GENERIC CONSISTENCY IN UNITED STATES PATENT LAW:

A CONCEPT-THEORETIC FRAMEWORK FOR BIOTECHNOLOGICAL PATENTS

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ABSTRACT

This article presents a concept-theoretic position to reconcile competing rights in the U.S. patent system. Addressing the question of whether or not a biotechnological patent should be considered permissible within the U.S. patent system, the study suggests a concept-theoretic position particularly useful in having the ability to adjudicate conflicting rights. I apply Alan Gewirth's Principle of Generic Consistency (PGC) to assess the morality of the grant of patents for particular biotechnological inventions. Using universal human rights principles and Gewirth's theory, this article challenges existing literature that sometimes views U.S. patent law as morally neutral. There are three parts. Part I focuses specifically on the U.S. patent protection of morally controversial biotechnical inventions. It provides arguments dealing with the way in which U.S. patent law, in effect, considers issues of morality, albeit indirectly. Part II presents the suggested theoretical framework and its justification in the U.S. legal system. I argue that U.S. patent law should engage with morality and that the appropriate way of doing so is via Gewirth's principle. Part III of this article applies the concept-theoretic position to the Hagahai people patent case to find out how the concept-theoretic framework can balance any conflict of rights.

Keywords: Human Rights; Biotechnological Patents; Principle of Generic Consistency

Introduction

This article attempts 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. Part I seeks to analyse the main legal provision and procedures in the United States patent regime. I analyse the concept of morality within the Constitution of the United States, and the case law influenced by the 'moral utility doctrine'. Part II presents the Gewirthian Principle of Generic Consistency. I intend to argue that, in spite of the differences

between the EU and U.S. systems, the proposed framework in this article will be equally applicable in both systems given that the main argument of this framework is based on a common belief in human rights to which both systems are committed. 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 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 the United States context of patent law. Subsequently, the main question of this article will be raised, which is whether the PGC is workable in balancing rights in the U.S. patent system. 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. I will argue that the law governing the grant of biotechnological patents in the U.S., like any other legal system committed to the idea of human rights, must be regulated and interpreted in line with the concept of human rights. In Part III, by way of an example to show how the concept-theoretic provides a rational and workable solution to the issues concerning morality in patent law, the proposed framework will be applied to a historical patent case in the United States.

Part I: The U.S. Patent System and Biotechnology

Having explained the content of this article briefly, the next section will be on the concept of morality in United States patent law, an analysis of the interpretation of the patent law by reference to the values embedded in the U.S. Constitution followed by a discussion of the moral utility doctrine and the role of politics in U.S. patent law.

a. Morality and Ordre Public in Patent Law

Morality exclusion provisions are contained in European patent law but are not explicit in U.S. patent law. European provisions are contained mainly in Article 53a of the European Patent Convention 1973, covering patents generally and now in Directive 98/44 EC[1], which is 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.'[2]Article 6 provides that 'inventions shall be

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

[2] 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.'

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. [3]

In contrast to the European position, the United States does not make moral permissibility an explicit requirement for the grant of a patent and biotechnology patents, including several already granted for human embryonic stem cells. The key U.S. case was the 1980 Supreme Court decision in *Diamond v Chakrabarty* [4] which 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.[5]

The U.S. position in the integration of morality and patent rights is dissimilar to the European position.[6] Article 1, Section 8.8 of the U.S. Constitution clearly recognizes intellectual property rights:

> 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 that patent and copyright laws are identified in the Constitution. Congress legislates on it and federal courts adjudicate the relevant laws. Furthermore, the intellectual property clause is viewed as evidence that the U.S. patent system is justified on utilitarian or consequentialist grounds.[7, 8] The patent system is known as one of the earliest instruments of economic development established by the young United States.[9] In the 19th century, American law – the most important 'working principle' – was the 'legal order should protect and promote the release of individual creative energy to the greatest extent

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[3] 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.

[4] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[5] CORINA SCHÜTT, PATENTS FOR BIOTECHNOLOGICAL INVENTIONS CURRENT LEGAL SITUATION AND CASE LAW IN EUROPE, THE US AND JAPAN 7 (2004) (Master Thesis available at: https://www.research-collection.ethz.ch/bitstream/handle/20.500.11850/149034/eth-28365-01.pdf.

[6] See e.g., Hayes, B. S. (2000). Integrating Moral Rights into U.S. Law and the Problem of the Work for Hire Doctrine. Ohio State Law Journal. 61, 1013-1033; Cynthia M. Ho. 2000. "Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men". Washington University Journal of Law & Policy. 2 (1); Donna M. Gitter, Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law, 19 BERKELEY J. INT'l L. 1 (2001).

[7] Wendy Lim (2003). Towards Developing A Natural Law Jurisprudence in The U.S. Patent System. Santa Clara Computer and High-Technology Law Journal. 19, 559-625.

[8] The Oxford Companion to Philosophy defines Consequentialism as a view holding that 'all actions are right or wrong in virtue of the value of their consequences.' THE OXFORD COMPANION TO PHILOSOPHY 154 (Honderich ed. 1995). Consequentialism and utilitarianism are sometimes used interchangeably although Consequentialism encompasses broader theories including non-utilitarian theories. See 2 ENCYCLOPEDIA OF ETHICS 1264 (Lawrence C. Becker and Charlotte B. Becker eds., 1992).

[9] R.P. Merges (2019). *The Hamiltonian origins of the U.S. patent system, and why they matter today*. Iowa Law Review. 104, 2559-2590.

compatible with the broad sharing of opportunity for such expression'.[10] The Patent Act of 1790 was the first of its kind enacted by the federal government.[11] Thomas Jefferson, at the forefront of the advocates for a new patent statute[12], subsequently administered the Patent Act of 1793[13] on which the foundation of the current U.S. patent system was laid.[14] 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'.[15] The position of U.S. patent law in relation to the morality exclusion is well researched in literature where many commentators argue that patent law is morally neutral and that there is no place for moral judgments in the granting of patents.'[16] It is the aim of this article to challenge this view by referencing the underlying morality of the Constitution and the 'doctrine of moral utility' used in the past to prohibit the granting of patents for medicines with questionable safety, misleading products, and gambling machines, as well as reference the case law.[17]

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[10] JAMES WILLARD HURST, LAW AND THE CONDITIONS OF FREEDOM IN THE NINETEENTH-CENTURY UNITED STATES 6 (1956).

[11] P. J. (Pat) Frederico, 1990. *Operation of the Patent Act of 1790*. Journal of the Patent and Trademark Office Society. 373-385.

[12] Edward C. Walterscheid, (1998). *Thomas Jefferson and the Patent Act of 1793*, Essays in history, The Annual Journal of Corcoran Department of History of the University of Virginia, Volume 39.

[13] Patent Act of 1793.

[14] However, several important changes were introduced at later stages e.g., in Patent Act 1836 and proposed changes regarding 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 the examiner in the examination process.

[15] 35 U.S.C.A. § 101 (1836).

[16] For instance, arguments proposing that there is no place for moral judgments in United States patent law see Elizabeth Joy Hecht's argument that 'Patent laws have not typically been amended to answer any of the kinds of ethical or moral concerns voiced by the animal rights groups. Instead, the United States patent system hinges on a principle of neutrality, whereby the system neither supports nor discriminates against technologies.' See Elizabeth Joy Hecht, Beyond Animal Legal Defense Fund v. Quigg: The Controversy over Transgenic Animal Patents Continues, 41 AM. U. L. REV. 1023, 1056-58 (1992).
Also see Terri A. Jones, Patenting Transgenic Animals: When the Cat's Away, the Mice Will Play, 17 VT. L. REV. 875, 915 (1993) (citing Robert B. Kambic, Note, Hindering the Progress of Science: The Use of the Patent System to Regulate Research on Genetically Altered Animals, 16 FORDHAM URB. L.J. 441, 464 (1988)). A similar position can be found in various areas of biotechnology patents.
See a solid discussion of issues concerning morality and biotechnology patents in Margo A. Bagley, Patent First, Ask Questions Later: Morality And Biotechnology In Patent Law, 45 Wm. & Mary L. Rev. 469 (2003).With regards to patentability of human embryonic stem cell research, it is argued that 'immorality exclusion have, in principle, no place in patent law' and that 'Law and morality are conceptually distinct' 129 (cited in Adcock, Mike and Beyleveld, Deryck (2016) 'Morality in intellectual property law: a concept-theoretic framework.', Intellectual property rights : open access., 4 (1). p. 154) referring to Thomas Gummer (2013) 'Rethinking Morality: Human Embryonic Stem Cell Innovation, to patent or not to patent?' 3 The Student Journal Part 2. and R Stephen Crespi (1997) 'Biotechnology patents and morality' Trends in Biotechnology, 15: 123.

