the ownership of control over body parts. This is further discussed below.

Reviewing the literature on approaches to law in relation to body parts, commentators can be classified into three groups. The first group favours the view that bodies should be regarded as property capable of being owned and transferred (Bjorkman and Hansson 2006). In contrast, there are others who argue that in order to protect the body's special status the property approach is not appropriate and alternative concepts including 'rights to bodily integrity', 'rights to privacy' or 'rights to autonomy' are better fitted for this purpose. Ultimately, a third group takes a middle-ground position

on the concept of property and argues that the ideal solution must have an 'appropriate mix of both the property and integrity/privacy approaches' (Herring and Chau 2007).

However, both anti-property and pro-property adopt the Kantian command in their favour, which is that persons must be treated not merely as means but as ends in themselves. The former group claims that exercising control over our body that is considering commercial property in our body means that we are perceived merely as means and not ends. Whereas the latter regards the denial of property rights in our body and possessing control over it as violation of our human dignity and therefore not in support of being seen as ends in ourselves (Beyleveld and Brownsword 2001).

These opposing views are basically grounded on different conceptions of (commercial) property rights and different assumptions on what is relevant in treating people as end and not merely means. Therefore, before any other analysis, it is necessary to scrutinise the impact of such different views with regards to the common discussion over patent rights in our body parts. The significance of this dispute can clearly be seen in our research context, for instance, the issues concerning the control over organs and parts of bodies after the removal from a person or cadaver or the dilemmas over using an individual's DNA structure by scientists for future commercial exploitation. It is crucially important to decide that to what extent individuals are entitled to claim ownership over the new commodity.

The general line of analysis I will follow during this property discussion is the proposition that we, all human agents, own our body according to what is called the 'rule-preclusionary' perception of property (Beyleveld &Brownsword 2001).

This proposition provides that:

> The claim that A owns P is the claim that A has the right to use P in any legitimate way and to exclude others (B) from using P, for the reason that A stands in a relation R to P that precludes A from having to account on a case by case basis for A's right to use P and to exclude B from using P." (Beyleveld& Brownsword 2001, p. 172)

In the next stage, the concept of property has to be defined under our PGC-compliant framework. Obviously, the right to property is a secondary right not an absolute one. This means that rights of apparent agents to their property can be overridden by conflicting (primary) rights of other agents in specific circumstances, but it does not mean that A has no property right over P, and A's right has ceased.

> Although A owns P, in particular circumstances where there are reasons why B should be permitted to use P against A's will that outweigh the considerations that determines that persons in the positions of A should be granted property control over P- A will not be permitted to control the use of P(Beyleveld &Brownsword 2001, p.172).

Furthermore, property rights, as only *prima facie*, are rights to legitimate uses. Therefore, intending to put P for illegitimate purposes or what is generally considered as 'intrinsically wrong' prevents A to extend his right to that use.

3.3.1 Gewirth's View on Right to Property

In this section, I examine how the PGC deals with conflicts of rights, particularly in a property context. Gewirth emphasised that the most important aspect of communitarian doctrine is its concern for 'social solidarity' and 'mutuality of positive consideration' among individuals. Under such line of thinking, 'to be conciliated with the principle of human right' is the most fundamental aspect of community (Gewirth 1996, p.97). In his

view, private property rights, either positive or negative, are the rights of individuals to 'exclusive powers to possess, use, transmit, exchange, or alienate objects' (Gewirth 1996, p.166). The relationship between rights and community is defined strongly in Gewirth's arguments. In his theory the necessary goods and interest of the people are the object of the 'rights'. The community however is responsible for the protection and fulfilment of these rights. The community is particularly important to those unable to effectively have their rights, because a community is built upon the very idea of recognition and fulfilment of common needs.

Therefore, in order to protect the rights of the community, particularly those who are the most deprived, the state has to intervene. The aim of such policies and possibly laws and the state's interference is a society in which the fulfilment of the above needs and maintenance of a balance is operative. Hence, we view the state as a community of rights that have to be promoted. Gewirth (1996, p.101) defines such community of rights as follows:

> ...in having succeeded in this attainment the state is a community of rights that have been fulfilled. There is no anomaly in this dual position. On the contrary, so long as the actual is not confused with the ideal, a society that recognises the actualities of its pervasive violation of rights can be animated by a relatively clear idea of what must be done to correct the violations and thereby to move from the actual to ideal.

Gewirth provides two justifications for property rights, one 'consequentialist' and the other 'antecedentalist'. The former is built upon the consequences for individuals as agents to have such legal rights, while the latter is based on the antecedents, the terms and conditions which makes one eligible to the right. It determines who has the right to what.

According to Gewirth, these types of justification can be correlated in some way to two kinds of necessary goods that are objects of human rights. Clearly, the consequentialist justification is associated with the element of well-being as a substantive generic feature of action and successful action. Hence, it is mainly relevant to the good consequences or results aimed for by the action. On the other hand, the 'antecedentalist' justification is mainly linked to rights like freedom and it considers the procedural generic features of action.[4] It means that the investigation is basically about the voluntariness of action and whether the agent has control over his behaviour and intended to do so. As discussed earlier the main aim of the community right is to protect the freedom and well-being of the individuals in the society, therefore it is crucial to scrutinise how this protection of well-being and freedom of agents can be raised in the context of property rights, and as a justification for granting a right to benefit from.

Here, it is necessary to elaborate on how the grant of a property right is considered legitimate if the possession of that right serves to protect the well-being and freedom required for purposive action, accordingly, a successful action. Under such analysis, it was meant to conclude that if the grant of a commercial property right is the necessary means to enjoy some degree of economic security through offering steady and adequate income, then it should be facilitated. The reason is that such financial status is essential for the basic well-being and freedom of individuals. It should be noted however that the protection of freedom and well-being of individuals in a PGC-based framework is not an absolute factor and conclusive justification for the individuals' right to property.

[4] For a detail discussion of the distinction between consequentialist and antecedentalist refer to:" Economic Justice: Concepts and Criteria" in Kenneth Kipnis and Dianna T. Meyers, eds., Economic Justice: Private Rights and Public Responsibilities (Totowa,N.J.:Rowman and Allanheld, 1985), at pp13-17.

Gewirth does not appear to accept the adequacy of the consequentialist justification by itself, mainly due to the weakness of this justification in terms of dealing with the following challenges; 'the amount of the property that different persons ought to have' (Gewirth 1996, p.181) and the question of 'who should have P when the claimants have equal need for P'(Gewirth 1996, pp.182-183). The above problem is properly addressed in the 'antecedentalist' argument. The primary justification for antecedentalist arguments rests on the assumption that 'property right belongs to the persons who have produced the good things or services that are the objects of the rights' (Gewirth 1996, p.182). It is noteworthy that the main aim of the right to productive agency is 'to enable persons to earn income through their own work' (Gewirth 1996, p.169).

The same applies in the context of intellectual property, where the importance of intellectual property rights and the valuable purpose it has for people is assessed irrespective of other factors e.g. whether they have achieved such right as a result of their own productive agency. Analysing the scenario through an 'antecedentalist' justification for IP, one can claim that individuals have rights 'in things they have produced for the purpose of having such right'. This means that since we as human perform actions to achieve respective agents' purposes, therefore one can expect to be given permission to achieve his purposes unless what they do result in the violation of the generic rights of other persons according to purposive-labour thesis of property (Gewirth 1996, p.184).[5]This example is particularly understandable with regards to IP rights. Let us assume that one has not secured any rights over his invention, hence, there is no restriction on others to use the invention, formula, etc. without the consent of the inventor. Some may believe that using the inventor's product, procedure technology, formula, etc. without any compensation for the IP right owner, or asking for his

[5]Gewirth views this perspective similar to Becker's version of labour theory of property acquisition in *Property Rights*, pp 49-56.

consent/permission to use the product, violates the requirements of mutuality. Lock raised one of the first arguments in this field built upon the idea of "self-ownership" asserting that "every man has a property in his own person." In the above theory, it is stated that because all individuals "own or have property in themselves, they should also have property in what they produce by their own labour" (Locke 1689, 2.27).

Despite the different direction of the consequentialist and antecedentalist argument, the two arguments are not necessarily incompatible. Gewirth emphasises the contribution needed by both sets of consideration, in order to establish the distribution of goods and services which is well-matched with the standards of a fair society (Gewirth1996: 200-13). However, given that these two arguments do not offer independent and parallel justifications for property according to which inconsistency emerges, the consequentialist approach has to be regarded as primary. This is however true in the absence of conflicting claims on goods and services by others where it is legitimate to grant agents 'control over objects that satisfy the needs of a consequentialist justification' (Beyleveld& Brownsword 2001, p. 185). Gewirth concludes that even if the antecedentialist justification for property right is available, the consequentialist consideration may justify overriding the property right in interest of a more necessary right (Gewirth1996: 200-201).

3.3.2 Rule Preclusionary Property

In order to distinguish between the two considerations proposed by Gewirth, it is best to note the essential difference between 'consequentialist' and the 'antecedentialist', which is that the former applies universally, whereas the latter only works particularistically in relationships between agents, (that are not universal) and particular object (Beyleveld&

Brownsword 2001, p.186). Additionally, there is a distinction between transferable and non-transferable rights. With regards to the latter, commercial and non-commercial rights exist. A's relation with his body parts attached to him is not the same as other agents' relation with his parts, in that A acts through his body, and if any harm is inflicted to his body part this affects his capacity to act or act successfully. This is against A's generic condition of agency. B may also need A's body part, but B does not have equal rights to A's body part as A does. In addition to Gewirth's general approach, which leads to the discussion in favour of 'my body part, product of my labour', it is logical to have a similar claim with reference to the consideration of first use or 'original acquisition.'[6] A's standing reliance on his body parts implies that he will clearly lose from any removal of his body part, whereas B stands to gain (Beyleveld & Brownsword 2001, p. 187). Therefore, the reality of A's body parts being attached to him is sufficient for him to hold exclusive control over the use of his body parts.

Although granting A this control over his body would best protect him, one may still question whether giving him this control is necessary. The view that it is necessary for agents to have such control over their body parts is in line with the Gewirthian dignity-based perspective. It requires us to hold that persons are entitled to rule-preclusionary rights to use their body parts exclusively. If agents are not granted rule-preclusionary rights to exclusively control what happens to their body parts, it is then contradictory to the provision of adequate protection of their generic rights, and is possibly against their human dignity because it impliedly denies their possession of generic rights. In practice, if A is not granted control over his body parts and he is placed in a situation in which he is unable to refuse the use of his body parts by others, B would not presume that A would be against this use, where the use is not specifically harmful to A. It follows that

[6]This consideration is often used in the context of land ownership (Beyleveld& Brownsword 2001, p. 118)

in case of conflict between A and B, the burden of proof is on A to justify why B must not be able to use A's body parts without his consent. Therefore, if A is not granted rule-preclusionary right to exclusively control what happens to his body parts, it means that A's generic rights would not be adequately protected .[7]

It may be argued that where A has achieved control over his body part, this implies that the possession of property rights may enable him to transfer this right to others, commodify them or grant permission to others to commodify them. However, there have been dissenters to this view. There are those who assert that for such entitlement, one has to have more than control. Having discussed the justification for the control over A's body parts, i.e. the fact that having such control protects A's generic rights, it should now be compelling to claim that if A already has rule preclusionary control over P (his body part)and intends to surrender such control over in order to transfer it to B, clearly B will acquire the rule preclusionary control, since it is against A's generic rights not to permit him to transfer his control over P. However, several key points must be taken into account when dealing with the preclusionary rule.

I. Where A surrenders his right, it does not have to become somebody else's property. Although there are some circumstances in which A's surrender of P to B will automatically transfer rule preclusionary control of P to B, it is important to distinguish between the following two situations. Where A merely gives up his rule-preclusionary control without intention to transfer it to others, and when A gives consent to transfer his rule preclusionary right to B.

[7]This rule does not always apply and Beyleveld and Brownsword (2001, p.188) explained 'at least two conditions under which placing the onus to justify control on me rather than others will not protect me adequately'.

II. It is acceptable for A to have property in his own body and to transfer his rule-preclusionary control over his body parts to B, subject to some terms and conditions. Most importantly, doing so should not violate the more important generic rights of others.

It is sufficiently justifiable that if A intends to transfer preclusionary control over X to B, or aims to make some commercial benefit out of it, there is no reason to prohibit his doing so unless it is in violation of the generic rights of others. It is noteworthy that under the Gewirthian dignity-based theory, the commodification of body parts is not in breach of human dignity; however, the commercial property right of the source may be overridden in the interest of the generic rights of other agents or their dignity (Beyleveld& Brownsword 2001).

3.3.3 Intellectual Property

I discussed above that as a secondary right, the consequences of the possession of a property right has to be taken into account. For instance, where holding a property right comes in conflict with another ostensible agent's right, property right may be overridden. Historically, even before the development of arguments about intellectual property, debates over the right to private property came to offer a type of communitarian approach toward it. Famously, there happened to be a statement likes "friends have all things in common even if its ownership is private."(See e.g. Irwin 1991, pp. 200-225).Furthermore, the development of the complex system of property rights which includes several elements of private rights and some communal property right is another confirmation evidenced by important empirical facts (Honore 1980,pp. 84-92; Becker 1980, pp.197-220). This can be considered as a moral support to

communitarian ideas that serve to emphasise the need for notions like ‘cooperation’ and ‘mutuality’. According to Becker (1992, p.206) in such culture, “passiveness is regarded as vice” and “self-esteem comes from producing things that are admirable.” This approach however, does not fully safeguard the privacy of property rights. Gewirth in the Community of Rights (1998, p.173) emphasises that the property right should not cause the breach of freedom element of individual control over external things, it means that we should not authorise one to exclude others from taking or using one’s things without one’s personal consent. This is why for instance, the right of scientists to benefit financially from their inventions should be respected, and IP infringements in support of respect for one’s property should be avoided. However, it does not follow that individuals do not have any obligation to the community to share some of their rights over an invention in that they are “social products” that the community has contributed in their ‘productive agency’.

As discussed earlier, it is justifiable under the PGC that the more important rights can be overridden by less important rights, in terms of their degree of needfulness for action, (Beyleveld& Brownsword 2007, p.297) and intellectual property rights like so many others, are concepts that are not absolute. Therefore, when we consider the legitimacy of IP rights for an invention, depending on the research value and other rights involved, the commercial property right may be overridden. The important factor in overriding others’ rights against IP rights in a research is the single fact that ‘it must be conceived of as itself protecting fundamental rights and values’ (Beyleveld & Brownsword 2007, p.276). This conclusion can be easily derived from the criterion of ‘degrees of needfulness for action’ as a consequentialist thesis.

The egalitarian structure of the principle of human rights also guides us to conclude that, although individuals have the right to freedom of expression (freedom of research) and

then the right to protect the outcome of their research, it does not necessarily allow them to have a type of IP protection over their inventions, which possibly exclude others from access to such knowledge, through which the lives of others may be affected. Hence, if such ownership results in 'harmful consequences' against others, then the ownership must not be allowed according to 'the prohibition of harmful use…the condition that uses harmful consequences to other members of society is forbidden.' (Honore1980 p.123).

In discussing different IP protection scenarios, let us say the patents over life-saving medicine such as HIV+ treatment, or breast cancer screening Myriad patents, which all have a common issue, the dispute over the rights of (often vulnerable) agents to benefit from advances in health and access to treatments to fight against life-threatening diseases, if as a result of world inequalities, the pharmaceutical companies and biotechnology firms in developed countries can monopolise the use of resources through different IP rights, just for their own purposes against the need of those in underdeveloped communities, patenting these products should be limited. I would add here why such limitation or prohibition is necessary. I would point to two major issues, which will be discussed in the subsequent chapters of this thesis.

The first issue is whether it is legitimate to use a type of IP protection when it may cause difficulty in access to health. A society should not deny the rights to freedom which individuals need in order to work innovatively and productively, and yet, there must be a fair balance between the IP rights of scientists and the rights of others. Secondly, taking into account important factors including social contribution, harmful use and ownership leads us to consider 'redistribution' from both consequentialist and 'antecedentalist' view. Hence as Gewirth asserts 'rights, far from being antithetical to community, supply the contents that the community uses to enable all persons to

mutually help one another to meet their respective needs of agency and thereby to live lives of dignity as purposive autonomous agents.'

With reference to commercialisation of body parts and possible violation of agents' dignity, the principal guideline of the concept-theoretic position is clear. The fact that an agent consents to the removal of tissues or any body parts from his body does not imply his consent for any future use of his body parts, including commercialisation and holding IP rights over inventions, regardless of the argument over the possibility of property rights in our body. It follows that even if we do not accept the idea that agents have property in their body, it is still not acceptable to imply consent to the removal of the tissue or body parts, as consent to future commercial exploitation. In order to respect the dignity of the sources, Gewirthian morality requires those who intend to take and exploit the commercial value to treat their sources to a free and informed consent.

Beyleveld and Brownsword (2001, p.205) draw an important conclusion on this matter stating that:

> Rather than arguing that the patenting of human genes is inconsistent with human dignity (as conceived by a particular community) or that the donor woman might have compromised their own dignity, we should continue to question whether the dignity-based autonomy of the donors was respected – whether in other words, the donors (as agents) were treated as capable of giving informed consent (or refusal) and whether steps were taken to ensure that their consent actually was free and fully informed.

3.4 PGC Dealing with Apparent Non-agents

I earlier discussed that the PGC provides that every agent must act in accordance with his or her own and all other agents' generic rights. This is logically derivable from the nature and structure of the human agency. Furthermore, the dialectically contingent

argument from the acceptance of human rights is about agents. The question therefore becomes: how the PGC deals with those who are less likely to be agents? In the following sections, I will discuss how we ought to deal with non-agents (apparent non-agents).

3.4.1 Gewirth original approach: the idea of partial and potential agents[8]

The Embryo orfoetus as partial agents

Gewirth provides that being an agent is 'necessary' as well as 'sufficient' only for the full entitlement of the generic right. Therefore, partial agents who indicate the properties necessary to be agent only partially, would be entitled to generic rights in proportion to the level they approach to being agents (Beyleveld& Brownsword 2000, p. 117).

According to Gewirth, the principle of proportionality provides that:

> When some quality Q justifies having certain rights R, and the possession of Q varies in degree in the respect that is relevant to Q's justifying the having of R, the degree to which R is had is proportional to or varies with the degree to which Q is had. Thus, if x units of Q justify that one have x units of R, then y units of Q justify that one have y units of R (Gewirth 1978, p.121).

If we consider 'being an agent' for Q and 'the generic rights' for R, then premised on the assumption that it is dialectically necessary for agents to be an agent as the justification of eligibility for generic rights in full, the agent must grant partial agents the generic rights partially, in proportion as they are approaching being agent. Although

[8]In terms of the application of the PGC in apparent non-agents, both human or non-human, I apply the precautionary reasoning over the Gewirth's original arguments grounded on the proportionality and potentiality. In doing so, I have immensely benefited from Beyleveld's more recent works (Beyleveld and Pattinson 2000, 2010; Beyleveld&Brownsword 2000, 2007, 2010, 2013; Beyleveld 2010) on justification and clarification of the role of precautionary reasoning in the epistemology of empirical applications of Gewirthian theory.

Gewirth believes this statement is necessarily true, there have been dissenters to his view on the ground of proportionality. For instance Beyleveld asserts:

> While it is necessarily true that, when having Q justifies having R, and the possession of Q varies in degree in the respect that is relevant to having Q's justifying the having of R, the degree to which R is had is a. function of the degree to which Q is had, it cannot be inferred (without further conditions being imposed) that having R is such a function of having Q that, if having x units of Q justify that one have x units of R, then having y units of Q justify that one have y units of R for all values of x and y (Beyleveld 2000, p. 65).

Therefore, it is proposed that the Principle of Proportionality should be applied in this way here:

> When having some quality Q justifies having some property R, and the extent of having Q sufficient to justify having R in full is not necessary to justify having R to any extent at all, the degree to which R is had is a function of the degree to which Q is had (Beyleveld 2000, p. 65).

Gewirth in his Argument from the Sufficiency of Agency (ASA), proves that in order to benefit from the generic rights in full, one needs to be an agent; this is 'necessary' and 'sufficient' to have the generic rights.[9] In contrast to agents who display all the generic capacities of agency, partial agents hold generic capacities of agency to 'a lesser extent' according to which they are entitled to generic right in part (Beyleveld& Brownsword 2001,p.118).This thesis however does not validate such a false view. Given that the generic rights are will-claim rights, those who have generic rights are free to surrender the benefits arising from the exercise of generic rights, unless it causes harm to other agents or is in violation of their duties toward other agents. It is 'necessary' and 'sufficient' to possess the generic rights in full i.e. neither greater generic capacities guarantee generic rights to greater extent, nor lesser generic capacities may mean partial entitlement of generic rights. Similarly, one ought to fully possess the capacities

[9] This is Gewirth's original approach. But I am not using the dialectically necessary argument. I need to link this to the human rights claim to use this.

required to be an agent to be able to waive the benefits of exercising the generic rights. Hence, it is a false claim that partial agents have generic rights in part (Beyleveld& Brownsword 2001, p.119).

As a rebuttal to Gewirth's use of the principle of proportionality to prove quasi generic rights for partial agents,[10]it might be convincingly argued that Gewirth has committed `the fallacy of disparateness' to some extent.[11] It is more acceptable logically that the possession of a quasi-generic right does not equate with having a generic right partially, whereas it can be translated as an entitlement to a 'different quality of protection' compared to what is granted by a generic right. In spite of the possibility that the embryo/fetus may be given quasi-generic rights, it must be taken into account that this by no means is a result of the principle of the principle of proportionality grounded on the assumption that since agents hold generic rights, then partial agents must be granted quasi-generic rights (Beyelveld 2000, p. 66).

The embryo or fetus as a potential agent

Human beings in their development route toward agency (and when they are not yet agent) must be given moral significance in that they are potentiality agents. Agency establishes 'normatively outstanding quality' for the agents. Having the potentiality to become an agent and being aware of such capacity allow a being to recognise a 'morally relevant connection' between herself, her dignity and such a being. This must apply to all agents, because otherwise, it would not be consistent (Steigleder 1998, pp. 241-242)

The above claim provides that:

[10]Quasi generic rights means 'unwaivable protections correlative to duties of agents not to harm partial agents, or to assist them in need'(Beyleveld and Brownsword , 2001: 119)

[11] Formulated by Gewirth himself (1960:313), 'the fallacy is committed where fields or subject matters are compared on disparate levels or disparate respect'(Beyleveld and Brownsword : 2001 note 10).

> Agents must (on pain of denying that they are agents) grant that potential agents, intrinsically, have at least some moral status (i. e., that they have at least some intrinsic moral status for the sufficient reason that they are potential agents) (Beyleveld 2000, pp. 67).

Having compared properties possessed by agents as opposed to potential agents, it is clearly evident that agents may once have been potential agents, but being a mere potential agent is not a 'contingent property' possessed by agents. In contrast, it is something that cannot be possessed by agents.[12] This follows that being an agent means that you are no longer a potential agent. However, regardless of the relationship between the status of being an agent and a mere potential agent, we cannot conclude that being a mere potential agent is sufficient to grant at least some intrinsic moral status (Beyleveld 2000, p.67).

3.4.2 Precautionary Reason: the solution to avoid the fallacy of proportionality

The PGC is viewed from the view points of agents themselves i.e. I only know for sure that I have generic capacities of agency. Beyleveld and Pattinson (2010, p. 260) who developed the debate on 'precautionary reasoning' in dealing with non-apparent agents emphasise that thinking of this concept initially occurred as a response to radical scepticism over the categorically binding relevance of PGC in practice,[13] although it is generally accepted that it is dialectically necessary in theory. Addressing the agency of others e.g. B who possesses and displays generic capacities of agency, there is clearly

[12]Beyleveld (2000, p.67) explains the properties possessed by agents as follows: 'Agents possess two kinds of properties: those they necessarily have by virtue of being agents, and those they possess only contingently. Being an agent is sufficient for full moral status, and possession of characteristics that are necessary for agency is necessary for full moral status. Thus, properties that agents necessarily possess are undoubtedly morally relevant in being necessary for full moral status.'

[13] It has no relevance in practice 'unless A can be shown to contradict that A is an agent by denying that those who behave as though they are agents actually are agents' (Beyleveld& Pattinson 2010, p. 260).

no way that A can know for sure that B is an agent or is not an agent, unless by making 'untestable metaphysical assumptions.'(Beyleveld 2012, pp.9-10; Beyleveld &Pattinson 2010, p.260) Neither the behavioural capacities nor physical and behavioural structure can provide valid assumptions capable of being measured and tested empirically. This is not believed to be necessary truth or necessary falsehood.

Given that the granting of generic rights to agents imposes correlative duties on them, and the fact that the exercise of generic rights is only exercisable by those who have generic capacities, therefore it is only rational and practical to treat those beings that we characterise as apparent agents as agents. Although under precautionary argument we only regard apparent agents as agents, it does not necessarily mean that no protection is considered for apparent non-agents. As discussed earlier in the last section, under precautionary reasoning, we must hold 'the evidence of apparent agency' sufficiently as 'evidence of agency' for practical reasons. This may include behaviour, capacities and features of a being which are necessary, but insufficient evidence, and this applies equally to human apparent non-agents and non-human apparent non-agents. Furthermore, for the same reason that A does not know that B, who appears to be an agent, is an agent, he cannot know for sure that C, who does not appear to be an agent, is not an agent, in that C may not be able to display the capacities of agency although he may be an agent. Therefore, apparent agency does not constitute actual agency and apparent non-agency does not prove non-agency. It does not however follow that C is entitled to generic rights. We only need to grant generic rights to apparent agents, since granting generic rights and treating beings as agents establish mutual duties. To support this claim, Beyleveld and Pattinson (2010, p.261) argue that 'we are not required to give generic rights to non-apparent agents given that "both "ought" and "may" imply "can,"

can only meaningfully be done with those who behave as agents or display the capacity to do so, which C does not'.

Although proportionality and potentiality under precaution does not require the agent to grant the generic rights to the foetus or embryo, we need to accord a degree of intrinsic moral status to them, and to take into account the sources of indirect application. Meanwhile, there are a number of important issues worth considering.

First, we need to be aware that to harm the embryo, there needs to be sufficient convincing justification. The claim that the embryo-foetus is a part of the mother's body, which qualifies her to do all action against it freely e.g. to cause serious harm is not valid. On this matter, the requirement of the PGC including the application of the method of consent must be taken into consideration.

Furthermore, the claim of the foetus or embryos' ownership by the parents before implantation, (or by mother even after implantation) would be rejected if the embryo or foetus is considered ex hypothesi as an agent, as the guardianship meets the meaning more. However, we do not know for sure that the embryo/foetus is an agent, therefore a 'precautionary' guardianship is given to parents. Still, anything harmful against the embryo needs a justification. For instance, in the context of in-vitro fertilisation programme, the most likely examples of causing harm to the embryo/foetus is either to be used for research or is to be discarded as surplus embryo. Clearly, under the PGC, both can be justified if they are necessary in order to avoid more serious harm. This more serious harm can be e.g. the avoidance of circumstances caused by the infertility

in the life of childless women. Therefore, such procedure may be allowed under precautionary reason if it is necessary, as long as it is treated with dignity.[14]

In addition, under precautionary reason we give the embryo or foetus a possibility of agency; this means that agents ought to impose a duty on them to protect the embryo or foetus. This duty should be assessed when it comes into conflict with the protection given to the embryo and the assessment for this purpose may vary theoretically and practically.

Finally, a crucial fact needs to be taken into account in terms of the sensitivities of other agents. The PGC does not require giving attention to sensitivities of agents (who may be offended), against a particular agent subgroup e.g. the prejudice of sexist, racist, and similar groups, are not taken into consideration. PGC however pays attentions to other agents' sensitivities when the action required to protect them is not in violation of the agents' rights that have to be protected under the PGC. In the particular context of embryos, we must not consider those who care about embryos as having 'optional preferences and psychological make ups' but to regard them as 'having rationally required views and dispositions of character protective of the PGC'(Beyleveld 2000, p. 68).

3.4.3 PGC dealing with the Question of Animals' Rights

In dealing with apparent non-agents, I tend to support the argument of precautionary reason, as presented by Beyleveld and Pattinson (2000), particularly with respect to their discussion in 'Precautionary Reason as a Link to Moral Action' as opposed to Gewirth's argument grounded on the principle of proportionality. Gewirth (1978, pp.

[14]For example avoidance of killing surplus embryo and permitting use of surplus embryos for women other than genetic mother (Beyleveld 2000, p.76)

119–125 & pp.140–145) put forward the view that agents are expected to grant the generic rights per se to marginal agents, partial and potential agents, 'in proportion to how closely they approach being agents'. Here, I do not follow his line of analysis. His 'proportionality' justification can be objected to on the basis that if these creatures are not agents and only approach to become agent, they are not entitled to any generic rights because these are rights under the will-conception (Beyleveld& Pattinson, 2000). The argument sounds more rational if we put it in the context of being an apparent agent rather than being an agent. It is therefore, a flawed view to believe that (real) agents are only those who behave like agents.

Generally, the apparent agency in precautionary reason argument establishes that while considering any creatures other than myself, the question is not whether they are agents or not, but whether their behaviour suggest they are agents. This means that all A knows about B, is that B behaves as though it is an agent, therefore B can be known as an 'apparent agent'. In contrast, if A does not behave like an agent, it is unlikely that B assumes it is an agent. For instance a non-human animal, a human foetus or embryo, or even objects like tables and trees that do not behave like they are agents and are therefore known as apparent non-agents. This means that A's belief that B is an agent is made speculatively and on the basis of 'unstable metaphysical assumptions'. This assumption may be assessed by the evidence of agency like 'behavioural capacity', and 'the physical or biological structures generally associated with them', although Pattinson and Beyleveld (2010, p.259) emphasis that such evidence is 'neither demonstrable as necessary truths (or necessary falsehoods) nor empirically testable in a non-circular way'. The important question here is why the distinction between apparent agents and apparent non-agents, under the precautionary argument is important. The essence of the precautionary argument is to avoid the violation of the PGC and

identifying this distinction will effectively works in favour of keeping our actions in line with the requirements of the PGC. Pattinson and Beyleveld (2010: pp.259-260) thoroughly justify the importance of such dissection in the precautionary argument.

> If A supposes that B is an agent (and acts accordingly) and happens (unknowingly) to be wrong, then A does not violate the PGC. On the other hand, if A supposes that B is not an agent (and acts accordingly) and happens (again unknowingly) to be wrong, then A violates the PGC. Since the PGC is categorically binding on A, A must avoid violating the PGC at all costs whenever this is meaningful and possible. Since it is possible that B is an agent and B behaves like an agent it is both meaningful and possible for A to treat B as an agent, in consequence of which A must treat B as an agent, on pain of being willing to violate the PGC, which A categorically may not entertain.

In addition to drawing a distinction between apparent agents and apparent non-agents, it is yet possible to differentiate between groups of apparent non-agents. There have been debates over behavioural evidence from chimpanzee and dolphins, which has led a group of scientists to classify them as possibly apparent agents, whereas studies on cats, dogs, or horses failed to find sufficient evidence to claim that they should not be considered as apparent non-agents, listed as 'probable apparent non-agents'. Another category 'certain apparent non-agents' includes human foetuses or those who have been previously classified as apparent agents but currently are in a vegetative state and thus, it is safe to claim that they are not apparent agents. However, the common factor between all the above categories is the fact that we are not allowed to conclude that the being is without doubt not an agent, due to various speculative possibilities which may make that particular being an agent. Although it is not possible to conclude that they are certainly not agents, we cannot treat them as agents either, since they lack the capacity for agency at the present time. Therefore, it is not the PGC that requires us to treat non-agents as agents, but other reasoning (Beyleveld and Pattinson 2010) which will be explained below.

To portray the issue in the precautionary argument term, I will first return to one of the basics of Gewirth's argument, the fact that agents ought to act in accordance with the interest of agents. The moment we accept the above premise, the first question emerges. How should we identify agents and their interests? The problem is A would be able to identify the interests of B only on the basis that B appears to have these interests. Consequently, A has their action limited to a certain point because A may have these interests. This, however, does not mean that B has these interests just like I have these interests. The reason is if they are real agents, then they must possess generic rights to those interests. And if those interests are with those who would have generic interest to it, if they were agents, then I have to respect those rights.

Notwithstanding the fact that human apparent non-agents, or that non-human apparent non-agents do not display the capacities of agency, it does not follow that it is not dialectically necessary for agents to acknowledge their duties to protect the interests of the above categories (Beyleveld 2012). The mere idea that a dog is a non-apparent agent does not make it legitimate for me to act with no limits in relation to dogs. The fact that dogs are not apparent agents makes it unintelligible for me to fit them into the agent category. I however have at least a prima facie duty not to 'cause debilitating pain to a dog', because causing such unnecessary harm to an agent against his will would be in violation of a generic right of an agent (Beyleveld 2012, p.10).

Clearly, the rational for our duty toward non-human animals is not the idea that we think 'they are actually agents' but the thought that we need to "guard them against mistakenly treated as non-agents." Clearly, this protection of apparent non-agents has to have a limit. Beyleveld defines it as the 'extent which is meaningful and possible' for agents (Beyleveld 2013, p.10). He argued that it is dialectically necessary for them to

that specific limit, to treat apparent non-agent, in a way to avoid the violation of their generic rights, if it happens that at any point, that they are agents.

> Albert has at least a prima facie duty not to cause debilitating pain to a dog because to do this to an agent against the agent's will would violate a generic right of the agent. In general, Albert has duties to apparent non-agents in proportion to the degree that they approach being apparent agents, the degree of approach being a function of the degree to which the characteristics and capacities of the apparent non-agent can be related to interests that correspond to the generic interests of agents (Beyleveld 2013, p.10).

The next question relates to the importance of such duty toward apparent non-agents i.e. the normative force of this argument and the way to resolve the conflict when such duty is against the rights of apparent agents. To address this question, there are a number of key elements to take into account including the hierarchy of generic rights and how the 'criterion of degrees of needfulness for action' is a guiding principle to reconcile the conflicting rights. On this ground we can argue that:

> …in principle, these conflicts are to be adjudicated by weighing the PGC-guided precautionary probability that an apparent agent is an agent (=1) multiplied by the strength of the generic right in question against the precautionary probability that an apparent non-agent is an agent multiplied by the strength of the conflicting generic right-corresponding interest of the apparent non-agent (Beyleveld 2013, pp.10-11).[15]

3.4.4 PGC Dealing with the Question of Human Embryo and Foetus

[15]In spite of sensible efforts to formulate a solution for adjudication of conflicting rights and duties between apparent agents and apparent non-agents, it is still a matter of doubt how to 'operationalise' these formulas in a totally objective way (Beyleveld and Brownsword 2001, pp. 119–134 &255–258).

Using human embryonic stem cells as research subjects and the commercialisation of these projects through different intellectual property protection, particularly patenting has become increasingly controversial. Clearly, the established status of human embryos in the regulatory system plays a crucial role in the legitimacy of such patents and possibly such research activities. As Beyleveld and Brownsword (2013, p. 13) state, 'a "yes" answer to any of these questions, "whether the human embryo is "a life", or "a life in being", or a "human life" or "an agent", or "a bearer of rights" means an important implication in the legitimacy of using human embryos, whereas being uncertain about the moral status of embryos makes the decision making on the legitimacy of such patents more problematic'.

Reviewing the political map of the debate on the moral status of embryos and foetus, three major positions is identifiable, 'pro-life', 'pro-choice', and 'compromise.' The 'pro-life' believes in a full-moral status for embryos from the conception and equal to any adult human, whereas 'pro-choice' refuses to consider any moral status for human embryos until the 'birth' occurs (Beyleveld 2000, p 59). The 'Compromise' on the other hand 'sits between the pro-life and pro-choice', in that it establishes that a minimal moral status may be considered for embryos through approaching the birth and progress to a full-moral status, after birth occurs (Beyleveld& Pattinson 2000, p. 251).

Various potential justifications may be presented in relation to the possession of intrinsic moral status. Beyleveld and Pattinson (2000, p. 254) discuss three items among these grounds that are suitably matched to the purpose of this research. It is argued that intrinsic moral status must be granted to those who are sentient, which means capable of experiencing pain; human which means members of Homo sapiens; and persons/agents that mean those who are capable of pursuing their purposes voluntarily. While the 'pro-life' position develops the claim that being 'human' or being a 'potential person' is the

ground for possession of moral status,[16] the 'pro-choice' opposes the idea of any intrinsic moral status for the embryos or foetus as a 'potential', 'partial', or 'possible' person. Taking a middle ground position, the 'compromise' supporters relate the possession of intrinsic moral status in proportion to gestational development, which if possessed in full, the requirement for a full moral status entitlement is met. Therefore, the possession of intrinsic moral status may generally relate to i) possible personhood ii) sentience iii) potential personhood; iv) the approach to an attribute such as personhood (Pattinson and Beyleveld 2000, p. 255).

Here the main task is to identify the right Gewirthian position. Clearly, a Gewithian approach must not support the pro-life position; in that the theory rejects the idea that (biologically defined) human life sufficiently guarantees entitlement or full moral status as opposed to the pro-life position. Now, the next question is whether the 'compromise' or 'pro-choice' approach is closer to Gewirth's position and which is more acceptable.

The idea of Chance of Actual Agency

Generally this precautionary approach towards embryos, to treat them as agents in that they would gradually become apparent agents is similar to the position of John Finis (Finnis 1995, pp. 30–5) who emphasises that we as human beings hold a radical capacity for choice, although we may not be able to display all the required capacities for this status (Holm and Coggon 2009, p.302). Clearly, it is not supported at least under the framework of this thesis given that under precautionary reason, it is never claimed

[16]As Beyleveld and Pattinson (2000) asserts, it is noteworthy that 'having such potential must be held to be sufficient for full moral status, rather than sufficient for moral status that is proportional to the degree of potential'.

that any non-apparent agent is eligible to receive generic rights. Clearly it is not possible logically to expect entitlement to generic rights equivalent to the adult normal apparent agents because they are potential agents, and PGC under precautionary reason does not require such action. Notwithstanding, a minimal moral status is what we claim is necessary, that is, to feel minimal moral duties to them, given that they have the potential to become apparent agents (Beyleveld& Pattinson 2010, p.265).

As discussed earlier, the fact that non-apparent agents do not display sufficient evidence of agency, cannot exclude them from agency, which means that in cases of nonsufficient evidence of agency, we cannot logically conclude 'non-agency'. Holm and Coggon (2009, pp. 302–303) referred to Beyleveld's suggestion (2000, pp. 73–75) that the reason that agents must consider potential apparent agency, providing some evidence of agency and not apparent agency is the fact that normally 'it is more likely that a being with the species potential to develop ostensible agency actually is an agent than is one without this species potential.'[17] If we are dealing with beings that have species capacity, of course the outcome would be more plausible as opposed to those beings who we cannot find such capacity. It is noteworthy that since the hypothesis is very approximate then only very minimal moral status may be granted merely on this basis.

Under precautionary reason, we may think of the mathematical probability of agents when an apparent agent having the chance of being an agent is 1, a rock may take a chance of 0, and the non-apparent agent's chance is between 0-1. The benefit of doing so is that it is easier to perceive a potential ostensible agent more as an agent than a non-apparent agent, lacking this potential. Beyleveld and Pattinson (2012) emphasise that it

[17]Beyleveld and Pattinson have set this example here 'the idea that a human embryo actually is an agent could be true on the basis of the metaphysical doctrine of metempsychosis coupled with the idea of locked-in agency'.

is because: ‘it facilitates (however slightly) our ability to form a picture in which the idea of, e.g., a human embryo, having generic agency interests is rendered intelligible. And this (schematically) affects the precautionary probability of a non-ostensible agent being an agent’.

3.5 Chapter Summary

This chapter reviewed specific applications of the PGC within the context of bioethics. The concept of property in Gewirth's original argument was examined and compared to Beyleveld's view, whilst relating it to the issues of agents' control over their body parts. Subsequently, the chapter considered how the concept-theoretic position, built upon the PGC as an agency theory, uses the precautionary reason to impose duty on apparent agents to protect the apparent non-agents' interest. Under the precautionary reason, the example of dealing with non-human animals, and embryos were discussed. The conclusion drawn from both arguments is that the status of 'apparent' agency implies that non-exhibition of agency qualities does not allow agents to violate the apparent non-agents' interests, unless the 'more important rights' of 'apparent agents' (in hierarchy of degree of needfulness for action) are at stake. Therefore, in order to strike a balance between conflicting rights, the seriousness of violation of non-agents' right needs to be assessed against the consequences of these activities on the generic conditions of agency of the apparent agents.

CHAPTER IV

INTELLECTUAL PROPERTY RIGHTS AND MORALITY: CONFLICT OR CO-EXISTENCE?

4.1 Introduction

This chapter aims to justify a broad concept of morality in EU patent law and proposes a co-operative model of relationship between intellectual property rights and human rights. First, an analysis of cases brought to European patent authorities will be presented in order to examine how the approaches of the patent office in relation to interpretation of morality exclusions have changed (section 4.2). Subsequently the narrow conception to morality is analysed which brings a conflict model of relationship between morality (human rights) and patentability (section 4.3.1) followed by the broad interpretation of morality and a co-operative model (section 4.3.2). The next section is allocated to arguments over 'wide margin of appreciation' for Member States in interpretation of morality exclusions in patent law (section 4.3.3).this section will be completed by a final section to concluding why a co-operative model needs to be adapted within the European system (section 4.3.4).

4.2 The Interpretation of Morality Exclusions in European Patent Proceedings, Past and Future

As discussed earlier in Chapter I, incorporation of morality exclusions in the Biotechnology Directive[1] attracted objections from different sources including large corporations and patent practitioners that rely on patents to recoup their commercial investments. Apart from this, the European position in relation to interpretation of these morality exclusions has changed from early EPO jurisprudence to more recent patent cases in EPO or those referred for preliminary reference to the CJEU. This section

[1]Directive 98/44/ECof the European Parliament and the Council of 6 July 1998 on legal protection of biotechnological inventions [1998] OJ L213/13 (Biotechnology Directive).

provides an overview of approach taken in such interpretation since 1980s to more recent cases.

