

PATENCY OF LIVING ORGANISMS: THE ROAD
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Introduction

Gerrtrui Van Overwalle refers to a patent as a “legal title granting its holder the exclusive right to exploit” an invention.¹ It is implicit in any patenting system that *someone*, if not the patent-holder, is usually entitled to exploit an invention for commercial purposes.² In fact, patents typically grant a limited monopoly to patent-holders in order to reward inventors for putting the details of their invention into the public domain. Even if the patent-holder does not own the patented invention, it is typically the case that someone else is entitled to do so; and is thus in a position to use, sell, profit from, and even give away or destroy the patented invention.

Patent law follows the traditional property law principle that “[from the moment] the inventor made the invention, he *owned* it.”³ Yet patent protection does not confer upon the individual the right to make the product, but the right to “*exclude others* from making, using, or selling [the product] for a limited time.”⁴ This grant of exclusivity is presumed to encourage the disclosure of new inventions to the public, which further encourages production.⁵ It has been posited that the patent system is the very reason why this nation has experienced such remarkable technological advances.⁶

LAW AND MORALITY: A QUESTION OF MORAL BANKRUPTCY?

Utilitarianism in Patent Regime-

The starting premise is that law is grounded in utilitarian notions.⁷ Arguably, the role of law is to create an organized society in which individuals are protected from harm that might

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¹ Van Overwalle, 1997 (pp. 139-148). The quotation comes from p.139

² Hence the significance of the denial of any positive rights by the EPO in the case of the onco-mouse. See Munzer, p. 447, who notes that the EPO stressed that all it was granting was the right to exclude others, rather than a “positive right to use the invention”.

³ Howard T. Markey, *Special Problems in Patent Cases*, 66 F.R.D. 529, 531 (1975).

⁴ Michael E. Sellers, *Patenting Nonnaturally Occurring, Man-Made Life: A Practical Look at the Economic, Environmental, and Ethical Challenges Facing “Animal Patents”*, 47 ARK. L. REV. 269, 292- 93 (1994) (emphasis added); see also 2 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND

*2 (defining a property right as “that sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe”)

⁵ Overwalle, *supra* note 1 at 531-532.

⁶ *Id.* at 533.

⁷ See John Stuart Mill, *Utilitarianism* (1863).

affect individual's interest. John Stuart Mill maintained that the 'only purpose for which power can be rightfully be exercised over any member of a civilized community against his will is to prevent harm to others', and liberty requires that the law not compel people to moral action simply because it is moral or ethical.⁸ Rather the law's concern is with regards to how best to achieve the 'greatest good for the greatest number of people'.⁹ This can be said to justify the present patent law regime.

It has been said that the main justifications for instituting the patent system are to promote and encourage creativity as well as to reward innovation.¹⁰ Accordingly, the patent system has been described as a social contract whereby limited monopoly rights in the form of patent grants will be awarded to those who create innovations which are 'socially enhancing' in terms of being 'conducive to social and economic welfare'.¹¹

So, it can be well observed that the patent law system both inherently accepts the concept of utilitarianism as well the underlying principles of the social contract theory.

Role of Morality in law:

Some consider that the patent law system is based on moral considerations to some extent, if not wholly based on it. One of such authors, Vaver contends that, as a matter of natural right, 'society is obliged to reward persons to the extent that they have produced something useful for it'.¹² Following this contention, it is a matter of 'natural' or moral right that patent laws reward the labour and product of one's mind or intellect.¹³ The other sense in which morality

⁸ John Stuart Mill cited in H L A Hart, „Law, Liberty and Morality“, in Don D Welch (ed), *Law and Morality*, (1987) 43, 43.

⁹ Jeremy Bentham, *An Introduction to the Principles of Morals and Legislation* (1789), 2; Jeremy Bentham cited in Rosemary Hunter, Richard Ingleby and Richard Johnstone (eds), *Thinking About Law: Perspectives on the History, Philosophy and Sociology of Law* (1995), 43.

¹⁰ William M Landes and Richard A Posner, *The Economic Structure of Intellectual Property Law* (2003), 294; Nicol and Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development', above n 3, 348; Robert E Thomas, „Vanquishing Copyright Pirates and Patent Trolls: The Divergent Evolution of Copyright and Patent Laws“ (2006) 43 *The American Business Law Journal* 689, 689. See also World Trade Organisation, „Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods“ in *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations* (1999), Annex 1C (hereinafter referred to as „TRIPS“), Articles 7, 27(1).

¹¹ William R Cornish, *Intellectual Property* (1981), 2; Richard Hoad, „Compulsory Licensing of Patents: Balancing Innovation and Competition“ (2003) 54 *Intellectual Property Forum* 28, 33; Weinrieb cited in Michael D Pendleton, „Challenging Law's Traditional Refusal to Protect Information per se for Fear of Stifling Innovation, Competition and Access“ (2002) 51 *Intellectual Property Forum* 32, 45; Thomas, „Vanquishing Copyright Pirates and Patent Trolls: The Divergent Evolution of Copyright and Patent Laws“, above n 20, 694; TRIPS Article 7.

¹² David Vaver, 'Some Agnostic Observations on Intellectual Property Rights' (1991) 6 *Intellectual Property Journal* 126, 128.