[17] The U.S. approach is also criticised by making reference to the examples of unpatentable inventions in U.S. biotechnology patents (without using the term 'morally problematic'). For instance, patenting humans is denied in practice in U.S. law, however this relates to issues regarding patentability of living subject matters. See e.g. Jennifer McCallum, *The Reality of Restricting Patent Rights on Morally Controversial Subject Matter*, 39 NEW ENG. L. REV. 517 (2005). 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 under 35 U.S.C.A. § 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.A. § 102, 103, or 112 must also be made'. *See* The United States Patent and Trademark Office (Manual of Patent Examining Procedure, 2012), Chapter 2100. Section 2105 available at http://www.uspto.gov/web/offices/pac/mpep/s2105.html#sect2105.

b. Interpretation of Patent Law by Reference to the Values of the U.S. Constitution

> *The Constitution is America's moral sail, and we must hold to 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.*[18]

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. I will investigate the U.S. Constitution to uncover whether there has been direct or indirect reference to morality. Specifically, this first section of the paper seeks to relate the position of the U.S. Constitution to U.S. patent law relying on the Supremacy Clause.[19]

This section identifies the way in which the interpretation of morality may be understood within the context of the U.S. Constitution. The section investigates whether U.S. law, including patent law, permits a claim of moral neutrality, and what, if any, would be the effect of the Supremacy Clause of Article 6, Clause 2 of the Constitution on U.S. patent law.[20,21] In the case of U.S. patent law, the argument is that although there is no explicit morality clause, the essence of commitment to human rights principles is present in the U.S. Constitution. Patent law clearly needs to be in line with the Constitution which recognises the universal principle of human rights. The United States is signatory to various human right conventions including the Universal Declaration of Human Rights (UDHR), the International Covenant on Economic, Social and Cultural Rights (ICESCR), and the International Covenant on Civil and Political Rights (ICCPR).

This analysis may, however, be criticised given that the relevance of international human rights to the U.S. Constitution and the status of treaty obligations as federal law is not free from scholarly debate and disagreement. The argument could refer to the conventions which the U.S. is yet to sign or the ones it has signed but is yet to ratify.[22] Furthermore, there could be concern regarding the conventions that have been ratified but with extensive reservations, understandings, and declarations (RUDs) that effectively deny that the covenant grants any rights beyond those already guaranteed by the U.S. Constitution 'as interpreted by the Supreme Court of the United States'.[23] The question of whether or not international human rights law is part of U.S. federal law is a subject of academic debate and disagreement.[24] Critics of this

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[18] RONALD DWORKIN, FREEDOM'S LAW: THE MORAL READING OF THE AMERICAN CONSTITUTION 38 (1999).
[19] U.S. CONST. art. VI, cl. 2
[20] In *Marbury v. Madison,* and *Fletcher v Peck* the Supreme Court of the United States asserted its power of judicial review with authority to strike down both federal and state laws on constitutional grounds. See Marbury v. Madison, 5 U.S. 137 (1803); Fletcher v. Peck, 10 U.S. 87 (1810).
[21] State laws are invalidated by courts for the mere fact that they do not conform to the Constitution's principles includi*ng* the Equal Protection Clause in cases such as *Brown v Board of Education.*
[22] M. Venetis, Making Human Rights Treaty Law Actionable in The United States: The Case for Universal Implementing Legislation (2011) *Alabama Law Review.* 63(1) 97. 99-100
[23] *Id.* 102
[24] For instance, Judge Scalia's scornful reference to the 'the law of nations — the so-called customary international law' (*Roper v. Simmons* 2005) may create an assumption that the federal judiciary is generally unmoved by the opinions of other nations when they conflict with domestic ones. However, it is argued that such a view 'disregards well-settled case law and the Restatement of the Foreign Relations Law of the United States, which both recognize

position may discuss the application and interpretation of international treaty obligations in the U.S.[25] and argue against the recognition of International HR treaties not part of federal law (unless and until specifically so enacted by Congress). [26]It may be argued that 'the acts of Congress remain on a par with treaties, prevailing over inconsistent treaty provisions only pursuant to either (i) the "later in time" rule[27] or (ii) an explicit congressional pronouncement'.[28] The key concepts of 'monism' and 'dualism' have long been used in the relevant literature[29] to analyse some of the relationships between treaty law and domestic law. This article does not deal with all legal and constitutional issues related to direct or indirect application of treaties in U.S. legal systems, as it is obviously beyond the scope of this research. However, an appreciation of the existence of these relationships may enhance understanding of the issues related to the concept-theoretic model proposed in this article for application in the U.S. patent system. Therefore, the following clarification explains how potential critique may not be relevant in the context of this article or could be responded to effectively using alternative arguments.

First, even if the immediate effect of the UDHR and other human rights treaties in the U.S. system has been debated, the U.S. commitment to human rights is clear as evidenced in the Constitution[30] and the Bill of Rights[31], which provide broad human rights protections. Many of the rights enshrined in the U.S. Constitution are equivalent to rights recognised in the Universal Declaration of Human Rights. The 14th amendment, for example, guarantees similar principles of non-discrimination as found in articles 2, 3, 6 and 7 of the UDHR: 'life, liberty…security…[and] equal protection'. Furthermore, the commitment to human rights can clearly be found in the Preamble to the U.S. Constitution and in the Declaration of Independence,[32] which emphasises, 'We hold these truths to be self-evident, that all men are created equal', and 'that they are endowed by their Creator with certain inalienable Rights, that among these are Life, Liberty and the pursuit of Happiness'.[33] The Declaration has been repeatedly cited by the Supreme Court as part of the fundamental law of the nation.[34]

customary international law as part of our federal law'. See e.g., Jeremiah Lee, Joining the World Against Juvenile Executions Jurist (March 2005).

[25] See e.g., John H. Jackson, Status of Treaties in Domestic Legal Systems: A Policy Analysis, Vol. 86, No. 2 (Apr., 1992), pp. 310-340.

[26] See e.g., Vasan Kesavan, The Three Tiers of Federal Law, 100 Nw. U. L. Rev. 1479

[27] Breard v. Greene, 523 U.S. 371, 376 (1998) (citing Reid, 354 U.S. at 18, Whitney v. Robertson, 124 U.S. 190, 194 (1888)). For a general discussion see Detlev F. Vagts, The United States and Its Treaties: Observance and Breach, 95 American Journal of International Law. 313 (2001).

[28] Breard v. Greene, 523 U.S. 371, 376 (1998) (citing Reid, 354 U.S. at 18, Whitney v. Robertson, 124 U.S. 190, 194 (1888)).

[29] See e.g., Sasse, The Common Market: Between International and Municipal Law, 75 YALE L.J. 695 (1966) IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW (4th ed. 1990);

[30] U.S. Const.

[31] U.S. Bill of Rights

[32] "We the People of the United States, in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defense, promote the general Welfare, and secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution for the United States of America."