At the very beginning, in Case C-377/98 *Kingdom of the Netherlands v European Parliament and Council of the European Union* which was a proceeding against the Directive, the CJEU asserts that the Directive is set merely to rule on the grant of patents. Therefore, it is not proposed to reinstate the restrictive provisions beyond the directive's scope by which fulfilment of ethical principles is assured. [2] Morality exclusions in the Biotechnology Directive are structured in a way that can be interpreted both narrowly and broadly. In early EPO cases, including *Relaxin*[3] and *Oncomouse*[4]*, a* narrow interpretation of Article 6 was followed. Harmon (2006) calls the EPO reasoning in the early patent cases as 'circumspect'. In the statement of the Examining Division, the first decision of *Oncomouse* provides that 'patent law is not the right legislative tool' for assessment of compliance with *ordre public* and morality. It is however noteworthy that this view can be traced back to July 1989,the date before even introduction of the Directive. Therefore, the decision basically made according to the EPC. It is noted that final decisions and means to test the compliance with *ordre public* and morality principle were definitely influenced by presence of the Directive.[5]

Relaxin is another patent case of importance applied and filed in mid 90s. Addressing the opponents of the *Relaxin* patent on the ground of immorality of the invention, in a discussion constructed mainly under Article 53(a) EPC, Opposition Division reduced

[2] Case C-377/98, decision of 9 October 2001, paragraphs 79-80.
[3] *Howard Florey/ Relaxin* [1995] EPOR 541. See Section 5.3.1 of this thesis for Facts and Summary of the *Realxin* case.
[4] *Harvard/Onco-Mouse* T 19/90 Examining Division (14 July 1989) [1990] EPOR 4. See Section 5.2.1 of this thesis for Facts and Summary of the *Oncomouse* case.
[5] The decision was initially referred to provisions on prohibition of patenting animals in EPC. Following the appeal, Article 53(b) EPC regarding exclusion on patentability of animals was cited. Granting the patent on 1992, 17 parties opposed the patent but this time on an argument based on Article 53(a) EPC. Resent to Opposition Division, after one more opposition and appeal decision on 2001 and 2004, it was concluded to maintain the patent on a newly amended form.

the moral standard to a level of 'public abhorrence', according to which for an invention to be considered contrary to *ordre public* and morality that invention 'must be universally regarded as outrageous'.[6] This meant a strict adherence to the 'narrower' public abhorrence standard which technically aimed to deprive patent protection only in 'extreme circumstances' that the invention is undeniably regarded as abhorrent and outrageous. Supporters of this narrower view in interpretation of exclusions claimed that the abhorrence standard is 'capable of reinstalling certainty and simplicity back into the operation of the morality provisions; removing the unnecessary task of performing an 'intricate balancing act of ethical issues' (Gummer 2012, s. 6.1).Those who oppose reducing the morality exclusions to the level of adapting abhorrence test in *Relaxin* claim similar to Alain Pompidou, the former European Patent Office president, who emphasise that this approach 'unduly limits the significance of the moral jurisdiction of Article 6, the purpose of which is the incorporation of higher ranking legal and moral principles into European patent law.'

This all means that the EPO initially followed a provisional approach in interpreting morality, reasoning that a narrow and strict interpretation of morality is needed to exclude only what is explicitly mentioned in the directive, e.g. only certain uses of human embryos. In cases like *Plant Genetic System,* the EPO pointed to the need for a 'common European morality', although avoided being engaged into articulating any 'commonly believed moral values.'[7]

[6]Decision of the Opposition Division of 18 January 1995.

[7]T 356/93P *Plant Genetic System* [1995] Technical Board of Appeal OJEPO 545. In the final decision, it is said that 'possibility of risks traditionally has no bearing on whether a patent is granted or not' (Paragraph 624 of the decision of 15 February 1993). Therefore, the Examining Board did not perceive any moral distinction between the method used in traditional selective breeding and the new genetic engineering techniques applied for the purpose of plant modification. The Board statement regarding the morality assessment of the patent read as follows '… plant biotechnology per se cannot be regarded as

The more recent EPO's jurisprudence including *Edinburgh* and *WARF* cases and CJEU preliminary reference in *Brustle* case seems to have been in favour of a broad interpretation of Article 6. The Opposition Division in *Edinburgh* case noted that if Article 6 (2) (c) is interpreted narrowly it excludes from patentability uses of human embryos for commercial and industrial purposes , whereas if interpreted broadly, it excludes from patentability any uses of human embryonic stem cells which involves the destruction of embryos regardless of their use.[8]In the *Edinburgh* case, the Opposition Division concluded that the legislator intention was beyond excluding from patentability only human embryos for commercial and industrial purpose but to exclude human embryos for commercial or industrial uses and/or any human embryonic stem cells obtained by the destruction of the embryo.

The reasoning of Opposition Division in University of Edinburgh patent case to support a broad interoperation of Article 6 was that 'only a broad interpretation can have been intended. In consequence, [Art.6(2)(c)] in order to have a purpose exceeding the one of [Art.5(1)] has to be interpreted broadly to encompass not only the industrial or commercial use of human embryos but also the human ESC retrieved there from by destruction of human embryos.'[9]Harmon (2006 a, 2006b) argued that patents are used to influence the regulation of science and in some circumstance like *Edinburgh* case to express moral values in a society. The *Edinburgh* patent ultimately asked to be amended

being more contrary to morality than the traditional selective breeding because both traditional breeders and molecular biologists are guided by the same motivation, namely to change the property of a plant by introducing novel genetic material into it in order to obtain a new and, possibly, improved plant …. none of the claims of the patent in suit refer to subject-matter which relates to a misuse or destructive use of plant biotechnological techniques because they concern activities (production of plants and seeds, protection of plants from weeds or fungal diseases) and products (plant cells, plants, seeds) which cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture' (Paragraph 17(1)(3) of the decision of the Technical Board of Appeal of 21 February 1995).

[8]Decision of the Opposition Division of 21 July 2003 on European patent No. EP0695351 (*University of Edinburgh.*

[9]Decision of the Opposition Division of 21 July 2003. *University of Edinburgh.* para 2.5.3

to eliminate any ambiguities regarding inclusion of human or animal embryonic stem cells.

Subsequently in the *WARF* case, the Enlarged Board of Appeal has got more experience in dealing with patentability exclusions. In the decision made in 2008, it was argued that the rationale to exclude inventions from patentability is to 'prevent commodification of human embryos' which makes the nature of invention immoral.[10]

Decision of CJEU in the preliminary reference requested in *Brustle* case however is known as a major milestone in recognition of morality exclusions in a broad sense. The Advocate General in this case declared that experts in courts and patent offices are assigned specifically to evaluate the *order public* and morality compliance of inventions and empathises with: 'the argument put forward to the Court at the hearing, that the problem of patentability which hinges on the removed cell, the way in which it has been removed and the consequences of such removal do not have to be taken into account seems unacceptable, in my view, for reasons connected with *ordre public* and morality' [11] and continues in support of a broad interpretation of Article 6: 'the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44 also covers the use of human embryos for purposes of scientific research'. [12] *Brustle* definitely refused to accept a strict and narrow interpretation of morality in patent law[13]. Specific references

[10]Case G 0002/06. Paragraphs 18 and 29 of the decision of the EPO Enlarged Board of Appeal (EBA) / 25 November 2008.

[11] Para 105 AG opinion, *Brustle* case.

[12] Para 43-44 *Brutsle* case

[13]While the opinion of Advocate General in *Brustle* seems to be grounded on a moral stance and suggests a broad interpretation of morality exclusions, the judgment appeared to be even more conservative than customary international law. *Brustle* decision rendered inventions involving destruction of embryos from the point of fertilisation as immoral indeed unpatentable and referred to patentability prohibition clause under Article 6 of the Directive whereas the customary international law allows practice of research activities on embryos provided that the embryos are not older than 14 days old (Chenny 2007, pp. 517-518).

were made to different EU provision in regard to protection of human dignity including Article 1 and 3(2) of the Charter of Fundamental Rights of the European Union.[14]

Here there are a number of concluding remarks to take into account. First, historically patent officers tended to support a narrow interpretation of morality exclusions in patent law. This early jurisprudence of the EPO in which patent officers avoided explicitly discussing morality questions and supported a strict and narrow interpretation of immorality exclusions has developed through more recent cases in which a broad interpretation of morality exclusions is supported in the Directive and the importance of immorality exclusions in EU law is acknowledged. This change in view was arguably influenced by the enforcement of the Biotechnology Directive. This however does not necessarily imply that the EPO's recent moral analysis is ideal (Harmon 2006) and/or the CJEU is prepared to provide clear and consistent preliminary reference decisions. Second, although in current EU patent system there is almost no space to doubt the necessity of moral exclusion in law, interpretation of morality in patent cases is still inconsistent. For obvious reasons, mainly related to importance of human rights as fundamental principles of EU law, inclusion of such morality clauses in patent law is of utmost importance. However, what is more essential is that morality must be interpreted in a broad, precise and consistent way. Thus, the morality assessment must be followed within an accurate framework, which guarantees both compliance with ethical norms in society and advances in science and technology.

What comes below is the analysis of the approach that the concept-theoretic position requires in interpretation of the morality exclusions. Furthermore, it will be discussed

[14] Charter of Fundamental Rights of the European Union [2000] OJ C364/1. The Charter was signed in Nice in December 2000 and acquired legal status in the EU with the entry into force of the Lisbon Agreement in December 2009.

whether concept of human rights will necessarily come into conflict with protection of intellectual property rights in the EU.

4.3 Interpretation of Morality Exclusion: Co-operative v Conflict Model

As discussed earlier, the opponents of immorality clauses in biotechnological inventions, particularly the patent community, argue that including such criteria enshrined mainly under Article 53(a) of the EPC, and in Article 6 and 7 of the Directive, concede too much to morality (See e.g. Nott 1998, p 347; Scott-Ram 1998, p.43). To that extent, it is argued that the consideration of morality places the European system at a disadvantage, economically, when compared to the United States and Japan (Schatz 1997 p.170).Therefore, it may be suggested that these morality exclusions are in contradiction, and conflict with protection of intellectual property rights of the inventors, as a result of the limitation arising from such provisions in the Directive and EPC. In this section, I present my comments on these objections and propose a new framework, the co-operative model.[15]

4.3.1 The Narrow Conception to Morality and the Conflict Model of Relationship with Patentability

According to what I choose to call 'the conflict model' of relationship between morality (moral rights) and patents in biotechnology, the two categories of rights always conflict, and in no way support each other. As Armitage and Davis (1994) argued, the patent law

[15]Deryck Beyleveld initially proposed and implemented the model in the Data Protection Context. See 'Conceptualizing Privacy in relation to Medical Research Values (2006:pp. 151-164).

is principally established to patent the inventions. In light of this, the patent community advocates this idea that the patent system has to be a neutral system with no position or only a very marginal place for morality. On the other hand, the existence of 'competing cultures of interpretation' not only within the European framework (as a result the Directive as a relevant EU instrument) but also within the English system (Adams and Brownsword 1999), together with the above mentioned claim of conflict between morality and patentability, may facilitate the patent community's type of reasoning that morality exclusions ought to be construed narrowly. Thus, such claims lay emphasise that morality exclusions in biotechnology regulations to be interpreted narrowly not broadly (Shum 2010).

With this in mind, at least two relevant patent cases are relevant. First, in the *Plant Genetic Systems* case the Technical Board of Appeal provided that:

> [T]he exceptions to patentability have been narrowly construed, in particular in respect of plant and animal varieties …in the Board's view , this approach applies equally in respect of the provisions of Article 53(a)EPC.[16]

Then, in the EPO's Board of Appeal in *WARF,* in relation to the claim of a misinterpretation of law by the CJEU, similarly addressed the issue emphasising that in the decision G 1/04 the Enlarged Board of Appeal reads as follows:

> The frequently cited principle to which exclusion clauses from patentability laid down in the EPC were to be construed in a restrictive manner, did not apply without exception.[17]

Provision must be considered in light of their

> Wording, the object and purpose of the provision, the interest involved, the consequences of a narrow or broad interpretation, respectively, and the aspect of legal certainty.'[18]

[16] T356/93 *Plant Genetic Systems* [1995] EPOR 357.

[17] G 1/04. *Diagnostic Methods*.[2003] 350.

Here, a number of different circumstances need to be taken into account in relation to the narrow interpretation and the conflict model. First of all, it holds that for those morality exclusions on the right to hold patent on medical research or biotechnological inventions in which granting the patent must be shown to be an impeding factor to offer live-saving treatments, the values that morality clauses aim to support are absolute values in support of human life and right to health. Under such lines of analysis, it is arguable that the values that morality clauses strive to support are always more important than the right to protect one's right over his intellectual property. Thus, in cases of conflict between patentability and morality, then patenting must bend for the benefit of morality.

Classic examples are scientists who are fond of holding patents on a human embryonic stem cell line potentially capable of offering treatments for life-threatening diseases, and who may claim that they have a duty to save the lives of patients. The scientists are not allowed to violate the apparent agent/non agent's right to its life or one's autonomy over its bodily integrity (informed consent) in the name of protecting their investment or IP rights unless the consequences of the patent can provide certain effects on the GCA of apparent agents. Therefore, priority is given to morality over patentability, unless the scientist's team can prove that the patent is the only way to support such inventions and introduce such treatments. Only in such situations might the scientist's team be given the right to pursue their research and commercialise the process to save the patients' lives regardless of the fact that their research may involve the destruction of human embryos.

[18] T 1374/04 *WARF* G 1/04 the Enlarged Board of Appeal . point 33.

In adopting the narrow concept of morality exclusions grouped together with a conflict model Beyleveld defines two different variables capable of influencing the effect of such coupling.[19] It provides as follows:

> 'The first of these is the view taken of the basis of the value at stake. The second, which might not be entirely independent of the first, is the view taken of the kind of exercise that must be performed to assess the weight that the conflicting values have' (Beyleveld 2006, p.156).

Bearing the above mentioned variables in mind, according to the first view, those in favour of the narrow interpretation-conflict model coupling, mostly regard the right to patent a life-saving invention as a right good for people in general opposed to e.g. right to give consent for a bodily material to be used as a part of a patent or life of the embryo.

With reference to the second category, the balance is sought to be assessed through a utilitarian approach, which means according to a manner in which the greatest good for the greatest number of people is served. As a result, the restriction on patenting the academic research (freedom of expression) or/and its associated duties- e.g. the duty of scientists to provide life-saving treatments for patients through patenting a research by which the general good aims to be supported- ought to be interpreted broadly whereas whatever relates to values grounded on personal rights or wishes must to be interpreted narrowly.

Inventors may refer to a diverse range of rights or duties in relation to their scientific inventions. It may vary from their right to protect their investment on their biotechnological inventions, right to benefit from scientific progress and freedom of research, to their duty to offer life-saving treatments for life-threatening diseases. Article 15.1.(b) of the International Covenant on Economic, Social and Cultural Rights

[19] Beyleveld (2006) illustrates such scenario in a different context. In chapter 10 of *first do no harm* he discusses 'conceptualising privacy in relation to medical research values'.

(the ICESCR) 'recognises the right of everyone both to enjoy the benefit of scientific progress and its application' and 'to benefit from the protection of moral and material interests resulting from any scientific, literary or artistic production of which he is author.' [20] 'Protection' in this section can be interpreted as the right to have an intellectual property right. Article 15.3 ICESCR serves to emphasise the importance of 'respect the freedom indispensable for scientific research and creative activity.'

It is however important that intellectual property law should be consistent with the norms of international and regional human right instruments such as the ICESCR, the Universal Declaration of Human Rights, the Charter of Fundamental Rights of European Union, the European Convention of Human Rights and any other documents that EU has become a party to. In light of this, the type and level of protection included in an IP regime must work to support and promote scientific progress in a way through which the society as a whole benefits. This is why a proposed invention must be consistent with the inherent dignity of humans and human right values. Such a human rights approach within IP law goes far beyond a mere economic calculus and puts into effect 'a right of protection from possible harmful effects of scientific and technological development (Weeramanty 1990, p14).' Interestingly, under such an approach, members of society are being given a right of choice to evaluate and discuss the new technologies and become involved in the decision making process about prohibition or the authorisation of registering a new technology.

This role of human right values as moral rights in the IP context is however disputed. Advocates of such a conflict approach between patentability and morality argue that the values in IP and human rights always conflict and suggest that the long–term development of the society must be weighed against the short-term drawback of

[20] Article 15.1 (c), ICESCR.

offering exclusive IP rights to inventors (Ostergard 1999, p.156-178). It is claimed that if the Intellectual Property Right is not protected, then no incentive remains to encourage innovation and productivity (Hettinger 1989, p.48). Therefore, if scientific and technological progress is hindered, this results in more violation of individuals' rights to health and benefits, over advances in technology and science.

Nevertheless, such an argument is seen as weak for various reasons. Firstly, a patent imposes a heavy financial cost for industries; this takes small, new entry industries off the market over the fear of extra cost and lack of human resources specialising in patent applications (Galen 1991, p. 110). Secondly, litigation of patents, and the time consumed in figuring out 'what patents must be licensed' and 'from whom', affects the expected level of innovation and productivity adversely. For instance, a significant increase of 52% in patent litigation was reported in 1980s (Galen 1991, p.110) although this does not necessarily prove the occurrence of any outstanding scientific progress within this period. Under same line of analysis, Rebecca Dresser for instance asserts that 'there is a lack of empirical data to establish definitively that patenting does stimulate innovation' (Dresser 1988, n.164).

In this regard, Fritz Machlup (1962, p. 170) emphasises 'the patent position of the big firms makes it almost impossible for new firms to enter the industry; patent litigation carried on by big firms, makes it difficult for small firms to defend their own patents successfully.' Under the concept–theoretic position, it may be acceptable to consider some specific types of biotechnological inventions unpatentable. However, since this may involve violation of some generic rights of apparent agents including the violation of academic freedom of scientists and the violation of other agents right to health and life, the patent may be allowed if the research projects are very likely to produce the

life-saving treatments, and if the patent is the only available, and thus necessary, mechanism to support these research projects.

In the next section, I present the idea of a broad interpretation of morality. Subsequently, I will discuss the justification for such approach in addressing the relationship between protection of intellectuals property rights particularly patentability and morality.

4.3.2 The Broad Interpretation of Morality and the Co-operative Model

Adapting a narrow conception of morality can be acceptable provided that, as Adcock and Beyleveld emphasise, 'no fundamental rights and values are at stake' (Adcock & Beyleveld in press, p.9). In other words, adopting a narrow interpretation of the patentability exclusions[21] is not a right approach as it is well reasoned that a narrow reading of the exclusionary test by the patent community can be used to marginalise the morality exclusions.

> …it could be used to marginalise the morality exclusions by detaching it together from the evolving framework of European law as well as distracting from the most fundamental constitutional and moral commitments of that legal order (Beyleveld et al. 2001, p.16)

Therefore, the concept theoretic position requires a broad interpretation of morality exclusions under which conformity with the fundamental principles of EU law comes first. Consequently, for balancing rights, moral exclusions ought to be interpreted broadly not narrowly due to the categorical importance of complying with morality. A broad interpretation of morality is necessary because the morality is technically categorically binding, and human rights in the context of EU law are taken to be

[21]It is principally because of weak drafting of Article 53(a) EPC and Article 6(1) the Directive and the lack of clarity in these sections.

fundamental and inalienable principles. This means human rights are taken to be as rights that override absolutely all other considerations. Only one human right can possibly override another one. In other word, only those things to which we have human rights can possibly take precedent over any other human rights. The adoption of a broad interpretation of morality is therefore necessary because we are working in human rights framework and morality in this framework is something that is categorically binding. If there is any type of doubt regarding the morality, the burden of proof is always on the other party.

It is worth mentioning that the concept of morality (or human rights as moral rights) within patent law has largely evolved. Interestingly, in a general view regarding intersection between intellectual property and human rights, as Deryfuss and Lownefeld (1997, pp.295-304) noted, different international Treaties from Bern to Paris Convention[22]to the TRIPS Agreement[23]are all mainly structured in a manner to set emphasis on articulating "minimum standards" of intellectual property protection. For instance, Article 1(1) of the TRIPS agreement provides that: 'Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this agreement.' Since nothing prevents states from enacting or joining the agreement with more stringent IP rights, we hence witnessed a number of bilateral agreements including Bern or Paris Conventions, [24] in which the United States and the EU considered imposing stronger rules for intellectual property rights than those already granted in the earlier Convention or agreements.

[22] Paris Convention for the Protection of Industrial Property 1883.
[23]TRIPS: Agreement on Trade-Related Aspects of Intellectual Property 1986.
[24]See e.g. Bern Convention Supra note 8 at Article 19 & Article 20 and Paris Convention supra note 8 at Article 19.

With such global issues surrounding IP law, and with the dominance of the pro-patent community, it took a while for the EU to establish and enforce the Directive in which strong support for morality exclusions was established. Prior to the EU decision to integrate morality or moral rights into its patent law, particularly in the biotechnology context, the global community addressed one of the worrying issues in relation to human right advocacy, the issue of access to medicine (Helfer 2004). Notwithstanding the U.S. approach often made concern over their compliance with the requirements of the observer status of the High Commissioner for Human Rights.[25] Furthermore, the majority of developed countries appeared to be less willing to make concession compared to earlier, as *Economist* define it (2003, p.26-28), by which a new gap came to emerge between developed and developing countries making the sense of any human rights or morality exclusions much more difficult (*Economist* 2003). Despite all the disagreements over the incorporation of morality or human rights in intellectual property, the European Union saw the integration of morality and human rights principles in IP law generally, and patent law in particular, as an approach capable of improving the legitimacy of the organisations involved, and a guarantee for 'enhancing both individual rights and global economic welfare' in long run (Helfer 2003, p.22).

In this current research, I use the co-operative model of a relationship between morality and patentability, built upon the key idea that although the two sets of values have the potential to conflict; one can also support the other. Morality exclusions can plausibly work in support of IP rights, particularly with regards to the right to hold patent right over an invention. As explained earlier in this chapter, the consideration of morality can even work in support of permitting particular patents, if the disadvantage of being

[25]High Commissioner Report, at 68. This highlights the important role of the High Commissioners for Human Rights which "intends to seek observer status at TRIPS council".

denied a patent involves 'morally bad consequences' (Beyleveld et al. 2000, pp.157-181).

To induce a disadvantaged position for the EU as a result of the premise of the morality exclusions in law, logically the following terms and conditions must logically be met:

First, it must be clear that patents (opposed to other IP rights or incentives) are necessary to encourage investment and inventions of new technologies.

Second, it must be evident that regardless of the implemented morality criteria the result would be equal, with Europe having lost its competitive advantage e.g. against U.S .and Japan

In light of this, one may discuss:

A. The premise that the prohibition of patentability with regards to immorality exclusions may place the European Union States at a disadvantaged position economically is not an absolute fact *per se* to override the objections in this field. Therefore the patent must be rejected according to the required criteria.
B. Nevertheless, the severity of the circumstances and the morally bad consequences arising from morality exclusions being in place in Europe may lead to overriding of *the prima facie* immorality involved in granting a patent. Therefore, morality exclusions may even work to the benefit of authorising IP rights including patents. It must be considered however that upon the implementation of different criteria for the identification of morality, different results would emerge (Beyleveld 2000, pp. 157-181).

C. Furthermore, it is not clear that patents are the only cause for the manifestation of innovation in inventions and the attraction of investment for inventions. As

> Cohen and Welsh in their research in relation to real impediments to biomedical research point out, investments for such research projects can be protected through other IP instruments other than granting a patent (Cohen &Walsh 2008).

Thus, I submit here that under the proposed co-operative model, two sets of values related to patentability and morality do not always conflict with each other; they sometimes appear to support each other.

4.3.3 Wide Margin of Appreciation or Strict Interpretation Test?

It is the place of controversy whether it is right that human rights must serve as 'corrective[s] when [intellectual property] rights are used excessively and contrary to their functions' (Geiger 2004,p.278), similar to what Hefler in *Human Right Framework* (pp.1017–18) analyses considering the 'external limits on intellectual property' which can be imposed through international human rights**.** Alternative discussion provides that fundamental rights including the right of property should be brought to place as a justification for protecting intellectual property and owners of these rights (Carrier 2004). It is what Raustiala (2001, p.1021) in *Density and Conflict in International Intellectual Property Law* states:

> the embrace of [intellectual property] by human rights advocates and entities . . … is likely to further entrench some dangerous ideas about property: in particular, that property rights as human rights ought to be inviolable and ought to receive extremely solicitous attention from the international community.

Referring to the Preamble, it is argued that ruling of the CJEU is subject to control of ECtHR given that the CJEU as an institution in EU should be legally bound by the

obligation imposed by the ECHR and the Protocols. This gives the Member States a margin of appreciation on disputed issues with regard to reading and application of the Convention (Plomer 2012).Article 1(2) c, and Article 9(2) TEU provides that: 'The Union shall accede to the [Convention]. Such accession shall not affect the Union's competences as defined in the Treaties'. It is however noteworthy that ECHR recognises the right to property together with more widely established civil and political liberties including freedom of expression, and such rights. Therefore, Article 1 in Protocol 1 in protection of "the peaceful enjoyment of . . . possessions" is known as one of the weakest rights under protection in the ECHR .Consequently the discretion in interpretation of the ECHR granted to Member States is allowed to enable them to regulate their private property on the basis of their public interest(van Rijn 2006,pp.863-864).

Greer (2000) in his study, 'the Margin of Appreciation: Interpretation and Discretion under the European Convention on Human Rights 'emphasised that granting Member States a margin of appreciation to define the scope of application of Convention rights is a fundamental principle of Convention law. it is also argued that to deprive the Member State from this right is acting unconstitutionally, as such margin of appreciation aims to provide ' … the flexibility needed to avoid damaging confrontations between the Court and the Member States and enables the Court to balance the sovereignty of Member States with their obligations under the Convention'(Fenwick 2005,pp. 34-37).

In order to evaluate the above argument it is needed to question the requirements of the margin of appreciation doctrine. Greer (2000) defines the terms margin of appreciation as 'the space for maneuver that the Strasbourg organs are willing to grant national authorities, in fulfilling their obligations under the European Convention on Human

Rights'. This enables Member States to interpret the Convention on some politically or morally sensitive and contested issues through granting them a degree of discretion. For instance on jurisprudence of Article 15 and on the basis that the national authorities are better qualified to make a judgment than the Strasbourg institutions. In cases like *Brannigan and McBride*[26] and *Ireland v. The United Kingdom*[27], the decision was made on the basis of the Court's statement that: 'By reason of their direct and continuous contact with the pressing needs of the moment, the national authorities are in principle in a better position than the international judge to decide both on the presence of such an emergency and on the nature and the scope of derogations necessary to avert it. In this matter Art.15 (1) leaves the authorities a wide margin of appreciation.'

However, the margin of appreciation doctrine in the jurisprudence of Articles 8-11 particularly in the 'protection of morals' is on a different ground. In *Handyside v. The United Kingdom* for example the court provides:

> Requirements of morals vary from time to time and from place to place, especially in our era, which is characterized by a rapid and far-reaching evolution of opinions on the subject.[28]

It was then asserted that the State's authorities have better capacity than an international judge with regard to the context and requirements of the issues at stake due to their 'direct and continuous contact with the vital forces of their countries'.[29] This approach however was not followed in cases engaged in fundamental violation of the Convention.

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[26] *Brannigan and McBride v. United Kingdom* 17 EHRR – 1993, 539.

[27] *Ireland v. the United Kingdom* 162 Series A 25 – 1978.

[28] *Handyside Case* 1 EHRR– 1976, 737

[29] *Handyside v. The United Kingdom*.737.

E.g. in *Dudgeon* case[30] in relation to the laws criminalising the private life of adult homosexuals in Northern Ireland the court decided that the law is in breach of the Convention and interestingly, the decision was not on the ground of states' sovereignty but the EU consensus on the fact that sodomy laws are serious violation of privacy whereas may only insignificantly affect the morality(McBride 1999,pp. 28-34). Similarly, the court affirms in *Open Door and Dublin Well Woman* that not making a pregnant woman informed of existing abortion facilities in other countries is violation of Article 10 of the Convention and emphasised that 'the national authorities enjoy a wide margin of appreciation in matters of morals, particularly in an area such as the present which touches on matters of belief concerning the nature of human life.'[31]

Having reviewed the above cases, it is clear that doctrine of margin of appreciation applied in specific situation and decided differently in Member States based on the facts of the cases involved, and no law has made the final word about the disputed matter. Legal differences have to be balanced against complicated political, social and economic factors and although Strasbourg Court has a supranational character (McBride 1999, p.23), and it is not easy to find one-size-fits-all model. Furthermore, it calls for an 'increasing burden of proof' to be submitted by individual applicants (Letsas 2007, pp. 79-98)[32] that may appear different dependent upon nature of applicants' issues and related interests. This, as *Feldman* notes, means the Strasburg Court should consider a wider margin of appreciation rather than a strict interpretation test. This however may apply only with regard to cases in which the existing controversy facts are subject of

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[30] *Dudgeon v. the United Kingdom*, 41 Series A 45 – 1981.

[31] *Open Door & Dublin Well Woman v. Ireland*, 246 Eur. Ct. HR (ser. A) 27 – 1992. 68

local variation and their legislation has not adapted any specific position. Therefore, the key requirement for the application of the ECtHR's doctrine is the idea that different positions are adopted regarding morally contested issues in the law of Member States (Adcock & Beyleveld Working Paper, p.17).

On the other hand, If CJEU would be supposedly bound by rulings of ECtHR's, the proportionality principle has come to be implemented as a guiding principle of the Strasbourg Court particularly for the interpretation of the Convention, although it is not directly expressed in the Convention (Eliss 1999).The principle of proportionality is based upon Protocol on the Application of the Principles of Subsidiary and Proportionality in the Treaty of Lisbon and requires all actions in the Community not go beyond of what is necessary to accomplish the objectives of the Treaty Article 5(4) TEU.

It is important to bear in mind that the margin of appreciation appears to be narrower in cases with fundamentals rights and where the freedom of individuals is at stake. This clearly causes more responsibility for national courts to identify the critical situations with regard to local conditions agreeing to domestic legislation(Harris 2009,pp. 12-13)[33] This nonetheless doesn't translate to grant of an unlimited power of interpretation to domestic courts and convictions are still subject to European supervision such as above case of *Dudgeon v UK* or case of *Norris v Ireland.*[34] As a consequence, even if application of margin of appreciation is accepted for such cases, to comply with the jurisprudence of ECtHR is still highly challenging for domestic courts mainly due to uncertainty in proportionality applications which makes it difficult for these courts to make decisions in relation to how ECHR ought to be interpreted by ECtHR.

[34]*Norris v Ireland* (1989) 13 EHRR 186 para45 .

Notwithstanding, this goes beyond the supranational courts and makes the decision making process in local court ambiguous too. This is what Moreham considers to be a lack of knowledge regarding establishment of a hierarchy for competing rights and interest while developing human right law in a national level (Moreham 2008, pp.45-46). It concludes that in order for making courts in any level able to make rational and consistent decisions, it is required to have a theoretical framework or a concept-theoretic position to refer in case of problems of dealing with rights. It is argued that if EU does comply with the ECHR then ECtHR ought to consider EU as a Member State of the Council of Europe. This (being a Member State of the Council of Europe) however does not follow that the doctrine of supremacy of EU law consented to be operated within EU. Therefore, if Member States have laws in hand which are contrary with EU law, ECtHR can not confirm these laws as laws eligible to be granted a margin of appreciation (Lewis 2007, p.720; Masterman 2007).

4.3.4 Concluding Justification on Adoption of the Co-operative Model

As explained earlier in section 4.1, there have been disagreements over the interpretation of morality exclusions in EU patent law. One approach believes in a narrow interpretation of morality exclusions, as identified by Shum (2010) in what he defines as *Moral Disharmony,* and defends the idea of narrow interpretation of morality exclusions. On the other hand, a concept-theoretic position requires a co-operative model in line with a broad interpretation of immorality. Since the co-operative model is mostly associated with a broad interpretation of morality exclusions in patent law, in this section I will defend the approach of adopting a broad interpretation.

The reasoning supporting the inclusion of morality in patent law was briefly discussed in section 1.3.1 of this thesis. It was stated that even if the EPC, the Biotechnology Directive and its relevant Recitals had never been enacted, the status of morality exclusions still would have been irradicable due to fundamental role of morality as categorically binding principles and human rights which, in the context of EU law, are taken to be inalienable principles. This justifies the emergence of requirements to act in compliance with human rights particularly those related to activities covered under the Directive. Patent law must be treated as any other area under EU law. The recognition of human rights within the EU system means that any activities regulated under such system must be in compliance with the regulation of human rights. As a consequence, any activities in violation of human rights within any legal context have to be prohibited. Patent law is obviously a part of the EU legal order and no exception applies to patent law (Beyleveld 2012, p.6). Thus, not only is the status of morality an eradicable position in EU law, the protection of morality can even lead to the promotion of biotechnology patents.

The arguments on human rights-intellectual property interface is not novel. Two very different approaches have been adopted in addressing the relationship between human rights and IP rights. The first approach discusses the status of conflict between these two sets of values. The UN Sub-Commission on the promotion and protection of human rights provides that: 'actual or potential conflicts exist between the implementation of the TRIPS Agreements and the realisation of the economic, social and cultural right.'[35] To reconcile the conflict of this specific treaty obligation in relation to above said rights, the proponents of this approach suggest that set values in relation to human rights must

[35]Intellectual Property Rights and Human Rights, Resolution 2000/7 UN Sub-commission on the Promotion and Protection of Human Rights , 52nd Sess., preamble Paragraph 11.

be given propriety over intellectual property rights.[36]Such view however may not be always necessarily true since it infers property rights, including IPRs (intellectual property rights), are not human rights. This feeds back to the argument about balancing rights under the concept-theoretic position as discussed thoroughly in chapter III of this thesis (especially arguments in sections 3.3.1-3.3.3 on property rights including rule preclusionary perception of property, and protection of intellectual property rights under the concept-theoretic position).Under the proposed framework, property rights , including intellectual property rights, can be easily fitted into different categories of generic rights depending upon the extent the possession of such right may affect on generic conditions of agency of agents in different balancing rights scenarios.

The next approach is similar to what the co-operative model proposes. It requires restriction on patent law, on the basis that morality or human rights (according to which the general good is promoted) should be broadly defined, whereas limitations on IP rights to protect the individuals' economic profit should be narrowly defined provided that there are no other rights involved. This equation however supports the relationship between intellectual property and moral rights (exclusions on the basis of morality). It means that intellectual property rights may be capable of protecting some generic rights of agents, including the right to health or right to benefit from advances in health and science. On the other hand, human rights as moral rights can be argued in support of the legitimacy for a specific patent to be granted. Such scenario is well explained in Beyleveld and others' article in relation to particular cases in which the morally bad consequences occur (Beyleveld 2000 p.161). It follows that morality exclusion are not always perceived as obstacles to the patenting process, but may facilitate the grant of

[36]In preamble paragraph 3 It emphasizes 'the primacy of human rights obligation over economic policies and agreement'(Intellectual Property Rights and Human Rights, Resolution 2000/7 UN Sub-commission on the Promotion and Protection of Human Rights , 52nd Sess., preamble Paragraph 3).

patent in some particular circumstances. As mentioned earlier, the recognition of the relationship between IP rights and human right is not generally novel. I however intend to defend the idea that within the particular context of this thesis, patents and morality exclusion or moral rights as a source of human right can make such relationship as well.

In this thesis, I will analyse different issues regarding the conflict of interest between rights of individuals and what is violation of *ordre public* or morality. These rights classified under the above said differ from the autonomy rights of patients over their bodily material, informed consent, our duty to protect embryos' interest under the 'precautionary reason', the right of indigenous people over their specific genetic material, the right to health and life for patients, the right of parents to have children with specific characteristic, and some other rights in which patenting always came to be weighed against these rights.

The *WARF, Edinburgh,* and *Brustle* patent cases are all more or less disputed due to activities which involve destruction of embryos. Some commentators consider *WARF* an 'extreme turnaround' or 'major volte-face' due to the broad exclusive approach taken by the Patent Office (MacQueen & Waelde 2008, p.502), although it is seemingly logical and literally interpretative. On the other hand, a position followed by some other commentators including Cornish et al. (2010, p.873) supports the idea that the tactical reading of the directive's text in cases like *WARF*, by the European Patent Office led them to properly and effectively exclude the patent claims over the exploitation of human embryonic stem cells obtained from fertilised human nuclei. The motive for the broad interpretation of Article 6 (2) (c) is not sufficiently clarified in the decision, and this issue is criticised by supporters of the hESC research. It is however reasonably clear that the decision to adopt a broad interpretation of this exclusion is made on the grounds of morality. It is evident that the key issue involved in this case is the concept of human

dignity. Indeed, the main reason for the Enlarged Board of Appeal's discussion of the EU Directive is to prevent a misuse in the sense of a commodification of human embryos and to 'protect human dignity' as well as to 'prevent the commercialisation of embryos'.[37]

It is clear that morality and human right principles are perceived as fundamental principles of EU law. Since the fundamental principles of EU law, enshrined in the ECHR and other international human right documents to which the EU is committed to, comply with building the legal order of the EU community (Scott 2011), therefore, the Directive or any other secondary instruments must be drafted in full agreement with the said fundamental principles otherwise they would be void (Meara 2011, p.1813-1832). This means that the position is very straightforward. Furthermore, given the binding force of the CJEU decisions in relation to interpretation of EU law, judgment of the CJEU in cases like *Brustle* is a guiding point to prove that a broad concept of immorality exclusions is legally justified.

Adcock and Beyleveld (Working Paper, pp. 4-8) support this argument while defending morality as categorical, indeed, a part of a categorically binding system according to which the morality exclusions ought to be operated broadly. They further submit that:

> If A categorically ought to do X, then A categorically cannot risk not doing X or doing not X if it is possible to avoid this risk. In a nutshell this means that if there is doubt about the application of e.g. , a human right , then subject to it being possible to act in conformity with what protection of right requires , the onus is on those who wish to dispute the application of the right to make their case rather than the other way around(Adcock Beyleveld pp.5-6).

[37]European Patent Office (2009), at 325-326.

Under the concept-theoretic position, apparent agents in a general sense and including those involved in biomedical research must be treated as an end, and not a mere means to achieve the advances in science and technology. This idea of preventing human dignity being diminished because of humans' idealistic and optimistic approach towards the potential of science, despite the consequences of its application on human subjects is largely supported within the scholars' arguments. For instance, the analysis by Albert Bergman (1990) on this serves to emphasise the importance of attention to the pitfall of modern technologies according to which we find a tendency to treat an increasing level of human relationship and things as 'commodities whose utility we measure and consume'(Borgmann 1990, p.355). It is immediately evident that we must avoid circumstances in which the human beings or other creatures are treated 'as objects to be exploited' because of emerging technologies attitude (Barbour 1993). Therefore, the concept-theoretic position in line with many other theories in relation to human rights and intellectual property interface requires human dignity as source of some generic rights, to be respected.

Scientists claim that their right to academic freedom is built upon the right to freedom of expression. As patenting hESC research is based on research works involving destruction of human embryos then a clash occurs between the interest of human embryos to be protected [38] and the scientists' intellectual property rights(IPR's). To address the above conflict I make the following discussion. Under the PGC, the concept of 'impartiality' driven from 'the idea of a categorically binding principle' is supported. This idea is also sufficiently supported by Article 1 and 2 of the UDHR, which lays emphasis on the equality of every human beings, to be entitled human rights and dignity.

[38]Only in a precautionary manner since embryos as apparent non-agents are not directly entitled to generic rights.

The idea of protecting IPR including patents to protect the investment and innovation in medical research, and supporting the production of life-saving treatment is not a new claim. The claim that the absence of an effective patent regime may lead to unwanted infringements of one's invention is a process that can easily be avoided through a strict patent system. Furthermore, it has long been declared that by supporting IP rights particularly patents in biomedical research, the society can harvest extended interests by enjoying advances in treatments of life-threatening diseases. Therefore, it is more in public interest, since rendering the hESC research unpatentable means that the risk/possibility that patients may lose their lives due to lack of proper treatments will be much higher.

Here, to assess whether the directive is in line with the PGC[39] and to examine the relationship between IPR (particularly patentability) and human rights (specifically morality exclusions) it is important to consider the preliminary ruling on *Brustle* with reference to Article 6(2)(c) of the Directive in which defines embryos as:

> Any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis…. [but that] it is for the referring court to ascertain, in the light of scientific developments , whether stem cell obtained from a human embryo at the blastocyst stage constitutes a human embryo.[40]

Now, suppose that we raise the following two questions in relation to the Directive. Recitals 3 and Recital 5-7 of the Directive provides that the aim of Directive is to

[39] Because if the directive is not in line with the PGC, it means it is in contravention with the fundamental principles of EU law. If any piece of EU legislation is in contravention with fundamental principles of EU law, it is void.
[40] Case C-34/10 Oliver Brüstle v Greenpeace e.V. para 38.

harmonise rules for the legal protection of biotechnological inventions. Bear it in mind, this protection includes the terms and conditions of commercialisation of inventions under the governance of the Directive. In light of this, the preamble to the Directive lays emphasis on the fact that 'uses of biotechnological materials originating from humans consistent with regard for fundamental rights and in particular dignity of a person.' In relation to patenting, Recital 16 provides that 'patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person.' It is worth noting that even if the Directive and Recitals never include such explanation in relation to EU biotechnology patent law, it is clear that for EU Member States, being a party of the European Convention of Human Rights follows their commitment to protection of fundamental rights and freedom.

It is clear that a uniform definition, e.g. here for embryo, is required in order to prevent any future misuse of the law that is a loophole encouraging inventors to apply for a patent in countries with the 'narrowest' definitions according to the CJEU's terminology or 'the least restrictive' definition. It is immediately evident, as the CJEU notes that it 'adversely affect on the smooth functioning of the internal market as the original aim of Directive.'[41]This, coupled with Article 5(1) of the Directive in relation to prohibition of patenting human body at the various stages of its formation and development, and the statement of Recital 38 of the Directive regarding the non-exhaustiveness of the exclusions in Article 6(2)[42] all lead to the conclusion that the concept of human embryo

[41] Para 28 and 29 of the *Brustle*.

[42] It provides that: "All processes the use of which offends against human dignity are also excludes from patentability". Also *Netherlands v Parliament and Council* Para 71 and 76. In this regard, Mike Adcock and Deryck Beyleveld (in press) argued that although the CJEU has not explicitly mentioned as such," the clear implication is that those exclusions of Article 6(2) that refers to the uses of human material are excluded because the legislator judged these uses to offend human dignity." In Mike Adcock and Dercyck Beyleveld (Working Paper) Morality in Intellectual Property Law; A Concept- theoretic Framework, note 35.

must be understood in a wide sense, to support the idea of excluding 'any possibility of patentability, where respect of human dignity could thereby be offered'.[43]

This means that there is support for the idea of a broad interpretation of the Directive's morality exclusions whatever the exclusion is. Hence, it is clear that the protection of morality, thus avoiding the unnecessary destruction of embryos, is necessary for the patentability of biotechnological inventions. The idea that patenting can support morality exclusions (or morality) is probably less straightforward to grasp quickly, although under a broad interpretation of such clauses this claim is credible enough to consider. The main point here is that a broad conception of morality supports the activities associated with protection of intellectual property or 'consequences' arising from protection of IPRs. . Intellectual property rights, far from the common assumption of being a threat to human rights, can be considered as another sub-set of human rights. It is arguable that intellectual property rights including patents, as Heins (2008, p.213-232) notes, initially were established by legal systems to 'promote socially desirable outcomes'.