[33] Declaration of Independence. U.S. (1776)

[34] JOHN EIDSMOE, CHRISTIANITY AND THE CONSTITUTION: THE FAITH OF OUR FOUNDING FATHERS, (Grand Rapids, Mich: Baker Book House, 1995)

Second, it is largely accepted from an international law perspective that an act wrongful under the law of nations remains so even if a nation's internal law deems otherwise.[35] The Vienna Convention clearly provides that 'neither a constitutional mandate nor the enactment of a statute provides an excuse for a treaty violation.'[36] In any event, even if one argues against the direct operation of international human rights treaties in the U.S., their indirect impact, as Lillich states, 'should not be discounted.'[37] Even the treaties some refer to as 'non-self-executing' [38], as Paust emphasises, 'can be used indirectly as a means of interpreting relevant constitutional, statutory, common law or other legal provisions.'[39] Furthermore, a wide range of scholarly works have condemned the U.S. position in enforcement of international human rights treaties[40] and proposed solutions such as introducing universal implementing legislation to apply to all treaties and integrating the international human rights treaty obligations into the U.S. legal framework. This is believed to strengthen the rule of law by fulfilling the United States' treaty obligations under both the Constitution and the treaties it has ratified.[41]

Lastly, commentators may argue against this position with reference to the fundamental division of spheres of responsibility in American federalism, the difference between the powers of the federal government and those of the state. Madison's dictum in Federalist 45 asserts that 'the powers delegated by the proposed Constitution to the federal government are few and defined. Those which are to remain in the state governments are numerous and indefinite.'[42] More specifically, one may criticise the role of morality in U.S. patent law that relies on no explicit reference to moral considerations in the Constitution and that federal government, in contrast to the states, has no 'police power'. The application of the regulatory

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[35] Under Article III of the International Law Commission's Draft Articles on Responsibility of States for Internationally Wrongful Acts, "[t]he characterization of an act of a State as internationally wrongful is governed by international law. Such characterization is not affected by the characterization of the same act as lawful by internal law." Report of the International Law Commission to the General Assembly, 56 U.N. GAOR Supp. (No. 10) at 1, U.N. Doc. A/56/10 (2001.
See also Restatement (Third) of the Foreign Relations Law of the United States § 111 cmt. a (1987) ("[F]ailure of the United States to carry out an obligation [of international law] on the ground of its unconstitutionality will not relieve the United States of responsibility under international law."

[36] See, e.g., William W. Park and Alexander Yanos, *Treaty Obligations and National Law*, 58 HASTINGS LAW REV. 251 (2006) citing Vienna Convention on the Law of Treaties art. 27, May 23, 1969, 1155 U.N.T.S. 331 ("A party may not invoke the provisions of its internal law as justification for its failure to perform a treaty. This rule is without prejudice to article 46.")

[37] Lillich, R. B. (January 01, 1990). The Constitution and international human rights. *Foreign Affairs and the US Constitution / Edited by Louis Henkin, Michael J. Glennon, William D. Rogers.*

[38] A non-self-executing treaty is widely known as a treaty that 'requires legislative implementation before it may be applied by the courts (and other domestic law-applying officials)'. See e.g., Carlos Vasquez, The distinction between self-executing and non-self-executing treaties in International Law, Oxford University, Inaugural Lectures and Special Lectures (10 May 2018).

[39] Referred to by Jordan Paust as treaties 'which cannot operate directly without implementing legislation'. Jordan J. Paust, *Self-Executing Treaties* (1988). 82 American Journal of International Law 760 760, 781 (1988) Available at SSRN: https://ssrn.com/abstract=2446624 (citing Iwasawa, The Doctrine of Self-Executing Treaties in the United States: A Critical Analysis, 26 VA. J. INT'L L. 627, 669-70 (1986). , at 686-92)

[40] See e.g., Peter J. Spiro, *The States and International Human Rights*, 66 Fordham L. Rev. 567 (1997). Available at:

[41] See e.g., Penny M. Venetis , *Making Human Rights Treaty Law Actionable In The United States: The Case For Universal Implementing Legislation* (2011) Alabama Law Review. 63(1) 97. 99-100https://ir.lawnet.fordham.edu/flr/vol66/iss2/9

[42]James Madison, "The Alleged Danger from the Powers of the Union to the State Governments Considered" (Federalist No.45).

power of states, generally referred to as the state police power, has traditionally implied the capacity to regulate and enforce laws to promote health, safety, the general well-being of the community, and the *morals* of citizens.[43] On that basis, one may argue that the commitment of patents to the federal government pre-empts the state's power in the field and so could limit the scope for a moral dimension. While it is crucial to acknowledge such division of spheres of responsibility in the U.S. federal system, the proposed model in this article explains the situation in patent law from a different point of view. The framework will not focus on explicit reference to morality considerations; instead, it will build arguments on the premise of the recognition of human rights within the federal system to establish that the U.S. Constitution is not morally neutral. In Part II, I will discuss how this fidelity to human rights relates to morality exclusions in patent law and the application of the framework proposed in this article.

c. Moral Utility Doctrine in the United States

To meet the requirements of patentability in the United States, an invention must be new and useful[44], novel[45] and nonobvious.[46] The requirement that an invention have utility is an essential factor in the U.S. system.[47] This requirement is also recognised in other jurisdictions in the form of inventions that have 'industrial applicability'[48] or are 'capable of exploitation in industry'.[49] Moral utility, the main subject of this section, is a doctrine introduced by Justice Joseph Story[50] in Lowell v. Lewis. [51] The doctrine allowed the courts and the United States Patent and Trademark Office (USPTO) to deny patents on 'morally controversial subject matter' by refusing to accept such inventions as 'useful'.[52] 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'.[53] To be 'useful', an invention must provide a benefit to the public, as the Supreme Court concluded in *Brenner v. Manson*.[54]

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[43] Pennsylvania General Assembly, Local Government Commission. What is the "police power"? *Pennsylvania Legislator's Municipal Deskbook, 2003 Oct.* 2003. Oct [cited 2003 Nov 3]. Available from: URL: http://www.lgc.state.pa.us/deskbook03/Issues17.pdf.

[44] U.S.C. § 101 (2001).

[45] Id. § 102

[46] Id. § 103.

[47] This concept is rooted in the U.S. Constitution: Article 1, Section 8 in relation to the power of congress to grant exclusive rights to inventors in order "[t]o promote the progress of Science and useful Arts."

[48] See World Intellectual Property Organisation, Patent Cooperation Treaty International Search International Search and Preliminary Examination Guidelines, § A14.01[1].

[49] See European Patent Office, Guidelines for Examination In The European Patent Office, pt. C, ch. II, § 4.12

[50] See e.g., Peter Menell et al., *Intellectual Property in the New Technological Age*: 2018: Volume 1: Perspectives, Trade Secrets and Patents 243-44 (2018).

[51] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.)*;*

[52]Margo A. Bagley. *Patent first, ask questions later: morality and biotechnology in patent law*. William Mary Law Rev. 2003 Dec;45(2):469-547. PMID: 15570677.

[53] DONALD S. CHISUM, CHISUM ON PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT c.4.03 (1995).