As discussed previously, for instance in the specific case of hESC research projects, if granting patents is 'necessary' to pursue this research, and there is no other efficacious option for the development of life saving treatments, the concept theoretic position should allow such patents. If any of above factors are dubious, then a patent involving destruction of human embryos needs to be avoided, not because embryos are entitled to generic rights but to avoid the violation of their interest under precautionary reason, unless there exists a justifying ground that this is the only way to secure generic rights of the right to life or health, or any other comparable generic rights of apparent agents.

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[43]Para 34 of the CJEU on *Brustle*.

Although adopting a broad concept of morality in patent law implies a co-operative model, limits on application of such model is inevitable. The next section addresses some of these limitations.

4.3.5 Limits of a Broad Concept of Morality in Patent Law

The first limit to a broad concept of morality in patent law is regarding the extent to which morality, human dignity or some other relevant concepts may be used to limit those intellectual property rights, particularly patent law in biotechnological inventions, which are capable of offering life-saving treatments for terminal disease. The ambiguity is due to a number of different reasons, central among these that the concept of human dignity has been viewed differently, sometimes as a source of rights and sometimes as right itself (Beyleveld & Brownsword 1998). Gewirth defines human dignity as the 'ground or antecedent of [human] rights' (Gewirth 1992, pp.10, 14).Under his moral theory two different views toward human dignity is identified. Human dignity can be recognised as source of rights to ensure that 'other agents do not compromise our dignity and safeguard to assist other agents not compromising their own dignity.

The process of adjudicating rights is not unproblematic and a possible reason for this is difficulty in the interpretation of the concept of 'human dignity'; it can be easily manipulated or abused (Rao 2008). It is for instance an abuse of the concept when in the context of genetic and biolaw we want it to operate 'as a veto on any practice that it is intuitively disliked' (Beyleveld & Brownsword 2003, p.680). Adapting a 'paternalistic view' (Beyleveld & Brownsword 1998) toward concepts like human dignity may result in dangerous outcomes, such as limiting valued scientific and medical progress. Although it is necessary to value the concept of human dignity highly, it is crucial to avoid any abuse or misunderstandings arising from the loose cannon of the concept of human dignity that may result in 'oversimplifying complex questions' and 'encouraging

the [misguided] paternalism' which does not support the essence of 'self-determination' which enlightens the human rights debates (Beyleveld & Brownsword 1998, p. 680). Another issue to take into account here is regarding the conflict of interest, which is always possible to happen even within a co-operative model. For instance, the right of individuals to consent can be overridden by other values. Article 6 of the European Union Treaty read as follows:

> the Union is founded on the principles of liberty, democracy, respect for human rights, and rule of law, principles which are common to the Member States…..the Union shall respect fundamental rights, as guaranteed by the European Convention for the protection of human rights and fundamental freedoms signed in Rome on 4 November 1950 and as they result from the constitutional tradition common to member state, as general principles of community law.

Similarly, the preamble to the Biotechnology Directive[44]itself provides that:

> Patent law must be applied so as to respect the fundamental principle safeguarding the dignity and integrity of the person.

The above briefly refers to the general framework specified through the EU rules and regulation in relation to conflicts between patentability of biotechnological inventions and morality clauses concerning violation of human dignity or any morality related issues. Applying the co-operative model, I submit that the right to hold a patent over an invention can only be offered to override the human dignity related rights (for the sake of argument assume for example 'the rights to give consent in providing bio-material for a research capable of a patent' or e.g. to 'the right to patent the cell-lines involving destruction of human embryos'), if to do so is necessary for the rights and values articulated in Article 6

[44] N.16. Preamble to the Biotechnology Directive,

of the European Union Treaty, or the Articles on the provision of health and right to life[45] for human beings in (Article 2) of the ECHR.

It is evident that whilst we suggest a framework to avoid the risks of causing harm to agents through violation of their generic rights, or their interests being ignored, it is still possible to encounter conflict within such co-operative model. Assuming the same example of patenting hESC research, it is questionable to what extent rendering a patent on human embryonic stem cell research results in protection of agents' health or right to life or any other right with such degree of importance. It is however clear that autonomy or consent, or right to life is of fundamental value and these fundamental values by their nature, can only be overridden for the purpose of protecting more important fundamental values. The next problem emerges with regards to the assessment of fundamental rights under ECHR. As discussed earlier, under the PGC, the conditions necessary for the exercise of, or having all rights, cannot be set aside by others. Therefore the difference between fundamental values and other rights are easily recognisable under the PGC, when we consider fundamental rights and freedoms as what Gewirth defines as the generic features of action (Gewirth 1978, pp. 48-63), 'those the absence of which is detrimental to having of any rights or their exercise and hence detrimental to any actions' (Beyleveld 2006, p.161).

With this in mind, it is arguable that avoiding harm to human embryos (as apparent non-agent) or protecting the right of agents to make free and informed decision and autonomy over our body can be 'necessary', dependent upon final assessment of the effects of these activities on the generic rights of other agents. For example, the prospect of embryonic

[45] Croft, J (1998) in *A Guide to Human Rights Act 1998* emphasise that the Right to Health is not established in the Human Rights Act and European Convention on Human Rights. He argues that 'the realisation of the international *right* to *health* is set out in other instruments but these cannot be directly enforced in domestic courts. The absence of a legal remedy does not diminish the importance of the *right* to *health* but reflects that the right must be achieved in other ways most notably through the allocation of resources.'

stem cell research and whether it is carried out for purposes like providing life-saving treatments for cancer or other terminal diseases that involve human rights and fundamental values. More importantly it is still questionable whether granting a patent for such research is a vital part of these projects, and therefore necessary for the success of the research. Furthermore, if any activities occur violating the informed consent of donors or providers of bodily materials, the justification for carrying out research on their bodily material, and making patent out of it, the necessity of carrying out research without participants' consent' has to be justified. It should be clarified whether it was possible for the scientist team to pursue the research without violation of participants' right to autonomy over their genetic material. Similarly, it is important to examine what would have happened if the participants would have been informed adequately about the research, or any possible future commercialisation. It is also important to investigate the availability of any compensation for participants and whether they have been offered any type of financial remuneration in return for their contribution to the research, in order to avoid the suspicion of exploitation of research subjects.

Under this line of analysis, I emphasise the importance of the consent under the concept-theoretic position according to which, if a valid consent is obtained, then there would be no concern with respect to the subsequent substantive justification. Therefore, valid consent in a co-operative model is required in order for it to be a significant driver to respect fundamental rights and freedom. The role of informed consent will be illustrated more in depth in chapter V in analysis of patent cases such as *Relaxin*, *Hagahai* indigenous people, *John Moore*, etc. The Gewirthian approach explains respect for human dignity as respect for agents as 'autonomous ends.' Therefore, in order to protect the fundamental rights of agents it is necessary that their freedom and wellbeing not interfered without their will. It appears very distinctive in some occasions

with respect to the notion of informed consent. For instance, under the concept-theoretic position an agent's free choice to end its life in order to 'die with dignity', or to trade in its gene should be recognised at least as its *prima facia* right. As Beyleveld and Brownsword note the PGC rejects duty-led arguments as misguided paternalism , where it claims such treatments amounts to as 'agents compromising their dignity'(Beyleveld & Brownsword 2003, p.680), or when the PGC as a framework inflicts some degree of self-harm (Beyleveld & Brownsword 1998).

Gewirth explain it as follows:

> What does the *PGC* require in cases where persons fulfil the cognitive and emotional conditions for voluntary consent and yet refuse to consent to interferences with their self-destructive or other projects whereby they intend to inflict basic harms on themselves? Such projects include suicide, selling oneself into slavery, ingesting harmful drugs, and the like. . . .[W]hen it is clear that the conditions of voluntariness have been met by the projected self-harmer, further interference with him must be discontinued (Gewirth 1978, pp. 264-265).

It is noteworthy however that the quality of informed consent procedure and laws must be evaluated regularly to ensure that a valid consent is obtained. There should be measures to assess the fairness of the system. There should be strategies to find out any conflict of interest for instance for scientists. If they have been financially involved in a research project, then there should be ways according to which the procedures of informed consent from donors of bodily materials e.g. human embryonic stem cells is monitored and governed carefully to avoid any further complexity or violation of rights.

4.4 Chapter Summary

This chapter proposed a co-operative model in balancing rights between intellectual property and human rights, concluding that although the two sets of values have the potential to come into conflict, one can also support the other. The chapter considered how the morality exclusions can plausibly work in support of IP rights. This thesis suggests that a PGC-based framework for the interpretation of morality within patent law does not necessarily limit the protection of IP rights, but also encourages and supports the greater benefits for IP rights holders.

CHAPTER V

APPLICATION OF THE PGC TO RECONCILE COMPETING RIGHTS IN EU PATENT LAW

5.1 Introduction

5.1.1 Chapter Structure

In this chapter, a number of cases relating to biotechnology patents will be discussed. In the first part, the facts of each case will be presented, in order to provide brief background information on the invention and its function. Subsequently, a chronological statement of the sequence of the events will be offered. In other words, the chapter aims to discuss the reasons for patent application, grant of the patent and challenges in granting or refusing the patent, whether the patent was opposed, or the patent brought to a particular Division or court. All these will be explained in this section. After describing the main events in each case, a separate section will be allocated to critical analysis of the issues raised by the judgment or by the facts of the case within the framework of the concept theoretic position.

Addressing the issue of patentability and how to strike a balance between competing rights is a complex issue which requires taking into account a diverse variety of justifications. Therefore while analysing those issues under the concept -theoretic framework, it is the aim of this chapter to look at controversial issues case by case and depending on the facts of the case and the judgements made at that specific case.

5.1.2 The Relationship between the PGC and other Theories

In this chapter, I examine the interpretation of EPO and preliminary ruling of the CJEU in patent cases from the viewpoint of the PGC for the same reasons given for the adoption of the PGC in earlier chapters. As aforementioned, one justification is 'dialectically necessary' and one justification is 'dialectically contingent'. The argument of this thesis provides that, if the legal system operates according to human rights

principles, anyone who adheres to human rights must also adhere to the PGC. I argue that this system of European law, and all these judgments in law, must comply with human rights (Beyleveld 2012, p.17). People with different stances to my own would say that some of the positions in the proposed framework of this thesis, such as avoiding animal suffering, seem quite obvious from the perspective of other moral theories. They may also criticise my approach as too partisan for the PGC. While this perspective is fine, I should be absolutely clear about some important issues here.

This thesis is about what the PGC requires. This is its subject because commitment to human rights requires the PGC rather than utilitarianism or any other approach. It is not that a commitment to human rights requires the PGC, as any theory holding that 'one ought to treat agents impartially'; utilitarianism holds this (Gert 2011, p.6)[1], in addition to various discourse theories and contractual theories (Parfit 2011, p.235), and so must accept the PGC. It is not therefore coherent or consistent to be a utilitarian and not accept the PGC. Since utilitarianism relies on the premise that 'everyone has to be treated equally and impartially with respect to their interest', if the first stage of Gewirth argument is right (as was established to be the case in Chapter 3 of this thesis) then the Principle of Hypothetical Imperatives is dialectically necessary. In order to be a utilitarian, you must accept the Principle of Hypothetical Imperatives. You must therefore also accept that you have duties to protect Generic Conditions of Agency, if you have the impartiality principle for any reasons.

It is because the commitment to human rights presupposes the impartiality principle that it also presupposes the PGC. Any theory that presupposes this impartiality has to accept

[1] A broad interpretation of utilitarianism means "morality requires impartiality with respect to all of a person's actions or inactions that might affect anyone, including oneself". John Stuart Mill in Utilitarianism (Chapter 2, Paragraph 17) says "As between his own happiness and that of others, utilitarianism requires him to be as strictly impartial as a disinterested and benevolent spectator."

the PGC. Therefore, other theories may indeed come to the same conclusion. It does not mean that the PGC is same as these other principles and this is not just because these theories may have requirements that the PGC does not. It is probable that these other theories accept certain principles that the PGC does not and that they presuppose the PGC in a somewhat self-contradicting fashion.

This section is about the relationship between PGC and other theories. It aims to go beyond the discussion of how PGC differs in its content, but to explain that there are 'some' other theories in play which may suggest the same position as discussed under the concept-theoretic position. The use of 'some' should be emphasised, as there are theories including ethical egoism (Hooker 2013) and complete immoralism (Leiter 1997, pp. 267-285) that do not have an 'impartiality principle'. Various moral theories including utilitarianism and contractualism hold an impartiality principle. The way in which they suppose the impartiality principle is being justified is via their own method and language. They may not think (or at least not all of them think) that the impartiality principle is justified in some sort of transcendental way (Bracanovic 2007, pp.19-21). However, they all are going to accept the first stage of Gewirth's argument. Even though the 'dialectically contingent argument' from human rights uses the first stage, the problem with the 'dialectically necessary argument' is how you prove the impartiality principle.

In brief, in this chapter I judge whether selected decisions made by the EPO and CJEU are in accordance with the PGC. I analyse these cases and explain to what extent they reached PGC-compatible decisions. Where this is not the case, I suggest what these decisions require to be compatible with the PGC. Decisions reached by the PGC will be very similar to decisions reached on the basis of some other moral theories in some cases. As a matter of the fact, many conclusions that they would reach are the same as

those that would be reached by the PGC, but some are certainly not. It is important to note that the way the 'dialectically contingent argument' from human rights, the source of the concept-theoretic position in this thesis, actually work is that it operates on the basis of the impartiality principle (Beyleveld 2012, p.6). As stated previously, various other theories adhere to the impartiality principle. If one starts with the assumption of human rights, whether one is a utilitarian or a contractualist, or anybody who believes in discourse ethics assume that they can prove the impartiality principle or think that a theory including the impartiality principle is better than any other. If they adhere to the impartiality principle, this means they are committed to the PGC if the first stage of Gewirth's argument is correct. However, if they do not, this is not that the PGC differs from them, but this means that they are inconsistent with themselves or have to give up the impartiality principle. In a sense, the fact that there is an overlap means that in practice adherence to the PGC does not necessarily make a difference, but that is not the point. The point is that there are circumstances in which it does make a difference and those cases are inconsistent. The PGC therefore fits best in this framework and makes more consistent conclusions and interpretations.

5.2Oncomouse Case

5.2.1 Facts and case summary

In 1985, the Harvard patent application [2] considering the patentability of transgenic [3] *Oncomouse* [4] was brought to the EPO. This controversial creation was initially introduced by Harvard University scientists who meant to develop cancer cells

[2]European patent application No. 85 304 490.7and published as No. 0 169 672.
[3]"Transgenic" in relation to animal means DNA from other species has been artificially introduced into their genome. The main purpose of creation of transgenic animals is to develop potentially beneficial applications, such as medical research, enhanced food production, and the production of proteins or organs.
[4]The name comes from the Greek word for tumour.

in the mouse's body, as it holds an inherent cancerous gene which is thought to be useful in cancer research and introducing cancer treatments. The lengthy litigation of *Oncomouse*, however, lasted until 2004 as it went through Examination and Opposition level in the EPO. One of the crucial issues regularly raised in the proceeding was regarding the application and interpretation of *ordre public* and morality exclusions under Article 53(a) of European Patent Convention. In spite of the recognition of ethical issues over using animals in cancer research in the law, the Examining Division initially ruled that patent law is not an appropriate venue to address these types of ethical issues.[5] The patent application, however, was rejected on other grounds and Harvard appealed the case to the Technical Board of Appeal.

The Technical Board of Appeal essentially provides the following arguments.

1. In the *Oncomouse* case 'there were compelling reasons to consider the implications of Article 53(a) EPC in relation to the question of patentability.'[6]

2. Due to ethical issues involved in cases of genetic manipulation of animals including the suffering of animals and potential risk in case they escape to the environment, there should be a test to evaluate the Article 53(a) in an *Oncomouse*-type case.

3. Therefore, the respective 'test' must be based upon 'a careful weighing up of the suffering of animals and possible risks to the environment, on the one hand, and the inventions' usefulness to mankind on the other.'[7]

Submitted to the Examining Division, the proposed test was applied for the first time. Under a number of justifications, EPO attempted to undercut the *ordre public* and morality exclusions of the Article 53 of EPC. It was claimed that patents do not offer a

[5]*Harvard/Oncomouse* T 19/90 Examining Division (14 July 1989) [1990] EPOR 4.
[6]*Harvard/Onco-Mouse*[1990] EPOR 513.
[7]T19/90 *Harvard/Oncomouse* EPOR. 513.

positive right to the patent holder but rather enable the inventor to exclude others from exploiting the invention for a limited period of time. It was also mentioned that the exclusions in Article 53(a) are to be narrowly construed. It was claimed that inventions involving genetic engineering are not generally excluded from patentability followed by the final claim that although the development of new technologies is normally afflicted with new risks, this does not mean that there should be a negative attitude to new technology (O'Sullivan 2008, p.3). In the subsequent sections, it will be considered whether these arguments are in accord with the concept-theoretic position.

In order to apply this balancing test, initially a number of issues in the specific context of genetic manipulation case, which were identified by the Examining Division, need to be taken into consideration. These issues include avoidance of cruelty to animals, environmental protection against 'uncontrolled dissemination of unwanted genes', and supporting the interest of human beings to 'remedy widespread and dangerous diseases'. The following conclusion drawn by the Examining Division on the case of *Oncomouse* is linked to one or more of the above list.

a. Although animal testing has been generally sanctioned in contracting states, the Examining Division mentioned that the interest of human beings in relation to the undeniable effect of these tests in remedying the disease and developing the cancer research should be taken into account.

b. In terms of avoiding cruelty against animals, it was reasoned that there would be a lesser number of animals in the long term to be required for research, hence less future animal suffering in principle, due to the accuracy of *Oncomouse* in developing cancer in the respective animals.

c. In relation to potential risks for the environment, the Examining Division found the probability as 'practically limited to intentional misuse or blatant ignorance on the part of laboratory personnel carrying out the tests'[8]. Hence, it was concluded that it cannot create a 'major determinant' regarding the grant of a patent. They also mentioned that specialised governmental authorities are in charge of regulating dangerous material (as opposed to the EPO) and it is not logical to reject a patent merely on the basis of dangers involved in the technology of that invention.

Therefore, it was concluded that the *Oncomouse* patent is not in violation of the *ordre public* and morality under Article 53(a) of EPC mainly because it brings great potential benefit for human health. Furthermore, it was reasoned that the patent results in a drop in the number of animals used in research in the long term and it has very minimal possibility of environment risk (animal escape). They however clearly mentioned that this conclusion is solely made on the basis of this particular case and decision in favour of *Oncomouse* should not be considered in favour of all future transgenic animals.

5.2.2 Opposition to Oncomouse and the EPO Ruling

Transgenic animals provide potential beneficial application for a variety of purposes including human health. The process of genetic manipulation in animals has, however, been a source of ethical controversy. Although the concerns around some of these 'inherently unacceptable' inventions are definitely much wider than the concept of 'patentability' and occur at the very initial phases of research and development, some new technologies are brought to the public attention as soon as the application is made to the Patent Office (WIPO 2006).

[8] *Harvard/Oncomouse*[1992]*OJEPO*588, Para 4.

Offering some future hope in cancer research, *Oncomouse* was carefully looked after to be patented (by Harvard College) not only in United States, but also in other countries. In its place of origin, initially a number of issues were raised. Apart from general concern regarding transgenic technology per se, two other major problems particularly in relation to patent regulation were brought to the public attention. The first question in the United States concerned the issue of whether or not animals or animal varieties specifically 'higher order animals like mammals' are patentable considering that they meet other patentability criteria.[9] The second one addressed the dilemma on the assessment of complicated notions like the suffering of animals, and the question of how moral implications like suffering in the process of genetic manipulation for transgenic animals should be evaluated. The *Oncomouse* patent was granted in the United Sates in 1988 to Harvard College in recognition of their invention, 'a transgenic non-human mammal whose germ cells and somatic cells contained a recombinant activated oncogene sequence introduced into said mammal'. [10]The next section will analyse the position of the EPO in addressing the *Oncomouse.*

First Decision of Examining Division

Since the case arrived at EPO in 1985, it had to be examined through a long process and at several levels, and only came to a final resolution in 2004. According to the law, EPO was obliged to apply the relevant patent regulation; at the time, the European Patent Convention. Under EPC, inventions must be excluded from patenting on a number of grounds which in this particular case, was Article 53(a). The EPC had to deal with the *ordre public* and morality exclusion in part (a) of Article 53 in order to investigate

[9] Patentability criteria may include novelty, industrial applicability/usefulness, inventive step, etc.
[10] Patenting of 'humans' is still excluded by the United States patent office due to ethical and legal issues on manipulation and modification of the human genome (WIPO 2006).

whether the *Oncomouse* should be specifically excluded from patentability as an invention 'the publication or exploitation of which would be contrary to *ordre public* or morality'. The utilitarian approach (risk-benefit test) that was developed within the EPO intended to evaluate the potential benefit of *Oncomouse* patent, e.g. for human health, against its possible harm, e.g. the suffering of the *Oncomouse*. As discussed in the last section, other issues, including environmental risk were also taken into account in the balancing test. They also considered if there would be any public concern or objection regarding the use of mice in cancer research for which no evidence in European culture could be found. It was eventually decided that the possibility of substantial medical benefit through using *Oncomouse* and progressing cancer research outweighs the suffering of the mice. The argument presented by the EPO in relation to assessment of the risks and benefits cannot stand alone. It definitely should be dependent on the level and importance of the benefits and risks, duties and rights involved. It is however not very clear how the EPO approach is capable of evaluating risk and benefits adequately. [11]

The Opposition Division and Technical Board of Appeal Decisions

Somehow different from the typical interpretation of Article 53, the Opposition Division decided to interpret Rule 28(d) of the EPC[12]by providing a three-stage test.

[11] A very relevant example of adapting the same utilitarian approach but achieving different outcome is the EPO's unreported *Upjohn*[11]case which was filed on 1989 and refused in 1993. The patent application was made by the Upjohn pharmaceutical company on a transgenic mouse. In order to test a new type of pharmaceutical product to treat the baldness and hair loss, the mouse would lose its hair upon introduction of a gene. Contrary to Oncomouse decision, the EPO this time concluded that the possible harm which is suffering by the mice outweighs potential benefits of this research to cure baldness. Therefore, the exploitation of the invention was not acceptable and the patent was refused on the ground of being contrary to morality (Bonadio 2015 p.159).

[12] Rule 28 was created as a result of the EPO incorporating the EU Directive on the Legal Protection of Biotechnological Inventions into the EPC (formerly known as Rules 23(b)-(e) EPC 1973) in year 2000. It provide that : 'Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:(a)processes for cloning human beings; (b)processes for modifying the germ line genetic identity of human beings; (c)[29]uses of human

The first two-step relates to evaluating the likeliness of the animal suffering, and the likeliness of the invention providing 'substantial medical benefit.'[13] This is followed by a third factor, 'the date to which this evaluation should be directed-the date of the patent application (the effective date) or the date of the oral hearing.'[14] Therefore, according to this interpretation of Technical Board of Appeal, which is in agreement with the previous decision of Opposition Division, the balancing test relates to the possibility of the suffering of animals against the likelihood of any potential medical benefits for animals or humans. The test, however, does not entail any factor relating to the availability of non-animal options or the degree of suffering. Assessing the likelihood of suffering against the possibility of substantial medical benefit is undertaken on the basis of 'present knowledge' while looking at 'future possibilities'. Hence, the Technical Board of Appeal reiterated the earlier position of the Opposition Division determining the date to be considered under Rule 28(d) as the effective/filing date. This statement however is not a definite one, because it makes provisions for taking into account any 'evidence, which demonstrates the state of affairs at the effective date'. Hence, it may appear contradictory with later definitive evidence related to the 'assessment of the provision grounded in reality'[15] when it considers a claimed invention regardless of its real substantial medical benefit or animal suffering.[16]

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embryos for industrial or commercial purposes; (d)processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.'

[13] An important distinction between the T 19/90 and the Rule 28 is that while the former suggests 'a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the inventions' usefulness to mankind on the other,' the latter aims to balance the suffering of animals with a 'substantial medical benefit to man or animal.'

[14] OJ EPO 10/2003 (7 November 2001) 419. Point 9.2. The Opposition Division. Comparing other language versions of the EPC, it was however decided that the word 'likely' when stating 'likely to cause them [the animals] suffering without any substantial medical benefit' is intended to apply on the entire phrase.

[15] *Harvard/Onco-Mouse*OJ EPO [2003] November 2001 419. Point 9.

[16] As discussed, the balancing test in Article 53(a) was to assess the suffering of animals and risk to the environment against the usefulness of the invention. It, however, considered some additional factors

The Board finally decided to cover some additional issues in a further investigation, including the threat of the *Oncomouse* to evolution; the increased use of animals in research; the public abhorrence to genetically modified animals, the situation in other non-contracting States, protection of animals in European treaties; opinion polls and surveys; statements and resolutions of organizations and parliaments.[17]

Reconsidered Decisions of Examining Division

The Board rejected the relevance of some claims made by opponents at the earlier stages. For instance, a claim was made regarding the public unease caused by the patent and the reference to this claim was Technical Board of Appeal's comments on the controversial nature of transgenic animals while this board on 2004 was not prepared to accept this comment as an evidence for public distaste or unease for such transgenic animals in general. The Board also refused to accept the opinion polls as a reliable

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including the European moral consensus on the concept of *ordre public* or the degree of suffering in animals or non-animal alternatives. Consequently, it was a broader test compared to Rule 28(d). Under the interpretation of Rule 28(d), although evidence were supposed to be related to the filing date, evidences that become available later could be also taken into account if relevant.
Soon after, the final decision in relation to European *Oncomouse*-heard by the Technical Board of Appeal in 2004-established a combination of two tests under Rule 28(d) and Article 53(a). (*Harvard/ Transgenic animals* [2005] EPOR 271)

This combined test consists of the first stage of evaluation made under Rule 28(d) and second stage (if applicable) under Article 53(a). It means that in the first stage, what should be sought and examined is the likelihood of the animal suffering in the case.

Then the likelihood and degree of medical benefit ought to be decided. This means an evaluation of how balanced the medical benefit are in relation to animal suffering, must be undertaken. By passing this stage, further tests would be required under article 53(a). However, if the invention fails at this stage, then it means that it is considered a failure for the entire *ordre public* and morality provision. Specifically in Oncomouse, the board first considered the existence of suffering in the animal unavoidable. Then applying Rule 28(d), they concluded that there is not necessarily evidence to support the claim that the exploitation of the invention would be necessarily useful as a model to obtain the medical benefit. As the case failed in the first stage of the test, there was no need for further assessment under Article 53(a).
It was appealed as a result of which the invention successfully passed the first stage of Rule 28(d) test. As such, a combined test became necessary, thus enabling the subsequent application of Article 53(a) within the broader *ordre public* and morality issues. The test was basically consisted of degree of suffering, possible risk to environment, and availability of non-animal alternative. The result of applying the new test was that this technique used in *Oncomouse* considered more effective, when compared to non-animal models. It was also further concluded that it was nearly impossible to measure the degree of suffering caused for the mice. With regard to environmental risk, it was decided that it could merely have a 'neutral effect' that is far from being convincing enough to have a negative effect, when compared to the substantial medical benefit of the invention (O'Sullivan 2008, p.15).

[17] *Harvard/ Transgenic animal* [2005] EPOR 333-336.

source of evaluation and understanding of the public perception as it deemed it to be mainly dependent on the nature of questions, methodology, and structure of surveys, etc. It was decided that there was not enough evidence to discover a 'status of moral disapproval' within the European public, although a general level of public unease existed against animal experimentation.

Furthermore, it is arguable that proving the likelihood of substantial medical benefit is to some extent subjectively on the inventor's side. Therefore, the fact that the burden of proof falls on the opponent results in impeding the challenge of *ordre public* and morality on the Opposition's Division. Moreover, for different reasons, including constant rejection of opinion poll the idea of reaching a European moral consensus would become less accessible although such harmony is the main aim of the EU legislations.

Warren-Jones (2008, p.193) emphasises the tendency of the EPO to exercise a system of *ordre public* and morality tests which undermines both the scope of provision and issues related to the appropriate application of this provision. This possibly occurs in three ways. Firstly, the EPO sometimes adopts the 'equivalence approach', which means that they equate the application under review with an invention in which that specific practice is accepted. For instance, chimeric animals in *Leland Stanford* [18] were compared to the accepted practice of using human tissues in inventions. Secondly, the EPO refers to the 'existing protection mechanism' in situation that they ought to imply the legislative obligation for assessment of *ordre public* and morality. Thirdly, the EPO often refers to the established principles of the patent system to undermine the scope and evaluation of exclusions. For example, it is regularly claimed that patents have a

[18] *R v. Leland Stanford/ Modified Animal Opposition Division 16 August 2001 [2002] EPOR 16.*

limited ability to give a positive right for the exploitation of the inventions, and that the patent system is mainly used to prevent others from using the inventions without the patent holder's consent (Beyleveld & Brownsword 1999). The above-mentioned type of justification leads to an overall destabilisation of Article 53 or the refusal of *ordre public* and morality evaluation.

The EPO approach of balancing test has brought inconsistency and delay to the system. This would be worse, when using a new legislation on the old patent application, where it is supposed that the filing date is to be considered as a valid date, but further evidence would to be acceptable and is taken into account. The implementation of such complicated test is definitely one of the main reasons why a patent application like *Oncomouse* goes forward and backwards in the EPO for almost nineteen years. Considering this, it is clear that it is not only the initial test in *Oncomouse*, which is flawed, but the later versions of the proposed test are flawed, unclear and unreasonably complicated.

5.2.3 *Oncomouse* as Viewed from the Concept-theoretic Position

Although the balancing tests adopted in *Oncomouse*[19] are considered in a sense as the broadest interpretation of Article 53(a), it has attracted heavy criticism from a large number of scholars including Beyleveld and Brownsword's argument in relation to inadequacy of such balancing tests in *Mice, Morality and Patents* (Beyleveld & Brownsword 1993).

[19] As discussed in footnote 17 of this chapter, three methods of interpreting *ordre public* and morality were used in patent cases in the EPO prior to the introduction of the Biotechnology Directive. The first method was balancing animal suffering (and environmental risks), versus its usefulness to human beings. The second method was relying on the individual evaluation of *ordre public* and morality, meaning evaluation based on the European society's ethical norms and criteria of acceptability, and third method is concerning *ordre public* and morality with European consensus on abhorrence to the invention[19] (where the burden of proof was on the opponents).

i. What does granting the patent do?

The patent applicant and examiner in the *Oncomouse* case claimed with reference to the research community, that animal testing in cancer research is both necessary and valuable. It was emphasised that no alternative to the use of *Oncomouse* can be considered at present, which means that granting the patent was necessary for the attainment of the cancer research ultimate aims. Professor Leder, one of the applicants in *Oncomouse*, claims that 'as a practical matter, it turns out mice have a number of advantages' and he particularly refers to the importance of Mice's '21-day gestation period, intact immune systems and known gene sequence among the benefits.' Defending the importance of patents on engineered mice models, he emphasised that the court's decision to permit the grant of Oncomouse could make the progress occur more quickly in the field, indeed '…other animal modifications will be patentable and will encourage people to be creative and to invest in this field of research' (Ho 2004).

In spite of the above, some arguments in literature emphasise the importance of avoiding animal cruelty and prevention of unnecessary intellectual property protection if doing so would unfavourably affect the patients' access to medicine or diagnostic treatment. If we accept that no other reasonable alternative can be found, it does not follow that we as human agents have no duty toward non-human creatures. It follows that if we accept that cruelty to animals should be avoided, as we have a duty not to make them subjected to cruel treatment, then the examiners' defence in favour of granting the patent may not be considered sensible. In the following paragraphs, an explanation of how the concept-theoretic position interprets the entitlement of non-human to rights and our duty of humans to non-humans is provided.

ii. What powers does it give to patent holder?

The patent holders have repeatedly claimed that the availability of patents for the biotechnology inventions, including *Oncomouse*, protects their investment in research and development, and allows researchers to invest again for future research projects upon completion of the project and receipt of its financial return. Also, they may argue that the income from patents including royalty or licensing fees is necessary for universities to providing Research and Development, because without such financial profit there would be no further investment, and therefore no hope for introducing new life-saving treatments. Since under the PGC we must avoid unnecessarily endangering the life of agents, it is necessary to find out whether patents are actually necessary for achieving the medical purposes of the invention. Now, let us first analyse this claim in the case of mice models, and see how such patents contribute to the development of *Oncomouse*-like innovations.

I begin the argument with the position of those who criticise the financially-oriented research environment of universities (Ho 2004). The claim that a laboratory mouse may contribute significantly to revenue has a history even before the Harvard *Oncomouse*. However, this claim on generating a large profit from an engineered mouse is yet to materialise. In spite of the resistance by academic institutions and pharmaceutical companies to continue with a tight patent protection system, surprisingly on average only 1% of the research budget in the universities is sourced from royalties on patented inventions. Let us forget the fact that most universities are breaking even and the fact that some universities lose money whilst undertaking the commercialisation process in biotechnology sector. Successful products at best may generate approximately 2-3% of their research budget from the typical benefit of these patented products. In the particular case of laboratory mice, it is believed that a successful model may contribute

'tens of thousands of dollars but not millions' (Ho 2004). Therefore, empirical evidence shows that the hope of creating a commercially successful laboratory mouse is portrayed as 'unrealistically high' by some academics (Ho 2004). On the other hand, the positive relationship between innovation and patents, on which many scholars have defended the permissibility of patents, is far from clear yet in the specific context of genetic research. Quite contrarily, latest research projects indicate that patents in genetic, hinder research and influence patient care negatively (e.g. Greenemeier 2010).

Considering the fact that developing patented engineered mice has not positively helped the system either financially through generating significant funding for the future research project, nor intellectually through creating a suitable environment of motivation and innovation for researchers, it is actually questionable whether the patent on *Oncomouse* granted any remarkable power to the patent holder. Clearly, the patent holder is given the right to prevent others from commercial exploitation of its patent. Most importantly, granting a patent to *Oncomouse*, like any other patent, authorises all activities carried out in the process of the invention. Therefore, here the patent holder is given the power to carry out the research and continue testing on mice, and commercialise the use of such research on the genetically manipulated mice.

iii. How can the exercise of those powers, directly or indirectly, lead to consequences which are contrary to the PGC?

Having analysed the actual power given to the patent holder through *Oncomouse*, it was noted that the grant of *Oncomouse* patent means that problematic activities (any activity in violation of the concept of *ordre publi*c and morality) carried out in the process of the invention, may be justified if a substantive health benefit for a human being can be proved. This however depends upon different rights, which are directly or indirectly

involved in this particular case to see whether one right can override another under the PGC. As discussed in previous chapters, agents *prima facie* have rights to anything which is Generic Condition of Agency. However, a *prima facie* right can be overridden by another prima facie right, which means that the rights agents actually have in a particular case are these that are overriding. It means that we do not have 'stand alone' rights. The rights agents always possess are what the PGC requires. The right agents actually have is what the hierarchy requires in relation to Generic Conditions of Agency. However, there are considerations that must be taken into account whenever we want to determine which rights one can have in a particular situation.

Here, it is required to find out what generic rights are involved, and analyse the factors which may have some bearing on a number of these generic rights. Then we must try to answer the question of why and in what way they are relevant to the criterion of degree of needfulness for agency. Since we, as agents, have a duty to protect animals under the concept-theoretic position, I should here analyse whether to cause suffering for the mice is acceptable here and how it can possibly be justified.

As discussed in section 3.4.3 of this dissertation, for the purpose of the concept-theoretic position, two different approaches can be considered, either Gewirth's original position on dealing with non-human animals or the Beyleveld and Pattinson (2000, p. 201) 'precautionary reasoning' justification on our duty for non-human animals. I would rather use Beyleveld's 'precautionary reasoning' as the basis of my argument for patent cases like *Oncomous*e. In Gewirthian terms, although it is true that generic rights are not granted to non-agents, since these are rights to assistance and non-interference in accordance with the right holder's will, agents have to protect the interests of non-humans as well for different reasons. The essence of both views is the idea that merely because a number of living creatures are not capable of displaying the agency features,

this does not mean they necessarily lack agency. Thus, if we believe that we are automatically entitled to act against the interest of these creatures, there is always the risk that they are agents and that we violate their rights. Interestingly, Dworkin argues that the wrongful denial of rights creates more serious risk from a moral point of view when compared to a wrongful grant of rights (Dworkin 1977, chapter 7). Gewirth (1978: pp.121-124 & pp. 144-145) believes that we should consider duties to non-human animals in proportion to the degree to which they approach the apparent agency. Relating the issue to the subject of *Oncomouse* case, this means that it is not morally accepted that the suffering of an animal is accepted only on the basis of its usefulness for the human. In order to decide whether such usefulness for humankind can justify the scientists' activities which cause harm to the mice, we need to carefully examine what this usefulness means in terms of affecting the Generic Conditions of the Agency of agents.

In a concept-theoretic position, PGC requires agents to act according to generic rights of all agents, and generic rights of all agents refer to duties not to interfere with the Generic Conditions of Agency of agents. The outcome will be varied on the basis of the level of rights and agents we are comparing and how harming the right of other agents will affect their conditions of agency or how it improves other agent's conditions of agency. Gewirth provides his argument by using the principle of proportionality, non-human animals can be entitled to some primary rights proportionate to the extent of their approach to the full agency (Gewirth 1978, pp.121-124), which means that if a living creature is in a status capable of experiencing pain they have to be protected against being tortured or being killed. Under this line of analysis, it is perceived that the

capacity to experience the pain is a necessary (but not sufficient) criterion for being considered as an agent.[20]

Gewirth's justification of our duty towards animals will not be used here because it was reasoned in the last Chapter that Gewirth is wrong in using the principle of proportionality in this context. Instead, I accept the 'precautionary reasoning' argument, which he does not use, and according to which it is a matter of duties to animals versus human rights not animal rights versus human rights or human rights versus human rights.

The immorality exclusions in Article 6(2) of the Biotechnology Directive may be viewed as necessary exclusions. However, there are other possible exclusions, which could be taken into account on a moral basis. It is also arguable that these exclusions can be viewed as discretionary, although it still requires a justification on the basis of human rights in that the duties that these exclusions make for agents may come into conflict with the rights of other agents. For instance, 'freedom of expression' is an inalienable right recognised in human right instruments and maybe viewed as a source for the 'right of freedom of research'. The right to freedom of research, however, might be restricted in favour of moral rights of animals recognised impliedly in Article 6(2)(d) (Adcock & Beyleveld Working Paper, p.7). This freedom of research may cover the rights of scientists to enjoy from the economic benefit arising from the invention including any benefit in relation to protection of the patent. As was mentioned above, the reasoning for recognition of such moral rights for animals can be a protection of human rights, in that, through a precautionary manner, human agents avoid any

[20] Hare (1969: pp.29-42) interestingly compares different levels of pain and suffering which can be experienced by non-human animals on the grounds of their capacity for pain and mental capacity for suffering. Hence, dogs, for instance, enjoy a higher degree of protection since they have a developed capacity for pain compared to e.g. earthworms. However, dogs may receive less protection compared to gorillas in that gorillas are believed to have a higher degree of mental capacity, which leads to more potential for suffering against the mere experience of pain.

violation of non-human possible agency rights (Beyleveld & Pattinson 2008, pp.45-47). One may go even further and argue that it is even much more complex than simply reasoning that the European Convention on Human Right is a Convention for the human beings and not nonhuman animals and therefore should not provide any protection for non-humans such as *Oncomouse*. In order to confine the rights to human beings based on the European Convention on Human Right, the "Entitling" properties possessed by human beings have to be specified (Beyleveld & Brownsword 1993, p.101). The European Convention on Human Right does not make any clarifications regarding the defining features of the human being, these entitling individuals to rights. It is arguable that patent examiners could have formulated a theory based on the 'European critical cultural morality' for the basis of the human rights to recognise these features in the silence of the law.

On the other hand, relying on contingencies, it may be viewed differently. In such view it is argued that since some humans have a contingent sensitivity to the suffering of an animal which means the violation of moral rights of animals threaten the rights of these human agents (Beyleveld & Brownsword 2007; Beyleveld 1998). It means that the source of non-human's rights entitlement can be duties of the human being either to other human beings or themselves. Similarly, Peter Caruthers (1992, p. 8-12) develops a discussion regarding the source of human duties to non-humans. We have duties on the basis of avoiding distress to other human beings who care very much about animals and ceteris paribus.

In cases like Oncomouse, it is very crucial to understand the hierarchy and importance of rights and duties at stake i.e. how substantial is the effect of tests on non-human agents in favour of generic condition of agency (specifically life) of human agents. In one side of scale is the right of scientist to freedom of research, which in its own can be

classified as a generic right. It may be classified under the category of basic needs (rights) which includes 'the freedom to act according to one's chosen purposes and freedom of thought' (Gewirth 1978, pp.52–53; Beyleveld 2012, p.2). The scientist may even argue that they are financially dependent upon such activities to afford their life expenses, which, again, is related to their generic right to basic well being. If not the above, it can be seen as a generic right under the category of additive needs which include access to new information and opportunities to learn new skills. In another side of scale, we have the duty to protect the interest of non-human animals under precautionary reasoning. Now my assessment based on the criterion of degree of needfulness for agency gets easier.

It is clear that mice are classified as highly developed animals more or less on the same par with animals like dogs. We need to specify how much protection is exactly required. It is necessary to distinguish between a number of situations, e.g. between cases in which treatment is accompanied by pain and suffering for animals and those which are not. Dresser (1998, p.409) refers to the case of mice genetically engineered for the purpose of their milk, biologically active human tissue plasminogen activator as a case, which does not involve pain and suffering. Furthermore, under the concept-theoretic position a line must be drawn between cases that no alternative can be found, and those which the use of animal models can be substituted or at least where there are alternatives for using animals in a way which does not inflict pain and suffering to the animals. It also requires differentiating between cases which human rights (or rights of any other animals in a higher level compared to mice) are threatened and cases where such threats are not seen (Beyleveld and Brownsword 1993, p 108).

Furthermore, it was claimed in *Oncomouse* as a justification for causing pain and suffering to mice, that tests on *Oncomous*e reduce a number of future tests on animal

and would gradually minimise the suffering of mice. If this is true, it is a positive factor to take into account while defending the grant of patent. Let us see if this is indeed a true claim. Addressing this issue in the genetic literature, it is noted that a potential obstacle in such research project is that these genetically-manipulated mice regularly become 'technologically obsolete' in a short period of 1-2 year and needs to be substituted by another model (Ho 2004). Interestingly, he added:

> obsolescence can occur easily if, while one company is expending resources to develop a strain for sale, another produces a mouse or even a rat on a better background strain, or one that has a slightly better gene construct or integration–expression site. Obsolescence might occur before income from the mouse has returned the cost of development.