[54] *Brenner v. Manson*, 383 U.S. 519, 534 (1966)

The doctrine of moral utility was used to invalidate patents in two main categories of gambling devices and fraudulent or deceptive devices.[55] In the 19th and early 20th century, 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.[56] In cases the patent was invalidated even if the invention has substantial other uses apart from as a gambling machine.[57] In 1977, however, the Board of Patent Appeals and Interferences disregarded the prohibition of the patentability of gambling machines and resumed granting patents for gambling machines.[58]

Similar to gambling patents, deceptive and fraudulent patents were not allowed and prohibited as immoral throughout the history of patent law in America. The case of *Klein v. Russel* is considered the first instance in which the Supreme Court invalidated a patent based on deceptiveness.[59] The patent was refused on grounds of consumer fraud as the product was viewed as a misleading device.[60] Nevertheless, the Court of Appeals for the Federal Circuit later in 1999 upheld a patent for a machine known as the *Juicy Whip.* The Federal Circuit refused to accept that a device being 'deceptive' is a factor that affects the utility of an invention.[61]

Another instance of the application of moral utility used to be 'the medicines of questionable safety'. Nevertheless, patents on drugs are not currently denied by the USPTO on the grounds of doubts of the safety of the drug.[62] It could be due to availability of systems and mechanisms introduced by the Food and Drug Administration (FDA) to evaluate pharmaceutical products. The existence of the FDA means the responsibility of 'clinical safety' will be afforded by the FDA while the assessment of 'functional utility' will be afforded by courts to avoid duplication of efforts on assessment of clinical safety.[63,64] The way patenting in the biotechnology sector operates in the U.S. may have a simple message: 'patent first, ask questions later'.[65] Within the specific context of determining patent eligibility of morally controversial biotech subject matter, this approach has created different morality-based concerns, although all similarly involve objection to the grant of a patent for the relevant subject matter.[66]

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[55] DONALD S. CHISUM, CHISUM ON PATENTS §§ 4.01, 4.04(2)(c)(iv) (2000)4.03; Bedford, 3 F. Cas. at 37

[56] See, e.g., Laura A. Keay, *Morality's Move Within U.S. Patent Law: From Moral Utility to Subject Matter*, 40 AIPLA Q. J. 409, 410 (2012)

[57]Andrew R. Smith, Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning, 53 DePaul L. Rev. p.161 (2003) (citing Schultze v. Holtz, 82 F. 448, 449 (C.C.N.D. Cal. 1897, 82 F. at 449)

[58] Ex parte Murphy, 200 U.S.P.Q. (BNA) 801 (B.P.A.I. Apr. 29, 1977).

[59] Klein v. Russell, 86 U.S. (19 Wall.) 433 (1873)

[60] Klein, 86 U.S. 433.

[61] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999).

[62] Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 Md. L. Rev. 1064(1987).

[63] *Id.*

[64] See e.g., Carter-Wallace, Inc. v. Riverton Laboratories, Inc., 433 F.2d 1034, 1039 n.7 (2d Cir. 1970).

[65] BAGLEY, supra note 54, at 474.

[66] BAGLEY, supra note 54, at 495. Bagley divided the cases in his study into two broad groups: 1) The moral objections to patents due to concerns regarding the 'morality of practicing the patents underlying subject matter' (e.g., human cloning or animal-human chimeras) or 2) Objections based on the 'morality of allowing anyone to limit the practice of the patent's underlying subject matter' (e.g., medical process methods)

The U.S. system has included some specific prohibitions, the most important of which is the Weldon amendment prohibiting patents directed to or encompassing human organisms.[67] This provision is 'a clarification' of the policy adopted by the USPTO with regards to the prohibition of patenting humans.[68] Proposed by David Weldon to be considered for the fiscal year 2004, it provided that '[n]one of the funds appropriated or otherwise made available under th[e] Act may be used to issue patents on claims directed to or encompassing a human organism.'[69] The main purpose of the Weldon amendment was to codify USPTO policy preventing the patenting of human organisms[70], and it was ultimately adopted as section 33 of the America Invents Act.[71] The key problem Congress discussed at the time was limitations to the definition of 'human', the appropriate measure of 'humanness' and indeed the way 'human organism' is to be interpreted.[72] It seems that patent eligibility, at least in relation to the determination of eligible subject matter in biotechnology patents, has not always been straightforward. The following paragraphs provides a more detailed analysis of the moral utility doctrine to examine the role of morality in the U.S. patent system.

In the important case of *Lowell v Lewis*, the court held 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 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.[73]

Therefore, the fact that an invention is in contravention of the 'sound morals of society' implies that the invention does not meet the utility requirement and is not useful in a way that the law is prepared to recognize. In another case, *Evans v. Eaton,*[74] the same definition for patentable subject matters was adopted where the court held 'useful' to mean 'applied to a beneficial use in society, in contradistinction to…injurious to the morals, health or good order…or frivolous or insignificant'. [75]

Thus, a broad definition of 'usefulness' was accepted in patent cases supported by judicially developed doctrines including the doctrine of 'moral utility'. Being 'useful' in *Brener v. Manson* was defined as the potential of an invention to provide a benefit to the public.[76] This

[67] The Consolidated Appropriations Act of 2004, H.R. 2673, 108th Cong. (2004).
[68] Amendment to Support Current U.S. Patent and Trademark Office Policy Against Patenting Human Organisms, Congressional Record Volume 149, Number 171 (November 22, 2003) https://www.govinfo.gov/content/pkg/CREC-2003-11-22/html/CREC-2003-11-22-pt1-PgE2417.htm
[69] 149 CONG. REC. H7248 (daily ed. July 22, 2003) (amendment offered by Rep. David Weldon).
[70] 72 Ryan Hagglund, Patentability of Human-Animal Chimeras, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 51, 70–71 (2009)
[71] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).
[72] It was later clarified that many biotechnology patents remain unaffected under this section and human embryos, human/non-human chimeras, human fetuses, and human beings were exclusively included in the 'human organism' list. 157 CONG. REC. E1178 (daily ed. June 23, 2011) (statement of Rep. David Weldon)
[73] Judge Story in Lowell v. Lewis, 15 F. Cas. 1018 (C.C.D Mass. 1817)
[74] Evans v. Eaton, 16 U.S. 454, 519 (1818).
[75] *Id.*
[76] Brenner v. Manson, 383 U.S. 519, 534 (1966).

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.'[77]According to the Revised Interim Utility Guideline Training material of the USPTO, a patent application has to meet the requirement of having a specific, substantial, and credible utility; however, no information is given with regards to moral utility. The latest checklist on patentability subject matter identifies three exclusions: laws of nature, physical phenomena and abstract ideas. [78, 79] Furthermore, the refusal decision occurred within the frame of exclusion from patentability on the grounds of distinction between an 'invention' and 'discovery', as explained in *Morton v. N.Y. Eye Infirmary.* [80] 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'.[81] The *Morton* case also meant a limitation on a 'patent for method of surgery involving administration of sulphuric ether to the patient to render the latter unconscious was invalid, but on basis that it involved new use of known substance.'[82] Furthermore, cases like *Ex p. Brinkerhoff*[83] 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.[84]

The above judgments shed light on the concept of moral utility. However, as discussed above, a different approach was adopted by the U.S. Court of Appeals for the Federal Circuit in *Juicy Whip Inc v Orange Bang Inc*, [85] in which a patent application was submitted for a juice machine potentially capable of misleading consumers. In defence of the patent, Circuit Judge Bryson stated, '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.'[86] Although the Federal Circuit 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 on a number of other occasions. On one such occasion 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 a patent operates 'to perform the functions, and secure the results intended, and its use is not contrary to law, moral principles, or public policy', one may establish that it has utility.[87] Therefore, while comparing *Geneva Pharmaceuticals, Inc. v. Glaxosmithkline PLC* with *Juicy Whip Inc v Orange Bang Inc* or *Whistler Corp. v. Autotronics*

[77] Brenner v. Manson, at p. 695.
[78]U.S. Patent & Trademark Office, Revised Interim Utility Guidelines Training Materials 3, http://Www.Uspto.Gov/Web/Menu/Utility.Pdf.
[79] The 2010 *Bilski* decision was a milestone case in which the U.S. Supreme Court by a majority acknowledged a slightly new approach to determine the eligibility for patenting on the basis of which the exclusions are limited to the mentioned three groups. Bilski v. Kappos, 561 U.S. 593, 130 (2010).
[80] Morton v. New York Eye Infirmary, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862)
[81] Judge Shipman in Morton v. New York Eye Infirmary. Pat. Cas.,320; Fed. Cas., No.9865.
[82] *Id.*
[83] Ex p. Brinkerhoff (1883) reprinted in 27 J. Pat. Off. Soc'y 797 (1945).
[84] EDDY D. VENTOSE, MEDICAL PATENT LAW: THE CHALLENGES OF MEDICAL TREATMENT (2011) and John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV, 634 (2009).
[85] Juicy Whip Inc v Orange Bang Inc, 185 F.3d 1364, 1366-67 (Fed. Cir. 1999)
[86] Juicy Whip Inc v Orange Bang Inc, 185 F.3d 1364, 1366-67
[87] Geneva Pharm., 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)).

Inc.[88], it is possible to argue 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 are, to some extent, related to a requirement of conformity to morality and public policy, such as *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft.*[89] In these cases, the court decided that the usefulness criterion 'has […] been interpreted to exclude inventions deemed to be immoral'.[90] Furthermore, in the case of *Am. Standard Inc. v. Pfizer Inc*.[91] it was decided that 'to be useful, the patent's purpose must not be illegal, immoral or contrary to public policy'. [92] U.S. patent law scholars point out that the interpretation of moral utility is not a matter that can be fixed in time but will vary across generations. 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'.[93]

Stuart Newman, a cellular biologist who opposed the patentability of inventions involving ethical controversy in relation to genetic engineering and the patenting of life forms, applied to register a patent for a half-human half-animal species in 1998. [94] Rather than intending to create such an animal-human hybrid, Newman aimed to 'reignite debate about the ethics of genetic engineering and the patenting of life forms'. [95] The USPTO rejected Newman's application on the grounds that 'claims "embracing" humans and human embryos are not patentable'.[96] As a consequence of Newman's patent application, a 'media advisory' relying on Justice Story's formulation of moral utility doctrine was issued.[97] Such an extreme application was probably one of the main reasons the USPTO denied the patent application, for being immoral. However, it is not clear why the Revised 2001 Examiner Guideline does not include any note of morality or public policy issues.[98] In another example, the USPTO claimed the authority to reject patent applications solely on moral grounds when the Organisation of African Unity decided to refuse drugs manufactured based on natural products found in Africa if the 'ownership' and contribution of the respective community in the new product was not officially acknowledged.

[88]Whistler Corp. v. Autotronics Inc., 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Texas 1988).
[89]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."
[90] *Id.*
[91] Am. Standard Inc. v. Pfizer Inc., 722 F. Supp. 86, 150 (D. Del. 1989).
[92] *Id.*
[93] PETER D. ROSENBERG, PATENT LAW BASICS 8.05 (10th ed. 2002).
[94] See Group Faults PTO for Issuing Patent on 'Method of Producing Cloned Mammal,' 64 PAT. TRADEMARK & COPYMGHTJ. 81 (2002)
[95] See Group Fault, at 81. 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.'
[96] Patent Application Is Disallowed As 'Embracing' Human Being, 58 PAT. TRADEMARK & COPYRIGHTJ. 203 (1999).
[97] Benjamin D. Enerson, Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine, 89 Cornell L. Rev. p 693 (2004)
[98] See Group Faults, *supra* note 94, at 81

This was intended to support the benefit and ownership of the indigenous local community over the products for 'all times and in perpetuity'.[99]

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.'[100] To be precise, the USPTO authorized 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'.[101] Opponents of patenting genetically engineered human materials, especially, the Centre for Technology Assessment (CTA) opposed the decision and the permissibility of human cloning emphasising 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 so in the case of the Missouri patent.'[102]

Decisions in *Newman*, *Missouri* and other cases discussed above illustrate the 'continuing controversy' around the idea of biotechnology patents in which the PTO and Federal Courts have been reluctant to fully revive the moral utility doctrine.[103] Courts, it seems, have dropped moral utility doctrine and now make decisions on biotechnology patents in reference to a new 'Products of Nature Doctrine'.[104] This 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'[105] – is now restricted by 'Products of Nature Doctrine'.[106]

Although there is no specific reference to morality or ethics in the section on utility of the USPTO's Manual of Patent Examining Procedure, the case of *Juicy Whip* is cited emphasising, 'A rejection under 35 U.S.C. 101 for lack of utility should *not* be based on grounds that the invention is frivolous, fraudulent or against public policy.'[107] The USPTO's website, however, states that inventions 'offensive to public morality' may not be patented. This may be viewed as leaving the door open for the rejection of patents on moral grounds.[108] The U.S. has addressed the issue of morality – in particular with biotechnology patents – through 'evolving

[99]Meredith Wadman, *US Office Claims Right to Rule on Morality*, NATURE 393, 200 (1998) at http://www.nature.com/nature/journal/v393/n6682/full/393200b0.html.
[100] U.S. Patent No. 6,211,429 (issued Apr. 3, 2001).
[101] *Id.*
[102] See Group Faults, *supra* note 94, at 81.
[103] ENERSON, supra note 97, at 685 (2004)
[104] John M. Conley & Roberte Makowski, *Rethinking the product of nature doctrine as a barrier to biotechnology patents in the United States—and perhaps Europe as well*, Information & Communications Technology Law, Volume 13, 2004 Issue 1. pp. 3-40 (published online 22 January 2007)

[105] Diamond v. Chakrabarty, 447 U.S. 303, 316-317 (1980).
[106]See e.g., John M. Conley, Gene Patents and the Product of Nature Doctrine, 84 Chi.-Kent L. Rev. 109 (2009). Available at: https://scholarship.kentlaw.iit.edu/cklawreview/vol84/iss1/6;
[107] U.S. Patent & Trademark Office, Manual of Patent Examining Procedure, 706 Rejection of Claims, https://www.uspto.gov/web/offices/pac/mpep/s706.html[perma.cc/QGW8-HUVY] (emphasis in original) (citing Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367–68 (Fed. Cir. 1999)
[108] Patent FAQs, *supra* note 46; *see* Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 Cornell L. Rev. 685 (2004)

case law'. However, it is argued that the current system may change, partly due to bipartisan interest within Congress to amend the patent statute.[109,110]

This section asserted the constitutional basis for protecting the values of human rights and advancing the moral utility doctrine. The next section will spell out the Principle of Generic Consistency and elaborate further on the setting of the concept-theoretic framework proposed in this article.

Part II: The Principle of Generic Consistency and the Possibility of Reconciling Competing Rights in Grant of Patents of Biotechnological Inventions

A. The Structure and Function of the Principle of Generic Consistency

Arguments for or against permissibility of actions unavoidably adopt a particular moral perspective. The concept-theoretic position proposed in this article rests on the moral theory of the American philosopher, Alan Gewirth. The approach which Gewirth follows in his argument is best known as 'ethical rationalism'[111], 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'. PGC is the 'supreme rational reference point for judging the permissibility of all action'.[112] 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'.[113] The fullest statement of Gewirth's principle is found in his *Reason and Morality*, although the principle was developed in his earlier work. The 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 its own agency if 'it does not consider the sufficient reason why it has the generic rights to be'. 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

[109] This means decisions such as *Myriad* may be overruled. Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[110] *See* Press Release, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act [https://perma.cc/KG55-PVWH]

[111] See e.g., DERCYK BEYLEVELD AND R BROWNSWORD, LAW AS A MORAL JUDGMENT (Sweet & Maxwell, 1986, reprinted by Sheffield Academic Press, 1994). Stanley Paulson suggests the ethical rational and legal idealism discussed by Beyleveld and Brownsword in this book is 'something akin to Kantian natural law theory. Stanley S. Paulson, *Review of Law as a Moral Judgment* (1994) 7 Ratio Juris 111.
[112]Deryck Beyleveld, *The Principle of Generic Consistency as the Supreme Principle of Human Right*, 13 HUMAN RIGHTS REV. 1, 2 (2012).
[113]ALAN GEWIRTH, REASON AND MORALITY, THE REVIEW OF METAPHYSICS, 579 (1978).

might contingently possess). Therefore, no additional or stronger generic rights can be conferred on agents by their having characteristics not necessarily possessed by all agents'. [114]

According to the Gewirthian moral theory, agents are 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.[115] It should be noted that under Gewirthian theory, agency is not [116] necessarily conterminous with possessing human life 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.[117] Furthermore, not all forms of human life as biologically defined – for example, infants and persons who lack full mental capacity – would satisfy the requirement.