This means a claim like 'let us do our tests now; so that we can do it less in the future as we expect the results to help us significantly for a long time' are questionable to some extent at least in the context of research in genetically manipulated animals.

iv. Are there other ways in which they could do this?

Having addressed different scenarios, which may have happened as a result of the grant of *Oncomouse* patent, we can now draw a fine line between different situations using the criterion of degree of needfulness for action. As discussed earlier, since the protection to mice as an apparent non-agent is given on a precautionary manner, if apparent agents' more important rights (meaning rights 'higher in the hierarchy' of the concept-theoretic position[21]) is in scale and there is no other way to protect the given

[21] Under the concept-theoretic position basic needs which agents need to be able to act at all are placed highest in the hierarchy of rights (needs) followed by non-subtractive needs which agents need to maintain their ability to act, and additive needs agents need to improve their ability to act. It is important

right, the mice's interest may be overridden. However, if it is e.g. only about additive needs of agents to carry out a research and learn for their own/their organisation's interest, with no hope at all to achieve any outcome which may ultimately have any effect on more important generic right of agents (like a research with significant potential to save lives), then that right can be overridden in favour of mice to live without suffering. This assessment came with some actual social and scientific factors in last section. Let us now summarise how this balancing criteria works.

First, the function of the patent and the benefit it offers in relation to agents' generic conditions of agency must be carefully examined. It is a matter of conflict of duties and rights. If the benefit given to agents is higher in the hierarchy compared to the duty they have toward non-agent animals, the suffering of such animals may be justified. This, however, does not mean that such cruelty is automatically permitted, merely because we are human and they are not. in support of this, the European case law is compatible with the requirements of the PGC while deciding the patentability of pharmaceutical products involving suffering of animals in cases like the EPO decision in *Upjohn* in 1992 in which the use of mice in cosmetic tests for baldness cures decided as being not acceptable unless no suffering or pain is involved for the mice. The patent application was made by an American pharmaceutical company called Upjohn in which a genetically engineered mouse used to test the potential treatment for baldness. It was argued that the patent is not likely to be granted on the ground of contravention of Article 53(a). It was rightly decided that the benefit for humans is not balanced with the suffering in which mice would be involved, that is, developing cancer caused by the hair restorative agent (The Independent 1992, p.4). Nonetheless, the development of any cures for cancer or another life-threatening disease should be evaluated as a different

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that non-subtractive and additive needs are needed for 'successful action' rather than 'action per se'(Gewirth 1978, pp.53-63).

scenario. Despite this, it is not acceptable that merely on the basis that there is a promise for a higher degree of human benefit in the development of such cure, the suffering of animals should be automatically undermined. In the same line of analysis, Recital 12 of the Directive provides that such benefit for humans is not sufficient for being patentable and it is necessary that the suffering caused by tests for the animal would not be disproportionate with the benefit achieved for the human.

Secondly, it is noteworthy for examiners to ensure that no alternative method of preceding the test is available, which holds an equal chance of success in finding a cure for the mentioned disease. If such method can be substituted, not only should it be prioritised over Oncomouse but also there is a duty to avoid the use of *Oncomouse*. It is evident that such assurance for the examiner has to be provided by a reliable source of expert advisors independent of the scientific community that is involved in patent application for research, and is sensitive to interest of the community. It is also suggested that examiners reach an in-depth understanding of scientific evidence offered by patentee and request for the maximum openness and accountability (Beyleveld & Brownsword 1993, p.11).

5.3*Relaxin* Case

5.3.1 Facts and Case Summary

*Relaxi*n is a hormone with the main function of comforting the uterus during childbirth. It was hoped that introducing *Relaxin* would reduce the need for caesarean deliveries in difficult pregnancies. Although *Relaxin* from pigs had been initially identified in 1926, the human form of the hormone was first isolated and determined in 1975. The Howard Florey Institute conducted research in this field and explored the second form of human insulin, which claimed it was not known previously. Because of differences between the

structure of human *Relaxin* and the hormone from other species, it was proposed that the expected medical implication would only be possible by obtaining the human samples in a sufficient quantity to manufacture the hormone in synthetic form. Therefore, scientists in Howard Florey initially attempted to isolate the sequenced gene coded for *Relaxin* hormone and subsequently utilise recombinant DNA techniques to clone the gene for further synthetic production (WIPO 2006). *Relaxin* patent application was claimed on the second form of human *Relaxin* and the synthetic form made by cloning technology. The examiner at the European Patent Office initially agreed to grant the patent for Relaxin in 1991. Later in 1992, members of the Green Party opposed the decision of the Examining Division and filed a notice of appeal against the *Relaxin* case.

In spite of disagreement on the definition of 'gene patents', the terminology is mostly used to refer to patents in which the claim is over the nucleic acid or for diagnostic purposes involved in genetic conditions. According to the Nuffield Council on Bioethics, gene patents are related to patents in which a DNA, RNA sequence or a method in relation to identifying the existence of a DNA or RNA is the main component (NCB 2002, p.25). Therefore, an inclusive definition of gene patents should consider any patent with a claim over a DNA, RNA sequence or the identification process to explore the existence of DNA or RNA in an individual. The key requirement for patenting an invention i.e. novelty, industrial application, and inventive step, may not intuitively be applicable to 'gene patents'. For instance, it is said that they are not new and the relation they have with a disease has always existed, although was not known before. In this sense, it is to some extent beyond the traditional assumptions and boundaries of the patent system.

5.3.2 Opposition to *Relaxin* Patent and the EPO Ruling

The *Relaxin* case[22] was partly objected to on the basis of morality exclusions. The case was brought to the EPO prior to the implementation of the biotechnology Directive. The patent claims a DNA sequence encoding a human protein obtained from human tissues in the pregnancy period.

As discussed above, the patent was initially granted in 1991. In January 1992 two oppositions were filed against the patent in suite for *Relaxin*. The opposition, consisting of a group of 26 individuals on behalf of the green fraction of the European Parliament, was represented by the president of the fraction and then separately for the president of Europe of the fraction himself. The objections were mainly divided into three categories. Firstly, it was argued that the patent subject matter is not patentable, and that it is in breach of *ordre public* and morality under Article 53(a) EPC. This is indeed the most relevant objection against the grant of patent in the EPO with regard to the subject of this thesis, which focuses primarily on the interpretation of *ordre public* and morality in EU patent law and relevant provisions in European Patent Convention and Biotech Directive. The second objection relates to lack of capacity in *Relaxin* to meet the (technical) patentability requirement. It was claimed that the patent lacks the novelty and therefore, the patent was challenged under Article 54 and 56 EPC. Finally, the argument of the distinction between invention and discovery was raised, indicating that Relaxin always existed in the women's body; hence it is a discovery and not an invention.[23]

[22] *Howard Florey/ Relaxin* [1995] EPOR 541.

[23] The main focus of this dissertation is to identify the issues which arise in relation to the concept-theoretic position. However it may be occasionally necessary to discuss a number of other associated issues raised in the process of deciding the case, but no detailed analysis is provided for such issues. For instance, here in *Relaxin* case the second and third objections are not sufficiently relevant to the application of concept-theoretic position; therefore, I will only list it here.

Green Party Oppositions

In the opposition procedure, it was claimed that *Relaxin* must be denied as it is in breach of Article 53 (a) of the EPC. The patent was opposed on the ground of contradiction with the *ordre public* and morality mainly based on following factors.[24] First, the patent was challenged on the basis that DNA Relaxin was obtained in a particular female condition (pregnancy) for a technical profitable process, and this offends the dignity of women; for this reason, it should be considered immoral. Furthermore, it was claimed that patenting on human genes is the violation of human rights to self-determination and a 'modern category of slavery' involving female members of society in which their body pieces are being sold to commercial enterprises. And finally, it was stated that it is morally unacceptable to patent the human gene as it means patenting human life. [25]

Since the first successful gene patent, there have been numerous efforts in literature to address the issue of morality in the biotechnology patents. Resnik in *Owning the Genome* (2004, p.3) clarified the main moral objections related to gene patents. A number of projects analysed the problem from the viewpoint of the religious groups (Charatan 1995). Interestingly, the concept of ownership of genes received a generalised but unstructured type of public opposition (Radford 2002). The common explanation includes the fact that patents on human genes are in contravention with respect for human life, where through commercialisation and instrumentalisation of human life, human dignity is devalued (Caulfield & Brownsword, p.73; Australian Law Reform Commission 2004, p. 68). However, it is widely confirmed that gene patents do not directly violate human dignity and any probability is indirect in nature (Resnik 2004, p.3).

[24] *Howard Florey/ Relaxin* [1995] EPOR 541.
[25] *Howard Florey/ Relaxin* [1995] EPOR 541, Para 6.1.

In 1995, the Opposition Division, however, concluded that Article 53(a) should apply on cases regarded universally as 'outrageous'. It was decided (through referring to Guideline C-IV 3.1) to evaluate the public perception regarding 'abhorrence of the invention' to the level that makes its patenting implausible. In Para 6.2.2, The Opposition Division then referred to T 19/90[26] and T 320/87[27] that Article 53(a) forms an exception for the general principle, that it ought to be narrowly interpreted. However, on the basis of the presence of donors,' informed consent, it never would be considered as abhorrent to the majority of public. The Patent Office also declared that claims like abuse of pregnant women or return to slavery is merely a misunderstanding about the effects of the patent, which is not applicable in this present patent. Furthermore, they stated that it only prohibits third parties from commercial exploitation of the invention. This applies similarly on other human tissue or material such as isolation or patenting of blood or bones which are accepted and even welcomed by the overwhelming majority of public. Responding to the claim that this patent is patenting the 'life', the Opposition Division clarified the reality of DNA as a chemical substance carrying genetic information rather than 'life'.

In March 1995, a number of opponents filed a notice of appeal against the EPO decision. Responding to the Board's question, in relation to public concern over the patent in the suite, due to the presence of uncertainty and disagreement against gene patenting on the Member States and institutions, the EPO was requested to run a referendum to evaluate public concern. This suggestion however was refused, on the basis that EPC ought to agree only on the patent application which is actively approved by the public. Furthermore in the opposition proceeding, the burden of proof lies on the opponent. As

[26]T19/90 *Harvard/Oncomouse* [1990] EPOR.513.

[27]T 0320/87 *Hybrid Plants* [1988] OJEPO 1990.71

discussed earlier, they also raised the issue that the public perception obtained from a referendum is to some extent dependent of the terminology of the surveys and the way the question are being asked.

In April 1999, an interlocutory decision was made by the Board. Later, the Enlarged Board of Appeal explained the questions in a decision (G 3/99) in 2002. Although it was requested that the patent must be revoked, it was suggested by the respondent that the appeal should be dismissed. One of the reasons for this decision was that the EU Directive on the Protection of Biotechnological Invention had entered into force since September 1999 and, therefore, was applicable to cases already pending before September 1999 including the *Relaxin* case. According to amendments made by the Administrative Council of EPO on Implementing Regulation of European Patent Convention, a Chapter VI titled Biotechnological inventions including Rules 28 [former Rule 23(b) to 23 (e)] was added to part II of these regulations which meant to help in the application and interpretation of provisions in relation to European patent applications and biological patents.

Finally, the Opposition Division stated that this invention is not in violation of widely accepted moral standard and that no clear consensus on the immorality of patenting the human gene is identifiable within contracting states.[28]

5.3.3 *Relaxin* as Viewed from the Concept-theoretic Position

Having already discussed the EPO Opposition Division's argument on patentability of *Relaxin*, particularly with a view on its morality, I aim to analyse the case according to the concept-theoretic framework here.

[28]Para 6.5, the Opposition Division.

The EPO essentially provides three main arguments in addressing the opponents' objections.

1. Patenting the *Relaxin* hormone 'would not be viewed by the public as too abhorrent not to be patentable' (WIPO 2006a).

2. *Relaxin* by no means 'amounts to a form of modern slavery merely due to the dismemberment of women and their piecemeal sale to commercial enterprise', mainly because 'gene patents do not confer any rights over individual human beings. There was no dismemberment of humans since the point of the invention was to synthesize the hormone' (WIPO, 2006a).

3. Finally, to grant a patent for *Relaxin* is not against the human dignity given that the tissue was 'donated with consent within the framework of gynaecological operations' (WIPO, 2006a).

Although these arguments seem in principle in accord with the requirement of the PGC, they require some further investigation. Addressing the question of whether or not the grant of patent violates *ordre public* or morality, the key rule is that it violates *ordre public* and morality if it is contrary to the PGC. This follows that patents ought to be refused if granting the patent is contrary to PGC. Here I need to find out the conditions under which the granting of a patent would be perceived as contrary to the PGC. To do so, it is imperative to analyse what granting the patent in *Relaxin* does.

Generally, according to what is called '**rule-preclusionary' perception of property**, it is important to emphasise that all human agents own their body (Beyleveld and Brownsword 2001, p.172). Therefore, all donors must consent specifically on commercialisation of their properties in addition to their consent for removal of tissues

from their body if it is intended to be commercialised in any way including patents, otherwise the initial transaction and any further development to tests and medicines will be wrong and illegitimate according to the PGC. Submitting the issue within the Gewirthian framework, there is a need to ensure that even if the idea that those agents have property in their body is not accepted, it is still not acceptable to imply consent to the removal of the tissue or body parts, as consent to future commercial exploitation. In order to respect the dignity of the donors, Gewirthian morality requires those who intend to take and exploit the commercial value to treat their sources to a free and informed consent (Beyleveld and Brownsword, p.172). It is necessary to discuss a series of questions:

> whether the dignity-based autonomy of the donors was respected – whether in other words, the donors (as agents) were treated as capable of giving informed consent (or refusal), and whether steps were taken to ensure that their consent was free and fully informed (Beyleveld and Brownsword 2001, p. 205).[29]

i. what does granting the patent do?

It is crucial to know whether the patent process has been involved in any activities that are debilitating or restrictive of agency or successful agency, and whether or not the patent is capable of any contribution to basically enhance the capacity of the agency to do action or to accomplish the successful action. *Relaxin* is a chemical substance, which carries a genetic code to produce medically useful protein, which can e.g. reduce the need for caesarean deliveries in difficult pregnancies (WIPO 2006). It is claimed that patenting genes like in *Relaxin* case enables biotechnology companies to do research on

[29] This will be discussed further in section iii, pp.177-179.

genes with no fear of competitors emerging with new discoveries. Furthermore, it will attract better opportunities for investment research and development and, therefore, will increase and support the innovation in the market through granting companies the right to gene sequences (Know genetics 2015).

The scientists or patent applicants in *Relaxin* may argue that the activities carried out during the patent process and the patent itself is a manifestation of their right to benefit from progress in science and technology and assist their human fellows to benefit from such progress. It is however important to understand that the right to benefit from progress in science and technology[30]is required to be higher in the hierarchy of rights under the PGC otherwise it would not be strong enough to override other competing rights.

Addressing the right to benefit from progress in science and technology in the concept-theoretic position, it can be considered as a generic right. Again, the position of this right in the hierarchy depends upon the specific context in which the technology is used; here the molecular cloning and characterisation of a further gene sequence coding, the real improvement is expected in relation to agents' capacities for successful action in general, and the quality of life for patients in need in particular. However this cannot be seen in isolation, and complex issues need to be taken into account: e.g. it requires further estimation of 'accessibility of the benefit' and the relationship of this right with other (generic) rights at stake. Therefore, a straight definitive answer is not possible to generally accept or refuse e.g. the patents on gene. As Beyleveld and Brownsword

[30]From a legal point of view, the right to benefit from progress in science and technology is not a new concept and has been referred to in various legal instruments, including Article 27 of the Universal Declaration of Human Rights (UDHR); Article 15(1)(b) of the International Covenant on Economic, Social and Cultural Rights (ICESCR); Article 13 of the American Declaration of the Rights and Duties of Man; Article 42 of the Arab Charter of 2004;15 and Article 14 of the Protocol of San Salvador to the American Convention on Human Rights of 1988.See Stephen Marks (2010)

(2001, p.112) note '[u]nless it is argued that patents on human genes impinge upon the status of agents as rights-bearers, there is no case to answer.'

In addressing the accessibility of benefit, the most essential question is whether all agents are given equal chance of access to the medical benefit of a given technology protected with the patent given that the PGC does not allow any discrimination between agents. Therefore to achieve an equal status a 'universal access', 'universal denial', or a 'completely random allocation' must be granted to all agents (Beyleveld & Pattinson 2004). The intellectual property rights in the right to benefit from advances in science and technology may not automatically interfere with any generic right. However, we should be cautious about any possible conflict of interest arising from: a) inequality in access to the medical benefit of the technology; b) any informed consent related concern including violation of agents' right to their physical integrity, autonomy over their body, and control over their bodily material. According to the PGC, the former suggests discrimination between agents which is contrary to the essence of Gewirthian agency theory and is not acceptable by any means. The latter argues cases in which the agents are treated as seemingly not capable of giving a valid informed consent, in absence of a justifiable reason.

The fact that the source of biological material has generic rights to her physical integrity means that she should have control over her bodily material. However it does not follow that no other reason would be justified to interfere with this right by other agents, not it does imply that future uses of his body needs to be always fully in her control. As it discussed earlier in 'rule preclusionary' conception of property, the agents' control over their bodily integrity is because agents reliance on their own body is so strong, which in turn means the challenge of the control over their body or body parts places the agents'

agency under threat. However if an agent is unable to act to defend her bodily integrity, she needs to be assisted.

It is also important to understand why advances in biotechnology like the *Relaxin* case on gene are given a sensitive and important status in intellectual property regimes particularly patent systems. Because, in most cases involving human or non-human genetic or biological material, to interfere with the control over these body parts may be considered as causing particular generic harm to one's physical integrity.

Under a Gewirthian framework, scientists, like all other agents must 'be permitted to do anything they like, provided only that this does not directly or indirectly threaten the generic rights of others' (Beyleveld and Brownsword 2001, p.194). However, if they deny the participants or research subjects' right to give consent and have autonomy for a free and voluntary choice, this mean sufficient protection is not given to participants' generic rights and the research is in violation of the PGC. Nevertheless, a right to physical integrity (as a non-absolute right), when comes in conflict with other generic rights, may be overridden. For instance, when the accessibility of the benefit offered to humankind through the use of the biological materials can be well balanced against the violation of one's right to free and voluntary choice. For instance in cases like *Relaxin,* the collection and processing of biological material from the human subjects and all issues concerning application of all cloning techniques need to be analysed.

The essential requirement for all procedures is that agents in any situation (including whilst as suppliers of biological materials) must be regarded as an end who are entitled to independently and freely act, and not merely as means. It is important to understand that interference with an agent's right to autonomously and freely give consent before undergoing any procedure involving her body parts, like removal and future commercialisation of the agents' DNA or gene sequence in this case, is a violation of

the PGC. Notwithstanding, no violation of the PGC would take place if the agents, here the research subjects, waive the benefit of their power to control their bodily material themselves.

ii. What powers does it give to the patent holder?

Many biotechnology companies advocate the legitimacy of gene patents mainly due to their alleged potential in producing more Research & Development and encouraging innovation. However, a number of empirical studies prove that gene patents hinder research as the exclusive right of a company; this is because the patent prevents other companies from working with the specific genes. It also leads to monopolisation of genes, and this emphasis on patents gradually leads to a secrecy culture among research institutions (Position Statement on Gene Patents and Accessibility of Gene Testing 1999) and indeed between industry and academia (Angell 2000, pp.1516-pp 1518). This is particularly reported among investigators in the field of genetics (Blumenthal D, et al., 1997, p. 224), which claims such patents ultimately make the research environment commercially oriented (Gold 1999, pp 63-78). It may lead to medical results eventually being slowed down as involvement with industry. For instance, it is claimed that in the life science faculties in the US, this affects the researchers' attitude toward the value of a research, which means that a researcher is more likely to believe that 'the choice of research topics had been influenced by the likelihood that the results would have commercial application.'

iii. How can the exercise of those powers directly or indirectly lead to consequences which are contrary to the PGC?

Addressing the above issues, the *Relaxin* decision, with regards to compliance with the requirements of informed consent, is in accordance with the PGC as it is clear that neither the researcher intended to violate the dignity of pregnant women, as they all very freely opt to participate in the research, and women themselves did not compromise their own dignity (Beyleveld & Brownsword 2003, p83). It also goes to reveal that there is no evidence of the breach of fellow agents' rights by researchers, and that there is no rationale to relate two issues of granting the patent and threatening such right of fellow agents at least directly. Therefore, the reasoning of the Opposition Division in EPO under Article 53 (a) is sound and in accord to the PGC in terms of complying with the consent requirement and respect to donors' autonomy.

This statement however is exclusively applicable in terms of interpretation of 'informed consent' and does not mean that there is no criticism on the approach of EPO regarding interpretation of Article 53 (a) in *Relaxin*. For instance, the EPO case law insisted that any exceptions to patentability must be narrowly construed (the Case Law of the Board of Appeal EPO 2010).However, according to the concept-theoretic position, the above position is not true given that this framework requires a broad interpretation of morality, which means the strategy is clear in the case of any contravention with the fundamental principle of human rights. These principles, including the principle of respect for individual's dignity and their free choice, would not be outweighing against agency rights in lower hierarchy including property right. If donors and/or sellers freely choose to do so for any reason, any feeling of loss of self-respect is not considered a violation of their rights. The question of permissibility, of course, would be a complex consideration, and usually a number of factors must be taken into account before

drawing any conclusion. As discussed earlier, the PGC allows more important rights to be overridden by less important rights, in terms of their importance on agency capacity (Beyleveld& Brownsword 2007, p. 297) and intellectual property rights like so many others are concepts that are not absolute. Therefore, when we consider the legitimacy of IP rights for an invention, depending on the research value and other involving rights, the commercial property right may be overridden. The important factor which justifies the possibility of some rights being overridden against IP rights in research is also related to how these rights may indirectly protect the generic rights of agents. In other word, it is important whether a right is 'conceived of as itself protecting fundamental rights and values' (Beyleveld 2007, p.276). Here, for instance, it requires considering the fact that 'consent' by itself is not enough if the grant of the patent would threaten the generic rights of others. Similarly, the 'absence of consent' may be justified if it supports the generic conditions of agency of other agents and this cannot happen through any other means. Therefore, in every decision making process it in necessary to analyse whether the rights that are threatened are significant enough (to be assessed according to the hierarchy of rights under the PGC), considering not only the consenting parties but also other agents in the society who stand to benefit in rights relevant to patenting.

As discussed previously, patents over human genes are likely to inhibit the 'translation of biomedical research to clinical application'. Licensing issues are often a crucial problem which affects access to diagnostic tests or medications. If the right to hold a patent over an invention neither supports the research and development, and encourages innovation (even may deter innovation)(Heller & Eisenberg 1998, p. 698), nor provides better access to the medicine, treatment or tests, even adversely affects the development or availability of products or clinical services (Knoppers 1999, pp.23-26), it means that

this patent system is not well-functioning. Also, it is likely that it is in violation of the PGC, provided that no justification is available in support of these patents. Clearly, high additive royalties and high royalties for patents are problematic given that it directly affects the availability and delivery of diagnostic tests for patients in need. The patent system is not there merely to restrict the access of patients to e.g. diagnostic test (Gaisser et al. 2009, p.407 & Hawkins 2011). If the availability of patents may lead to consequence which impede progress in research and providing new treatments, or limit the access to medical benefit in a serious way, it means it is in violation of agents' generic rights as it may threaten their health and life.

Furthermore, it is worth considering whether the informed consent regime in *Relaxin* case take into account the rights and interest of vulnerable agents. If commerce in human genes is allowed, with no doubt it ought to be on the basis of free choice. However, it is unclear how effective the informed consent procedures do work in respect to vulnerable members of societies. The gene resources supplied from the Third Word, patient in need of treatment, prisoners, and many more are all examples which can be set in regard to asymmetric of information and bargaining strength between parties (See e.g. Pottage 1998). If adequate safeguards are not implemented, it clearly opens the way for abuse, and potential occurrence of activities against human dignity which eventually makes the patent contrary to PGC and indeed, *ordre public* and morality.

iv. Are there ways in which they could do this?

Examining the *Relaxin* case, it was important to understand that a PGC-complied framework aims to strike a balance in giving weight to important issues like the consent

of agents in case of conflict. According to Brownsword's reasoning in 'The Cult of the Consent: Fixation or Fallacy' (2004, p.223) both 'overestimation' and 'undervaluing' the role of consent must be avoided given that the former lead to '**the Fallacy of Necessity**' which means the misunderstanding in thinking that 'consent is the necessary justifying reason' and the latter results in '**the Fallacy of Sufficiency'** which means the 'consent is a sufficient justifying reason' (Also see Beyleveld and Brownsword 2007, p.32). Addressing the 'procedural justification' like informed consent and 'substantive justification' like limitation in the right to benefit from progress in science and technology, and the rights of agents in access to medicine , it is also crucial to know how to deal with these competing rights.

Although there is the possibility of a defective informed consent procedure, it does not follow that it would necessarily lead to conditions that violate the PGC due to nature of consent as a procedural justification, to violate a right without consent does not imply that such activity cannot be justified substantively, however it is quite likely to do so unless some other conditions are in place. Therefore, the informed consent procedure should be examined carefully in order to understand how effective it works regarding individuals' autonomy and if it is not working as it is supposed to function, then we need to make deliberate attempts to either find the ways to improve the circumstance or promote a general prohibition on gene commerce (Beyleveld and Brownsword 2003, p.83).

It is also of importance to consider whether the donors have been given any compensation or benefit in return for the contribution they have made, by providing their genetic material. Using individuals' DNA structure by scientists for future commercial exploitation, there is the problem of dealing with the extent to which individuals are entitled to claim ownership/or a fair share in benefit over the new

commodity. If they have not been compensated or benefited in any ways for their participation, it needs justification to understand whether the participants considered this as fair deal.

Furthermore, it is important to examine how the patent itself contribute to the benefits of science and health.In order to evaluate how patents in genetic science may contribute to development of clinical test in general, a pilot study analysed the behaviour of directors and clinical laboratories personnel who are involved in DNA-based genetic tests. The study proved that 25% of these researchers 'had been prevented from continuing to offer or conduct a clinical test that they had developed and validated'. Apart from this, 48% reported that they 'had not developed or conducted at least one test' as a result of 'a known patent' (Cho 1998, pp. 47-53). Such results indicate the adverse role of patents in relation to protecting the GCA of agents in general instead of supporting it in any way. If it is proved that patents in genetic research may have adverse consequences in developing beneficial medical tests to improve health conditions of agents, then it becomes necessary to investigate other types of intellectual property protection to see whether other IP instruments can replace patents. Alternatively, if the patent is already granted then we should try using post-grant mechanism like patent pools or compulsory licensing (in a reasonable fee) in order to minimise the risks of patents limiting access to medical benefits.

In brief, while assessing the patentability of an invention the maximum effort needs to be made to ensure the generic rights of agents are well-respected, that all informed consent safeguards are complied with in order to protect the interest of donors of genetic material including the interest of vulnerable agents, and to ensure that nothing against their dignity and human rights will be permitted. Furthermore, although the right to intellectual property is of importance as a secondary right, seemingly to protect the

right to advances in science and technology, it could be overridden if it is necessary to protect the more important rights of agents. The Patent Office must take into account the actual impact of the invention per se i.e. isolation of *Relaxin* gene sequence indeed the individual contribution of the *Relaxin* invention to research and development of medicines or treatments. For instance, how important was the invention to the development of research generally, furthermore, the role the *Relaxin* patent must play in order for the invention to function. Therefore, if e.g. *Relaxin* gene is used in a diagnostic test or medication, which is necessary for treatments in a life-threatening disease and the patent on *Relaxin* hormone, restricts the delivery and access, this clearly is problematic. The situation will be more serious if, through high additive and royalties or no compulsory licensing, access for patients is minimised.

5.4 The *Edinburgh* Case

5.4.1 Facts and case summary

In the UK case of *Edinburgh*, a patent was granted in 1999 for laboratory methods that entitled the University of Edinburgh to 'isolation, selection and propagation of animal transgenic stem cells'.[31] Using the word 'animals', which includes humans, while considering a method of somatic cell nuclear transfer, caused serious challenges for the patent. The patent application however was based on examples with mouse embryonic stem cells and neither the EPO nor the University of Edinburgh meant to claim the right to make, use, and sell human beings created in the university's laboratory. Greenpeace filed an opposition after the patent was granted in the European Patent Office, mainly claiming that it is against morality to patent human stem cell as a subject matter (Eisenstein 2006).

[31] *The University of Edinburgh* patent. European Patent Office, Patent No. EP 0695351.

Article 53(a) EPC and Rule 28, which deal with non-compliance with the regulation of Biotech Directive are referred to in this case where the governments of Italy & Germany, Greenpeace, and the European Parliament, opposed the patent on the basis that it was contrary to *ordre public* and morality. The Parliament of Europe asked the European Patent Office 'to ensure that 'all….patent applications in Europe do not violate the principle of non-patentability of humans, their genes or cells in their natural environment….' (Salter 2009, p.9).

5.4.2 Opposition to the *Edinburgh* Patent and the EPO Ruling

Opposition to the *Edinburgh* patent

Compliance with the requirements of Article 83 or Article 53(a) in conjunction with Rule 28(c) of the European Patent Convention (EPC) was disputed by the Opposition Division in the *Edinburgh* patent (THE 2002). According to Article 83, the invention 'must be disclosed in a manner sufficiently clear and complete for it to be carried out by an expert in the relevant field'. This means that according to the early decision by the EPO's Technical Board of Appeal, the hearing on November 2007 would only be on the issue of sufficiency of disclosure, and would not include any issue on a breach of rule 28 (c). Since this was an early procedural decision, no mechanism to challenge this decision existed (Schlich 2007).

However, the most relevant objection to the subject of this thesis is the claim of the Opposition Division on the breach of Rule 28(c), which specifically prohibits patenting of uses of human embryos for industrial and commercial purposes. The Board of Appeal was questioned on whether this rule ought to be interpreted narrowly or broadly. Considering the broad interpretation, a 'legislator should have meant to prohibit both

patenting of uses of human embryos and also stem cells derived from the destruction of embryos, whereas by narrow interpretation it was meant to only forbid patenting of uses of the embryo as such' (MacQueen et al 2008, p.365).

In this case, the Opposition Division concluded that the broader interpretation was the main intention of the legislator in which patenting of human embryos ought to be prevented not only from industrial and commercial uses, but also on any uses including research on human embryonic stem cells that involve the destruction of the human embryo. The Opposition Division later specifies the acceptable stem cell claims for patenting. According to the Opposition Division's list, only pluripotent and multipotent stem cells isolated from adults, and cells derived from foetal tissues of terminated pregnancies are acceptable for patent claims (Nettleton 2009, p.306-308). The outcome of the opposition hearing in 2002 meant that the patent needed to be amended and that the patent holder was required to ensure that human or animal embryonic stem cells were not included in the patent. It was however allowed that modified human and animal stem cells other than embryonic stem cells would be covered under the patent. The University of Edinburgh appealed this decision.

Appeal decision

In 2007, fourteen years after the Edinburgh patent was filed, a resolution was achieved. The appeal was withdrawn by the University of Edinburgh during oral proceeding. Currently, the patent is considered valid in its amended form, the same form as approved in the opposition hearing in 2003 (Baracclough 2007).

5.4.3*Edinburgh* case as viewed from the concept-theoretic position

The concept of respect for human dignity and the unpatentability of the human body at various stages of its formation is emphasised in the judgment of the *Edinburgh* case. Likewise, Para 71 of the Judgment of the Court in case 377/98, *Netherlands v Parliament and Council*[32] in October 2001 reads 'respect for human dignity is guaranteed in principle by Article 5(1) of the Directive which provides that the human body at the various stages of its formation and development cannot constitute a patentable invention.'[33] Subsequently in Para 76, it provides that additional security is offered by Article 6 of the Directive, which cites as contrary to *ordre public* and morality, and therefore excluded from patentability, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes. This list is not exhaustive according to Recital 38 of the Preamble, which states that all processes the use of which offend against human dignity are also excluded from patentability.

The judgment of *Edinburgh* is well reasoned to a high degree, specifically based on requirements of the Directive. Initially, as Recital 16 of the Directive provides 'the human body, at any stage in its formation or development, including germ cells is unpatentable'. Obviously, if the Directive intends to consider germ cells as a stage in human body then totipotent cells clearly will be included in the same category. Therefore it seems that judges in the *Edinburgh* case have appropriately interpreted the meaning of human embryos from the Directive text provided that human embryo is defined as a 'fertilised egg' or 'an egg in the process of fertilisation' (the latter is

[32]*Netherlands v. European Parliament and Council (Biotechnology Directive) Case C-377/98*, 2002 All E.R. (EC) 97 (2002).
[33]Para 71, *Netherlands v. European Parliament and Council (Biotechnology Directive) Case C-377/98*, 2002 All E.R. (EC) 97 (2002).

compatible with the definition of embryo in Human Fertilization and Embryology Act 1990).

Considering the definition of embryo scientifically, the embryos come to existence 14 days after fertilization. However, similar to what Adcock and Beyleveld argued in 'Purposive Interpretation and the Regulation of Technology' (2007, pp. 307-308), the purpose of the Directive or Human Embryology Act is not to regulate the use of scientific or medical terminologies but to serve the normative purpose of legislation. For instance providing some degree of protection for embryos is the main objective of introducing the Human Embryo and Fertilization Act 1990.[34] Bearing this in mind, the interpretation of the judge in the *Edinburgh* case could even appear as a narrower definition. Interestingly the same approach toward defining the human embryo was followed by the Enlarged Board of Appeal of the EPO in the decision of *WARF*[35]and also in *Brustle* patent case. Overall, the judgment may be consistent enough with the requirements of the Directive, although it needs more analysis to find out whether it follows the concept-theoretic position.

i. What does granting the patent do?

As it was discussed in previous section, the Edinburgh Institute for Stem Cell Research filed a patent application on the method of selection for stem cells, enabling the stem cells that one may want, from contaminating cells. The original research project was carried out on mouse cells, however it was claimed that the methods are also applicable to 'embryonic stem cells' generally. It also 'covers methods carried out on the human embryonic stem cells'. Furthermore, it relates to the 'human embryonic stem cells which have been genetically modified so that they can be used in the selection methods'

[34]Human Fertilization and Embryology Act (1990) Section 3(4).
[35]G0002/06 (Use of Embryos/WARF) of 25/11/2008. European Patent office.

(CIPA briefing paper 2005). In other words, the methods consist of 'using genetic engineering to isolate stem cells-including embryonic stem cells-from more differentiated cells in a cell culture in order to obtain pure stem cell cultures which makes up a 'controversial illustration' (Sevile 2009, p.139).

ii. What powers does it give to patent holder?

It was claimed that the patent may be read so as to embrace the human cloning and creation of transgenic animals. Edinburgh University confirmed that they had no intention to extend to the creation of transgenic animals. Thus, the amended patent no longer includes the human or animal embryonic stem cells.

However according to the *Edinburgh* patent, the patent holder may still have a right to modify human and animal stem cell other than embryonic stem cells (Sevile 2009, p.140). The patent also is capable of germ-line therapy in which a deliberate modification of the gene is expected to provide the patients with therapeutic effects. The Edinburgh patent holder can think of using the patent for such function, however, in some circumstance it may raise ethical concerns.

iii. How can the exercise of those powers directly or indirectly lead to consequences which are contrary to the PGC?

Under the Gewirthian framework, the agent has the duty to 'act in accord with the rights of all agents to the generic conditions of agency' (Beyleveld and Brownsword 2007, p.39).Therefore, a clarification is first required here on the rights involved. Like all other previous cases discussed here, this is not a straightforward answer since a complex series of rights and interest may be involved. As discussed previously , the

simplest answer seeks to make a balance between the rights of the inventors and scientists to academic freedom (based on freedom of expression) and inventors' other commercial interests affiliated to this, including the right to commercialise one's own results of work (possibly through a patent) and potential interests of other apparent agents to have a reasonable access to benefit from advances in science. Furthermore, we may consider the indirect consequences of carrying out the prohibited activities, which may be the potential for introducing the cure. This may affect some agents' Generic Condition of Agency to a certain level. What we also need to analyse is how to justify assigning a full moral status to a human embryo within the concept theoretic-position. In other words, the reason for assigning such status for embryonic stem cells must be compatible with the idea of full intrinsic moral status assigned to human agents. Within the concept-theoretic position, the embryo has a 'minimal moral status' rather than a full agency status. [36]

As discussed in section 3.4.2, the concept-theoretic position provides protection for non-apparent agents including human embryos on precautionary reasoning. Now, if the concept-theoretic position is compared with the position of the Biotechnology Directive, it does not necessarily mean that these two positions are incompatible because it is not clear that the Directive considers a full moral status for embryos. Interestingly, prohibiting circumstances in which commercial uses of embryos are patented can be translated into a proportionate moral status. However it is noteworthy that research on embryos (involving destruction of totipotents) can be allowed only when the research necessarily requires patents to be granted for the products or processes of research.

[36] In Gewirth's view, this status develops as the embryo develops agency. I however argue for protection of non-apparent agents under 'precautionary reasoning'.

There is nothing intuitively wrong with scientists having the right to benefit financially from their inventions, and the fact that the IP infringements in support of respect for one's right to property should be avoided. However it does not follow that individuals do not have any obligation to community to share some of their rights over an invention in that they are 'social products' that the community has contributed in their 'productive agency'. Therefore, in order to evaluate the legitimacy of granting monopoly over an invention, the research value and other involving rights must be taken into account for which the commercial or intellectual property may possibly be overridden. It is clear that a determinative cause in making the IP rights being overridden in research is the single fact that it is necessary to support the grant of rights that 'supply the contents that the community uses to enable all persons to mutually help one another to meet their respective needs of agency and thereby to live lives of dignity as purposive autonomous agents' (Gewirth 1996, p.213).

The question that needs to be asked here is whether the *Edinburgh* patent provides such benefits for the society, or the right of the patent holder, or whether the benefit offered through the grant of patent may 'conflict with the respective needs of agency' and offering them a life to live 'with dignity as purposive autonomous agents'. One of the objections over the patent relates to being sceptical about the invention leading to 'cloning'. According to Article 11 of the Universal Declaration '[p]ractices which are contrary to human dignity, such as reproductive cloning of human beings . . . .' should be prohibited. Whether or not having the 'copies' may appeal is a matter of debate in which advocates claim such a prospect of having 'exact mirror images' as 'horrifying' (Heyd 1992, p.217) whereas supporters discuss example scenarios that such cloning activities may appear appealing including to parents who wish to replace a lost child, to parents who wish to use a cloned sibling as a donor for a kidney transplant to help their

child dying of kidney failure or those who wish to 'replace an aborted fetus', or the argument over 'self-cloning'(HGAC & HFEA Consultation paper 1998, Para 8.3). The question is whether human cloning is in violation of human dignity and therefore incompatible with the requirement of the PGC. The concept-theoretic position distinguishes between the cloning technology itself and the purposes for which the technology may be used. It is not proven that cloning technology itself is in violation of human dignity, however the purpose and interest that agents might have in advancing the technology and holding a patent over an invention with such technology might not be acceptable as it may be used in a way that 'instrumentalise others.'[37]

A distinction should be made between the totipotent stem cells, which individually have the capacity to produce an entire human body, and pluripotent or multipotent stem cells, which have no such capacity. However, considering the possible benefits of the stem cell research, it is not acceptable to make a blanket ban on all categories of stem cells. This position is also in line with the UK patent office's position on this matter (UK Patent Office: *Practice note* 2003; See also Laurie 2004, p.59-66). It is also important to know how the *Edinburgh* patent is associated with germ line modification as it is a broad area with diverse function. While making decision about violation of morality in cases like *Edinburgh*, it is crucial to analyse the reasons for which the patent is sought. Therefore, the intention of the patent holder for future use is of significant importance in analysing the expected consequences of the patent. The technology can be used in a wide range from 'designer babies' to 'eugenics'. It is crucial to distinguish between the circumstances in which the technique is intended to be used to offer therapy and correct a disease, from when a therapy is intended to enhance the human species. Considering

[37] Para 3 of the Explanatory Report accompanying the draft cloning Protocol provides that '[E]thical reasoning for a prohibition to clone human beings is based first and foremost on human dignity which is endangered by instrumentalisation through artificial human cloning.'

the fact that the germ line therapy has the potential for life-threatening diseases such as Huntington and cystic fybrosis, it is arguable that a complete prohibition of germ line therapy may be disproportionate (Nott 1998, pp. 347-351; LIewellyn 1997, pp.120-23). In analysing the permissibility of the *Edinburgh* patent, it is important to answer all relevant questions about the activities involved in the research, the purposes for which the scientists carry out this research, the consequences arsing from such patent. Furthermore, under the PGC it is significantly important to investigate whether the clone source consents to cloning. In terms of other-cloning or self-cloning it is not possible to claim that it is 'dignity-treating' in itself as almost all claims (e.g. in cases related to parents wishing to have a cloned sibling or replace a lost children, etc) raise issues about the cloning technology being capable of 'offering new opportunities for instrumentalising reasoning around the reproductive process.' This means that in the example about cloned children, all accusations against the parent causing 'instrumentalisation' of 'to be donor' babies may equally apply on them if they naturally give birth to a baby (Beyleveld 1998, p.679).

However if the patent is used for self-cloning purposes, it is again important to evaluate whether the patent facilitate conducts which may be viewed as 'undignified'. If it does, then it is in violation of the PGC and therefore contrary to morality. It is also necessary to examine whether the patent assists some agents to get engaged in some activities which may be irresponsible 'relative to their duties, as agents, against fellow agents' (Beyleveld 1998, p.679). For instance if a patent is used only as a means to facilitate the 'self-cloning' process and conducts such as attempts to prolong agents' life or keeping their youth, the clone source might have consented to self-cloning; still there might be legitimate concerns over violation of human dignity if the process of cloning, as

Beyleveld (1998, p.679) put it, 'damage the culture of human rights, reversing agents' prioritisation of morality over mortality.'(See also Callahan 1996, p.13)

iv. Are there ways in which they could do this?

In the concept-theoretic position, the legitimacy of the grant of a patent still depends upon the benefit offered through the patent and how likely it is that the patients get such benefits, if the technique is protected under a strict IP system. In principle, if there exists the possibility of alternative use of adult stem cells as opposed to human embryonic stem cells, this should be prioritised. If no other alternative exists, but the use of embryonic cells, it may still be allowed but we need an evaluation of what benefits would be offered in return.