To define the generic rights of agency, Gewirth argues that features are generic, in so far as that the possession of such characteristic is necessary for all agents to act. In other words, 'generic rights are rights to generic needs of agency'.[118] Generic needs of agency or generic features of agency are those capacities required 'to be able to act at all or with any general chances of success, whatever [the] purposes might be'.[119] Based on this definition, Gewirth draws the line in a way that suggests 'action' as a necessary foundation of morality, and the mentioned generic features as the 'substratum of action'.[120] He argues that a comprehensive analysis of action can ground a normative structure, 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.[121]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 emphasizes 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'.[122] In *The Epistemology of Human Rights*[123] he claims that:

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[114] Deryck Beyleveld, *The Moral Status of the Human Embryo and Fetus in* THE ETHICS OF GENETICS IN HUMAN PROCREATION, 59-85 (Hille Haker & Deryck Beyleveld eds., 2000).
[115] GEWIRTH, *supra* note 113 at 41-43, 52-53.
[116] Phil Bielby (2008, p.68, 248) states that 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. See Phil Bielby, Gewirth's Theory of Agency Rights. In: Competence and Vulnerability in Biomedical Research. International Library of Ethics, Law, and the New Medicine, vol 40. (2008, Springer, Dordrech); DERYCK BEYLEVELD. THE DIALECTICAL NECESSITY OF MORALITY. AN ANALYSIS AND DEFENSE OF ALAN GEWIRTH'S ARGUMENT TO THE PRINCIPLE OF GENERIC CONSISTENCY (Chicago: University of Chicago Press, 1991); ALAN GEWIRTH, HUMAN RIGHTS: ESSAYS ON JUSTIFICATION AND APPLICATIONS (Chicago: University of Chicago Press, 1982).
[117] Deryck Beyleveld & Roger Brownsword, *Human Dignity, Human Rights, and Human Genetics* 61 MOD. L. REV. 661 (1998).

[118] GEWIRTH, *supra* note 113, at 25-26.
[119]Deryck Beyleveld and Shaun D. Pattinson, *Precautionary Reasoning as a Link to Moral Action in* MEDICAL ETHICS 39 (Michael Boylan ed., 2000).
[120] GEWIRTH, *supra* note 113, at 26
[121] *Id.*
[122] Deryck Beyleveld and Roger Brownsword, *Human Dignity in Bioethics and Biolaw* 71 (2001).
[123] Alan Gewirth, *The Epistemology of Human Rights* 1 SOC. PHIL. & POL'Y18 (1984).

> …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.[124] 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'.[125] 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.[126] A common factor between non-subtractive and additive needs is that both classes of needs are needed for 'successful action' rather than action itself.[127]

In order to identify the generic condition of agency, an analytical approach is needed, and the examples are neither inclusive nor conclusive of the validity of Gewirth's argument and are set here only to clarify a number of key issues about the abstract idea of the generic conditions of agency.[128] Hence, these terms will be elaborated on further through the application of the PGC in part III of this article.

Addressing the question of morality, one of the most common and crucial concepts in human rights debates, is of utmost importance for human dignity. 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 in legal systems exists and needs to be dealt with. To strike a balance between these conflicting rights, different approaches may be adopted. For instance, the European Court of Human Rights implements the proportionality

[124] GEWIRTH, *supra* note 113, at 52-54.
[125] GEWIRTH, *supra* note 123, at 71.
[126] GEWIRTH, *supra* note 113, at 56.
[127] Gewirth in REASON AND MORALITY (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.
[128] GEWIRTH *supra* note 113, at 2.

test to decide which right should override another.[129] However, in order to evaluate the importance of one right over another and make it the basis for striking a 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 right 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.

Human rights documents often provide no statements regarding the hierarchy of rights even though it seems that rights explained in earlier Articles hold greater importance than the rights in later articles.[130] However, using the PGC enables users to understand how and why they are allowed to act or not act. The Generic Condition of Agency (GCA) 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.[131] Hence, if an agent loses the requirements for the GCA, then they 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'.[132] 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 – there is no exception.[133] 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 binding when they are in accordance with the PGC.[134] However, actions might be in accordance with the PGC in some

[129] See e.g., Stavros Tsakyrakis, *Proportionality: An assault on human rights?* International Journal of Constitutional Law, Volume 7, Issue 3, July 2009, Pages 468–493, available at: https://doi.org/10.1093/icon/mop011.

[130] GEWIRTH, *supra* note 123, at 85.

[131] GEWIRTH *supra* note 113; ALAN GEWIRTH, THE COMMUNITY OF RIGHTS (Chicago: Chicago University Press, 1996)

[132] GEWIRTH, *supra* note 123, at 85.

[133] 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.

[134]Due to radical nature of Gewirth's claims there have been academic resistance to the PGC. Here, I do not intend to defend Gewirth's original dialectically necessary argument in its entirety, but to explain the alternative approach proposed by Deryck Beyleveld, the dialectically contingent argument and its limitations and force. I argue that if it can be shown that three propositions are true, then the PGC is the categorical imperative (BEYLEVELD 2016, at 5). The first proposition is that it is dialectically necessary for agents to accept the 'Principle of Hypothetical Imperatives' (PHI). BEYLEVELD (2013, at 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 action. This is because, as GEWIRTH (*supra* note 113, at 53-54) notes, 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, 4). This is how the 'dialectically necessary' argument is spelled out by Gewirth & Beyleveld. However, there are 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. See e.g., Dercyk Beyleveld, A Theoretical Framework for Integrating Ethics and Law (2016) available at: https://www.dur.ac.uk/wolfson.institute/news/?itemno=27806. accessed 10 January 2018.

circumstances and not in accordance with the PGC in other circumstances.[135] 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 (listed in the sentences below) must yield to the second alternative.

> ….[W]hen 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.'[136]

I emphasize that the main function of this part of article is to develop an applicable framework based on the Principle of Generic Consistency, in order to apply it in the next part of the article. 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. The PGC provides that all agents categorically ought to respect the generic rights of all agents. The principle grants rights of the generic condition of agency to all agents.[137]

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)[138], whereas in direct application of

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[135]DERYCK BEYLEVELD, THE DIALECTICAL NECESSITY OF MORALITY: AN ANALYSIS AND DEFENSE OF ALAN GEWIRTH'S ARGUMENT TO THE PRINCIPLE OF GENERIC CONSISTENCY 32 (1991).

[136] GEWIRTH, *supra note* 113, at 341-42.

[137] In this article, I focus on the Beyleveld's alternative argument that builds upon the conclusion of stage I for the interpretation of human rights. The Alternative Argument was first established by Deryck Beyleveld and Roger Brownsword and 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 *supra* note 112). To apply Gewirth's theory, I use only the first and the least controversial stage of his argument for the Principle of Generic Consistency that emphasises the first element of his theory, his claim that PHI is an *a priori*, or dialectically necessary, principle.
I argue that, supposing the first stage is sound and valid, if I accept there are human rights and that it is dialectically necessary to accept the Principle of Hypothetical Imperatives, I have to accept the Principle of Generic Consistency or give up the idea that there are human rights, or I show that the Principle of Hypothetical Imperatives is not dialectically necessary (BEYLEVELD *supra* note 112, 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 categoric. What the alternative argument does is 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 the UDHR provide that all human beings are equal in dignity and rights. This notion of equality in dignity and rights 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 stays firm, and the categorically instrumental requirements are universalised. It means that de facto rights have to be under the will-conception.

[138]GEWIRTH, *supra note* 113, at 340.

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.[139]

b. Is the PGC workable in balancing right in the U.S. patent system?