In addressing the permissibility of patents for therapeutic purposes, we need to bear in mind that drawing a line between therapeutic and non-therapeutic purposes is a complicated task since it will be dependent upon, and relative to, our judgment of badness and abnormality. This is because a therapeutic purpose is primarily meant to replace 'bad' or 'abnormal' genes with 'good 'or 'normal genes' (Schwartz 1996, pp.24-26). Under the concept-theoretic position, it is important to evaluate such characteristics in accord with the requirements of the criterion of degree of needfulness for agency i.e. according to the degree they have on agents' GCAs. If the patent is there to assist agents to tackle their agency debilitating conditions, then the right to hold the patent may override other rights in lower rank provided that it is the only way or the most effective means to protect the right of agents to therapeutic enhancement technologies. However, it is yet questionable whether totipotent stem cells are the only options for this gene therapy research (as pluripotent stem cells came to be known as

efficacious enough as an alternative). It is also questionable whether granting the patent is the only way to protect the investment (Cohen & Walsh 2008).

5.5 *WARF* Case

5.5.1 Facts and Case Summary

European Patent Office gave its ruling in November 2008 the Wisconsin Alumni Research Foundation (WARF) application with reference to the extent to which Rule 28(c) EPC applies on stem cell products.[38] As discussed earlier, Rule 28 prohibits a grant of patent concerning biotechnological inventions, particularly uses of human embryos for industrial or commercial purposes thereby implementing Article 6(2)(c) of the EU Biotechnology Directive. The *WARF* patent was filed in 1996 by James Thompson who attempted to explain culturing primate embryonic stem cells in the laboratory for a long period, while sustaining their potential to differentiate and develop into any other cell type in the body.[39] Utilising the most commonly used human embryonic stem cell lines, this product expected to attract significant commercial interest, due to its potential clinical application. The patent had already been granted in the U.S. Patent and Trademark Office when it was applied for through the EPO.

At the time the *WARF* patent was filed, the destruction of human embryos as a result of the composition process was inevitable. Similar to the decision of the Opposition Division in the *Edinburgh* case, the claim on Wisconsin embryonic stem cells (on a culture of cells and the list of desired characteristics)[40] involved the question of the

[38]G 0002/06 (Use of Embryos/*WARF*) of 25.11.2008 European Patent Office.

[40]The European Patent Application No. 96903521.1

scope of Article 53 EPC Rule 28 (formerly rule 23(d)c). This was mainly due to the silence of patent application on the techniques and process used to derive the cells.

Two-step examination established under Article 53(a) EPC and Rule 28, which consisted a first requirement to examine whether the application is acceptable under Rule 28 and then if it is approved, in next stage, Article 53(a) would be applied. Upon the reasoning that no uniform moral standard is identified in the Europe regarding human embryonic stem cells, the Technical Board considered a balancing test, which had been previously established in the *Oncomouse* case, as the most appropriate approach in order to evaluate the moral objection against the invention's significance in human life.

Having been addressed by the Technical Board, the Enlarged Board was required to submit a clarification on the value of word "use" in Rule 28 (former 23(d)c), as it could be interpreted that only claims that directly involved the use of human embryos for commercial and industrial purposes ought to be covered under exclusions. Furthermore, further explanations regarding patenting the products, including human embryonic stem cell cultures, where the process and methods of production necessarily involve destruction of human embryos from which the product is developed, even though the technique is not part of patent claim,[41] were requested.

5.5.2 The European Patent Office ruling

Opposition to the WARF patent

The decision made in *WARF*, seemingly sound and literally interpretative, has been viewed by some commentators as an 'extreme turnaround' or a 'major volte-face' due to its broad exclusive approach (MacQueen et al. 2008, p.502). On the other hand, some

[41] Court of Justice of European Union, Case C-3777/98,9 Oct001.

other commentators including Cornish support the idea that tactical reading of the Directive's text in cases like *WARF* by the European Patent Office led to appropriately excluding the patent claims over the exploitation of human embryonic stem cells obtained from fertilised human nuclei (Cornish et al. 2010, p.873). The motive of adopting a broad interpretation of Article 6(2)(c) is not sufficiently well clarified in the *WARF* decision and this issue is criticised by supporters of the hESC research. It is however clear that the decision to follow a broad interpretation of morality exclusions is made as a matter of recognition of morality in the system. In fact, the decision of the *WARF* case is handled in a very similar way to the UK *Edinburgh* case. The Boards of Appeal announced that any patent claims capable of being extended to human embryonic stem cell research would be considered invalid on the basis of immorality exclusions. It further explained that according to Article 6(2) (c) of the Directive, industrial use of embryo is prohibited. This rule similarly applies to using embryos in generating products with industrial application.[42]

The applicant *WARF* claimed that it is not the role of the courts to make moral judgments, the broad interpretation of human embryos-which would not involve courts in making moral judgment- must be preferred over the narrow interpretation of human embryo.[43]

Furthermore, in Para 22, the Enlarged Board of Appeal stated that the original intention of the legislator needs to be taken into account. According to such reasoning, it is arguable that if human embryo is used in the process of making something and that thing is later used as a base material for another invention, then considering any commercial benefit from the invention equates to commercialisation of the human

[42] T-1374/04 Wisconsin Alumni Research Foundation (*WARF*) [2009] EPOR 15, the Examining Division.
[43] Applicant *WARF* in appeal against decision of the examining division of the EPO in the decision of the board of appeal T 1374/04, 3 March 2008.

embryo. This reasoning is of particular importance since if any other approach is selected then, through skilful drafting of the patent claim the intention of the legislator could possibly be evaded.[44]

This sounds true unless the concept of morality is considered in a narrow sense. However as discussed earlier, the concept-theoretic position requires a broad interpretation of morality and this approach seems sound because, if adapting a definition that implies a broad exclusion leads to courts making moral judgment, this similarly applies on adapting a broad interpretation (Adcock & Beyleveld Working Paper, p.17). This means that, even if we adopt a broad interpretation and decide to permit patenting of fertilised egg (which is not allowed under a narrow interpretation of a human embryo), the nature of the decision is still a moral judgment.

A number of scholars including Shum (2010) also supported the idea of a narrow interpretation of morality exclusions in patent law rather than a broad interpretation. [45] Point 33, T 1374/04 of The EPO's Board of Appeal in *WARF* addresses the issue of broad or narrow interpretation of morality exclusions:

> The frequently cited principle according to which exclusion clauses from patentability laid down in the EPC were to be construed in a restrictive manner, did not apply without exception (point 33, T 1374/04).

Provisions must be considered in the light of their

> wording, the object and purpose of the provision, the interests involved, the consequences of a narrow or broad interpretation, respectively, and the aspect of legal certainty.

[44]See point 22 *WARF* decision, Enlarged Board of Appeal.

[45] Also European Patent Office, Guidelines for Examination in the European Patent Office, pt. G, ch II 4.1 (2012) (http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_1.htm).

The Enlarged Board of Appeal issued its decision in response to the questions referred to them by *WARF* in the following manner;[46]

In 2004, and following the *Edinburgh* case, the Opposition Division announced that the *WARF* application is in contravention with the requirement of Article 53(a) together with Rule 23d(c) and the case was brought to the Enlarged Board of Appeal.[47]

Appeal decision

The *WARF* patent applicant filed an appeal against the rejection of the patent application. In the EPO hearing, a number of questions were raised regarding the interpretation of Article 53 and Rule 28 to the Enlarged Board of Appeal. As discussed earlier, the Rule provides that '[u]nder Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern uses of human embryos for industrial or commercial purposes.'Parties were invited to comment, criticise and raise their objections. Following these discussions, the main hearing was held in 2008 in which the *WARF* and EPO president discussed their positions.[48] The

[46] According to European Patent Convention, supra note 27, art. 112(3) decisions by the Enlarged Board of Appeal are binding on the EPO

[47] T 1374/04 (Wisconsin Alumni Research Foundation, WARF), referral by the Technical Board of Appeal to the Enlarged Board of Appeal.

[48] In addition to questions raised, to be responded to by the Technical Board of Appeal, *WARF* requested the opinion of the Court of Justice of the European Union, regarding the interpretation of the wording in Rule 28. In spite of the Enlarged Board of Appeal's status as the highest authority to comment on any question of law under the European Patent Convention, the request for a CJEU preliminary ruling was denied on the ground that the Boards of Appeal of the European Patent Office are not supposed to be considered as 'courts' or 'tribunals' of an EU Member State . Therefore, the Enlarged Board of Appeal is not eligible to request the CJEU preliminary ruling.

Enlarged Board of Appeal issued its decision in response to the questions referred to them by *WARF* in the following manner;[49]

I. In response to the question of the application of rule 28(c) on the *WARF* case, the Enlarged Board of Appeal announces that Rule 28(c) EPC will be applicable to any pending applications even though the filing date precedes the rules' entry into force.[50]Therefore, the Enlarged Board of Appeal concluded that the Rule had to be applied on the *WARF* application.[51] However, it is arguable that there needed to be a comprehensive analysis of the subject, and a comparative study of the scope of Rule 28 and Article 53, in order to make it clear what to prevail in case of any conflict between the Article and the Rule.

II. Addressing the question of whether the Rule precludes patentability, it was discussed that patenting claims involving a process in which the destruction of embryos occurs unavoidably will be denied. It simply applies, if the method that ultimate products are derived from, involves the destruction of human embryos. It is also applicable if the method is not a part of the claims. The Enlarge Board of Appeal clarifies that the text of Rule 28(c) is not directed toward the claims but refers to 'inventions' as a whole.[52]

In order to reach a conclusive remark on this matter, the Enlarged Board of Appeal by looking at preparatory works of the EU Directive holds the view that:

[49] According to European Patent Convention, supra note 27, art. 112(3) decisions by the Enlarged Board of Appeal are binding on the EPO

[50] Justifying this decision it was said: 'the introduction of this new chapter [i.e. of the Rule] without any transitional provisions, can only be taken as meaning that this detailed guidance [i.e. that provided by the Rule] on what was patentable and unpatentable was to be applied as a whole to all then pending applications (Official Journal of the European Patent Office 2009, p.322).

[51] Enlarged Board of Appeal Decision, supra note 26, at 17-19, 30.

[52] Enlarged Board of Appeal Decision, supra note 26at 19–28, 30; EPC, supra note 27, R. 28(c)

> On its face, the provision of Article 6(2) (c) of the Directive and thus also of Rule 28(c) … EPC is straightforward and prohibits the patenting if a human embryo is used for industrial or commercial purposes. Such a reading is also in line with the concern of the legislator to prevent a misuse in the sense of a commodification of human embryos ... and with one of the essential objectives of the whole Directive to protect human dignity (Official Journal of the European Patent Office 2009, p.324).

Considering that the *WARF* claim about the prohibition clause is to be applied only if the use of human embryos is part of a claim, the Enlarged Board of Appeal set the emphasis on the fact that, while interpreting the law, the intention of the legislator must be taken into account. Under this line of analysis, if the focus of the patent office is wrongly made, only on the basis of what the patentee has chosen to put explicitly in the claim, then a detrimental consequence of evading the patent exclusions may appear merely by a skilful drafting of the patent application (Dodler 1984, p.3).

III. Addressing the question of whether Article 53, as a basis for rejection of European patents on the ground of being morally dubious, preclude patentability, the Enlarged Board of Appeal does not provide any explanation and simply decided not answering to this item as previous question 1 and 2 were addressed. This analysis presented by the Board is viewed as incomplete and is one of the serious shortcomings in the *WARF* decision.

It is argued that the Board should have analysed the ethical discussion regarding the definition of an action being 'contrary to morality', instead of dismissing the need to answer this question. Preferably, such an analysis could have been on the specific subject of this case, not a 'one fit all' rule (Sterckx 2008, pp. 486-493). Even under the Enlarged Board of Appeal's discussion of the EU Directive, it is evident that the key

issue involved in this case is the concept of human dignity. The purpose of the Rule was also defined in the EPO decision of the *WARF* case to be 'to prevent a misuse in the sense of a commodification of human embryos' and 'to protect human dignity', as well as to 'prevent the commercialization of embryos' (Official Journal of the European Patent Office 2009, p.325-326).

Overall, the Board of Appeal concluded that the *WARF* is to be rejected under Article 53 on the basis that the exploitation of the *WARF* patent subject matter would result in the commercialisation and commodification of human embryos, which would be seen as violation of human dignity. This clearly implies granting some level of human dignity to human embryos (Sterckx 2008 p.491). Based on such analysis, the reason that the *WARF* subject matter is in breach of Article 53 is that granting patent over *WARF* enables patent holders to gain financial reward through the use of human embryos.

IV. Finally, the Board commented on the fourth question referred by *WARF*, saying that the issue that same product may be produced after the filing date of the *WARF* patent, without the need to imply a method involving the destruction of embryos[53] is not relevant in the *WARF* patent argument.[54]

It was argued that it is not acceptable for researchers to use the information obtained through unethical means to promote their research, which means that while analysing probable violation of morality in an invention, the position of a skilled third party is not of any relevance (Amicus Curiae Submission of the United Kingdom 2009, p.14). However, it all depends upon the extent of complicity, which may lead to a second act considered as not being contrary to morality. The scientists, of course, needs to be

[53]In specific case of *WARF* it translates to derivation of material from existing human embryonic cell lines.

[54] Enlarged Board of Appeal Decision, supra note 26 at 28–30.

aware of not sending the signal that as long as the information has benefit to society, the source where it has been obtained becomes unimportant.

Finally, in 2008, within further stages of the *WARF* case, the decision of the Examining Board was again endorsed, and the EPO highlighted its policy indicating that patents related to embryonic stem cells will not be awarded if destruction of a human embryo is involved by any means. The Enlarged Board of Appeal finally concluded that its decision was "not concerned with the patentability in general of inventions relating to human stem cells or human stem cell cultures" but the supra note 26 at 29–30 provides that patents are prohibited for "inventions concerning [human stem cell cultures] which can only be obtained by the use involving their destruction of human embryos."[55]

In summary, the Enlarged Board of Appeals' decision to reject the WARF patent sounds well concluded, however, as it discussed earlier, the reasoning presented over the decision (in some parts) is not well-clarified and to some extent problematic. The Enlarged Board of Appeal could have clarified issues in a much more comprehensive way particularly on the question about the 'commercial exploitation' of an invention, and the questions regarding the application of Rule 28(c). The Board could have shed light on future patent cases involved with the implication of patentability exclusions under the EPC or the Directive.

5.5.3 The Case of *WARF* viewed in the concept-theoretic position

One of the claims made by the *WARF* Applicant in the appeal against the decision of the Examining Division of the EPO in the decision of the Board of Appeal T 1374/04, was

[55] Alain Pompido the president of the EPO between July 2004 to July 2007 emphasised the necessity of a halt on human embryonic stem cell patents in 2005 stating that ' there are too many ethical aspects that have not been resolved at the political level' (Schubert 2005, p.720). He attempted to justify a non-restrictive approach asserting that such restriction would 'unduly limit the significance of moral jurisdiction under Article 6' (CIPA Life Science Committee A, 2012).

that the wrong morality test was used.[56] Here I present the position which the concept-theoretic framework requires, examining whether the approach adopted in the *WARF* is compatible.

The Principle of Generic Consistency will be applied in this case as well. Similar to the *Edinburgh* case, the right of the patent holder to protect the invention will be assessed against the harm inflicted to others as a result of the patent. Here, we have to examine whether protecting the interest of human embryos as apparent non-agents, must be given the same weight as the apparent agents. On the one hand, embryos are not entitled to enjoy a similar status to born agents under the PGC as living human agents are a step forward compared to embryos on this matter. However, a generic harm caused by an action against another agent is not simply justifiable on the ground that it produces the greatest good. Nonetheless, it may be justified on the basis, that in a precautionary sense, the action will prevent occurrence of a generic harm, and it is dependent upon the fact that the harm is not avoidable by any other alternative means (Gewirth 1987, p.216).

Therefore, the benefit arising from the patent is an important factor to be taken into account when considering the violation of the future occurrence of existence for embryos. This implied that in granting a patent for conducting human embryonic stem cell research (even when it involves the destruction of embryos), it is necessary to assist apparent agents to protect more important rights in relation to the hierarchy of rights under the criterion of degree of needfulness for action. Apparent non-agents need to be granted some respect in relation to the extent to which they can be treated as agents. In cases like patents over human embryonic stem cell lines , this is no longer the mere protection of intellectual property rights but possibly more important rights which are

[56]T 1374/04*Use of Embryos/WARF* [2008] OJEPO 313.

indirectly protecting GCA of agents, possibly protection of the generic 'right of agents to life' though benefiting from live-saving treatments . Below, I attempt to present the *WARF* patent within the concept-theoretic framework.

i. What does granting the patent do?

The Wisconsin Alumni Research Foundation is operating in streamlining technology transfer through commercialisation of the scientific research carried out in the University of Wisconsin, which aims to benefit the sponsoring of the institute's future research activities. In order to address one of the key challenges of today's scientific world, the disconnection between the innovative ideas and technologies developed in laboratories and beneficial biomedical solutions available for public use, Wisconsin claims that they help researchers through commercialising innovative ideas, inventions, and discoveries which will eventually provide benefit for both the university and society. It is claimed that their research projects in the context of stem cell is an 'important asset' and 'pivotal player' (Kuo 2008, p. 628-629).

The widely used methods specified in the WARF patent have the prospect of numerous potential clinical applications. The Wisconsin Alumni Research Foundation (2015) defines the method in the patent application as, 'the first to successfully isolate and culture human embryonic stem cells that can grow in vitro. The provision of these is a major scientific breakthrough and pioneering invention opening up a new and very exciting field of research having great potential for promising medical therapies and other applications.' Some other commentators emphasise that the EPO decision could hold back the research of stem cell companies for commercial purposes (Reuter 2008). In contrast, some other stem cell experts claim that this will result in a 'boost for European companies' developing hESC-based products.

ii. What powers does it give to patent holder?

The *WARF* holds key patents on an embryonic stem cell line, which means that they have a monopoly right over the techniques used in isolating human embryonic stem cells. This implies that all other companies are prevented from using the patented techniques unless the official request for a license is submitted. It is very important to bear in mind that including the widely used methods in the *WARF* application implies that any application of human embryonic stem cells or cells derived from them would have been virtually covered by the patents, which meant that all companies which develop such therapies involving hESC could have been asked to pay license fee for using the technology upon the grant of patent (Randerson 2008).

Wisconsin claims that patenting the technology and further efforts to commercialise it enables them to achieve 'further scientific gain' by generating revenue for reinvesting in future research projects (Kuo 2008, p.628). This means that holding the key patents on embryonic stem cell lines gives the *WARF* a unique powerful position both scientifically and financially for a long period which may affect the easy free share of scientific information and possibly biomedical implications.

iii. How could the exercise of those powers directly or indirectly lead to consequences which are contrary to the PGC?

It is important to establish when the commercial exploitation of an invention is in violation of *ordre pubic* and morality. According to the Biotechnology Directive, this violation occur in any situation in which the grant of a patent would be contrary to *ordre public* or morality, *including* circumstances in which commercial exploitation of the invention *would independently of considerations of patenting,* be contrary to *ordre public* or morality. Analysing this within the context of the *WARF* decision developed

by the Enlarged Board of Appeal, it sounds like the EPO is mistaken, particularly in Para 29, emphasising that the Board considers the 'performing' of the invention as commercial exploitation. It was later said, 'it is important to point out that it is not the fact of the patenting itself that is considered to be against *ordre public* or morality, but the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts'.[57] It is arguable that such statement is not compatible with the Board's statement in Para 25, indicating that 'A claimed new and inventive product must first be made before it can be used. Such making is the ordinary way commercially to exploit the claimed invention and falls within the monopoly granted, as someone having a patent application with a claim directed to this product has on the grant of the patent the right to exclude others from making or using such product.' [58]

Although the EPO as a non-EU body does not have to follow the Directive's instruction as an EU instrument on patenting of the human embryonic stem cell research, when it comes to the fundamental principles of EU law including human rights, EU Member States still have to adhere to these principles. The concept-theoretic position, premised on the acceptance of human rights favours such view, though a number of scholars have made objections accordingly. In terms of the specific circumstances in which the exercise of the patent holder's powers directly or indirectly leads to consequences which are contrary to the PGC, the following issues should be taken into account.

First, the patent caused a fear among the customer groups that the licensing fees attached to the *WARF* gives a monopoly only to large biotechnology companies that can afford the fee, and therefore prevents small and medium sized biotechnology companies

[57] T 1374/04*Use of Embryos/WARF* [2008] OJEPO 313.

[58] Rule 28(C) EPC.

from carrying out research effectively and having some impact in this important field, with massive biomedical implications. This actually may be true given that, in reality, only a few large biotechnology companies including Garon could afford to buy licensing for the Wisconsin stem cell line patents (Kuo 2008, p. 629).This means that the right of the scientist to carry out research projects which are beneficial to human beings has to be respected as a generic right both from the point of view of their right to do research and acquire new skills, also from the perspective of future medical benefit prospects. However if it is proven that granting the *WARF* patent (protection of IP of *WARF* scientists) have adverse consequence in other agents' GCA, then the right to hold the patent may be overridden by more important rights. Imposing unreasonable 'licensing fee', which may limit the access or cause unfair access to treatments, is in violation of the requirements of the PGC and contrary to morality.

Secondly, *WARF* has switched the constructive and benefit-sharing environment of research to a stem cell business through which *WARF* has invested in new biotechnology start-up companies, and in return takes an equity stake and applies for biotech patents for the invention (Kuo 2008, p.629). This means that their scientific and financial power would be extended beyond *WARF* to a network of many smaller biotechnology companies which are mainly connected to each other for economic benefit. Although the concept of property is well-recognised under the Gewirthian framework, it is still a secondary right and may be overridden for the benefit of more important interests of agents in a society. Among them, for instance, he has strongly emphasised the key aspects of communitarian doctrine; its concern for "social solidarity" and 'mutuality of positive consideration' among individuals. Under such line of thinking, 'to be conciliated with the principle of human right' is the most fundamental aspect of community (Gewirth 1996, p.97). Adapting an 'antecedentalist' approach, the

inventor has the right to claim 'in things they have produced for the purpose of having such right.' Since we as human perform actions to achieve respective agents' purposes, therefore one can expect to be given permission to achieve his purposes, unless what they do results in violation of the generic rights of other persons according to purposive-labour thesis of property (Gewirth 1996, p.184). Now, the question here is whether or not these monopolies held by the *WARF* and its associated companies have consequences on the open and relatively easy (reasonable and affordable) access to embryonic stem cell research, and its biomedical implications.

Thirdly, the patent may underestimate the violation of morality and *ordre public* which may indirectly occur. We must be careful of the position of a skilled third party and the extent of complicity which may make an act contrary to *ordre public* and morality to seem like a second thing which is not contrary to morality. The defence of providing benefit for society does not always necessarily work for the benefit of scientists to authorise their actions, giving them a false impression that the source from which the material has been obtained is not important, provided the information is beneficial to the society.

Addressing the above issue, Green in his vigorous discussion of moral problems of human stem cell research explains some circumstances in which the degree of benefit for society can outweigh some potential undesirable effects (Green 2002, p.16). Based on his analysis, amongst three categories of moral encouragement which he distinguishes, the first 'direct encouragement through agency'[59]and the second 'direct

[59]Green at pp.544-556 'where one person asks someone else to commit a wrongful deed and benefits from her agent's wrongdoing, although she is not directly involved in the performance of the wrongdoing. In these cases, moral responsibility obviously cannot be escaped by the first person.'

encouragement through the acceptance of benefit'[60] are of particular concern for the society, whereas the third category 'indirect encouragement through the legitimization of a practice[61] in this context does have much concern. For instance, it is arguable that if a researcher is inspired by some information or obtains some information which he finds may be used for the benefit of the society or humanity (if used in an invention), then we may consider not applying the patentability exclusions for the new invention (made by the help of those information) under Article 53(a) of the EPC. Since there are different views in this regard, the question of complexity which is not quite well analysed by the Enlarged Board of Appeal may result in a 'deposit loophole', which is difficult to handle since the deposit provision is neither strong nor well defined enough to avoid the exclusions, at least under Article 53.

Under the PGC, it is not only the outcome of the invention or the consequences which may occur upon the grant of invention but it also matters how scientists have obtained the material , and legitimacy of all activities in the process of carrying out the research. It is also important how significant the benefit they are offering to the society is. Then, using the criterion of degree of needfulness for action it will be decided which right can override the other.

[60] Green at pp. 549-550 of his book provides that 'this kind of benefiting from others' wrongful deeds is morally objectionable and inadmissible. Although less pernicious than wrongdoing through agency, it provides a powerful incentive for misconduct.'

[61] Green defines this category at p 550-551 of his book as following 'it does not require the existence of an identifiable wrongdoer or wrongdoers who are encouraged to repeat their wrongful deeds as a result of one's acceptance of the benefits of their misconduct. It is not the immediate impact of one's acceptance [of benefits] on identifiable wrongdoers that concerns us in this case, but the future impact on people generally of the public rule of conduct that is created by one's acceptance of the benefits of wrongdoing. … [S]ome benefits may be wrong to accept even in cases where we do not (or cannot) directly encourage the wrongdoers who created them, for in doing so we implicitly legitimize a morally repellent practice'.

iv. Are there ways in which they could do this?

As discussed previously, one of added value of the application of the PGC is providing a hierarchy for the generic conditions of agency. According to this hierarchy 'the most needful for action' has the power to outweigh other generic conditions of agency. Therefore, if for instance, destruction of embryos is in conflict with violation of the rights to life and dignity of apparent agents, in that it prevents development of treatments with a strong likelihood of success by rendering the stem cells patentable, then such interest of embryos have to be overridden under the concept-theoretic position. If granting the patents on stem cell research on embryos is really necessary for the development of life saving treatments, then the concept-theoretic position allows such patents.

In particular case of *WARF* it is questionable whether it is necessary to use embryonic stem cell lines as opposed to adult stem cells, which were 'programmed to an embryonic stem-cell like state by introducing the genes important for maintaining the essential properties of embryonic stem cells'. It is also questionable whether the embryos have to be obtained via a process involving the destruction of embryos, as there are other options available, such as pluripotent stem cell taken from blastocyte, which does not involve such destructive process. Although the technique is yet to be well-developed and additional research is needed, it is hoped that the technology provides a platform for 'drug development', 'modelling of disease', and the 'transplantation medicine' (Goldthwaite 2011, Chapter 10).

Moreover, it is also questionable whether it is necessary to use patents to protect the investment over other IP methods. It does not seem likely that the grant of the patent in many biotechnology projects necessarily equates to an enjoyment to some degree of

economic security, by offering steady and adequate income. If it was, then it may have been authorised, if not, harming other agents' generic rights means that such financial status is essential for the basic well-being and freedom of individuals. Recently, strong debates have been published on the issue of emerging alternatives to conventional IP practices in which it has been tried to prove that, by using intellectual property rights and patents differently, legal society would be able to control or alter the impact of specific IP practices on the conduct of science (Goulding et al. 2010, p.20-21). It is arguable that patents are not necessarily an effective safeguard for recouping the investment, and the investor and inventor's rights. Even strategies like 'public domain', which is the absence of IP altogether can help to protect an invention.[62]

5.6 *Brustle* Case

5.6.1 Facts and Case summary

The important judgment of the Court of Justice of the European Union in the case of *Oliver Brustle v Greenpeace* was released in late 2011.[63] The patent was titled 'Neural precursor cells, and the methods for their production as well as their use in neural defect therapy' was initially filed by the inventor Professor Oliver Brustle, as a German patent in 1997, and later granted as a European patent in 2006 (EPO 2013). The subject matter mainly covered isolated and purified neural precursor cells processed from embryonic stem cells and removed at the blastocyst stage. The invention however did not refer to the use of human embryo because the patent claimed that the problem of producing unlimited quantity of such isolated and purified precursor cell would be resolved. It was

[62] Eisenberg (2000, p.70-72) argues that: 'The public domain can also be used in other ways as part of an effort to preserve access to certain types of genetic material. Publicly-funded researchers frequently place their research results in the public domain (via publications and databases) immediately, rather than wait for IP rights. This practice is used to achieve scientific recognition, to make such information more available for widespread use, and to try to prevent patenting of that data and information.'

[63] Case C-34/10 Brüstle [2011] ECR I-0000.

claimed that the method presented in this patent has the promise of introducing effective cure for neural deficiencies including Parkinson (Sautier 2012).

Prior to being referred to the CJEU, the patent was declared invalid by the Federal Tribunal of Patents, upon request by Greenpeace, on the basis that the patent involved the destruction of human embryos from which precursor cells are obtained. This means that the patent had been challenged on the ground of morality exclusions before it was raised in the CJEU. In 2006 an opposition was filed against the grant of the *Brustle* patent through a US company, where revocation of the patent was requested. Later in 2009, Germany's Federal Court of Justice (Germany's highest court of civil and criminal jurisdiction) decided to refer the case to the Court of Justice of European Union to inquire about the appropriate interpretation of the Directive. The reason for such referral through Germany's highest court was because in Article 6(2)(c), the Directive excludes the patentability for an invention that uses human embryos for industrial or commercial purposes. It however was claimed that the notion of a human embryo or the precise meaning of use, and industrial or commercial purpose were not well defined in this context. An appeal was filed over the decision of the Federal Court of Justice (Pupinck 2013).

At this stage, the Court of Justice of the European Union was supposed to make a preliminary ruling to clarify the following;

I. The referring court asks the CJEU to interpret the concept of 'human embryo' within the meaning of and for the purposes of the application of Article 6 (2)(c)

and to explain clearly in which stage of development it can be counted as human embryo. [64]

II. The referring court asks whether the term 'uses of human embryos for industrial or commercial purposes' within the same Article covers the use of human embryos for purposes of scientific research..[65]

III. The referring court asks the CJEU whether the technical teaching is unpatentable, even when the claim does not necessarily involve the destruction of the embryo which means whether 'an invention is unpatentable even though its purpose is not the use of human embryos, where it concerns a product whose production necessitates the prior destruction of human embryos or a process for which requires a base material obtained by destruction of human embryos'. [66]

It is noteworthy that Professor *Brustle* owns a parallel German patents which was maintained in an amended form under the ruling of Bundesgerichtshof in 2012 and the proceeding was totally independent of the European patent case for him. Interestingly, (although the case is still on going) in 2013 the Opposition Division of the EPO decided to revoke the European patent *Brustle* (EPO 2013).

[64]Para 23, Case C-34/10 Brüstle [2011] ECR I-0000. it was specifically asked from the CJEU under the first question on the meaning of embryo that:

' (a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?
(b) Are the following organisms also included:
- unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;
- unfertilised human ova whose division and further development have been stimulated by parthenogenesis?
(c) Are stem cells obtained from human embryos at the blastocyst stage also included?'

[65] Para 39,Case C-34/10 Brüstle [2011] ECR I-0000
[66] Para 23, Case C-34/10 Brüstle [2011] ECR I-0000

5.6.2 The Court of Justice of the European Union Preliminary Ruling

With reference to the first question from the Bundesgerichtshof (Germany) on the 'meaning' of embryo, the CJEU in Para 38 of its ruling provides that:

> any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo' within the meaning of Article 6(2)(c) of the Directive;

The Court later emphasised that

> it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2)(c) of the Directive.

Before making the above conclusions, the CJEU provided some important introductory paragraphs. The Court stated that, given the express objective of the directive which is to harmonise rules for the legal protection of biotechnological inventions[67], any provision of EU law that 'makes no express reference to the law of the Member States for the purpose of determining its meaning and scope [e.g the term 'human embryo' in the directive[68]] must be given 'an independent and uniform interpretation throughout the European Union'.[69] Later in para 28, the court clarifies that the reason for a uniform definition requirement is that the lack of such definition may tempt inventors to apply for patents in countries with the least restrictive definition ('narrowest' in the CJEU's

[67] Recitale 3, and 5-7 of the Directive
[68] Para 26 Case C-34/10 Brüstle [2011] ECR I-0000

[69] Para 25Case C-34/10 Brüstle [2011] ECR I-0000

terminology), and this would 'adversely affect the smooth functioning of the internal market which is the aim of the Directive' [para 28].[70]

Furthermore, the ruling in *Brustle* implies that 'human embryo' is any totipotent structure able to develop into a born human being. In support of this view, the Advocate General attempted to clarify the concept of embryo with reference to Article 6(2)(c) of the Directive by stating that 'totipotent cells carrying within them the capacity to evolve into a complete human being must be legally classified as human embryos and must therefore be excluded from patentability'. It is however worth noting that, had the Court decided that the definition of embryos covers creatures only at or after the blastocyst stage, this would have meant even a fertilised egg would not benefit from any protection and would not therefore be excluded by Article 6(2)(c). Scientists could then apply for patents on stem cells produced by the destruction of pre-balstocuyst humans in Member States which define embryos more liberally and consider an embryo as a blastocyst or post-blastocyst human. This would lead to a patent practice that is not uniform (Adcock & Beyleveld Working Paper, p. 13)

The judgment however included several key notes which make the answer to the first question appear sound. Among them is the reference to fundamental rights and, in particular, the dignity of the person in biotechnological material originating from humans in Paragraph 32 and, in the same Paragraph, highlighting the importance of Recital 16 in the Preamble to the Directive stating that 'patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person'. This judgement took into account another significant issue about the concept of

[70] At paragraph 29, the CJEU claims that (by its case law, specifically *Commission v Italy* paras 78 and 79) Article 6(1) gives a wide degree of discretion to member States to determine what it excludes, but that Article 6(2), by specifying examples of what is in particular excluded by Article 6(1), gives Member States no discretion, and that this supports this premise.

human embryo which was decided to be understood in a wide sense, so as to exclude 'any possibility of patentability where respect for human dignity could thereby be effected'.[71] In paragraphs 35-37, the court concluded that 'the human embryo must cover any process that begins the process of development of a human being', in relation to which it is for Member States to decide whether a cell taken from a human embryo at the blastocyst stage is, in the light of scientific developments, a human embryo (i.e., totipotent).[72]

It is clear that the CJEU ruling has gone further than the Enlarged Board of Appeal which previously decided to interpret 'embryo' in a wide sense that counts only embryos which are 14 days or older, while discussing the application of Rule 28(d)(c) and uses of embryo for medical purposes . Hence, the *Brustle* decision is not only in line with the EPO decision in *WARF*, but also goes beyond *WARF* in considering that the definition of an embryo needs a broad interpretation (Schlich & Eyre 2013). A broad interpretation of the concept of human embryos would cover 'any cell capable of commencing the process of development of a human being'. The Advocate General, Mr Yves Bot makes the point that 'the blastocyst stage of development, reached around five days after fertilisation, must also be classified as an embryo, since, the principle of human dignity, to which the directive refers, is a principle which must be applied not only to a living human being and to a child who was born, but also to the human body from the first stage of its development, i.e. from fertilisation'.[73]

[71] Para 34, Case C-34/10 Brüstle [2011] ECR I-0000

[72] Advocate General Bot, stated in his Opinion that it is not. He is correct. However, the CJEU is right to refer this to the Member States to decide, because its remit is restricted to a legal interpretation, and does not extend to making scientific judgments. Opinion of Advocate General Bot delivered on 10 March 2011(1) Case C-34/10 Oliver Brüstle v Greenpeace eV

[73] Opinion of the Advocate General in Case C-34/10 Brüstle v Greenpeace eV, The Court of Justice of the European Union, Press release No 18/11.Luxumburgh 10 March 2011.

The Opinion of Advocate General, although not binding for the CJEU[74], implied that a broad interpretation should be given to the concept of human embryos and further suggested a consideration of the inventions, involving the destruction of embryos, on this basis unpatentable. After the opinion of the Advocate General, the Court ruled that 'any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitutes a "human embryo."' [75] Under such definition provided by the CJEU the blactocyt stage also needs to be considered as human embryo.

This argument is in accord with the requirement of the PGC, and acceptable particularly with reference to Recital 16 of the Directive where it reads: 'the human body, at any stage in its formation or development, including germ cells is unpatentable'. If the directive considers germ cells as a stage in the development of human body, and not a stage toward it, then totipotent cell must be regarded similarly. With regards to this point, the Directive is well interpreted with one term in mind. The term is similar to Human Fertilization and Embryology Act 1990 position, the embryo has to be defined specifically as a fertilised egg or an 'egg in the process of fertilization'. Interestingly, the Directive could have been read on the basis of a narrower interpretation of the human embryo compared to what the CJEU offered (Adcock and Beyleveld Working Paper, p.14).

In relation to second question regarding the uses of embryo for commercial and industrial purposes with reference to Article 6(2)(c), the judgment provides that the

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[74] The Advocate General main role is to 'propose to the Court, in complete independence, a legal solution to the cases for which they are responsible', although the opinion is not binding on the CJEU (Curia 2012).
[75] Para 39,Case C-34/10 Brüstle [2011] ECR I-0000

exclusion from patentability set out in this Article will include the use of human embryo for scientific research purposes. It is noted, that the 'only use is for therapeutic or diagnostic purposes, which are applied to the human embryo and are useful to it being patentable'.[76] The ruling emphasises that although the aim of scientific research needs to be distinguished from commercial and industrial purpose[77], the CJEU's reasoning is based on the fact that when the human embryo are used in a research and specifically as a subject matter of a patent application, this process of patenting is toward a commercial purpose. Recital 42 of the Directive however only distinguishes 'inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it'. Consequently, the reasoning is clearly acceptable.

Addressing the third question, the CJEU decided that an application is likely to be excluded from patentability even though the use of human embryo is not claimed in the patent.[78] It is argued that 'Article 6(2)(c) of Directive 98/44, excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application, requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos'. The CJEU emphasised that 'the fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant.'[79]Therefore even in circumstances, which may not have an immediate connection between the patent and the prior

[76] Para 46,Case C-34/10 Brüstle [2011] ECR I-0000
[77] Para 43, Case C-34/10 Brüstle [2011] ECR I-0000
[78] Para 49, Case C-34/10 Brüstle [2011] ECR I-0000
[79] Para 49, Case C-34/10 Brüstle [2011] ECR I-0000

destruction of the embryo, it is not possible to isolate one of theme from the other (Puppinck 2013).

The line of analysis used in *WARF* in relation to laying emphasis on the actual intention of the legislator in the interpretation of the Directive was similarly adopted in the *Brustle* case.[80] As discussed earlier, it was meant to minimise the situations in which the skilful drafting of the claims is aimed to simply evade the intention of the legislator.[81] This means that if an embryo is used at any stage of the invention, even if it has been part of a research, it would not be acceptable. Naturally, this sounds logical in patent law (or any other area of law), unless we accept a framework in which a narrow interpretation of morality[82] is suggested.[83]

Overall, the Court of Justice of the European Union was rigorous in deciding the *Brustle* case, and convincingly, at least based on the requirements of the Directive. The *Brustle* decision is binding on the national courts and indirectly on the national patent offices, though not directly on the EPO, as it is not an EU body. This is particularly since the EPO has the exception rule on the prohibition of using embryo to patentability, thus, the EPO has to take into account the instructions of the directive as a supplementary means in interpreting the law.[84]

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[80] *P*oint 22,The reasoning of the Enlarged Board in *WARF*

[81] Para 50 Case C-34/10 Brüstle [2011] ECR I-0000

[82] However, the concept-theoretic position requires a broad interpretation of morality particularly when the fundamental principles of EU law are at stake.

[83] See Adcock and Beyleveld's (Working Paper) example on this matter: 'If James steals Martha's car and use its material to make a metal sculpture which he then sells for profit, can he claim that he has not used Martha's car to make this profit? Why is it different here? '

[84] Interestingly, the EPO Guideline for Examination was revised in June 2012 to add the following (CIPA Scientific Committee 2012): 'A claim directed to a product, which at the filing date of the application could be ***exclusively*** obtained by a method which necessarily involved the destruction of human embryos from which the said product is derived is excluded from patentability… even if said method is not part of the claim (see [WARF decision]). The point in time at which such destruction takes place is irrelevant.'

Post-Brustle: International Stem Cell Corporation

After *Brustle*, the case C-364/13 *International Stem Cell Corporation* attracted the attention of the scientific community.[85] In this case, the International Stem Cell Corporation seeks to register as two national patents in the UK on the process of 'parthenogenetic activation of oocytes for the production of human embryonic stem cells'.[86] The International Stem Cell Corporation, in appeal to the Patents Court, commented that the phrase *'capable of commencing the process of development of a human being' – used earlier by the CJEU in Brustle case* – required both 'the capacity to start the process of development into a human being' and the 'capacity to complete that process'. It means that cells incapable of producing human beings should not constitute a human embryo. The court decided that the meaning of *'capable of commencing the process of development of a human being'* was unclear and the matter was sent to CJEU for a preliminary ruling. In a request for a preliminary ruling, the High Court of Justice (England & Wales) asked the CJEU 'whether Article 6(2)(c) of Directive 98/44 must be interpreted as meaning that an unfertilised human ovum whose division and development to a certain stage have been stimulated by parthenogenesis constitutes a "human embryo" within the meaning of that provision'.[87] The Chancery Division (Patent Court) specifically emphasised that 'unfertilised human ova whose division and further development have been stimulated by parthenogenesis'- in contrast to fertilised ova- 'contain only pluripotent cells' and are 'incapable of developing into human beings'.[88]

Some commentators assert that *International Stem Cell* changed the principle of the CJEU and in a sense suggests a narrower interpretation of an embryo compared to the

[85] C364/13 *International Stem Cell Corporation v Comptroller General of Patents(ISCC)*
[86] Para 9-10, C364/13 *International Stem Cell Corporation v Comptroller General of Patents(ISCC)*
[87] Para 21, C364/13 *International Stem Cell Corporation v Comptroller General of Patents(ISCC)*
[88] Para 20, C364/13 *International Stem Cell Corporation v Comptroller General of Patents(ISCC)*

one found in *Brustle*. The way they interpret is that the CJEU in *Brustle* held that parthenotes are 'capable of commencing the process of development of a human being' and therefore are covered under the word human embryo, whereas in *International Stem Cells* it was decided that parthenotes are not embryos. They argue that this would to some extent limit broad interpretation of human embryos in practice (Minsen Nordberg 2015, p.1) given that the decision would result in allowing 'patent claim on pluripotent parthenotes which had not been genetically modified to achieve totipotent capabilities.'

This view is not correct though, and I discuss below why *International Stem Cell* is completely compatible with *Brustle.* In *Brustle*, the question was whether or not the parthenogenic stem cells were embryos. The Court never made a judgment on it, but then it said that if parthenotes are capable of developing into human beings they are embryos. In fact the court was not prepared to rule that say that parthenotes are embryos. It is important to mention that the technical evidence presented to the Court in *Brustle* was different from *International Stem Cell's (Rooney & Truscott 2016).* In *Brustle* the CJEU held that the term embryo *'must be understood in a wide sense'*, and included any human ovum from the moment of its fertilisation *'since that fertilisation is such as to commence the process of development of a human being*.' The CJEU did not make any technical distinction between fertilised ova, non-fertilised ova subjected to somatic-cell nuclear transfer, and parthenotes in *Brustle*. With regards to parthenotes, the CJEU commented that '*they are, as is apparent from the written observations presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so.'*[89] This was the background of CJEO's decision in *Brustle* in relation to parthenotes and why the court in *Brustle* decided that, on the basis of evidence presented to the court, "a non-fertilised

[89] Para 36, Case C-34/10 Brüstle [2011] ECR I-0000

human ovum whose division and further development have been stimulated by parthenogenesis should be treated in the same way as a fertilised ovum and, therefore, be classified as an "embryo".'[90]

However, the Court in *International Stem Cell* acknowledges a divergence of scientific information in the written observation before the court in this case and *Brustle.*[91] In Paragraph 33 of this case, the Court refers to 'written observation' presented to the Court which indicates that according to 'current scientific knowledge', a human parthenote, due to the effect of the technique used to obtain it, is not as such capable of commencing the process of development which leads to a human being. The court decided that current scientific knowledge suggests that a human 'parthenote cannot develop past the blastocyst stage'; it has not been fertilized and so only contains maternal DNA. Consequently, a parthenote cannot develop all extra-embryonic tissues and hence is not capable of developing into a human being (Davey et al. 2015). This simply means, in *International Stem Cell*, all that happened is not that there was a change to the judgment. *International Stem Cell* is a decision made by the court on the basis of the evidences now presented to the court that parthenotes are not embryos. Therefore, the actual principle has not changed. The court simply commented that if they have this capability they are embryos and, if they cannot, they are not. The Court, in *International Stem Cell* announces that, on the basis of scientific evidences, it is persuaded that parthenotes are not embryos. It does not therefore seem that the difference between decisions of the Court in *Brustle* and *International Stem Cell* is a changed definition or principle, as some scholars have suggested.

[90] Para 32 C364/13 *International Stem Cell Corporation v Comptroller General of Patents(ISCC)*
[91] Para 31-33 C364/13 *International Stem Cell Corporation v Comptroller General of Patents(ISCC)*

In conclusion, the key issue affecting the decision of the Court in *Brustle* and *International Stem Cell* is 'the state of current scientific knowledge', which may exclude the possibility of a particular cell body's inherent capacity to develop into a human being. In *Brustle*, the scientific evidence did not rule out the possibility of parthenotes having the inherent capacity to develop into human beings. A cautious approach was therefore adopted, which seems justified. However, in *International Stem Cell* the court based their judgement on evidence presented to them ruling out the possibility. Accordingly, the dignity and integrity of the person was, on the evidence, no longer at risk, which means the CJEU's decision to exclude parthenotes from the definition of 'human embryo' is also justifiable. As emphasised in *Brustle*, the concept of human embryo must be understood in a wide sense, i.e to exclude 'any possibility of patentability where respect for human dignity could thereby be affected.'[92] Clearly, there was no change in the CJEU's view in adopting a wide definition of human embryo.

In the next part, an analysis based on the concept theoretic position would be undertaken in order to respond to the objections made against the *Brustle* decision.

5.6.3 *Brustle* as viewed from the concept-theoretic position

i. What does granting the patent do?

The *Brustle* case is known as an important decision among biotechnology patents and particularly among human embryonic stem cell patent applications. As already discussed in *WARF* and *Edinburgh* one objection was made with respect to the definition of the embryo and how to interpret it. The grant of the *Brustle* patent was similar to some other hESC patents

[92] Para 34 Case C-34/10 Brüstle [2011] ECR I-0000

The CJEU ruled that the term 'human embryo' covers all of 'the early stages of human development after the fertilisation of the human ova', and includes similar cells, which are capable of turning into a complete human being. It was also decided that all stem cell inventions which require the destruction of human embryos at any stage in the production of the invention will fall into category of inventions against *ordre public* and morality (CIPA Scientific Committee 2012).

ii. What powers does it give to patent holder?

The patent gives the patent holder, Oliver Brustle, a monopoly right on a method for turning mammalian ES cells into neurons. The Court ruled that the definition of an embryo is a very sensitive one; however, the definition must restrict itself to the legal interpretation of the relevant provisions of the Biotech Directive. The power it gives to *Brustle* is similar to the previously discussed *WARF* case.

ii. How could the exercise of those powers directly or indirectly lead to consequences, which are contrary to the PGC?

One of the issues to take into account while discussing controversy on definitions of the human embryo is the idea that some commentators believe that any meaning which ought to be given to terms in patent law is required to be the ordinary scientific definition, (Adcock & LIewelyn 2001, pp.91-101). That is not acceptable under the proposed framework of this thesis, as medical terminology determines that an embryo does not exist until 14 days after fertilisation,[93] whereas the purpose of the Directive or Human Embryology Act is not to regulate the use of scientific or medical terminologies

[93]Human Fertilisation and Embryology Act (1990) Section 3(4)

but to serve the normative purpose of the legislation (Adcock & Beyleveld Working Paper, pp.19-20).

Furthermore, the reason the concept-theoretic position suggests the protection of human embryos, to a certain extent, is the fact that merely because apparent non-agents do not display sufficient evidence of agency, does not give us permission to exclude them from the agency. This means that in cases of nonsufficient evidence of agency, we cannot logically conclude 'non-agency'. It is true that, in cases like *Brustle,* it is not possible logically to expect the entitlement to generic rights for human embryonic stem cell equivalent to adult normal apparent agents, and the PGC under precautionary reason does not require such action. Notwithstanding, considering a minimal moral status is necessary. This means to feel minimal moral duties toward them, given that they have the potential to become apparent agents (Beyleveld & Pattinson 2010, p.265). Therefore, analysing the matter under a Gewirthian framework, the embryo is not entitled to a full moral status. Addressing the status of the embryo in the Directive, the Biotechnology Directive happens to be in consistency with what the PGC requires. In case of conflict between the interest of embryo e.g. its life and corresponding rights of an apparent agent, the right-corresponding interest of embryo can be overdriven by the right of an agents (e.g. a mother) to life because mother is more likely to be an agent as opposed to embryo. However if the patent protects the rights of agents or mother in lower levels against the life of the embryo, decisions have to be made differently. [94]

If the use of the embryo is the only chance, it is against the requirements of the PGC if the possible violation and harm caused is not justifiable. For instance, in cases like

[94] Practically when such complexities in the process of right balancing occur, the concept-theoretic position requires to 'delegating the power to democratic legislator' (courts or other bodies) to make the final decision. such delegation is subject to limitation that derive directly from the PGC (Adcock & Beyleveld in press, p.20)

Brustle, it is important to understand why there is a need to use the methods which involve destruction of embryos, because currently hESC can be developed without any destruction involved. There is also the need to explain why the use of adult stem cells may not work. The positive consequences of violating the protection for the benefit of human embryos, together with the probability of the future event should be justified. Moreover, it is important to examine how the embryos are sourced, whether it comes from discarded or surplus embryos or it is freshly made for the purpose of research. If there are no surplus embryos from research or fertility treatments, then there may be the need to think of producing new lines. However, if this occurs to protect avoidance of more serious harms, it may be allowed in some occasions. This 'more serious harm' means for instance, the avoidance of circumstances in which apparent agents may lose their lives due to a rare genetic disorder or situations caused by infertility in the life of childless women. Therefore, such procedure may be allowed under precautionary reasons, if it is necessary as long as the embryo is treated with dignity (Beyleveld 2000, p.76).[95]

iv. Are there ways in which they could do this?

There is almost nothing new to add with respect to interests involved, and the overriding conditions in the *Brustle* case, when compared to two previous cases. If granting the patents on stem cell research on embryos is necessary, and there is no other efficacious option for the development of life-saving treatment, then the concept theoretic position needs to allow such patents. However the essential conditions which allow us to permit the destruction of embryos is not satisfied as:

[95]For example avoidance of killing surplus embryo and permitting use of surplus embryos for women other than genetic mother (Beyleveld 2000, p.76)

i) Developing stem cells from pluripotent human blastocyst cells which do not involve the destruction of human embryos can function as effective as those cell lines developed from totipotent cells (Adcock & Beyleveld Working Paper, p.21).

ii) Similarly, the second term is not satisfied, as patenting is not the only successful option to recoup the investment and as discussed in the *WARF* case, other alternative methods of IP protection and even the absence of IP protection (like putting the invention in 'public domain') can be implemented to protect the inventions (Cohen & Walsh 2008, pp.1).

5.7 Chapter Summary

This chapter examined a number of patent cases brought to the European Patent Office, and one recent request for preliminary ruling to the CJEU in addition to objection to these cases in relation to violation of *order public* and morality. Having learnt general principles derived from the PGC within the context of medical law and intellectual property law, this chapter applied the concept-theoretic position principle in historical patent cases within the European system. In addition to benefit from the unique and very effective system of balancing rights in the concept-theoretic position, the criterion of degree of needfulness for action, the analysis provided in this chapter in each case aimed to take into account the social economic context, and the political context in which the principles will be applied. The Principle of Generic Consistency is an absolute rule, however what rules or social arrangements are required to actually give effect to the PGC were discussed thoroughly in all cases.

CHAPTER VI

A PGC BASED PATENT REGULATORY FRAMEWORK FOR THE US: A COMPARATIVE ANALYSIS OF THE MORALITY EXCLUSIONS IN PATENT LAW WITHIN BIOTECHNOLOGY IN THE EU AND US

6.1 Introduction

In Chapter I and III, the thesis has argued that that even if the European Directive was not enacted, and no legislation in relation to immorality exclusions passed, the essence of EU law, enshrined in European Convention of Human Rights and other relevant pieces of international law could never legitimise patentability of biotechnological inventions in which the morality, in a broad sense, is violated. As discussed, the concept of human rights is contained in the Universal Declaration of Human Rights. It provides the States with all necessary information about what human rights are, what status it has, and to whom it applies. Since the PGC is the 'supreme principle of human rights' and all agents must accept the PGC, any rights inconsistent with the PGC cannot be a right. Similarly, any activity inconsistent with the PGC cannot be permitted. If anything is contrary to human rights, then it is possible that some of the rights which are granted are not in line with the PGC. If they are not in line with the PGC, that means that there are some contradictions within the Convention itself, and implies that the Convention recognises activities that the concept of human rights does not allow.

Furthermore, I seek to raise the issue of necessity of morality in law from a US constitutional perspective and from a precedent and past practices point of view to analyse the use of moral utility in the US patent system.

Based on the above, this chapter argues that it is of little or no relevance whether the U.S patent system independently claims the 'morally-neutral' patentability requirements since it is contrary to the very fundamentals of their legal system, commitment to human rights, to legitimise actions against human rights. The chapter aims to analyse the situation from the U.S. patent regime perspective to find out whether it is consistent with the requirements of the PGC. To do so, It aims to examine to what extent the

United States law recognises the existence of human rights and morality in general. My main argument is that the PGC-based framework should be applicable in any legal system committed to the very principles of human rights; hence, what is known as the US 'morally neutral' patent system is questionable on the basis of the PGC. The reason is if we accept that there are human rights, then all the laws must be consistent with the PGC. Therefore, the patent regime must be consistent with the PGC. The only way that one can argue that the U.S. regime ought not to comply with requirement of the PGC is that if the system refuses to accept that there are human rights. It is therefore clear that the system cannot be possibly consistent with the requirement of the PGC, as it exists.

Part I of the chapter includes a brief analysis of U.S. patent law (6.2). The section provides an argument on the concept of morality, within the United States constitution (section 6.2.1) followed by a section on how case laws influenced by the 'moral utility doctrine' (section 6.2.2).

The chapter then argues that even if these fundamental issues would have never been explicitly mentioned in the law; still these principles should have been considered undetachable from the body of law. Under the same line of analysis, a discussion will be made to the effect that although the patent codes in the U.S. may seem morally neutral, the U.S. Constitution, which is the appropriate place to declare the 'fundamental principles' of the states is not morally neutral. The fact that the U.S. patent law does not include the particular wording and clear reference to exclusions of patentability based on morality and *ordre public*, this does not affect the position of human rights principles, which of course, remains relevant even in United States context of patent law. This discussion would then be followed by some discussion on the 'politics' of patents in the US (section 6.3). Part I of the chapter would then conclude by raising the major

question, whether or not PGC is equally effective in balancing rights in the U.S. patent system (section 6.4).

Part II of this chapter consists of a combination of two historical cases, *John Moore* (section 6.5) and *Hagahai* case (section 6.6). These sections will examine how the concept-theoretic position fits suitably in such situations and in light of this framework what the outcome will be.

Part I
The Uncertain Relationship between Morality and Patentability Requirement in the U.S. Patent Regime

6.2 Patent Law in Biotechnology: The United States Context

Having introduced the United States patent law very briefly in Chapter 1, this section consist of an analysis of the interpretation of the patent law through the U.S Constitution and a discussion of moral utility doctrine in U.S patent law.

6.2.1 Interpretation of the Patent Law through the US Constitution

'The constitution is America's moral sail, and we must hold the courage of the conviction that fills it, the conviction that we all can be equal citizens of a moral republic. That is a noble faith, and only optimism can redeem it' (Dworkin 1999, p. 38).

The position of the U.S. patent law in relation to limitations based on morality has been well examined in literature. This literature mainly analyses why the U.S. patent

legislator and practitioners prefer to adopt a neutral patent system with no place for morality. Using the approach adopted in this research, whilst analysing the EU patent law, the thesis investigates the U.S. Constitution to uncover whether there has been direct or indirect reference to morality. Specifically, this section of the thesis seeks to relate the position of the U.S. Constitution to the U.S patent law as the U.S. Constitution clearly takes precedence over, in order of hierarchy, federal statutory law, a state constitution, state statutory law, a local ordinance, administrative rules and rulings, and common law.

This section would identify the way in which the interpretation of morality may be understood from the U.S Constitution. The section would also investigate whether it can be permitted within U.S. law, including patent law, to claim moral neutrality. It is clearly evident that the role of the Constitution is significant in defining and limiting the authority and power of the state and the law. Historically, cases such as *Marbury v. Madison,*[1]and *Fletcher v Peck*[2] were among the first cases that the Supreme Court of the United States granted the power of judicial review, based on the judicial power granted through Article III of the Constitution. Under this line of analysis in jurisprudence, if a law is found to be against the Constitution, the court will be given the authority to strike down the law. The above supremacy clause is embodied in the provision of Article 6, Clause 2 of the Constitution in which the Constitution, federal statues, and treaties are defined as 'the supreme law of the land'. According to this provision, the above said are the highest in importance in order of hierarchy in the legal system of the United States. State laws are invalidated by courts for the mere fact that they do not conform to the Constitution's principles including Contract Clause e.g. in

[1]*Marbury v. Madison*5 U.S. 137 (1803)

[2]*Fletcher v. Peck*10 U.S. 87 (1810)

Dartmouth College v. Woodward[3], the Equal Protection Clause in cases such as *Brown v Board of Education*[4], and the Commerce Clause for instance in *United States v Lopez*[5]. United States is signatory to various human right conventions including UDHR, International Covenant on Economic, Social and Cultural Rights (ICESCR), International Covenant on Civil and Political Rights (ICCPR), and many others. The point is that the UN declaration and ICCPR and so on all came to service for long time (OHCHR 2015). The U.S. commitment to human right conventions is further evidenced by several references to human rights principles in the actual constitution and Bill of Rights . All these activities are clearly the recognition of morality and human rights. Since the dialectically contingent argument (Beyleveld 2012) is used in developing the concept-theoretic position, this means that if a legal system accepts the UDHR and its Articles including Article 1 and 2 of the UDHR, emphasising that all human beings are equal in dignity and ought to be treated with equal concern and respect and that 'everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind', that is what is needed to recognise the validity of stage 1 of the PGC. The reason is that human rights conventions because of the Article 1 and 2 of the UDHR actually adhere to 'impartiality'. In the case of Unites Sates if they adhere to this impartiality premise, which they do, then they are running a system that is bound to the PGC. This means law in this system must be in line with the PGC.

The United States legal system is built upon the recognition of human rights, impartiality, and morality; therefore, the system is bound to follow the PGC. Does it actually follow the PGC? That now becomes the question of all various doctrines they had about moral utility, and all the actual features of the way in which they grant patents.

[3] *Dartmouth College v. Woodward* (1819) Supreme Court17 US 250
[4] *Brown v. Board of Education* (1954) Supreme Court 347 US 483.

[5] United States v. Lopez, 514 US 549 - Supreme Court 1995

Practically, it is very much like when the European system was analysed in this thesis. It was discussed that regardless of what the Patent Office or the Court decided, the main point is that the Europe belongs to a system that is governed by primacy of human rights and therefore its law has to be interpreted in line with the PGC as supreme principle of human rights; anything in violation of morality and human rights cannot be acceptable. The same analysis applies in the case of United States patent law. The argument is that there are no explicit morality exclusions in United States patent law. Although there is no explicit morality clause, the essence of commitment to human rights principles is in the United States constitution. Patent law clearly needs to be in line with the United States Constitution which recognises universal principle of human rights. Because this fidelity to human rights is present in the United States constitution, this means that the PGC applies. Therefore, permissibility of any activity requires to be assessed according to the PGC.

6.2.2 Moral Utility Doctrine

It is clear that precedents and past practices are distinctively important in the U.S. as a common law system (Strauss 2010). Therefore, keeping in line with the previous judgments is indeed a key fact. Within the specific subject of this section, the requirement of patentability, it is known that the utility of the patent is an essential factor in the U.S patent system. Utility is classified into general, specific, and moral utility. The moral utility as the main subject of this section is concerned with the inventions involved in an immoral conduct or designed for an immoral purpose.

A category under moral utility is to hold a patent in ‘misleading devices’. Historically, objections towards rendering a patentable invention out of misleading devices or attempts to defraud consumers first arose in the 1920s. At that time, a patent for

seamless stockings with fake seams was rejected, as those stockings with seams were widely perceived as products with higher quality. Therefore, the patent was refused on grounds of consumer fraud, and viewed as a misleading device. Nevertheless, the Federal Circuit later in 1999 upheld a patent for the *Juicy Whip* according to which Federal Circuit removed the condition of deceptiveness as a factor affecting the utility of an invention. The machine was basically a lemonade dispenser that could circulate an inert yellow liquid inside a visible tank; however, in spite of what it looked like, the customers receive the actual lemonade from a hidden tank below the tanker.[6]

Another important class under immoral utility was in relation to 'gambling devices'. In the 19th and early 20thcentury, the doctrine was invoked to invalidate many patents on gambling machines. Interestingly, some machines including coin return devices and horse racing games were invalidated on the basis that they could be used for gambling purposes. After 1970s, however, patents were granted for gambling machines although no justification was given in relation to moral utility argument. Another instance of application of moral utility used to be 'the medicines of questionable safety'. Nevertheless, patents on drugs are not currently denied by the US Patent Office on the ground of doubts on the safety of the drug. It is probably because there is always assurance that the FDA makes a proper scientific judgment in relation to pharmaceutical products. In the United States the way patenting works is generally what is known as 'patent first, ask questions later'(Bagley 2003, p.469). This approach however has its own difficulties including the controversies which occurred in cases of transgenic animal patents, methods of cloning, or mixed human-animal chimeras. The issues

[6]United States Court of Appeals for the Federal Circuit 01-1263, -1317 JUICY WHIP, INC., Plaintiff-Appellant, v. orange bang, inc., unique beverage dispensers, inc., david fox, and bruce burwick, Defendant.

involved may be relevant to animal suffering, human dignity, patient access to life-saving treatments, and the destruction of human embryonic life.

The US system has included some specific prohibition, the most important of which is prohibition of patents directed to or encompassing human organisms.[7] This provision is called 'a clarification' of the policy adopted by the United States Patent and Trademark Office with regards to the prohibition of patenting humans. The key problem with this Weldon amendment is the fact that USPT has not been given any guidance in relation to the definition of "human", appropriate measure of "humanness", and proportion of body cell requirement to qualify as a human. Therefore, it does not provide any basis for the patent examiner to decide about the grant or refusal of a patent. It seems that patent eligibility, at least in relation to the determination of a subject matter, is vague and unclear, and amendments such as Weldon have not categorically amended the patent statute. The following paragraph provides a more detailed analysis of the moral utility doctrine to examine the role of morality in the US patent system.

The United States model changed to some extent from the Patent Act of 1973 to the Patent Act of 1870 in terms of definition for a patentable subject matter that the subject matter can be about 'any person who has invented or discovered any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement thereof….'[8] In the important *Lowell v Lewis* case, the judgment provided that:

> the law will not allow the plaintiff to recover if the invention be of a mischievous or injurious tendency…All that the law requires is that **the invention should not be frivolous or**

7 The Consolidated Appropriations Bill of 2004, Pub. L. No. 108-199, 118 Stat. 3.

8 Patent Act of 1793, ch 11, s. 1 (US); Patent Act of 1870, ch 230, s. 24 (US).

> **injurious to the well-being, good policy, or sound morals of society**. The word 'useful', therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people or to promote debauchery, or to facilitate private assassination, is not a patentable invention.[9]

Therefore, the fact that an invention is in contravention with the "sound morals of society" implies that the invention does not meet the utility requirement and is not useful. In another case, *Evans v. Eaton,*[10] the same definition for patentable subject matters was adopted, according to which it was decided that 'useful' means "**applied to a beneficial use in society, in contradistinction to … injurious to the morals, health or good order… or frivolous or insignificant**". [11]

Thus, a broad definition of 'usefulness' was accepted in patent cases supported by judicially developed doctrines including 'moral utility doctrine'. Also it occurred within the frame of exclusion from patentability on the ground of distinction between an 'invention' and a discovery including the *Morton v. N.Y. Eye Infirmary,*[12]in which it was decided that ' in its naked ordinary sense, a discovery is not patentable. A discovery of a new principle, force, or law operating, or which can be made to operate, on matter, will not entitle the discoverer to a patent'. The Morton case also meant limitation in patentability of the subject matters of a 'patent for the method of surgery involving administration of sulphuric ether to the patient to render the latter unconscious was

[9] *Lowell v Lewis* (CCCD Mass 1817) 15 F Cas 1018
[10] *Evans v. Eaton* (1818) 16 U.S. (3 Wheat.) 454, 519.

[11] *Evan v. Eaton*. note 9.
[12] *Morton v. N.Y. Eye Infirmary* (CCSDNY 1862) 17 F Cas 879

invalid, but on basis that it involved new use of known substance'[13]. Furthermore, cases like *Ex p. Brinkerhoff*[14] in which the claimed invention involved the 'use of surgical treatment for the treatment of human body' were decided in a way that 'the methods or modes of treatment of physicians of certain diseases' were judged as not patentable (Ventose 2011; Duffy 2009, p. 634-637).

The above judgments shed light on the ambiguous definitions of the word 'usefulness'. However, as was discussed above, a different approach adopted by the US Court of Appeals for the Federal Circuit in *Juicy Whip Inc v Orange Bang Inc,* [15]in which a patent application for a juice machine potentially capable of misleading consumers was accepted. In defence of the patent, the Circuit Judge Bryson stated that ' the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years.' Although the Court of Appeal upheld the validity of the patent for a product with capacity to misinform some members of public, the moral utility doctrine has been referred to in a number of other occasions.

Being 'useful' in *Brener v. Manson* was defined as the potential of an invention to provide a benefit to the public. This case provides that 'the basic quid pro quo contemplated by the Constitution and Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.'[16] According to the Revised Interim Utility Guideline Training material of the United States Patent and Trademark Office, a patent application has to meet the requirement of having a specific, substantial, and credible utility, whereas no information is given with regards to moral

[13] *Morton v. N.Y. Eye Infirmary.* note 11.
[14] *Ex p. Brinkerhoff* (1883) reprinted in 27 J.P.O. S. 797 (1945)
[15] *Juicy Whip Inc v Orange Bang Inc* (Fed. Cir. 1999) 185 F.3d 1364, 1366-67
[16]. *Brenner v. Manson* (1966) 383 U.S. 519, 534

utility (USPTO 2004). The latest checklist on the patentability subject matter comprises three exclusions: laws of nature, physical phenomena and abstract ideas. Although this shift attracts controversy, the 2010 *Bilski* decision was a milestone case in which the majority of the US Supreme Court acknowledged this approach. Having stated such positions with regards to the obscurity of the moral utility doctrine in the US patent system, there are still supporters of this doctrine in the patent system and the justice story's classic formulation of utility is still being referenced.

In *Geneva Pharmaceuticals, Inc. v. Glaxosmithkline PLC,* the moral utility argument in relation to patentable subject matter was raised again in the judgment supporting the idea that 'if it will operate to perform the functions, and secure the results intended, and its use is not contrary to law, moral principles, or public policy.'[17] Therefore, comparing *Geneva Pharmaceuticals, Inc. v. Glaxosmithkline PLC* with *Juicy Whip Inc v Orange Bang Inc* or *Whistler Corp. v. Autotronics Inc* [18], it proves that courts had and may still have the tendency to apply a moral standard to determine the usefulness of a patent.

More patent cases can be listed here in which patentability and usefulness of a subject matter is, to some extent, related to not being contrary to morality and public policy; cases like *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft*[19] in which the court decided that the usefulness criterion 'has **...** been interpreted to exclude inventions deemed to be immoral' or the rationale of the court in *Am. Standard Inc. v. Pfizer Inc*.[20] where in determination of 'usefulness' it was said that 'to be useful, the patent's purpose must not be illegal, immoral or contrary to public policy'.

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[17] *Geneva Pharms., Inc. V. Glaxosmithkline Plc*, 213 F. Supp. 2d 597, 610 (E.D. Va. 2002) (Quoting Callison V. Dean, 70 F.2d 55, 58 (10th Cir. 1934)

[18] *Whistler Corp. v. Autotronics Inc*., 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Texas 1988

[19] *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft*, 945 F.2d 1546, 1552 (Fed. Cir. 1991): the patent was about invention of "a radar detector, designed for the exclusive purpose of circumventing the law, useful and noting that it is a matter for legislatures and Congress to prohibit such devices."

[20] *Am. Standard Inc. v. Pfizer Inc*. 722 F. Supp. 86, 150 (D. Del. 1989)

Notwithstanding, the interpretation of moral utility doctrine varied within US patent law scholars, among them Professor Peter Rosenberg asserts that '[w]hat is immoral varies from generation to generation **....** [and] cases denying the protection of the law on the ground of immorality are not of this generation'(Rosenberg 2002, 8.05). Others, including Professor Donald Chisum, acknowledge moral utility as a valid doctrine of public policy which has to be interpreted broadly, emphasising that '[a] patent will be withheld only if the invention cannot be used for any honest and moral purpose' (Chisum 1995, c.4.03).[21]

Stuart Newman, a cellular biologist who opposed the patentability of inventions involving ethical controversy in relation to genetic engineering and patenting life forms, applied to register a patent for half-human half animal species in 1998. Such an extreme application was probably one of the main reasons the PTO denied the patent application, for being immoral. Rather than any intention to create such animal-human hybrid, Newman aimed to 'reignite debate about the ethics of genetic engineering and the patenting of life forms'.[22] The patent was refused as the potential creature would 'embrace [d]' a human being, and thus did not constitute patentable subject matter. As a consequence of Newman's patent application, a 'media advisory' was issued in which Justice Story's formulation of utility, moral utility doctrine, was again relied on. However, as discussed earlier, it is not clear why the Revised 2001 Examiner Guideline does not include any note of morality or public policy issues. In another example, the U.S. patent office claimed the authority to reject patent applications, merely on moral grounds (Wadman 1998) where the Organisation of African Unity decided to refuse drugs manufactured based on natural products found in Africa if the 'ownership' and

[22]It is further argued that: "Newman, who opposes such patents, is allied with social activist Jeremy Rifkin, a long-time foe of intellectual property protection for biological organisms and genetic compounds."

contribution of the respective community in the new product is not officially acknowledged. This was intended to support the benefit and ownership of the indigenous local community over the products for 'all times and in perpetuity' (Massod 1998, p.423).

Contrary to the decision in Newman's patent, the University of Missouri was granted a patent on a controversial invention involving 'a method for producing a cloned mammal.'[23]To be precise, the PTO authorised a patent involving ways to 'transplant a nucleus from (1) a cultured mammalian cell, (2) a mammalian embryo, (3) a mammalian fetus, or (4) an adult mammal to a recipient mammalian oocyte, to produce a cloned mammalian embryo and, ultimately, a cloned mammal'. [24] Opponents of patenting genetically engineered human materials, especially, the Centre for Technology Assessment (CTA) opposed the decision and the permissibility of human cloning saying that '[t]he PTO has the legal authority under both national and international law to reject patents that offend public morality or order, but did not do sue the case of the Missouri patent.'[25]

Decisions in Newman, Missouri and other cases discussed above evidence the 'continuing controversy' around the idea of biotechnology patents in which the PTO and Federal Courts have been reluctant to fully revive the doctrine. Courts have dropped moral utility doctrine and now make decisions on biotechnology patents through 'Products of Nature Doctrine'. The doctrine, context specific in terms of life sciences, restricts patent-eligibility of biotechnological inventions including isolated DNA. Therefore, the broad approach adopted in *Diamond v. Chakrabarty* –allowing subject matter to include 'anything under the sun that is made by man'- is now restricted on

[23]U.S. Patent No. 6,211,429 (issued Apr. 3, 2001).

[24]*Ibid. note 22.*

[25]*See Group Faults.*

‘Products of Nature Doctrine. This means in spite of fidelity of long established patent law principles in the U.S a change is always possible in any system.

Having discussed the moral utility doctrine within U.S case law and the morality in Constitution, the next section will analyse another determining factor in the governance of patent law in the U.S, the politics of patents in a capitalist system.

6.3 Patents, Politics and Rights

Evidently, patents influence the way in which science is carried out, as they define how science is translated to a market product. Interestingly no biotech industry existed prior to 1976, hence no patenting issues had been raised in this industry until that date. Biotech in the United States is a huge success contributing immensely to the Business Market. For instance, 410 Billion Dollars was spent on market capitalisation in 2005. Considering such huge market and economic benefit, it is no surprise, that a significant number of U.S scholars in both law and science claim that ‘with no gene patent protection there would be no biotech industry’ (Noonan 2012).

In spite of the historical diminutive interest and even opposition by U.S. universities towards patenting inventions, patenting inventions became popular among U.S universities. The statistic of patent registration increased drastically from 500 per year in 1980s to 3000 patents issued in 1990s (National Science Foundation 2006). Universities generate substantial amounts of funding through licensing their patents to corporations. This licensing fee grew under $200 million in 1993 to more than $800 million in 2003 (National Science Foundation 2006). These changes however brought some controversy into academia. The concept of ownership and the profit engaged in science raised concerns particularly in a system believed to be still largely ‘communistic and Mertonian ’where the whole idea of IP rights were totally different from what is

now as Merton (1942, p.273) stated: 'The scientist's claim to 'his' intellectual 'property' is limited to that of recognition and esteem...'.

Some scholars including Leaf in 'the Law of Unintended Consequences' strongly believed that patenting encourages universities and academic institutions to prioritise their own self-interest from the pocket of the public as their project was mainly funded from tax payer's money. Moreover, the fairness of patenting in this way is disputed considering the costly litigation for defending the patents (Leaf 2005, p.255). On the other hand, other scholars including Heller and Eisenberg raised the spectre of 'anticommons' in which the classic 'tragedy of commons', which asserts that the common ownership of a resource, resulting in its overuse, was challenged. Under such line of analysis, they submit that 'anticommons' hinder the advancement of science because it significantly limits the ability of others to build on knowledge, and because it occurs in circumstances where high levels of claims of ownership exists in field of knowledge (Heller & Eisnberg 1998 , p. 698-701).

Supporters of patents however argue that those scientists who have the technical knowledge or know-how can uniquely turn such knowledge into marketable products. There is considerable amount of literature on university patenting, although the focus of most of the research projects are not properly analysed from a socio-economic perspective. The literature is predominately policy-oriented, discussing the causes and consequences of patenting. However some valuable research has been accomplished; including the works authored by Murray and Stern (2005) or Welsh and others (2003) on the effect assessment of the university patenting and the cumulative nature of science , or, the very distinctive projects of Woody Powel with his collaborators including Colyvas and Powel (2006) or Owen Smith and Powel (2001 & 2003).

Industrialised economies, specifically U.S. pharmaceutical manufacturing industries experienced a significant decline as a result of the emergence of the developing world's manufacturing trajectory three decades ago. In the 1980s, newly industrialised economies in Asia and Latin America caused losses and put pressure on the former nearly sole manufacturer of the worldwide market. The U.S economy suffered from a dramatic increase in trade deficit, from $36.3 to $148.5 billion between 1980 and 1985 (Sell 2006, p.176). Such losses made the U.S more diligent about relocating trade competiveness in technological innovation and research-intensive areas including biotechnology (Capling 1999, p.83). In particular, the protection and enforcement of intellectual property rights proved to be relevant to the U.S position in the global business, as IP constituted less than 10 % of the U.S total exports in 1947, growing to 37% and then over 50% in 1986 and 1994 accordingly (Vandana & Radha 1996; Ryan 1998, p.2).

In the pharmaceutical industry alone, the U.S is host to 13 of the top 20 worldwide leading producers according to a late 90s statistic (Schweitzer 1997, p. 21). 70% of the top selling products were introduced and sold by these 20 leading firms, representing 45% of the total worldwide sale. Around the time that the EU was drafting the EU Directive on the Protection of Biotechnological Inventions and trying to regulate the biotech patents, the U.S. was thinking about ways in which the issue of IP protection could best be achieved as an urgent matter for the affected industries, as they had witnessed a drastic rise in the share of knowledge intensive or high technology products in total world trade.[26] It is claimed that an approximate cost of $500 million is spent on manufacturing a new drug and not all the drugs find the market (Noonan 2000, p. 22-26). Manufacturers claim that holding a patent protects the inventors at least for a

[26] To be precise, the increase was from 12% to 24%. Fink and Primo Braga, 1999: 2.

limited period, in order to prevent others from commercially exploiting their inventions, in which their high risk investments and their efforts, carried out through a lengthy process of research would be compensated to some degree (EPO 2011).

The life science industry has contributed approximately $69 billion annually to the U.S economy. The economy had $1 billion public investment in medical Research and Development in 2011, through which it was expected that the GDP would grow by 0.048 percent annually. In spite of all the above said facts, the United States' international competiveness in biomedical research has experienced a decline in leadership for many reasons, including a negative trade balance in pharmaceutical products reported every year since 1997. This happened in definite contrast to economies such as Singapore, which managed to grow their pharmaceutical trade balance as a share of their GDP successfully went from 0.25 to 2.63 per cent in the 2000s (Atkinson et al. 2012). Other economies such as China started to get involved in medical technology. The Beijing Genomic Institute in China is now the world's largest next generation sequencing capacity and stands even higher than the entire U.S in terms of sequencing capacity.

The leading position of the U.S. in biotechnology is indeed questionable. Although the United States still owns the highest number of biopharmaceutical patents, its share of total biopharmaceutical patents awarded reduced by 5 per cent from 38 to 33 per cent, whereas China for instance experienced a dramatic growth in the first decade of the 21st century.[27]

[27]It increased 12 per cent from 4 percent in 2000 to 16 percent by 2009. National Science Board. 2012. Science and Engineering Indicators 2012. Arlington VA: National Science Foundation (NSB 12-01). And The Partnership for a New American Economy & The Partnership for New York City. "Not Coming to America: Why the US is Falling Behind in the Global Race for Talent." May 2012.

6.4 Is the PGC workable in balancing right in the US patent system?

"The PGC is the constitutional norm of any legal order."(Beyleveld & Brownsword 1986, p.162)

In the previous chapters, the thesis defended the PGC as the basis of the concept-theoretic position advocated in this work. The thesis suggested the implementation of the framework for interpretation of morality exclusions in EU patent law. In this section, the thesis will investigate the same concept in the US patent system in order to find out if it is applicable in their patent regime.

Research works like 'the Enforcement of Morals', lectured and published by Sir Patrick Devlin for the British Academy in 1958 offered a different perspective to the notion of morality in the world (Devlin 1959). He argues that 'morality is part of the fabric of the society and that immoral conduct therefore presents a clear threat, the neutralisation of which takes precedence over individual freedom'. Clearly, such perception of the morality in the law appeared to be very distinctive from what the key argument in Hart (1958) was or Ronald Dworkin's arguments (Dworkin 1979) in relation to morality in law. H.L.A Hart strongly objected the position of Delvin because he believes that there is no need to maintain morality in the interest of societal integrity and that it must be consistent with the society's advancement (Hart 1958). Interestingly, one of the common arguments regarding the necessity of morality in the law and whether law, irrespective of whether its field is relevant to private lives or not, is about the existence of an effective and adequate measure to public morality. Now, a question put to Devlin below seems logical:

> Granted that a challenge to deep-seated and genuine public morality may conceivably threaten society's existence, and so must be placed above the threshold of the law's concern, how shall we know when the danger is sufficiently clear and present to justify not merely scrutiny but action? What more is needed beyond the fact of passionate public disapproval to show that we are in the presence of an actual threat? (Dworkin 1966, paper 3611)

In addressing the question of whether a PGC-based framework is equally workable in US patent system, the answer is clearly in the affirmative for different reasons, most importantly the following argument. In previous sections of this thesis, the key focus was within the European Union law and specifically the Directive on the protection of biotechnological inventions. The proposed PGC based concept-theoretic position is premised upon the acceptance of the EU law and the fundamental principles of EU law, and importantly human rights principles as enshrined within the Universal Declaration of Human Rights and the European Convention of Human Rights. Therefore all matters conceptually or logically follows the adoption of these instruments included. It is clearly evident that this concept–theoretic position is tied to the positive law of the EU, and its reasons for actions according to the value given to human rights within the Member States through their legislative bodies and courts. Yet it is not in full compliance with the positive law, in its independent form. The jurisprudence of the relevant courts are not taken into account as a concluding measure to interpret the adoption of human right principles. Thus, what is primarily assumed in this position is based *on the current status given to human rights within the EU.* It follows that the jurisprudence of the Court and any EU law must be in consistency with the concept of human rights in the respective Member States. Patent law, like any other branch of EU law, is not an exception to this rule. Therefore, in order to be valid, the regulation of the EU patent law must be consistent with what follows as the idea of human rights in EU.

Having compared the US system with the one in EU, it is clear that the above premise with regard to application of the PGC in the European law can simply be fitted into the US law even without an explicit morality exclusion. In fact, the validity of stage I of the dialectically necessary argument follows the adoption of the PGC as the supreme principle of human rights (Beyleveld 2012). As discussed in the Chapter 2 on the justification of the PGC as a theoretical framework, any system of law, including the U.S. Intellectual Property system, that is committed to the adoption and implementation of the UDHR, has to declare all permissible actions in compliance with the requirements of PGC, otherwise they would fail to recognise the idea of equality of human beings with regards to the possession of dignity and inalienable rights.

The United States courts have relied upon the rights granted to citizens under the UN Charter and the UN Declaration of Human Rights as a supplement to rights protected by the Constitution.[28] The United States has ratified the universal human rights treaties including the International Covenant on Economic, Social and Cultural Rights. Furthermore, the International Covenant on Civil and Political Rights (with some reservation) has been ratified in the US as a binding instrument opposed to the UDHR which may be known as a legally non-binding instrument. More importantly, such human rights treaties have been given prominence by the framers of the Constitution by which a treaty, according to Article VI; Clause 2, similar to the Constitution itself is called the 'supreme law of the land' (Venetis 2011, p.2). Having said the above, the US patent system does not seem very different in its essence, even though the morality exclusions may not be explicitly mentioned in the law. The PGC fits perfectly into the

[28]See e.g. *Hurd v. Hodge* (1948) 162 F.2d 233, 245-46 (D.C. Cir. 1947) ; *Oyama v. California* (1948) 332 U.S. 633, 649-50 (concurring opinion) ; *Sei Fujii v. State*, (Cal. Dist. Ct App. 1950) 217 P.2d 481, 486-88)

US patent system in order to interpret the conflict of rights and it would be equally effective in their system.

The next section of this chapter is designed to implement the concept theoretic position in two historical cases in the U.S. context.

Part II:
Selected United States Historical Patent Cases

6.5 John Moore Case

6.5.1 Facts and case summary

Moore v Regents of the University of California case[29] raises the issue that, if a biotechnological invention is created basically with genetic material taken from human body and that invention then is intended to be patented, does the initial consent given by donors extend to patenting research output or it is required to take the donor's consent in every stage and for any individual purpose?

The U.S. case of John Moore was about the research work undertaken on a spleen line discarded from a leukaemia patient (In 1976 from Mr John Moore).This research resulted in a cell line from the extracted T-lymphocytes which was successfully granted a U.S. patent in 1984 whereby the patient was not informed about either the research or the patent.[30]

[29] *Moore v Regents of the University of California* (1990) 793 P2d 479.

About the time Dr Golde filed his patent, John Moore became sceptical about the way their medical team, particularly Dr Golde, managed his treatments, and their requests for frequent visit to the UCLA Medical Centre. Having been suspicious about the whole treatment procedure and as he believed his bodily substances were used by the medical team for commercial endeavour, John Moore confronted the issue with Dr Golde, who denied the allegation. This however resulted in a medical team request for Moore to sign a consent form that surrenders the 'all of his and his heirs' rights to a cell line or any type of product that may be developed in future from his blood cells (Stone 1996). Under pressure from the medical team he signed the form, but employed a lawyer and claimed that he will not relinquish the rights. Subsequently the lawyer proved that Dr Golde and his assistant had recently filed a patent on a cell line developed from Moore's blood cells. Mr Moore took all medical team involved, specifically Dr Golde and his associate and the university, to court for breach of his professional obligation, and claimed an ownership interest in the respective patent.

6.5.2 Appeal Decision for John Moore

The Supreme Court of California however refused his claim of ownership interest on appeal on the basis that he has not involved in the invention and asserts the issue that a patient is not entitled to property right over body tissues.[31] In this ruling court still emphasised on 'the fiduciary duty' of a physician to obtain an informed consent from patients, including explanation of any financial income or personal interest in taking his

[30] U.S. patent 4438032.

[31] *Moore,* 51 Cal. 3d at 140-141. It says '[b]y restricting how excised cells may be used and requiring their eventual destruction, the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to "property "or "ownership"'.

tissues.[32] Through this line of analysis, the importance of fiduciary trust on using genetic material and distinction between access to genetic material and patenting an invention obtained from such material is noticeably highlighted.

The *John Moore* case was ultimately settled for an undisclosed sum, however as Melaman (2004, p.55) estimates , the damage that Mr. Moore claimed as a result of violation of his property right, if accepted in the court, would have brought him far much money as opposed to damage from a claim of breach of fiduciary duty.

6.5.3 John Moore viewed in the concept theoretic position

i. What does granting the patent do?