"The PGC is the constitutional norm of any legal order."[140]

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.[141] 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[142] was or in Ronald Dworkin's arguments.[143] Hart strongly objected to Devlin's position because he believed that the questions of what the law is and what the law ought to be are different.[144] Writing in the context of the Wolfenden Report, however, Devlin argued that public morality should influence the development of the law. Devlin's arguments are believed to be in favour of 'society's right to protect its own existence' and to protect the majority's right to follow its own moral convictions in defending its social environment from change it opposes'.[145] Analysing the debate between the two, Peter Cane states, 'Underpinning the Debate is a picture of the relationship between the legal answer and "moral" answers according to which conflict between them should be resolved in favour of morality. This is (partly, at least) because the "moral" answer is understood to be the product of reason whereas the legal answer is conceived as the product of political conflict and compromise rather than reason'.[146] 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

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[139] Gewirth, *supra note* 123, at 70-71.
[140] DERYCK BEYLEVELD & ROGER BROWNSWORD, *supra* note 111, AT 162.
[141] PATRICK DEVLIN THE ENFORCEMENT OF MORALS (1965).
[142] H.L.A. Hart, *Positivism and the Separation of Law and Morals,* 71 HARV. L. REV. 593 (1958).
[143] Gerald Dworkin, *Paternalism in* PHILOSOPHY, POLITICS, AND SOCIETY, FIFTH SERIES: A COLLECTION (James S. Fishkin & Peter Lasletteds.). 1979).
[144] Ronald Dworkin, *Lord Devlin and the Enforcement of Morals,* 75 YALE L. J. 986-1005.
[145] *Id* p.988
[146] Peter Cane, *Taking Law Seriously: Starting Points of the Hart/Devlin Debate*, The Journal of Ethics, Jan., 2006, Vol. 10, No. 1/2 (Jan., 2006), p.50.

beyond the fact of passionate public disapproval to show that we are in the presence of an actual threat?[147]

Whether the PGC as 'a framework principle for integrating ethical and legal analysis'[148] is a useful tool for analysing the U.S. patent system is clearly in the affirmative for several reasons, most importantly the following argument. The concept-theoretic position can simply be fitted into the U.S. law even without an explicit morality exclusion.[149] Even if one questions the enforceability or commitment to the UDHR as international human rights law in the U.S. system, as discussed in the first part of this article, the answer can be provided using the American equivalents of article 2 of the UDHR in the U.S. system, which are of course fundamental parts of the nation's law. As discussed earlier in the justification of the PGC as a theoretical framework, any system of law 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 implication of the concept-theoretic position based on the recognition of human rights[150] is that in order to accept the PGC, a legal system needs to accept the UDHR and its Articles, particularly Articles 1 and 2, and have national equivalents of such articles in place that effectively provide equal protection under the law.[151] The reason is that because of Articles 1 and 2, human rights conventions actually adhere to impartiality. In the case of the United States, if the legal system adheres to this impartiality premise, which it does, then the system is bound to the PGC. This means the law in this system must be in line with the PGC. The United States legal system is built upon the recognition of human rights, equality and impartiality as evidenced in the preamble to Constitution, Bill of Rights, Declaration of Independence.[152] The system is therefore bound to follow the PGC. Whether or not it actually does follow the PGC becomes the question of various doctrines, including moral utility, and all the actual features of the way in which patents are granted.

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. Furthermore, the International Covenant on Civil and Political Rights has been ratified (with some reservation) in the United States 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

[147] Ronald Dworkin, *Lord Devlin and the Enforcement of Morals,* 75 YALE L. J. 986-1005.
[148] Deryck Beyleveld *A Theoretical Framework for Integrating Ethics and Law*, WOLFSON BLOG & NEWS (Apr. 25, 2016)
[149] 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. *Supra* note 113, at 13.
[150] See Beyleveld (2012), note 67 on Beyelveld's alternative model: a dialectically contingent approach.
[151] This is to emphasise 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.' This is what needed to recognise the validity of stage 1 of the PGC.
[152] See e.g. pp. 5-7.

a treaty – according to Article VI, Clause 2, similar to the Constitution itself – is called the 'supreme law of the land'.[153]

Practically, an analysis of morality in U.S. patent law is to a great extent similar to an analysis of the European patent system. In a European context, I argue that regardless of what the European Patent Office or the Court of Justice of the European Union decide, Europe belongs to a system governed by the primacy of human rights and therefore its law has to be interpreted in line with the PGC as the supreme principle of human rights; anything in violation of morality and human rights cannot be acceptable. The same analysis applies in the case of U.S. patent law: There are no explicit morality exclusions. However, fidelity to human rights is explicitly present in the U.S. Constitution. Even if one questions the effect of international human rights treaties in the U.S., it could be argued that this commitment, as discussed earlier, comes mainly from the Preamble and the Declaration of Independence. The U.S. patent system does not seem very different in its essence, regardless of what may seem dissimilar in incorporating morality exclusion in patent law. This means the PGC fits perfectly into the U.S. patent system in order to interpret the conflict of rights and would be equally effective in the system.[154] Therefore, the permissibility of any activity requires assessment, according to the PGC.

The next part aims to implement the concept-theoretic position on *Hagahai* patent case. In Part III, I will elaborate on the structure of the Principle of Generic Consistency, focus on Gewirth's conception of agents and generic rights, and discuss how far the Gewirthian analysis supports the view that respect for human dignity requires prohibitions on commercialization of genetic materials in some circumstances, particularly as found in the patent case of the Hagahai people.

Part III: The Case of the Hagahai People

The case of the Hagahai people[155] regards the connection between the donation of biological materials and the purpose of medical research, and the proximity between the donor and the potential benefit gained from a product that is patented – in this case, a medical test. In fact, the Hagahai case is relevant to obtaining consent from patients and the link between consent arrangement and a patent system. The significance of this case is in regard to a cell line infected with the virus of T-Lymphotropic developed from the DNA of a Hagahai donor, a member of an indigenous group in Papua New Guinea, which the U.S. National Institute of Health attempted to patent in 1991.[156]

The Hagahai tribe lived in isolation and had no contact with outsiders until 1984 when some tribe members sought outside help to cure a disease in the population. While helping the Hagahai people, scientists noticed the human T-cell leukaemia virus ('HTLV-I') that usually produces severe leukaemia had infected the Hagahai people but was benign in the

[153] Penny M. Venetis, *Making Human Rights Treaty Law Actionable in The United States: The Case for Universal Implementing Legislation (*2011) Alabama Law Review. 63(1) 97. 333
[154] 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) 247
[155] Papua New Guinea human T-lymphotropic virus, US patent 5397696.
[156] David Robie, Cell lines and commodities: The Hagahai patent case (1997) *Pacific Journalism Review.* 4, 78.

population.[157] Researchers created a cell line of Hagahai DNA, which offered potential for the development of diagnostic tools or vaccines for certain types of leukaemia. In 1995, the patent titled 'Papua New Guinea Human T-lymphotropic Virus' was granted to U.S. scientists and 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 had been explained to the Hagahai donors.[158]

The controversy was not limited to the informed consent procedure but included the accusation of bio-piracy. As Shiva in *Biopiracy: The Plunder of Nature and Knowledge* emphasizes,[159] if a technologically advanced country or organization intends to commercially develop an invention in genetic research like this, there has to be fair compensation to the nation from which the material research is sourced. The government in Papua New Guinea raised issues concerning the violation of the nation's sovereignty[160], and non-governmental organisations started to investigate the case in order to understand whether consent should have been obtained from the Hagahai donors before the patent application, as well as whose consent should have been obtained – the individual's, the state's or that of the Hagahai people. Obtaining genetic materials from indigenous people understandably gave rise to sensitivity and controversy over this patent due to the possibility of bio-piracy.[161] 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 materials and resources were discussed at the time to better understand the legality of performing research and the commercialisation of inventions in this situation and similar scenarios. [162]

With regards to the concept of ownership of the materials, the researchers in this project claimed that the tribe were aware of the idea of a patent and had a 'clear understanding of the concept of ownership'. [163]They also claimed an agreement existed, the details of which were not clear, but where the Hagahai people were given the promise of receiving royalties coming from any commercial income generated from the vaccine or any diagnostic tool.[164] Ultimately, and under considerable pressure, the U.S. National Institute of Health 'disclaimed' the patent at the U.S. Patent and Trademark Office (PTO) in late 1996. The NIH, without any clear justification, opted to abandon all U.S. government rights in relation to the patent, indicating