The patent filed by Dr Golde and Shirley Quan was on the basis of developing a cell line from John Moore's T-lymphocytes called the Mo cell line. It was claimed that the cell line patent has benefits, which is their capacity to biologically produce lymphokine protein (instead of synthetically manufactured lymphokine proteins) appears to be very important from a commercial point of view, particularly since synthetically manufactured lymphokine produces the protein at a very high cost as opposed to the new cell line (Stone 1996).

ii. What powers does it give to the patent holder?

The patent holders applied for what they called the Mo cell line in order to establish and protect the invention. The patent was awarded under the name of Dr Golde and Shirley Quan with the Reagents University of California named as the assignee of the patent. The Mo cell line has the capacity to be used in developing medicines and varied

[32] *Moore*, 51 Cal. 3d at 128-129.

potential treatments. Whilst waiting for the patent, they received an offer from the Genetic Institute requesting ‘to gain privileged and exclusive access’ to the Mo cell line, and in return, they would receive a good amount of shares of its common stocks, high paying salaries and fringe benefits. The patent holders accepted the deal (Stone, 1996).

iii. How could the exercise of those powers directly or indirectly lead to consequences which are contrary to the PGC?

Addressing the key issues in the John Moore case, this section analyses how the powers given to patent holders may result in consequences which are in contradiction with the requirements of the PGC. One of the important issues requiring further analysis is whether John Moore was treated as capable of giving a valid informed consent, which requires taking into account the procedural or prior justification. The next issue will be making a decision regarding the reconciliation of competing rights under the PGC. The medical team may have claimed that they sought to make contributions to the advancement of treatment options for patients, and that this may be justified as result of their freedom to carry out research and do benefit from progress in science and technology.

As discussed earlier, according to the PGC, only a generic right can override other generic rights, therefore the right to benefit from advances in science and technology has to be a generic right to enter the competition. This is dependent on the technology and science at stake, and if it is a type of technology which involves improvements to an 'agent’s capacity for successful action'. It is arguable that biotechnologies in medicine

that affect the beginning of life, the quality and enjoyment of life, and the end of life, are required to be in this category.

In this scenario, John Moore was informed that the treatment included further extraction of biological material from his body. However, he was suspicious regarding the need for it because he was objecting to the use of his bodily material without his consent in order for financial gain of the researchers. In 1990, the Supreme Court ruled that: 'a physician who is seeking a patient's consent for a medical procedure must . . . disclose personal interest unrelated to the patient's health, whether research or economic, that may affect his medical judgment'.[33]

The patent holder may claim that the donated cells are not Mr. Moore's property because he signed the informed consent form. It seems that the medical team who were involved in the patent ownership communicated information about the research and intentions before they obtained the spleen sample and other material. However they did not communicate the financial gain they were about to make from the cell-line.

Considering the characteristics of some biotechnology research projects (as discussed above and in the earlier chapters) right of scientists to pursue some of these projects may be regarded as generic rights, therefore we must examine its positive and negative rights. If the right is understood as a positive right, this means that other agents ought to help to secure the generic need, if she is unable to do so by unaided effort if she wishes so. However, because of imposing obligations to other agents, there is a possibility of conflict between these positive rights to GCA, which will result in the limitation of other agents' generic rights (Gewirth p.44). It is also significant that the proposition of sharing those benefits as the generic rights of all agents means that the financial interest

[33] *John Moore v. The Reagents of the University of California et al.* ' Supreme Court of California No. S006987.

of the researcher may affect the decision-making. As a right based-theory PGC imposes no direct duties on the agent; therefore, as analysed earlier, the agent should have property of their own body such as tissues (Beyleveld and Brownsword 2001, p.204).

In *John Moore* case, similar to any other case involving the human material and body tissue, it is important to ensure that agents are 'used as a means rather than an end' because if not then it is contradictory to the recognition of the holders of the generic rights as agents. This approach is consistent with the 'dignity as empowerment' argument, which claims that 'it is the intrinsic dignity of humans that acts as the foundation for human rights' (Beyleveld and Brownsword 2001, 203).

Several crucial issues need to be taken into account at this stage. First, considering Rule preclusionary argument, and all other property arguments related to agents right to property in their body and bodily integrity, there is still the possibility of X having control over A's body, when X needs 'to act through A's body. It however needs to be fully justified under the criteria of the degree of needfulness for action. Here, in John Moore case if there is any potential benefit available in the patent (and carrying out the research), then the protection of this generic right is necessary as long as the right is in higher hierarchy compared to the right of agent to consent for using their biological material in the research (regardless of whether or not we consider it as property right).

Second, the potential benefit 'must be available to all or to none' (Beyleveld and Pattinson 2009). However it does not matter for instance, how many people may use the drug, but how effective the drug will be in improving the GCA of agents. It means that priority should be given to the level of generic conditions of agency based on the criterion of the degree of needfulness for action, rather than the number of agents affected.

iv. Are there ways in which they could do this?

Consent, as discussed repeatedly in this thesis, is not an absolute concept and we need to be careful of what Beyleveld and Brownsword (2007, p.32) discuss as a misunderstanding of consent considering 'consent as the necessary justifying reason (the Fallacy of Necessity),' or thinking of 'consent as a sufficient justifying reason (the Fallacy of Sufficiency).

There are two main issues to take into account here. First, the ambiguity, uncertainty and flaws in the procedure of consent should have been removed. This would have been beneficial to Mr Moore, (Johnston et al 2001, p37) given that if he had known his medical team were particularly searching for specific cells that bolstered the immune system in order to help other patients; this would have encouraged more confidence in Dr. Golde's research. Of course at any point, Dr. Golde who wished to pursue his research with regards to Moore's tissues should have respected the autonomy of his patient. According to a PGC-compliant framework, researchers involved in a human-subject research must give primary consideration to the consent, as required by the principle of 'priority of consent' (Beyleveld and Brownsword 2007, p.337). It is crucial that the researcher who receives consent should in the first place look for the consent giver's consent, 'rather than doing the wrong and then seeking to justify it by making reference to overriding rights'(Beyleveld and Brownsword 2007 p.63, p.120). The principle of 'priority of consent' is considered by Beyleveld and Brownsword as 'in the absence of consent, a wrong will be done to agents whose rights are violated even if, all things are considered, the wrongdoing can be substantively justified as the lesser of two evils'.

Furthermore, if we support the argument in relation to the rule-preclusionary conception of property (as discussed in chapter 3), then Mr Moore should legitimately be granted a right to control his own body and body parts, including those 'body parts which have been removed' or the 'tissue containing genetic information' about him.

There are several salient issues which need to be taken into account before considering whether the breach of consent is justified. Below is a short list of these issues.

(1) It is not clear what justification there is for the initial absence of the consent in terms of collecting and extracting biological material from John Moore.
(2) It is questionable why Dr Golde refused to communicate his research plans and potential financial interest to John Moore.
(3) It is not clear why Dr Golde could not initially think of offering any fair compensation to Mr Moore, at least in return for his time and inconvenience in travelling several times.
(4) It is questionable whether filing a patent out of Mr Moore's cell line is necessary for the development of the drug.
(5) It is not clear how effective the new substance will be? Whether and how it will improve the GCA of agents?

Therefore, the above arguments conclude that it is unlikely that the interference with Mr Moore's right to the consent is justified in this case.

6.6 The Case of Hagahai People

6.6.1 Fact and case summary of Hagahai case

This case is to a large extent similar to John Moore's case. The case of the Hagahai people[34] is about the connection between the donation and purpose of the research, and the proximity between the donor and the potential benefit gained from the medical test. In fact, the Hagahai case is relevant towards obtaining consent from patients and the linkage between consent arrangement and patent system. The significance of this case is regarding a cell line (infected with the virus of T-Lymphotropic) developed from the DNA of a Hagahai donor, an indigenous group in Papua New Guinea, and in 1991, the National Institute of Health in the USA tried to make a patent out of it (Robie 1997, p.78).

This cell line which was specifically important to the scientists as a gene was carried by the member of this tribe, who had lived in isolation till 1984, which predisposes humans to leukaemia, but they themselves did not manifest any symptoms of the disease and were not affected by the T-lymphotropic virus. Therefore, there was potential for the development of vaccines for certain types of this fatal disease. In 1995, the patent titled 'Papua New Guinea human T-lymphotropic Virus' was granted to U.S. inventors represented by the U.S Institute of Health. Later it was revealed that there was no stage in which the purpose and subsequent use of the samples were clarified for the Hagahai donors (Gibson 2009, p.128).

The controversy was not limited to the informed consent procedure but included the accusation of bio-piracy. As Shiva (1997, p.4) in *Biopiracy: The Plunder of Nature and Knowledge* emphasise , if the commercial development of an invention like the genetic cell lines is intended by a technologically advanced country or organization, it definitely

[34] Papua New Guinea human T-lymphotropic virus, US patent 5397696.

must be with fair compensation to the nation where the material research is carried out. In this particular case it was questioned whether the consent should have been obtained from the Hagahai donor before the patent application, and whose consent should have been obtained, the individual, the state or the Hagahai people. Obtaining the genetic material from indigenous people gave rise to sensitivity and controversy over this patent due to the possibility of bio-piracy. Therefore, along with human dignity and autonomy as the basis of informed consent, the interest of the indigenous people and communities and the sovereignty of nations over their bodily material and resources were taken into account in discussing the legality of performing research and the commercialisation of inventions .

Ultimately, the U.S National Institute of Health under high pressure and controversy had to 'disclaim' the patent at the U.S. Patent and Trademark Office (PTO) in late 1996. The NIH without any clear justification opted to abandon all US governments' rights in relation to the patent indicating that 'past and future rights in each and every claim of United States Patent No. 5,397,696... Thereby relinquishing all control over said patent' (The National 1996).

Addressing the above matter, there is still controversy regarding how, when and in which stages the consent ought to be obtained from patients. This controversy is based on the question of whether the initial consent can be extended to include further uses of the material in research, and even, the commercialisation of the invention which is based on the donors' tissues or if there is a requirement to ask for the patients' consent at different stages and based on different purposes of research. Nonetheless, such doubt and lack of clarity entitles no body to misuse the genetic resources of an individual or a group of individuals without obtaining their proper consent, either officially or unofficially.

6.6.2. Controversy over the Hagahai Case

As discussed above, opponents of the patent argue that such patent or research or development of the product compromised the dignity of the people involved as they were not effectively informed about what was supposed to be done with their genetic material. It is a requirement that it is completely a free choice, which will not happen unless all information regarding the purpose of research and any future use is made known to the donors. If the way the researchers treated the donors gives the impression that they failed to recognize that they have right to control over their bodily material, then it is definitely problematic. There is, of course, no strong basis to question the Hagahai's capacity to make decision and consent uncoerced and freely.

6.6.3 The Cases of the Hagahai People viewed in concept theoretic position

i. What does granting the patent do?

As discussed above, the cell line infected with the virus of T-Lymphotropic developed from the DNA of a Hagahai donor was filed as patent (Robie 1997, p.78). The gene carried by the member of this tribe, which normally predisposes humans to leukaemia, does not cause any symptoms of these disease in Hagahai people. For U.S National Institute of Health this means potential for the development of vaccines types of such fatal diseases.

ii. What powers does it give to the patent holder?

The patent, if not abandoned by the U.S National Institute of Health (NIH), could provide an exclusive right for NIH to exploit the patent on Papua New Guinea human T-lymphotropic virus. If developing vaccines, it could bring the NIH significant income and earning over royalty/ licensing fee. Due to tragic consonances of Leukaemia in human health, developing a vaccine, if successful, could have contributed remarkably to the position of pharmaceutical corporations involved. This case is the result of a system which puts a general ban on the primary transaction commerce on human genome, although it permits patenting the products derived from human genome base material. Therefore, it unreasonably approves biotechnology firms taking the profit from the exploitation of human genome (Boyle 1996).

iii. How can the exercise of those powers directly or indirectly lead to consequences which are contrary to the PGC?

In the Hagahai case, the fact that the genetic material of an underdeveloped tribe was used in a patent in a developed country -without suppliers of biological material being properly appreciated or compensated- results in doubts over presence of a fair balance between parties due to significant asymmetry of information and bargaining power amongst them. The fact that they are not fairly compensated, also may affect the dignity and self-respect of the vulnerable party (in this case, the Hagahai people). Furthermore, if the transactions among the Hagahai people are not freely entered into, it means that the researchers violated such rights in relation to the Hagahai people, who supplied the tissue for the research, which was patented later.

Addressing the issues in Gewirthian terms, it is arguable that opponents of the patent could claim that such a patent, or research or development of the product, compromised

the dignity of the people involved if they were not effectively informed about what is supposed to be done with their genetic material. It is a requirement that it should be a completely free choice which will not happen unless all information regarding the purpose of the research, and any future use is communicated with the donors. If the way the researchers treated the donors gives the impression that they failed to recognise that they were dealing with fellow agents, this presents a problem.

Under Gewirthian terminology, all human rights must be granted as rights of agents for the possession of the generic condition of agency, compatible with the principle of generic consistency with no exception, unless the generic rights of other agents are threatened. If an agent cannot secure their generic condition of agency without any external aid, other agents have the duty to assist him to secure GCA (Gewirth 1996, p.59). This assistance to secure other agents' GCA may however come together with disproportionate risk to their own possession of GCA. Therefore, as Gewirth provides, it is mainly the responsibility of collectives rather than individuals to protect the positive generic of other agents.

Under such line of analysis, it is necessary to find out whether e.g. the Hagahai People's generic interest is in conflict with the generic interest of the people who benefit from the outcome of the tests, and how important these generic rights are. In this case, a number of issues including 'human dignity', 'autonomy' and 'interest of indigenous people' were discussed. Considering the concept of human dignity, according to article 1 of UDHR, all human beings are equal in dignity and rights which follows that all agents should be treated equally in order to enjoy dignity and rights. Generic rights are known as rights to assistance or non-interference in accordance with the right holder's will. Therefore, ideally, agents have the duty to protect the interest of other agents who are vulnerable or who for any reason cannot secure their GCA.

As discussed earlier with reference to the Principle of Hypothetical Imperatives, Generic Conditions of Agency or generic rights are ranked hierarchically. This hierarchy depends upon the degree to which their absence would affect their 'ability to act'. Therefore if there is a conflict between an agent for her GCA and another agent to another agent's GCA, the priority will be given to the most needful for action.

In this case, the U.S. researchers may argue that the patent (built upon samples taken from the Hagahai people) has the potential for the development of vaccines for certain types of such fatal diseases, which means it probably supports the interests of other agents with high levels of importance. It may be argued that this is a promising way to introduce cures, and that there is a probability that this would happen for a serious kind of health condition, or that it affects the generic condition of agency to this certain level. However, under the PGC framework, it cannot be claimed that this potential interest has the power to override the autonomy of the Hagahai people over their autonomy and dignity, unless it is properly justified that this is the only way or the most effective way to protect the more important generic rights of agents.

iv. Are there ways in which they could do this?

To address the topic of this section, it is necessary to answer a number of questions under the concept-theoretic position. The first question is whether it is necessary to get their consent. The Theoretical framework provides as a starting position that agents should not in any way affect other agents' generic conditions of agency in a negative way. However, the consent or the autonomy of the Hagahai is not completely overriding, because consent is not an absolute principle. Agents' right to their bodily integrity and to give consent for future use of their bodily material can be overridden for certain important objectives. If certain things perhaps can be carried out without the proper

consent of the donor, a justification for doing these activities without the agents' consent is that it is necessary in order to fulfil various other objectives, which may not be fulfilled if their consent was obtained.

The next question is whether there exists a necessary and sufficiently justified objective. In other words, the necessity for something means that if A does not do X in a particular way, A would not be able to achieve it. The common justification that genetic researchers use is that using and analysing the genetic material from groups of indigenous people aims to develop new treatments for life-threatening diseases and if they are not allowed to advance their research projects, then they will not be able to cure these diseases.

In the absence of consent, 'it might be possible to justify a violation of generic rights substantively, by reference to overriding rights' (Beyleveld and Brownsword 2007, p.123). However there is an obvious burden of justification in such a special case. If it is true that the scientists in Hagahai patent will not be able to get these advances and cure people with these diseases unless they get these biological materials from these indigenous people without their consent, and are allowed to obtain the patent on it, again, without their consent and with no financial remuneration for them, then the right of scientist to carry this research project and progress the science may override the right of Hagahai people. However, these arguments are all questionable.

The scientists' claims would have been accepted if there was a convincing answer for the following questions:

First, is it necessary to obtain this genetic material only from this tribe?

Second, is it necessary to get this genetic material without a proper informed consent? Have they refused to consent to participate in the research? (All or some of them)

Third, is it necessary to file a patent to carry out the research?

Fourth, is it necessary to obtain this material without considering any fair compensation, benefit sharing, incentive, etc.?

According to the concept theoretic position, in order to be able to override the consent, the answers to the following questions should be affirmative (which in this case is not).

I. Whether they can get these genetic materials from them rather than other tribes is questionable.

II. The idea that they will not give their consent, or at least that some of them will not give their consent is questionable.

III. The whole idea that they are carrying out this research in order to get these results is questionable.

IV. It is questionable whether the objective of this research is in the general interest of the indigenous people or even other people involved in life-threatening health conditions, or the commercial benefits monopolised for the benefit of a specific company or government.

V. The fact that this cell-line actually needs a patent in order to enable them to do this research is questionable. In spite of statements like the industry would not be interested if there was a patent minefield, as was discussed earlier, a patent is not the only available IP means for protection of biotechnological inventions. Cohen and Walsh (2003) in a study regarding the impediments to biomedical research highlight the existence of other methods rather than patents in which the investment on a research can be

protected. Interestingly, it is argued that not granting a patent can even conversely affect the research, which would stimulate rather than inhibit the research. Therefore, a patent is not the mere intellectual property means necessary to recompense the investment in biotechnology sector.

VI. Even if they could somehow show that all of above issues are necessary, there is the issue regarding the propriety of giving something back to research subjects in return to their participation and the contribution they have made.

It is dubious that they can do that without all sorts of rewards, benefit sharing, compensation, etc. In the Hagahai case the Hagahai people's autonomy and informed consent cannot be overridden by other existing rights or interests. This is concluded through the application of the PGC and the criteria suggested in this framework. Therefore, if the concept-theoretic position had been implemented in the EPO or CJEU this patent clearly would not be granted.

6.7 Chapter Summary

Having analysed the similarities and differences of inclusion of morality in the EU and U.S. patent system, the thesis attempted to evaluate the adequacy of a PGC-derived framework to govern the interpretation of morality and to reconcile the conflict of rights with a particular focus on the biotechnology sector.

The basic argument in this chapter is that even if there were an official notion of moral neutrality in the court or legislation, this approach is still problematic. When we examine the relevant references in the constitution and compare it with the common law practice of the court, what makes the difference is that the common law practice of the

court cannot be strong enough unless there is something within the constitution that is contrary to inclusion of morality within the U.S patent law. This means that the common practice of the court cannot have any significance in a decision making or setting a policy, if the constitution never said anything about it at all.

As discussed earlier in this chapter, the U.S. is signatory to different UN human rights covenants. These conventions incorporate 'impartiality.' and because these declarations incorporate the 'impartiality' principle, and because the Principle of Hypothetical Imperative is dialectically necessary, unless these principles are going to be thrown away (the whole idea that human rights are inalienable and possessed something by virtue of human beings equal in dignity and human rights) then they have to conform to the Principle of Generic Consistency. The argument is in a sense parallel to the argument in the EU case. There are some differences though. In the EU case, even if it was not in the directive, because it is there in effect, the fundamental principles recognised by the Members States, and in the EU Constitution, then it must be followed. This means that even if it was not explicitly included within any exclusion, one still has to interpret it in this way. Furthermore, the system of law in the United States is actually easier in some ways because the United Kingdom and some other European countries have problems with dualism which makes some activities more complicated whereas in the U.S, if it is proved that a subject of a right is in the Constitution, then the United States constitution is something that courts have to follow.

This chapter concludes that the PGC-derived framework can be also fitted in the U.S. system. In fact the EU framework with some minor corrections, roughly matched with the requirement of PGC, is a more effective model resulting in more consistent decisions to be applied in the patent system, as it is more consistent with the universal

principles of human rights, whilst the US regime as a morally neutral system, even is not fully consistent with the US constitutional values.

CHAPTER VII:

IMPLEMENTATION OF CONCEPT-THEORETIC POSITION IN SELECTED HYPOTHETICAL CASES

7.1 Introduction

Within Chapter V and VI of this thesis, it was discussed how the concept-theoretic position is capable of providing assistance in terms of balancing rights within the biotechnology patent law in the EU and United States. The framework enables the judges and courts to interpret the rights according to degree of needfulness for action (agency). Furthermore, two guiding principles, the identification of 'Generic Conditions of Agency', and the distinction between apparent agents and apparent non-agents were employed in different scenario to analyse the situation.

In this chapter, two hypothetical cases are discussed in order to implement the concept-theoretic position and evaluate the outcome of the cases. The first case concerns a patent on 'designer babies' filed in the U.S in 2014. The second patent was filed in the same year in the Netherlands. Neither 23andme patent nor the Corona virus have ever brought to any courts or Patent Office in the EU or U.S. However, this chapter is an effort to assume how a PGC-compliant framework will effectively work on the hypothetical patent cases in any other legal system with a commitment to the idea of human rights.

7.2Patent for 23andMeDesigner Babies Technology

7.2.1 Facts and summary of the hypothetical case

23andMe, the California direct to consumer genomic company, launched a new service in which parents were given the autonomy to select their offspring traits; although they claimed that it does not mean using their DNA based system to generate what they called 'baby in order.' The company applied to file a patent for this service

in 2008 and the patent was granted on 24th September 2013.[1]Informed about their genetic information, the parents would be enabled to make decisions about the desired genetic combination to produce their children. This similarly applies to infertile couples, assisting them in selection process of donor sperm and egg to choose preferred donor among the plurality of donors, based at least in part on the statistical information determined' (Sifferlin 2013). Although the principal claim of the patent is over the computer program used in this patent, the focus of the argument in this section is regarding a method involved in this patent for gamete donor selection. The patent application illustrates the following facts regarding the patent specification: 'A method for gamete donor selection, comprising (i) receiving a specification including a phenotype of interest that can be present in a hypothetical offspring; (ii) receiving a genotype of a recipient and a plurality of genotypes of a respective plurality of donors; (iii) using one or more computer processors coupled to one or more memories configured to provide one or more computer processors with instructions to determine statistical information including probabilities of observing the phenotype of interest resulting from different combinations of the genotype of the recipient and genotypes of the plurality of donors; and (iv) identifying a preferred donor among the plurality of donors, based at least in part on the statistical information determined, including comparing the probabilities of observing the phenotype of interest resulting from different combinations of the genotype of the recipient and the genotypes of the plurality of donors to identify the preferred donor.'[2]

[1]US Patent No. 8543339 on 24 September 2013. This patent however claimed priority over the other patent US Patent Application Serial No. 12/592950 claimed in 208.

[2] US Patent and Trademark Office. Notice of Allowance in Relation to US Patent Application Serial No. 12/592950. 2013.

Therefore, 23andMe offers would-be-parents the opportunity to select prospective donors of ova and sperm who are more likely to produce a human baby matched with their desired traits. This method employs a computerised program to compare the genetic data of the egg providers. Future parents are given the liberty to choose from a list of both disease-related and non-disease related traits, varied eye colour, personality characteristic and athletic attributes to some types of cancer. To be parents would be given the option to choose between for instance the 'longest expected life span' or 'least expected life cost of health care'/'least expected cumulative duration of hospitalization.' Moreover, amongst other offspring's possible traits, there would be a choice to '0% likely endurance athlete' and '100% likely sprinter'. It is noted that the option of sex selection as one of phenotypic characteristic is listed among 23and Me's patent claim (Wojcicki et al 2010, Figure 4 and 6).

Since the subject of this patent is the selection of any phenotypic trait, the patent should cover polygenetic attributes as well, although these traits are more complex to guarantee. In favour of 23andMe, Sterckx et al discusses the fact that the company merely suggests a method for improved chances of producing an offspring with the parent's desired traits or the 'right' characteristic, whilst no promise for the eventual emergence of the selected traits in babies and no definite evidence is guaranteed (Sterckx et al 2014).

In fact the 23andMe patent is not limited to previous methods of diagnosis, connection of genes or changes in genetic structure, not only to avoid disease, but to acquire desired traits both physically and behaviourally including athleticism and congeniality in future babies what is so called 'Designers Babies'. IVF embryos are routinely tested against diseases such as Tay-Sachs and Huntington's disease, based on their genetic mutation. As a consequence, parents are advised to avoid implanting those embryos

less likely to survive the term. The technique used in the patent is based on the implication of 23andMe's knowledge regarding genetic changes associated with cancer risk. In addition to genetic screening for the purpose of exploring genetic disorders, this patent now provides a service to select the physical characteristics of the new baby (Sifferlin 2013).

At this stage it may not be clear what services will be offered out of this patent merely on the basis of the patent specification. There have been a number of patents including the one filed by Newman and Rifkin by which the patent holders intend to prevent others from adopting the technology in it for a specific period of time. Interestingly, in the mentioned patent in relation to human and non-human chimeras, patent holder Stuart Newman opposed patenting the living thing himself, confirming that '[H]e had no intention of making the creatures. His goal was to set a legal precedent that would keep others from profiting from any similar ''inventions"'(Rabin 2006, pp. 517-519; Also Weiss 2005). The U.S Patent Office made no objection about the possibility of any moral concern in the said patent. It is however is important to analyse whether or not it is important what the actual outcome of the patent will be versus the intention of the patent applicants.

Interestingly, the U.S. Patent Office never doubted the legitimacy of the patent subject matters in 23andMe or questioned the appropriateness of techniques through which designing of future human babies will be carried out. It was discussed earlier that the U.S. patent system, unlike EU patent law in which moral exclusions are integrated into law, contains no direct clause to exclude inventions on the ground of immorality. Considering differences in the U.S. and EU patent law and policy, it is attempted in the following sections to investigate what moral objections could have been raised if the patent were to be brought to the EPO or possibly CJEU for a preliminary ruling.I

however only concentrate on the issues and aspects that are relevant to critique from the concept-theoretic position. Subsequently, the patent will be viewed through the lens of the concept-theoretic position to find out how the concept theoretic framework can balance any conflict of rights in this case.

7.2.2Potential Objection to 23andMe Patent

Although advances in modern biotechnology have enabled prospective parents to influence traits of their offspring before their birth, the concept of manipulation of genes regardless of its purposes has attracted attention and somehow objection of ethicists and legal theorists. This section focuses on a number of key objections (and some possible opposition) which are made or could be made with regard to the permissibility of trait selection, in order to examine whether this subject is morally acceptable as a patentable subject matter.

It can be said that the "Design" of future babies, the service offered on the basis of 23andMe patent is not an appropriate subject matter for a patent because:

I. The genetic service based on 23andMe patent is not an accurate measure technically.

The company received concern from prospective parents and ethicists regarding this DNA based service. Thereafter, the company began to convince customers that this technology is meant to be used to help parents to get an idea of what traits their offspring will be born with, including any signs of probability of cancer and heart disease. The company declared that they will remain transparent about their service and that nothing will go beyond their Family Traits Inheritance Calculator discussed in

the patent. Genetic experts have mainly opposed the statement of 23andMe on the ground that offering any products or services based on this patent is not acceptable. It provides that complex traits including cancer risks are not exclusively dependent upon genetic, but environmental factors as well. As Baker and others (2006) asserts, almost all behavioural disorders are connected to a genetic component. Hence, evidence of association between a gene and a trait does not automatically translate to the subject that the claimed gene is the 'necessary' and 'sufficient' condition for emergence of that specific trait.

The above argument regarding single gene traits will be more complex whilst discussing multi-factorial or polygenic traits. The need for a much larger study sample causes difficulty in producing statistically satisfactory level of research (Pattinson 2002, p.47). Additionally, being able to distinguish between correlation or association, and a cause is not an easy task. As Darnovsky (2009), the Executive Director of the Centre for Genetics and Society put it, this patent in which the extreme technology is used cannot be claimed to be safe without conducting unethical human experimentation. Furthermore, finding a new association between a specific gene and a trait in a small sample is not the same as exploring a casual factor scientifically.[3]

Therefore, using the service that 23andme company offers which is not always a guarantee for the manifestation of the desired traits in offspring, is not only problematic scientifically, but is also troublesome ethically because it is a service with no strong probability of efficiency and accuracy.[4]

[3]For instance manifestation of a specific region of X-chromosome in male homosexual individuals. apparently this is not included in patent specification and the example is just to elaborate the explanation in the text. in Pattinson, S. (2000, p47).

[4] This will be further discussed under the concept-theoretic position.

II. Would be parents are advised to avoid implanting embryos that lack desired traits (e.g. a long life span)

As previously discussed, the 23andMe patent is not limited to previous methods of diagnosis and connection of genes or changes in genetic structure, in order to avoid diseases, but to acquire the desired traits both physically and behaviourally including athleticism and congeniality in future babies so called 'Designers Babies'. The technique used in the patent is based on the implication of 23andMe's knowledge regarding genetic changes associated with cancer risk. In addition to genetic screening for the purpose of exploring genetic disorders, this patent now provides a service to select the physical characteristics of the new baby (Sifferlin 2013).

In this technique, IVF embryos are routinely tested against diseases such as Tay-Sachs and Huntington's disease based on their genetic mutation. As a consequence, parents are advised to avoid implanting those embryos less likely to survive the term. Consequently a number of IVF embryos would be discarded deliberately due to a lack of desired traits.

Considering the moral permissibility of prenatal techniques, a number of facts need to be taken into account. First, the risk and effectiveness of a diagnostic technique must be considered before the legitimate application of the technique on a potential child. Second, the prenatal technique with lower risk (e.g. PGD)[5] must be prioritised over a method with higher risk of abortion of a foetus (e.g. PND)[6]. This claim however depends on different factors. For instance whether abortion itself either in general or regarding trait selection, is legitimate and whether the abortion provisions would

[5]Preimplantation Genetic Diagnosis

[6]Prenatal Diagnosis : Techniques used to genetic diagnosis of embryo during its gestational development .

distinguish failure to implant an embryo and abortion taking place after implantation. This also is dependent on the different moral approaches adopted. For instance, Watt considers a full status position for embryos in which even PGD is rejected in all circumstances while other moral positions allow the procedure for some or all PGD, particularly in severe and debilitating genetic disorders (Watt 2004). Furthermore, it is noteworthy to consider that although PGD may lead to an improved chance of producing an offspring with some desired traits, the prevention of parents acting with certain specific motives would be more difficult (Pattinson 2002, p.63).[7]

As a consequence, it is argued that the legitimacy of causing risk, or even the decision or failure to implant the embryo is dependent upon different approaches by which a legal system or a moral theory is governed. It may relate to the moral status of the oocyte and embryo before implantation, indeed the intrinsic moral status given to the embryo and whether and to what extent this moral status may be affected by the manifestation of the specific traits diagnosed in the embryo.

III. It could harm both the new child and existing children

Opponents of prenatal techniques assert that mere reliance on genetic components of embryos (when confirmed that the presence of certain traits are unlikely) may make them perceive it as a lack of ability to display the mentioned trait (Pattinson 2002, p.64) On the other hand, if the characteristic selected for the new baby are those lacking in the existing children, it may result in a feeling of rejection or inadequacy for the existing children (Pattinson 2002, p65).

[7] Shaun Pattinson, Influencing trait before birth,p63.

Addressing the question of whether the patent 23andMe could be objected to under morality exclusion is not an easy task and the answer could differ according to the moral theory adopted. On one hand, a number of philosophers including Savulescu and Kahane (2009) assert that even if the benefit of both the child and parent is guaranteed through the use of genetic selection methods and support the genetic selection of children according to which the best chance of the best life would be guaranteed for both would be parents and children asserting that this is the right of prospective parents to 'aim to have the child who, given his/her genetic endowment, can be expected to enjoy most well-being in his/her life'. No difference is made in this approach between the permissibility of disease-related characteristic or non-disease related selection.

On the other hand, opponents of this view, including Sandel in his argument 'The Case Against Perfection' (2007) emphasised that these techniques are often against the child's benefit and therefore, objects the selection of non-disease related traits on the basis that this is in conflict with the norms of unconditional love for a child, emphasising the fact that we should

> 'appreciate children as gifts or blessings is not to be passive in the face of illness or disease … In caring for the health of their children, parents do not cast themselves as designers or convert their children into products of their will or instruments of their ambition. The same cannot be said of parents…who aspire to bioengineer their child's intellectual endowments or athletic prowess' (Sandal 2007).

In 23andMe, patenting the computerised process assisting prospective parents to choose their 'phenotype of interest' for their baby seems to offer broader service than merely the selection of disease-related characteristics.

IV. It may violate the principle of medical information confidentiality

Objections to patenting activities with regard to confidentiality might be linked on two different grounds. First, it is not clearly evident that providers of genetic and phenotypic data, the 23andMe biobank are giving their informed consent to participate in the gamete donor selection technique of the company. Specifically in this case, announcing the news about the introduction of 23andMe's first patent in May 2012 (Wojcicki 2012) resulted in a list of complaints coming from dissatisfied customers or those who apparently were not well informed regarding the new patent of 23andMe, through which the company intends to test the propensity to develop against Parkinson disease (Sterckx et al 2013, p. 383).

The fact that 23andMe pursued the mentioned patent with no genuine public discussion while receiving feedbacks from unsatisfied customers makes it a real concern, particularly for a business with a vital need to customers and their good will to make and sustain their biobank. This fact is however noteworthy that for a commercial entity like 23andMe, filing a patent and attempts to generate some income is quite acceptable and there is nothing inherently problematic with this activity. However, what makes the issue problematic is whether providers of this biobank are well informed about this and have given the company authority to use their data to develop a new method, or whatever the purpose of their research is. Public trust is of central importance in human genetic research and specifically bio bank research (Sterckx *et al*. 2013). Damaged transparency and not working under an effective informed consent regime affects terribly the legitimacy and morality of the genetic research and any other activities in connection with the research including patenting.

Second, one important issue which makes some techniques of prenatal influence unethical is the potential violation of the 'right not to know' of the embryo's close family. It is reported that genetic diagnosis may reveal medical information about close relatives. For instance Huntington disease which leads to progressive neurodegeneration and symptoms including loss of motor control and dementia and a death during 10 or 20 years after diagnosis manifests in ages of 40 to 50 (Sermon et al, 1998) with no treatment yet discovered except symptom relief and support (Braud et al, 1998, p.1422). The result of diagnosis about the embryo will reveal the fact that one of the parents (at least) has Huntington disease although they may not wish to know their status. In order to protect the rights of parents to 'not to know' about the risk from Huntington, the company who provides the service must check the details of customer consent with them and if they do not want to receive any specific test result, this option must be offered to them as Sermon et all suggests, that this is absolutely possible through having IVF with preimplantion biopsy to test the embryos only (Sermon et al 1998, p.1434).

7.2.3 Patent 23andMe viewed in a Concept-theoretic Position

i. What does granting the patent do?

As discussed above, the recently granted patent 23andMe revived the controversy over the permissibility of gene selection techniques. According to what was discussed earlier this is beyond a disease related tool or possibly a sex selection means, but a program to enable parents to choose a wide range of phenotypic characteristics including eye colour, height, life span, etc. a number of moral and legal objection raised with regard to the concept elaborated above.

ii. What power does it give to patent holder?

23andMe company claims that possession of patents for their technology give their company confidence that their investment will be commercially viable. The company emphasise that, due to the very resource-intensive nature of the biotechnology and pharmaceutical industries, being a pioneer in biotechnology sector and a 'drug lead' requires the companies to ensure they can 'recoup their investment.' The patent protection provides their company with the confidence to invest heavily in their research and development.

With regard to their right for licensing fees, 23andMe (2013) declared that they:

> will not prevent others from accessing their genetic data or its interpretation specific to our patents. Other entities can present information about the genetic associations covered in our patents without licensing fees. As has always been the case, 23andMe customers can freely apply their raw genetic data to other interpretation tools whenever they wish.

The company claims that their mission is 'to improve lives' and while holding patents, the company aims to present 'better treatments, diagnostics, and prevention of disease' to 'benefit everyone' (23andMe 2013).

iii. How can the exercise of those powers directly or indirectly lead to consequences which are contrary to the PGC?

Whilst exercising patent 23AndMe, two scenarios may occur which will be further elaborated below.

First, when characteristics are debilitating or restrictive of agency or successful agency, although compatible with being an agent.

Second, the characteristics basically enhance the capacity of the agent to do action or to accomplish successful action.

According to the PGC, agents owe duties to future agents equal to those that they owe to present agent. Thus, if there is a possibility to choose between either assistance to a future agent to exist or damage the future agent, the duty is to do what avoids the damage. The right at stake is the protection of the potentially future agent to exist and the duty of other agents to avoid something to damage his right. Embryos do not hold any generic rights as apparent non-agents. In contrast, if an agent fails to select the second group or 'enhanced characteristics' then no violation of human dignity is involved.

Below are the claims which could have been raised by 23andMe together with the analysis of how the concept-theoretic position addresses this issue.23andMe could have claimed that this patent protects the rights of parents to reproduce their offspring with some specific desired traits. How accurate this hypothetical claim is under the concept-theoretic position?

Addressing the concept of human dignity, different moral philosophers consider a specific basis to define being entitled to intrinsic moral status. According to the Gewirthian theory however, all agents are qualified for dignity. All agents possess dignity and therefore generic rights equally. To address the concept of autonomy of parents and violation of human dignity two separate discussions are considered. First the agency relevant characteristic and second the agency irrelevant characteristic will be examined to find out whether these two issues should be distinguished.

With regards to choosing the agency relevant characteristic, under the concept-theoretic position choosing the agency-relevant characteristic by prospective patent

should be permissible; it means that if the patent assists the future parents to decide about having (or not having) a characteristic in their child which affects the agency capacity of that child seriously, it can be acceptable to avoid that specific characteristic in that it is a violation of dignity of the parent not being able to avoid damaging their potential child.

In principle, the use of assisted reproductive technology can be justified under the PGC since the technology is a necessary means of assisting the affected agent to participate in the reproduction activity and it is of value for them to take part in this project. The main reason is that the agent's ability to act or act successfully will be affected seriously because of the involuntary childlessness. Suffering generic harms, victims of childlessness usually experience loss, anger, and inadequacy at some point . Interestingly, even a failed IVF ameliorates their feelings of inability to have a child, through acceptance of the situation (Greil et al 2010)

Now assume that by using the PGD, prospective parents aim to find out about any abnormality or severe genetic problems. This can be used either to identify a defective embryo, and deciding whether or not to implant it, or to choose from a number of embryos considering a particular genetic abnormality (Pattinson 2002, p.89). Both from the legal and moral perspective, it is not allowed to give preference to the defective embryo over a healthy one specifically when the defect is related to the moral status of embryo. Choosing between an embryo with a chromosome abnormality relevant to its moral status and a healthy one, it is evident that the defective embryo, unable to further develop or to become an apparent agent is not entitled to similar moral protection as the other embryo. However if an abnormality irrelevant to the agency capacity of the embryo such as Down syndrome is the subject of the decision, it is not inherently immoral to choose the defective one over the

healthy one. Although some other considerations may arise. Therefore, if the patent helps the future parents to avoid the defective embryo over a healthy one this is justifiable under the PGC.

Furthermore, the embryos not selected for implantation are likely to be discarded. This destruction must to be avoided. In some specific cases, it is necessary to consider the conflict of interest between the life of the embryos, and the interest of those who avoid the birth of the child with an undesired characteristic, which will be affected seriously (a true generic harm). The former sometimes outweighs the latter. However there should be an attempt to limit the harm by any means e.g. as Pattinson suggests through donation to be used either for infertility treatments or research purposes (Pattinson 2002, p.90).

Particularly a patent company may raise the issue that they protect the right of parents to prevent their offspring from having some undesired traits. This includes a very limited range of life-threatening diseases in which the agency capacity of an embryo is of relevance. This however it is less likely to encompass any right to agency irrelevant traits e.g. sex selection as the 23and me patent offers. Not only there is no right to select the future child's sex recognised under the EU law, but also according to Article 14 of the European Convention of Human Rights and Biomedicine, the use of the technique of medically assisted reproduction to select the sex of the child (except conditions with serious hereditary sex-related disease) shall not be allowed.

The question is why under the concept-theoretic position sex selection may not be allowed. Under the PGC, it is important to examine why do people want to gender select? The PGC is gender-neutral. It does not allow any gender discrimination. However, in some circumstance the sex selection may be justified. If some types of

catastrophically event caused imbalance in biological structure in a society and this in fact became the case that it was never before, agents may be able to justify selection on the basis of that.

Another issue is whether sex selection should be allowed under the concept-theoretic position if families have genetic problems in one sex. If they have a sex related disease and they want to prevent children from having this condition and have children rational in following the PGC, we can expect that they wish their children not born with such traits.

But the above scenarios are different from all conditions that people do not like their children to be a specific gender. Therefore, its permissibility depends upon why parents are doing sex selection, and it does not necessarily mean that sex selection is always wrong. This means the motivation is always important in analysing the situation.

Addressing the issue of motivation, another claim made in the 23andMe company's defence is worth mentioning. The company declared that this technology is not meant to guarantee a hundred percent outcome and is designed merely to provide parents with an idea of what traits their offspring will be born with, including any signs of probability of cancer and heart disease. The question here is, whether or not under the concept-theoretic position, it matters that they are able to accurately and properly provide what they claim. The answer is it does not matter whether or not the company guarantees a 'certain outcome' or just a 'probability'. if they aim to defend their activities by saying that the company is not doing any wrong activity since they do not guarantee the outcome, this will not work. The point is what is wrong here is not the outcome, because basically the one time that really would be 100% clearly justified it

is when the company can say it is a 100% success rate. If a company is going to have a reason for sex selection, the reason is actually better for doing it if the company is 100% sure about the outcome rather than when the company is less confident about the outcome. The idea that the company does not make it certain and it is only got the probability, so it is somehow acceptable or justifiable is wrong. It would be most justifiable or 23andMe can justify it more, if the company could have guaranteed hundred percent outcomes. This argument just point to the fact that we need to assess what is the most justifiable outcome. Replying to this question is in relation to what the PGC requires to commit. If a company got a justification for doing it, it is because the company got a reason in the PGC terms for doing it, which is justified.

Another issue of concern in 23andMe is related to confidentiality and informed consent of the participant and suppliers of genetic material. There were concerns about the consent procedure in relation to providers of genetic and phenotypic data in the 23andMe biobank, whether they have been fully informed about the terms and conditions to participate in the company's gamete donor selection technique to develop a future patent. This is specifically reflected in the customer's complaints after 23andMe first patent, through which the company intended to test the propensity to develop Parkinson disease, claiming that they were not well informed of 23andMe intention for using their genetic material in future commercial activities of the company (Wojcicki 2012). The analysis here is similar to previous cases in this thesis in relation to violation of agents' right to make free and informed decisions to control their ownership over their bodily material. Even if the property right over bodily material is not accepted, agents must still be given full control over their body and genetic material. It is violation of the PGC if at any stage agents have been treated in a way that their agency capacity is undermined, unless it is the only way or the most

effective way to protect the more important rights of agents (applying the criterion of degree of needfulness for action). It is not clear here why 23andMe Company should have not communicated the aims of the projects and their intention for commercialisation of the technique in an appropriate way with the customers.

23andMe patent holders could have claimed that what they have offered has aimed to support parents to have children with specific traits and they have to continue offering their service based on the patent, since parents have the right to access medically assisted reproduction, and they should be given autonomy over specific characteristics which they desire for their offspring. Thus, the company has to undertake its duty to assist the parents. To address this claim, it is necessary to investigate further to see whether parents have this right of reproduction and whether this right includes a right to reproduce with their desired traits. If a *failure to select* against some characteristic is against human dignity then the company has the positive duty to provide assistance for parents.[8]

Considering the hypothetical situation, two scenarios can be drawn here. First, when characteristics are debilitating or restrictive of agency or successful agency, although compatible with being an agent. Second, the characteristics basically enhance the capacity of the agency to do action or to accomplish successful action (Beyleveld & Brownsword 2001, p.154). According to the PGC, agents owe duties to future agents equal to those that they owe to present agents. Thus, if there is the possibility to choose between either assistance to a future agent to exist or damage the future agent, the duty is to do what avoids the damage. It is noteworthy however that the right at stake is the right of future agents to exist and the duty of other agents to avoid

[8]However, it is not about the necessity of holding a patent over the service yet.

something to damage his right. Thus, we are discussing damaging the future agent and the duty to avoid this right can be positive as well as negative. It means that it can be either an omission or a positive commission to cause the damage to future agent. It follows that it is the violation of human dignity to fail avoiding the debilitating characteristic only and under circumstances in which the same child can exist regardless of employing this means or not (Beyleveld & Brownsword 2001, p.155). In contrast, if an agents fail to select the second group or 'enhanced characteristics' then no violation of human dignity is involved.

The same reasoning applies to the patent. If the patent is to provide a technique to protect agents avoiding characteristics with debilitating effects, it would be a violation of their right to deprive them of the facility that patent offers. A different scenario takes place when failure to select an agency-irrelevant characteristic is at stake. For instance traits such as impaired motor capacity, sight, hearing, sex, race or sexual orientation are all characteristics according to which possession of the agent's intrinsic moral status would not be affected. Therefore any discrimination against agents who have these traits to some extent, or related by any means to these characteristics are definitely in violation of the PGC and are therefore not permitted. This premise follows the fact that usually any patent introducing a technology to encourage prejudice against having or not having specific agency-irrelevant attribute violates the PGC and is not morally acceptable.

There would, however, be a different scenario if the selection of genes involves abortion or embryo destruction. In patent 23andMe, parents are advised to discard or not implant the embryo if the embryo is not capable of producing a baby according to the parent's desired traits. Considering the fact that under a Gewirthian framework, agency is the requirement for dignity entitlement, and then human beings at some

stage after their birth can be the subject of 'rights'. This however does not mean that other agents do not have any duty toward an embryo or a zygote before implantation. Precautionary reasoning imposes agents a duty not to damage unborn babies given that that they may have agency capacity to some extent but we are not aware of that. It concludes that there should be a sound adequate reason to destroy an embryo. The question here is whether the reason in PGD or PND techniques used in 23andMe is satisfactory enough to authorise the destruction of embryo (on circumstances that the embryo is not matched with the desired traits of parents). This again depends on the nature of characteristic I question and the method of test.

Considering the above-mentioned fact in a patent context, it is noted that for instance, the legitimacy of patenting a PND which causes higher risks for the embryo or zygote depends on the context of its use and the availability of any other alternative (Pattinson 2002, p.81). For example, if the patent is used to diagnose an incurable late onset disorder, the knowledge acquired through diagnosis of e.g. Huntington disease. A positive test result may affect the patients psychologically in ways that statistics on death due to suicide, allocates a number four time greater compared to other US Caucasian populations (Farrer 1986, p. 308). It also may cause generic harm to the future child and there would be the violation of PGC at some point while attempting to put the truth out of sight (Pattinson 2002, p.80). Therefore, it is assumed that the moral interest of the tested subject will be better protected if the PND or any other prenatal diagnostic is prohibited. It follows that any means including a patent to facilitate, encourage, and financially support any form of prenatal screening or testing for diseases with no available cure (e.g. Huntington) should not be allowed.

Overall, precautionary reasoning imposes on agents a duty not to damage non-agents since they may have some agency capacity to some extent, which we are not aware of.

There should be a sound adequate reason to destroy an embryo. Any discrimination against agents who have specific non-agency related traits, are usually in violation of the PGC, mainly because of the intention of the parents and the consequence the decision may bring and not because of the technology itself, and are not permitted. Therefore, any patent introducing a technology to encourage prejudice against having or not having specific agency-irrelevant attribute violates the PGC and is not morally acceptable.

7.3 Corona Virus argument

7.3.1 Facts and summary of the hypothetical case

The Corona virus patent has not brought yet to any court including the EPO, it however is analysed here as a hypothetical case to examine how this patent could have been objected to and how it would have been decided in the court. This patent was applied for in 2012 through a Dutch company under the title of 'Middle Eastern Respiratory Syndrome Corona virus (MERS-CoV)'. The virus has very high fatal risk (laboratory reported of at least 53 people globally since June leading to death for 31 person of the total number) (Mayer 2013). It involves patients with fever and symptoms of lower respiratory illness, such as cough or shortness of breath. The virus is diagnosed mainly in travellers from countries in the Arabian Peninsula including the Saudi Arabia, Qatar, Jordan, United Arab Emirates, etc (Benett 2013).WHO Director-General in the assembly expressed concern regarding Saudi Arabian Ministry of Health's approach that did not dispatch the virus initially to WHO labs for further analysis. Saudi Arabia MOH was faced with an alleged lack of openness about MERS-CoV(Benett 2013). Following this statement, however a number of animal samples

were sent to WHO labs as source of Middle East respiratory syndrome corona virus (MERS-CoV).

Fouchier, as one of the scientists involved in Corona virus, attempted to publish a scientific study regarding five genetic tweaks related to a terminal bird flu virus examined in ferrets whose reaction to the virus highly resembles the human one. Facing a delay in the publication of this study (as there was concern over their work being misused by bioterrorists), his team together with another group in University of Wisconsin, made a voluntary moratorium on their research (Lopato 2013). The decision to patent the corona virus has faced heavy criticism from the WHO and Saudi Arabian officials on several grounds.

7.3.2 Potential Opposition to the Corona Virus

This section covers the argument related to issues on the corona virus which may arise in relation to the concept-theoretic position. Clearly there could have been technical arguments regarding the patentability of a virus; Discussions on the genetic sequences of diseases are not technically patentable because a patent is not granted for something naturally occurring which is not considered as invention. Or the fact that through modification of the organism by any means these inventions become patentable, which means that the viruses identified previously such as Chickenpox are “unpatentable” unless the virus is a modified, mutated, or gain-of-function is achieved form of the previous one. Such arguments however will not be discussed here as it is not the focus of this research. The section exclusively focuses on issues in relation to the concept-theoretic position.

One of the main objections to the patent was the claim that the virus was meant to be sent for a sample analysis rather than for commercial exploitation. The legitimacy of the activities leading to the Corona virus patent is unclear. The reason for such a claim is that the virus initially was sent by the doctor who treated the first patients to Foucier and Osterhause for identification as 'he didn't know what he had'. After receiving the sample, a team of virologists at Erasmus Medical Centre including Ron Fouchier and Ab Osterhaus filed a patent on the 'use of the sequence and host receptor data to corona virus' (Arnold 2013). The Saudi Arabian official, on behalf of the medical team who provided the medical samples, raised concern over illegitimate use of patient samples for reasons which never communicated with them at first place. They also expressed concern over any future limit in accessing vaccines or any diagnostic means for the patient in such a fatal disease which may happen as a result of this patent.

The medical team in the Erasmus Medical Centre however emphasise that the patent is widely published immediately in order to be available for research community. This follows the fact that a patent is not necessarily used for commercial exploitation and, as Dickens asserts, making investment for the public good is part of the mission of universities. The patent holder in this case also declared that no commercial profit is aimed in this patent and samples are freely accessible for academic public research and no negotiation has been made with any company 'at this stage' and this patent may never have any financial recompense for them. The team however admit that developing vaccines with no patent will not bring any prospect of pharmaceutical companies' investment in the potential vaccines or diagnostic tests (Mayer 2013).

7.3.3 Corona virus as viewed from the concept-theoretic position (if brought to CJEU)

The grant of a patent on the Corona virus was objected to in a number of public health arguments as discussed above. This section aims to apply the concept-theoretic position on the corona virus.

What does granting the patent do?

After filing the patent out of Corona which was dispatched to Foucier's laboratory, Earl Brown, the Executive Director of the Emerging Pathogens Research Centre at the University of Ottawa, affirmed that they should have used a 'deep sequencing' method in the novel corona virus case (Mayer 2013). In this method, scientists use the infected sample against a data base of known genes and viruses which results in a determination of its genetic composition. The sequence is then typically removed from its chromosome and will be copied to accomplish further tests. The patent covers various receptors and other surface proteins on the virus and these proteins are likely to be immunogenic. Because of such characteristics, the patent sounds a chief candidate in vaccine development (Kupferschmidet 2013).

What does it give to patent holder?

The company may be entitled to use the patent for monopolising the IP rights over any future use of the Corona Virus samples for any future vaccine/diagnostic test. This means any pharmaceutical company who intends to produce and market a new medication which uses the sample needs to pay a royalty and a licensing fee to the company. The fact that the Erasmus Medical Centre allows the researcher access the virus sample and patent specification does not necessarily mean that they will not gain

any profit out of a patent or will not charge any licensing fee in future. It is noteworthy that patents enable research institutes to control how the sample is being used, even if conducting tests on patents is freely allowed.

How could the exercise of those powers directly or indirectly lead to consequences which are contrary to the PGC?

After filing the patent, there were concerns over the fact that the patent may impede the process of research on MERS-CoV and developing treatments. It therefore threatens the life of those diagnosed with the disease. Soon after the death of a large number of diagnosed patients with Corona virus, it was claimed by Saudi Arabian officials that, through signing contracts with companies that make anti-virals and vaccines, scientists caused delays in the development of a diagnostic tests (Saudi Deputy Health Minister 2013). Therefore, the patent is in violation of the requirement of *ordre public* and morality. Here, I apply the test that the concept-theoretic position requires if the case brought to the court.

First, if the patent in corona virus assists the scientists in Erasmus Medical Centre with some sort of power, why do these scientists need this power? It should there be asked whether the team need this patent to monopolise the commercial exploitation of the invention. And finally what implications granting the patent has for the general needs of other agents. It is followed by considering questions like how conflict between the interest of the patients diagnosed with this virus and the inventor are to be dealt with. It also needs to be clarified whether there is a conflict between identifiable interests of patients (for instance their life) with the corresponding rights of medical teams (patent

applicant) by any means. This means we must weigh the life of the first group against a less important right of the second group.

The issue with regard to patenting in case of Corona Virus is essentially related to understanding the fact that if to grant a monopoly right over the corona virus or some aspect of corona virus or the genetic make-up of this virus would inhibit research on the Corona virus and finding the cures, then it is in violation of the PGC to allow such activities which have debilitating consequences on others' generic rights.

However if granting a patent is necessary for conducting research on the corona virus in order for the life saving treatment and diagnosis to be developed, provided that it is not possible to be carried out in any other way, then the concept theoretic position will agree with this patenting. The first argument is about whether patent on the genome sequence of the virus is *necessary* for producing the treatment. This question can be addressed from two different perspectives.

First, it could have been claimed that this is the inventors' right to protect their intellectual effort and their right, as it is investment of their creative imagination, scientific works and efforts. They could claim that rendering different biotechnology products like 'genetic composition of a virus' unpatentable on the basis of being contrary to *ordre public* and morality is in violation of academic freedom and contravention with freedom of expression of agents. Hence, they should have a right to recoup their investment and make profit as a result of patents. This condition is satisfied if the scientists prove that this patent is needed in order to recompense their effort, which is entangled in their generic needs. Thus, unless this recompense is received, the generic needs of them are harmed, which means the inventor claims 'My generic needs will be harmed if I don't get this recompense'. In other words, we ask

whether recouping the investment is necessary to protect the generic needs of the scientists. The response is definitely related to different factors, including how much has been invested and it also depends on the consequences of the investment. On the basis of the affiliation of these scientists with universities, and indeed the absence of any personal investment or financial return in the project, it is not likely that they are heavily dependent on such patents to survive their lives.

The second issue in this argument is whether it is really necessary to file patents in order to satisfy the needs? It means that if the inventor can not have the opportunity to get recompense in this specific way, are there any other means to achieve this aim? Whether it is necessary to have patents in order to recoup the investment or the investment can be recouped in some other way. Although Osterhause state that 'Industry would not be interested if there was a patent minefield', it is argued that there exist other methods rather than patents in which investment on a research can be protected (Cohen and Walsh 2008). Interestingly, it is argued that not granting patent can even conversely affect the research, which means stimulate rather than inhibit the research (Walsh et al. 2007).

The scientists involved in corona virus patents may argue that it is inventors' duty to protect other agents' generic needs. Apart from the above mentioned argument on the ground of the agents' rights to patent an invention, this can be discussed from another point of view. Scientists can reason that people in the society have generic right to health or to be treated and alleviated under certain kind of condition. Hence, people have a right to medical treatment or a right to health; indeed, a right to life. In order to be able to progress in the development of treatments and vaccines I, as a scientist, ought to be allowed to patent my invention. They would claim that this is the most efficient and effective way to bring about treatments of Corona virus disease for which

the people have the right. Therefore, it is the duty of society to grant me the right to patent the samples for future use in development of vaccines. Interestingly, Osterhaus and Fouchier used the same terminology of duty or "ethical obligation" with regard to patent the virus as they assert its importance in accelerating the development of vaccines and anti-virals (Mayer 2013). In this case, the seriousness of disease and the consequences it may have on GCA of agents is clear, however it is questionable whether filing a patent is the only means to proceed the development of vaccines. It is also not clear why they have not properly communicated with the suppliers of genetic materials regarding their intention to use the sample in a potential patent. It is a violation of the requirement of the PGC to use an agent's bodily material or genetic samples without their consent.

Are there ways in which they could do this?

The argument is rarely viewed in this way. Scientists often claim their rights on patenting a research, and having a right to do something can exist without having a correlative duty. Clearly, duty implies the right, but right does not imply the duty. Addressing this issue specifically within a PGC framework, agents have categorically instrumental needs for their Generic condition of agency. To ensure that their need is satisfied, it is necessary for them to be assisted 'in defending their generic condition of agency' when they are not able to do so without any assistance as it is necessary for them 'not to be deprived from this conditions by others' (Beyleveld 2012). Hence, in order to support other agents' needs to health and medical treatment, scientists have the duty to provide that for them unless there is more important consideration of their own generic needs or somebody else's generic needs which override that duty.

However, another argument could have been formed in essence as follows: How may this patent have impeded the research on diagnoses or possibly affected the *life* of patients diagnosed with this disease? This part of the case is, however, in favour of Erasmus Medical Centre scientists. It is far from clear that in this particular case the patent resulted in impeding the research on diagnostic test for the disease. Albert Osterhaus and Ron Fouchier who consider this patent as a 'normal thing to do' confirm that the virus genetic composition has been freely shared with more than 40 labs worldwide. They also express their willingness to continue sharing the information 'with everyone who wants to do public health research'(Mayer 2013).The claim of an agreement being signed for making profit out of this patent was refused highlighting the fact that 'diagnostic tests were developed instantly and were made freely available immediately to anyone who asked for them.' Noonan, approving above said Dutch scientists assert that 'It's great publicity to say they're sharing it. They're trying to be good citizens because they're a university' (Mayer 2013).

7.4 Chapter Summary

The chapter provided an analysis of the 23andMe designer baby patent and the recent patent filed on corona virus. Examining both cases, of course, the question of permissibility would be a complex consideration. However, using the concept-theoretic position it was attempted to effectively answer a number of key questions. including whether it should be permissible to grant the patent on these particular cases and under what circumstances it would be permissible. The permissibility of the patent under certain condition was analysed, clarifying the conditions that make the patentability justifiable when it should not be permissible. It implies we have to take into account many factors concerning the use of the patent, patentable invention, the

grant of the actual patent, and all sort of issues in relation to what does needed to actually develop the invention.

The chapter once again reaffirms the strength and capacity of the PG truly as the guiding point for balancing rights and making decisions about permissibility of actions. The framework again proves to be perfectly fitted in any legal system committed to the very idea of human rights.

CHAPTER VIII:

CONCLUSION AND RECOMMENDATION

8.1 Summary of Main Findings

Although the European Directive on Protection of Biotechnological Inventions was initially established to encourage inventions in the biotechnology sector and harmonise regulations concerning patenting in biotechnology, effective efforts to provide the courts and patent offices with a framework to interpret conflicting rights in the context of patent law in biotechnology is predominately absent in the literature as it is generally assumed that philosophical problem do not bear on patent law. However, the result of this research suggests that the application of an effective guiding principle to interpret morality exclusions in patent law will assist the CJEU and patent offices in understanding and addressing philosophical problems that have been discussed for decades in patent cases, and in generating clear and more consistent decisions.

The concept-theoretic position suggested in this research argued that 'ethical rationality' can be used to shed light on proposing a framework for permissibility of actions in the patent law. It is reasoned how the content of a PGC complied framework is capable of adjudicating conflicting rights in different contexts including the topic of this thesis, intersection between intellectual property rights and morality (indeed human rights). In this sense, the Principle of Generic Consistency, as Beyleveld (2012, p.2) puts it, is 'the supreme rational reference point for judging the permissibility of all actions'.

8.1.1 The Theoretical Findings

The key objective of this thesis is to ***critically analyse and refine the current approach to morality exclusions,*** which entails ***developing a framework for delivering correct coherent decisions in EU patent law.*** In light of the above research objective, the following finding was reached to address the main research themes below.

A. Identify the appropriate theoretical framework to address the research questions

Chapter I provided an essential overview in emerging biotechnology sector and the concept of intellectual property protection and the historical background of inclusion of morality and *ordre public* exceptions for patentability in biotechnology within European and U.S legal frameworks. The chapter first provides a brief overview on the legal basis of *ordre public* and morality exclusions in the European framework and U.S patent law. It was discussed that *ordre public* principles shall be considered as a special subset of moral principles, fundamental principles and moral values that a society has to believe in when they are committed to democracy and rule of law- indeed, moral values that individuals in a society have to embrace when they are committed to democracy and rule of law. Subsequently, the inclusion of morality within patent law within European legislations, particularly under European Patent Convention and Directive on Protection of Biotechnological Inventions, was analysed. The changes made by the Directive in the wordings of the EPO in terms of exclusions of patentability were explained. Having compared the concept of morality between the EPC and the Directive, it was described that the EU directive is expanded as compared to general exclusion stated in the EPC; however the cases listed under morality and *ordre public* exclusions in the Directive are, in substance, exactly the same as what is stated under Article 52(a) section 1(3). This was followed by a brief introduction to the US system in terms of inclusion of morality in addressing the patentability question. Having explained the aims and objectives of the research and finalised the research questions and the methodology adapted, the chapter ended with a brief analysis of the problem in the current patent system and how the theoretical framework proposed in this thesis is capable of addressing the problem.

The result of chapter I indicates that the EPO or/and the CJEU have failed to address the question of morality effectively, mainly due to absence of an applicable theoretical guideline for interpretation. This means the moral principles and the criteria they have adopted have either not been an appropriate instrument or have not been used consistently. Furthermore, the Convention itself and other human right instruments (e.g. UDHR) do not specify any hierarchy in relation to rights specified in the document in order to enable judges or courts deciding consistently in case of conflicting rights (Beyleveld and Brownword 2001, p. 85). Therefore, the courts' decisions in different cases in EU patent system are not sufficiently clear and consistent in the reasoning about reconciliation of competing rights. To this end, there should be an effective framework to interpret the immorality exclusions.

In **Chapter II**, the thesis examined how adapting a PGC-based framework will benefit the EU patent system by defining and interpreting the concept of morality and the rights protected under this concept. The chapter briefly explains the theoretical framework adapted in this research built around the Alan Gewirth's Principle of Generic Consistency.

In order to justify the theoretical framework adapted in this thesis, two arguments were presented. The first argument is the dialectically necessary argument, the Gewirth's original justification in defence of the PGC discussed by Beyleveld through 3 stages. The essence of this argument provides that PGC is categorically binding on agents because it is dialectically necessary for agents to accept it. This implies that an agent is unable 'to think coherently of himself as an agent if he thinks that he may act in ways that are inconsistent with the PGC' (see specially Beyleveld in press, p.3; also Beyleveld 1991; Beyleveld and Brownsword 2009; Beyleveld 2013). Considering three stages of dialectically necessary argument, stage II and III attracted most objections. Although

most objections to dialectical necessary are mere misunderstanding of Gewirth's arguments and have not convincingly defeated the idea of dialectical necessary, Beyleveld's dialectically contingent model was presented as an alternative argument to be implemented in this thesis. According to the alternative argument, anyone who believes in impartiality of all agents, which includes all legal systems that are committed to the very idea of human rights enshrined in the Universal Declaration of Human Rights 1948 and all other legal instruments enacted to give effect to UDHR, must accept the PGC is categorically binding (Beyleveld 2012). Acceptance of the alternative argument as a sound justification for PGC implies that 'any system or theory of norms that incorporates the impartiality premise must be construed as governed by the PGC' (Beyleveld in press, p.3). Comparing the dialectically necessary argument with the dialectically contingent, it is important to note that the former prescribes that the PGC must be generally known as 'the supreme principle of practical reason' whereas the latter provides that beside being the supreme principle of morality PGC must be known as the supreme principle of human rights as well (Beyleveld in press, p.3.).

Having considered the rationale that the PGC is superior to utilitarian theories in adjudication of rights**, Chapter III** elaborates a specific application of the PGC, direct and indirect application to reconcile competing rights and interests, to selected issues in the context of biolaw and medicine, PGC dealing with animals, human embryos and foetuses, and property rights in human body.

Having discussed the concept of agency, generic rights, and the relation between them generally, Chapter III raises issue on specific situations dealing with the question of rights to agent or non-agents. Specifically, the chapter clarifies how the concept-theoretic position views the balancing rights while dealing with property rights for

bodily parts, animals, human embryos and foetuses. The first issue discussed in this section was regarding the view of PGC on human agents and the possibility of owning property rights in their body and the right to control what may happen on their organs and tissue after removal from their body. The section concluded that even without proving the availability of property rights in their bodily parts for agents, according to rule-preclusionary theory, human agents have exclusive control over their body parts i.e. If they are not granted a rule-preclusionary right to exclusively control what happens on their body parts, this contradicts the providing of adequate protection of their generic rights and is possibly against their human dignity as it denies their possession of implied generic rights. With regard to human embryos, Gewirth's original argument was criticised and Beyleveld and Pattinson's (2000) Precautionary Reason argument selected to be used in relevant cases as a solution to avoid the fallacy of proportionality. In terms of the PGC dealing with animals rights, the justification of our duties to protect animals' interest is also analysed on the basis of the 'precautionary reason' rather than the Gewirth's original 'proportionality'. If these creatures are not agent and only approach to being agent, this means they are not entitled to any generic rights.

Chapter IV proposed a co-operative model in line with a broad interpretation of immorality exclusions. The model defends the view that morality or moral rights are not always necessarily in conflict with intellectual property rights and these two sets of values even can be perceived as capable of supporting each other. In order to justify this model, it was argued that the concept theoretic position requires broad interpretation of morality exclusions under which conformity with the fundamental principles of EU law comes first. Consequently, for the purpose of balancing rights, moral exclusions ought to be interpreted broadly not narrowly due to 'categorical importance of complying with

morality'. If a broad concept of morality is justified, then the co-operative model shall be justified too.

B. **Analyse the concept of *ordre public and* morality in EU patent law and decisions made in relevant cases** (to examine how the Court of Justice of European Union or the European Patent Office have dealt with actual cases with the question of morality)[1]

The main objective of carrying out the present research was to evaluate the practicability of a PGC-complied framework in real situations mainly by considering the EU as a case study. In this respect, in order to present a more comprehensive conclusion, the research also examined selected patent cases in the U.S. system, accepting allegedly opposite positions in relation to formally incorporating morality as a part of patentability assessment. In addition to an analysis of decisions made in patent cases in the EU (Chapter 5) and the U.S. (Chapter 6), a separate chapter (Chapter 7) was devoted to discussion of hypothetical patent cases, which are examples of possibly controversial cases never brought to any court but which could possibly be brought in future. Therefore, it not only examined the analysis of decisions made in biotechnology patent cases in EU countries , but it also assessed the achievability of this concept-theoretic position in the U.S or possibly in any other jurisdiction committed to very principles of human rights.

[1] In current research the analysis of decisions made by the courts (ObjectiveB) and implementation of the concept-theoretic positions (Objective C) merge together at most places , discussed through analysis of EU cases (Chapter 4), the U.S. cases (Chapter 5) and hypothetical cases (Chapter 6).

C. **Implement the proposed applicable framework regarding how these concepts ought to be interpreted, and evaluate the capability of the developed framework to answer the said questions.**

Chapters V and VI were devoted to fulfil the mission of analysing and evaluating the historical patent cases in Europe and U.S. accordingly. **Chapter VII** was allocated to examine the hypothetical cases.

Chapter V analyses selected biotechnology patent cases brought to the European Patent Office, or questioned for preliminary ruling in the Court of Justice of the European Union. The cases analysed in this chapter covered a variety of subject matters including the synthetic form of a human hormone made by cloning technology in *Relaxin,* the transgenic mouse capable of developing cancerous cells in *Oncomouse*, the isolation, selection and propagation of animal transgenic stem cells considering a method of somatic cell nuclear transfer in *Edinburgh*, on a culture of primate embryonic stem cells and the list of desired characteristics in *WARF,* and on isolated and purified neural precursor cells processed from embryonic stem cells in *Brustle*. If I want to focus on a common ground for all these cases, that would be the generic right to benefit from scientific progress and its application, particularly advances in (medical) science and new (bio) technology. The rational for this recognition is the medical benefit that biotechnology sector would offer and gradually will increase the overall general chances of success for agents in need of those technologies. Apart from its benefit from an agential point of view, the right is recognised in relevant international human right instruments. However, in each case, a potential conflict with other agents' generic rights were identified which possibly could cause harm to other agents' GCAs. The intellectual property protection, particularly the right to patent the inventions, came together with the latest biotechnology advances. In conflict with the rights to benefit

from advances in technology and sciences and the monopoly brought by it, a number of conflict with other issues were analysed in each case, including autonomy and dignity related issues in *Relaxin*, concerns about transgenic animals in *Oncomouse*, and issues on destruction of human embryos (human embryonic stem cells) in *WARF*, *Brustle* or *Edinburgh*.

With regards to **patentability of molecular cloning and characterization of a further gene sequence coding for human *Relaxin***, particularly the decision of EPO in *Relaxin* case, it was argued that according to Beyleveld and Brownword's (2001, pp.171-194) 'rule preclusionary conception' of property, all human agents have control over their body parts and all agents need to avoid interfering with their right to possess free will and autonomy over their body. The agents' consent needs to be respected at all time. However the concept-theoretic position guides us how to avoid both 'overestimating' and 'undervaluing' the role of consent where former implies '**the Fallacy of Necessity**', the misunderstanding in thinking that 'consent is the necessary justifying reason' and the latter results in '**the Fallacy of Sufficiency'** which means that 'consent is a sufficient justifying reason' (Beyleveld and Brownsword 2007, p.32). Instead it requires a through case-by-case analysis to understand the situation in which the 'consent' may be overdriven in conflict with other generic rights including 'the right to benefit from advances in science and technology'. However, permitting this violation is dependent on a whole series of factors such as the possibility and accessibility of the medical benefit arising from gene sequence used in *Relaxin* and post-grant remedies such as availability of compulsory licensing. In addition, another factor discussed in addressing the competing rights in *Relaxin* was the assessment of the informed consent regime governing the gene sequence in order to understand whether it covers only taking of the material from the participant body or whether it also considered consent for filling of

the patent application. However all these factors need to be taken into account while knowing that, under the concept-theoretic position, only a right to Generic Conditions of Agency with more importance of needfulness for action has the power to override the generic right with lower importance of needfulness for action. The right of patent applicants to protect the intellectual property rights of their inventions is at least an additive right which improves the agents' purpose achieving ability by providing the financial possibility to carry out the research projects. This however may be claimed as a basic right, where claimed as a definite means to facilitate a basic right such as right to life.

Protection of intellectual property rights, specifically patenting in biotechnological inventions as the main topic of this thesis, which may provide incentives for scientists to invest and innovate and sufficient funding for carry out future R&D activities for creation of new drug lines is not something forbidden under the PGC. However, when to protect the intellectual property rights threatens the generic rights of other agents, this of course needs to be addressed. It was discussed that PGC allows both procedural and substantive justification. In terms of consent as a procedural justification, consent has to be used in a balanced way without any positive or negative exaggeration. Although the priority of consent must be taken into account, it must not be considered as a 'cause of action' or as a substantive justification (Beyleveld and Brownsword 2007, p.242). The importance of consent in issues involving donation or transactions of biological material however is deeply rooted in the respect of agents' right to physical integrity, individual autonomy, and the sense of ownership all humans have to their own bodies. Furthermore, addressing the substantive justification of the patent applicants to the right to academic research or benefit from advances in science and technology, it was discussed that, although it can be considered as a generic condition of agency, it still

need further examination through the criterion of degree of needfulness for action. It was discussed that e.g. the PGC does not accept any discrimination in relation to how agents are treated, therefore a substantial serious harm to a particular agent is not allowed even if the outcome is very favourable in a larger scale. In *Relaxin*, apart from consent as a procedural justification, a variety of substantive issues discussed mainly with regard to the impact of the patenting on issues like possible limitation of access to the potential medicines, limitation for further research projects, and compulsory licensing, which are all of importance in the final reconciliation of rights under the concept-theoretic position.

In relation to **patentability of transgenic animals and carrying out scientific research involving suffering of animal subjects**, the *Oncomouse* case was analysed under the concept-theoretic position. It discussed that the concept theoretic position, built upon the principle of the PGC, is an agency theory which may imply that that non-human animals as apparent non-agents are not entitled to any generic rights. Although this may appear to be true to some extent since generic rights are not granted to non-agents because these are rights to assistance and non-interference in accordance with the right holder's will , it does not follow that agents have no duty to protect the apparent non-agents interest. Beyleveld and Pattionson's **'precautionary reason'** argument (2000) was adapted in relation to apparent non-agents instead of the Gewirth's original proportionality argument. The essence of the precautionary argument is the fact that not being capable of displaying agency features may not mean that non-human animals necessarily lack the capacity for agency. Therefore it was concluded that assuming that we are automatically entitled to act against the interests of these creatures exposes us to the risk that they are agents and that we violate their rights.

According to the ‘precautionary argument’, it was then discussed that we need to strike the balance between the scientists' right to academic research and their duty to provide life-saving treatment to patients ,that are generic rights, and the agents duty not to inflict harm to apparent non-agents. It was discussed that a complex collection of issues must be taken into account with regard to legitimising the patents which involves research on transgenic animals (possibly with pain and suffering). The probability of eventual materialisation of the benefits, the accessibility of benefits for all agents, and the level of benefit in hierarchy of needs in Gewirth’s model must be assessed. Only if the benefit given to agents is higher in the hierarchy compared to the duty they have toward animals, may the suffering of animals be justified. The availability of alternative models which have the equal chance of success in finding a cure for the mentioned disease and can help improve the ‘agency’ status of receivers of the service is of significant importance. If such a method can be substituted, not only should it be prioritised over Oncomouse but also there is a duty to avoid the use of Oncomouse.

With respect to **legitimacy of patents in human embryonic stem cell research** under the PGC, stem cell patents in the *Edinburgh, WARF*, and *Brustle* cases were analysed. In spite of differences in these cases, they all have a common ground, the legal and moral status of human embryos. Similar to the reasoning on entitlement of the generic rights in non-human animals as apparent non-agents, the argument in cases established on the same ‘precautionary argument’ restating that in cases of non-sufficient evidence of agency, we cannot logically conclude ‘non-agency’. Therefore, to grant a minimal moral status to the embryos is necessary; it is not however possible to logically expect the entitlement to generic rights. A number of issues , including the possibility and availability of creating therapeutic medicine/procedure/vaccination from hESC, the real benefit of possible future treatments/medication in improving the agency status of

apparent agents, the necessity of ‘filing patents’ to protect the right of inventors as opposed to any other IP rights, also other mechanisms like research or healthcare exemption and remedies like using patent pools and compulsory licensing, must be taken into consideration.

8.1.2 The Comparative Analysis: EU and US Patent Regulations in Biotechnology

This research was undertaken to design a theoretical framework for interpretation of morality exclusions in European patent law, and to evaluate how the proposed concept-theoretic position would be capable of being used in both EU and US frameworks.

The findings of Chapter V indicate that the EU has taken some major steps towards building more logical and practical laws to address intellectual property issues in biotechnology sector. This study suggests that a PGC-based framework for interpretation of morality within patent law does not necessarily limit the protection of IP rights, but also encourages and supports the greater benefits for IP rights holders. Comparing European position with the U.S. system of patent law in **Chapter VI**, it is concluded that this PGC can also be flawlessly fitted in the U.S. system.

It was concluded that the European patent regime, particularly the biotech directive roughly matches the PGC's requirements. It is important that the examination of the U.S. patent system did not aim to bring upon new or different conclusions in terms of the application of the PGC and the chapter mainly intended to show that, although the U.S system does not incorporate morality exclusions in its patent law in the context of biotechnology, the system is committed to the same principles the European model is established upon; the universal human rights principles. With this in mind, both the European and U.S system share a high level of equivalent protection of human rights,

including concepts like respect for human dignity, autonomy, free will and informed consent. Although the Directive is a very effective instrument in giving direction to patent activities in Europe, even if it was not enacted, it is clear that no (patent) activities in violation of fundamental principles of EU law including any moral values would not have been permitted under EU law. The same applies to the U.S specifically given that the **U.S Constitution as the supreme law of state is not morally-neutral**. This together with the historical background of '**moral utility doctrine'** the United States and **precedent judgements**, and most importantly ratification of international human rights instrument including Universal Declaration of Human Rights and all other associated 'legally binding' means to implement the UDHR in the U.S. means that the patent system in the U.S. with regard to morality exclusions does not differ systematically with the EU framework. Therefore, the proposed concept-theoretic position in this thesis is equally applicable in the American patent system.

Chapter VII examines two hypothetical cases in field of biotech patents, the case of 'designer babies' and 'Corona virus'. In each case, an analysis of the case is attempted according to the requirements of the PGC, to consider how the court would have decided according to the concept-theoretic position if the case had brought to the court.

Overall, the finding of this research suggests that the concept theoretic position requires a broad concept of morality (broad interpretation of immorality exclusions) to be employed in the context of patent law in biotechnology. Adapting a broad concept of morality is justified by both ethical and pragmatical reasons. It is important that broad interpretation of morality exclusion needs the employment of a co-operative model in striking the balance, instead of a conflict-model. Although, the issue is not very clear in the directive, the recent EU case law, particularly the preliminary ruling of the CJEU in the *Brustl*e supports the thesis proposed in the concept-theoretic position regarding

narrow v broad morality exclusions. Furthermore, the concerns over free and 'informed consent' mean that all agents including medical research subject have to give consent to participate in any medical research, treatment, etc. before filing the patent, a valid consent must be obtained from participants who specific purpose of the specific research, future commercialisation plans, etc. The consent, under PGC, however is not an absolute right. Therefore, the 'right to consent' can be overridden depending on the generic rights and interests involved. In brief, this research proposed a concept-theoretic position, which suggests a careful consideration and update of 'informed consent' regime in EU patent context. In addition, the research suggests 'precautionary measures' to avoid causing harm to 'non-apparent' agents, to protect the interest of apparent non-agents in the processes leading to a patent, particularly interests of human embryos and animals in scientific research.

This dissertation worked around several distinctive principles. The whole thesis was based on the idea that the categorically binding principle is the Principle of Generic Consistency. The PGC is completely unconditional; nothing can override it, and all agents have an absolute duty to apply it consistently. The Principle of Generic Consistency prescribes that agents have rights to Generic Conditions of Agency, all according to the 'criterion of degree of needfulness for action'. Agents have rights to the Generic Conditions of Agency as ordered by the 'criterion of needfulness for agency'. The entire thesis applies a principle that the rights agents have in any particular circumstances is what the hierarchy defines in relation to their Generic Conditions of Agency.

In absence of any measurement guideline for the purpose of balancing rights any within the European position, the proposed framework in this thesis provided a clear instruction. The main rule provides that agents *prima facie* have rights to anything,

which is Generic Condition of Agency. But actually some of these *prima facie* rights can be overridden. What it simply means is that a *prima facie* right can be overridden by another prima facie right which means that the rights agents actually have in a particular case are these that are overriding. It means that we do not have 'stand alone' rights. The rights agents can always have is what the PGC requires and what the PGC requires can be varied. The right agents have is what the hierarchy requires in relation to generic conditions of agency. What that means may still vary in different circumstances. In balancing right situations, if a right is overridden it does not mean the right is violated but It means that that right never exist. It is as 'rights carrying weight' and these are consideration that must be taken into account whenever we want to determine which rights one can have in particular situation. The actual rights an agent have in any situation depend upon the hierarchy of needfulness.

In the process of adjudication of rights under the concept-theoretic position, in addition to efforts in recognition of generic rights themselves, any other non-generic rights were examined which may have some bearing on a number of generic rights . The point was to decide why and in what way they are relevant to the criterion of degree of needfulness for agency? The thesis attempted in numerous scenarios to emphasise that the patent system is part of another system; and it is not possible to separate it from the rest of the system, let it be the European patent system or U.S. law. It is as if we treat patent law as though it does not belong to society. It is as though we perceive patent law as a system of law cut off, abstracted from everything else which happens in society. It is like it is absolutely nothing to do with commercial exploitation, nothing to do how the patent holders act, what the corporation are incentivised to do, what pharmaceutical firms are motivated to do, and so many other considerations. This dissertation tried to show that such perception is absolutely wrong.

All the above issue were first viewed in the concept-theoretic position in general terms. This dissertation began with such general rules and principles that are developed within the concept-theoretic framework, but it continued the analysis with examination of diverse external factors knowing that the application of the concept-theoretic position has to take into account the social, economic, and political context . Clearly, what rules, and social arrangements are required to actually give effect to the PGC will depend upon those things. That has to be separated from the actual justification of PGC in the first place.

8.2 Recommendation for Future Research

Overall, this thesis has sought to draw attention to the fact that the biotechnology Directive does not address the issues over interpretation of immorality exclusions in patent law. However, it is clearly evident that any EU law must be compliant with fundamental human rights principles enshrined in European Convention of Human Rights and the Universal Declaration of Human Rights. This thesis aimed to propose a concept-theoretic position and developing appropriate principles and guidelines to be applied in interpretation of competing rights in the context of biotechnology patents. Using the dialectically contingent argument from the PGC, which begins with the premise of human rights, makes the proposed framework appealing, applicable, and effective in any legal system with the commitment to human right principle. The historical cases which inspired this thesis , either those discussed Chapter IV and V or the hypothetical situations in chapter VI, were chosen from controversial areas in the general context of biotechnology but varied in terms of patenting technologies used in each case, from DNA sequence, transgenic animals, and human embryonic stem cell

research to the most recent issues on patenting 'designer babies' and Corona virus. The field of biotechnology develops more rapidly than other fields of technology like the automobile, the telephone, television and jet air travel, which 'accelerated for a while, transforming the society along the way, but then settled into a manageable rate. The stunning rapidity in the biotechnology may lead to conditions that are 'unstable, unpredictable and unreliable'(Brand 2000). Instead of constant attempts to put a brake on modern technologies, society needs effective planning and regulation in effect to address the limitations and borders of new technologies. New technologies are not self-determining, and require constant renegotiation with the law and society. Furthermore, ever-increasing introduction of new technologies means the importance of right to benefit from advances in science and technology will become more essential. The theoretical framework which is proposed in this thesis has been implemented on a diverse range of biotechnological inventions, however the concerns over morality of new technologies make the arguments over the competing rights in this context more complex than ever. This clearly calls for constant examination of the latest technologies and analysis of different mechanism to avoid violation of immorality in these new-arrival inventions. Therefore, I propose two possible avenues for future research.

The first avenue for future research concerns the analysis of competing rights in the most recent controversial inventions and trends in biotechnology. First, the law has to keep abreast of various developments in science. The EU biotechnology directive, the most relevant EU legal instrument which covers permissibility of biotechnology inventions and protection of intellectual property rights, needs regular updates in order to include new statements on the latest inventions. Although I have tried to provide a diverse list of biotech inventions in my research, a future study may focus on the very latest events in biotechnology most importantly the revolutionary gene-editing

technique called 'Crispr-Cas9'. The technology is revolutionary as well as 'perilous', given that it may allow genetic researchers to progress in controversial technologies like designer babies, invasive mutants, species-specific bio-weapon, or any other apocalyptic sci-fi tropes (Wired 2015).

It is of importance how the EU will respond to the invention, its intellectual property rights, and whether grant of a patent for such technology is compliant with the biotech directive. Similarly, it is of importance to examine another controversial activity, patentability of 'mitochondrial replacement techniques'. Both two experimental methods of doing mitochondrial replacement, pronuclear transfer and maternal spindle transfer, involve the transfer of nuclear DNA. The technology is allowed only in the UK, the first country to authorise scientists to create human babies with genetic material from more than two people, whereas development and use of mitochondrial technology is illegal in all other countries (Baylis, 2013).

The second possibility for future research concerns the introduction of new 'regulation' to address the issues arising from interpretation of the Biotechnology Directive. One of the important critiques to the existence of immorality exclusions in the directive, and proposing a theoretical framework to interpret these immorality exclusions in the directive, is that the legislator could instead pass effective 'regulations' e.g. in the context of informed consent or regulating scientific regimes accordingly. Although 'regulations' are not substitutes for either immorality exclusions, or the concept-theoretic-position to interpret the exclusions, it can be an effective mechanism to address issues and uncertainties in the biotech sector. A future study may examine the need for relevant regulations in biotech in order to respond to ever-increasing challenges of the industry.

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