[157] Gary Taubes, Scientists Attacked for 'Patenting' Pacific Tribe, Science, Nov. 17, 1995, at 1112
[158]J. GIBSON (2009). INTELLECTUAL PROPERTY, MEDICINE, AND HEALTH: CURRENT DEBATES. Farnham, England, Ashgate, 128. The Modern Law Review , Sep., 1998, Vol. 61, No. 5, Human Genetics and the Law: Regulating a Revolution (Sep., 1998), pp. 740-765
[159] VANDANA SHIVA (1997). BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE. Boston, Massachusetts: South End Press, 4.
[160] Tempest Ending for 'Cell Line:' U.S. Stepping Back from Genetic Patent, Arizona Republic, Sept. 22, 1996, at A18
[161] David Robie, Biotechnology-South Pacific: Tribe Caught in Blood Tug-of-War, Inter Press Service, Oct. 25, 1995, available in 1995 WL 10135200.
[162] Alain Pottage, The Inscription of Life in Law: Genes, Patents, and Bio-Politics, The Modern Law Review , Sep., 1998, Vol. 61, No. 5, Human Genetics and the Law: Regulating a Revolution (Sep., 1998), pp. 740-765
[163] ROBIE, *supra* note 161, at 81.
[164] Gary Taubes, supra note 257Scientists Attacked for 'Patenting' Pacific Tribe, Science, Nov. 17, 1995.

that it fortified all the government's 'past and future rights in each and every claim of United States Patent No. 5,397,696[...] thereby relinquishing all control over said patent'.[165]

Based on the controversy regarding this patent, the question of how, when and in which stages consent ought to be obtained from patients is still alive and well. The question also includes the debate over whether initial consent can be extended to include further uses of the material in research, whether invention based on donor tissues can be commercialised, and whether it is required to ask the donor's consent at each stage of research development and subsequent commercial exploitation. As things currently stand, clarity is lacking on these issues.

The Case of the Hagahai People viewed in concept-theoretic position (PGC)

i. What power does the patent give to the patent holder?

Had it not been abandoned by the U.S. National Institute of Health (NIH), the patent could have provided exclusive rights to develop a vaccine with considerable revenue-generating capability for the NIH.

ii. How can the exercise of power directly or indirectly lead to consequences contrary to the PGC?

In the Hagahai case, the fact that the genetic material of an underdeveloped tribe was used in a patent for a developed country without the suppliers of the biological material being properly appreciated or compensated raises concerns of significant asymmetry of information and bargaining power.

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 was to be done with their genetic material. It is a requirement that donors choose freely to participate and be fully informed about the purpose of the research and any future use, and that the research would not continue without that communication. Finally, it becomes problematic if researchers fail to recognise or give the impression that they do not recognise the donors as fellow agents.

Under Gewirthian terminology, all human rights must be recognized 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.[166] This assistance to secure other agents' GCA may however come together with disproportionate risk to their own possession of GCA. Therefore,

[165]Sally Lehrman, 'US drops patent claim to Hagahai cell line' (1996 Dec 12) *Nature* 384(6609):500.
David Robie (1997). Cell lines and commodities: The Hagahai patent case. *Pacific Journalism Review.* 4, 78-91.

[166] ALAN GEWIRTH (1996). THE COMMUNITY OF RIGHTS. [Chicago: University of Chicago Press] 59.

as Gewirth provides, it is mainly the responsibility of collectives rather than individuals to protect the positive generic interests of other agents.

Under such line of analysis, it is necessary to find out whether 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. A number of issues including 'human dignity', 'autonomy' and the 'interest of indigenous people' are relevant to this case. Considering the concept of human dignity, according to Article 1 of UDHR, all human beings are equal in dignity and rights from which it 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 interests 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 two agents over their GCA, priority will be given to the GCA that most requires action.

In this case, the U.S. researchers listed as 'inventors' could argue that the patent – built upon samples taken from the Hagahai people – has the potential for the development of vaccines for certain types of fatal diseases, which means it may also support the high level interests of other agents. This is a promising way to introduce cures for serious health conditions, and it may gaffect the GCA to this certain extent. 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 the patent owner could do this differently?

To address the topic of this section, it is necessary to answer a number of questions under the concept-theoretic position proposed in this article. The first question is whether it is necessary to obtain the Hagahai people's 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.[167] If certain actions can be carried out without the proper consent of donors, the 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 consent was obtained.

[167] See e.g., DERYCK BEYLEVELD & ROGER BROWNSWORD (2007). CONSENT IN THE LAW. Oxford: Hart Publishing.

The next question is whether an objective is necessary and sufficiently justified. 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. Genetic researchers commonly claim that developing new treatments for life-threatening diseases justifies the use and analysis of genetic material from groups of indigenous people,[168] 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.'[169] However, there is an obvious burden of justification in such a special case. If it is true that the Hagahai patent scientists would not be able to make these advances and cure people with these diseases unless they obtain these biological materials from these indigenous people without their consent, and they are allowed to obtain the patent on it again without their consent and with no financial remuneration for them, then the right of scientists to conduct this research and progress the science may override the right of Hagahai people. However, these arguments are all questionable.

If proposed by the inventors in this case, such hypothetical claims would have been accepted given convincing answers for the following questions:

1) Is it necessary to obtain this genetic material only from this tribe?

2) Is it necessary to obtain this genetic material without proper informed consent? Have the Hagahai people (all or some of them) refused to consent to participate in the research?

3) Is it necessary to file a patent to carry out the research?

4) Is it necessary to obtain this material without considering any fair compensation, benefit sharing or incentive?

According to the concept theoretic position, in order to be able to override the consent, the answers to the above questions should be affirmative, which in this case they are not.

I. Whether they can obtain 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.

[168] See e.g., Teresa Riordan, Patents; A recent patent on a Papua New Guinea tribe's cell line prompts outrage and charges of 'biopiracy.' (*The New York Times*, Nov. 27, 1995)
[169] DERYCK BEYLEVELD & ROGER BROWNSWORD, CONSENT IN THE LAW (Oxford: Hart Publishing, 2007), at 123.

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, in a study regarding the impediments to biomedical research, highlight the existence of other methods rather than patents in which the investment in a research can be protected.[170] 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 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 have been granted.

Concluding Remarks

In this article, I 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. I have briefly argued the similarities and differences of inclusion of morality in the EU and U.S. patent system. I have also argued that even if there were an official notion of moral neutrality in the court or legislation, this approach is still problematic.

Comparing the European position with U.S. patent law, a PGC framework can also be fitted in the U.S. system. The U.S. is signatory to different UN human rights covenants[171] making the arguments presented in this article, in a sense, parallel to the argument in the EU case. The article 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 upon which the European model is established: universal human rights principles. With this in mind, both the European and U.S. systems share a high level of equivalent protection of human rights, including concepts like respect for human dignity,

[170] Wesley M. Cohen & John. Walsh, 'Real Impediments to Academic Biomedical Research' (2007) *Innovation Policy and the Economy* 8, 1-30.

[171] As discussed in part II of this article, because these declarations incorporate the principle of impartiality, and because the Principle of Hypothetical Imperative is dialectically necessary, unless these principles-that human rights are inalienable and possessed by all, and that human beings are equal in dignity and in having rights- are tossed aside, the declarations have to confirm to the Principle of Generic Consistency.

autonomy, free will and informed consent. Although the European Biotechnology Directive is an effective instrument in giving direction to patent activities in Europe, even if it were not enacted, it is clear that no patent, or other, activities in violation of fundamental principles of EU law, including any moral values, would 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 the 'moral utility doctrine' and the recognition of human rights via international means and national equivalents of the UDHR, means that the patent system in the U.S., with regard to morality exclusions, does not differ systematically from the EU framework. For these reasons the proposed concept-theoretic position in this article is equally applicable to both the European and American patent systems.