¹³ Liebling cited in Pendleton, „Challenging Law's Traditional Refusal to Protect Information per se for Fear of Stifling Innovation, Competition and Access“, above n 21, 45. See John Locke, *Second Treatise on Government*, in John Locke, *Two Treatises of Government and A Letter Concerning Toleration* (ed.) Ian Shapiro (2003), 111-121 for more on private property and natural rights.

subsists in patent laws is in its concern to protect societal interests in the areas of health and nutrition as well as socio-economic and technological development.¹⁴ On this account, it may be conceded that morality and ethicality plays only a secondary or a subsidiary role in defining or construing the patent law system, and therefore, anyhow morality should not be allowed to overshadow the utilitarian role of the law.

Pollock purports that it is not the obedience to moral precepts that makes a man 'righteous', but that a man is righteous by virtue of the fact that his conduct is grounded in his own personal moral precepts.¹⁵ On this view, law could only be said to be moral if it was grounded in a moral basis. It would not be possible for law and indeed patent law to fully accommodate morality in its entirety. Gitter maintains that 'morality is an exceedingly complex standard to implement as a criterion of patentability'.¹⁶

There are inherent interpretative problems that are associated with any morality clause such as that in TRIPS that patents should be excluded to 'prevent the commercial exploitation of the invention' and to 'protect *ordre public*'.¹⁷ A problem arises as to how far commercial ventures can go before they become a commercial exploitation that would render them contrary to the *ordre public*. Another problem with basing law on moral conceptions is that what society deems morally appropriate tends to change from time to time.¹⁸ All types of morality or morality as a whole cannot completely exist in law as some are directly contrary to the notion of utilitarianism, which are known as non-utilitarian morality. This is the type of morality which Lord Devlin referred to as being "outside of law's business".¹⁹

In the context of biotechnology patenting or patenting of life forms, issues relating to morality fall into both the categories of utilitarian and non-utilitarian morality. Whereas morality of a utilitarian nature may be more easily justifiable as serving to promote the general public interest, moral opinions that are not in line with utilitarian principles, i.e., non-utilitarian morality, tend to be regarded as highly subjective. An example of this is the morality clause in patent laws in some jurisdictions that exclude patentability on the basis that it would amount to a disregard for the sanctity of life.²⁰ It is this highly controversial nature of biotechnological developments which deals with living organisms or components of living organisms that raises non-utilitarian morality issues more prominently than in other areas of

¹⁴ TRIPS Articles 8(1), 8(2).

¹⁵ Frederick Pollock, *Essays in Jurisprudence and Ethics* (1882), 298.

¹⁶ Donna M Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law* 19 *Berkeley Journal of International Law* 1, 21 (2001).

¹⁷ TRIPS Article 27.

¹⁸ Rafal Witek, 'Ethics and Patentability in Biotechnology' (2005) 11 *Science and Engineering Ethics* 105, 110.

¹⁹ Lord Devlin cited in H L A Hart, „Law, Liberty and Morality“ in Don D Welch (ed), *Law and Morality*, (1987) 43, 44.

²⁰ See, for eg, *European Patent Convention*, Article 53(a), 53(c).

patent law.²¹ Therefore, it is said to be an inevitable consequence that biotech patent laws have been criticized as being morally bankrupt.

INTERNATIONAL PATENT REGIME

Economic Significance of Patenting:

On an economic logic, intellectual property rights (IPR) are regarded as an essential component of economy because they commodify the intangible capital of knowledge, generate value and facilitate trading. Without IPR, and in particular patent protection, emerging markets would find it difficult (or more difficult) to develop since the tangible product has yet to appear and economic value is embedded in the potential application of the knowledge. This problem is particularly acute in high-tech and research based Small to Medium Enterprises (SMEs) for whom their IPR is their main asset.²²

The economic significance of patents is further enhanced by the need for new forms of knowledge to compete for attention in an increasingly global venture capital market with its own clear demands: investors, often institutional investors, make their decisions in the light of the patents held by companies.²³

In a perfectly rational world where economic arguments dominate, the political implication of this logic is that states will seek to adjust their patenting policies to enable more knowledge to be patented more efficiently with the intention of maximising their capacity to compete effectively in the global knowledge economy. Patenting policy will be harnessed to the national interest. Further, that having made the domestic policy adjustment themselves they will then apply international pressure for the harmonisation of inter-state patenting policies along lines consonant with their national approach.²⁴

International Scenario:

Although individual states may resist the economic logic of patenting so comprehensively embraced by the United States, the national level is not the only, nor necessarily the most critical, political site where the conflict over the appropriate definitions of ownership of the products of the life sciences takes place. Three international bodies have provided a continuing target for political pressure through their attempts to promote the international harmonisation of patenting rules: the United Nations' (UN's) World Intellectual Property Organisation (WIPO – established in 1967), the World Trade Organisation's (WTO's) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the

²¹ A Jauhar & S. Narnaulia, *Patenting Life the American, European and Indian Way*, 15 Journal of Intellectual Property Rights 55-65 (2010).

²² Gitter, *supra* note 16 at 2.

²³ Florida R and Smith D., *Venture capital, innovation, and economic development*, 4 Economic Development Quarterly 345-60 (1990).

²⁴ Gitter, *supra* note 17.

European Patent Office (EPO – of which more later). The creation of TRIPS in 1994 by the Final Act of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) was in large part a response by developed countries, and in particular the United States, to the manoeuvrings of developing countries within the WIPO during the 1970s and 1980s seeking to resist international encroachments on their sovereign intellectual property rights.²⁵ TRIPS drastically limited their political space in two ways. First, it tied membership of the WTO (which most developing countries wanted and needed) to agreement on TRIPS. (Currently 144 states are members of the WTO and therefore signed up to TRIPS). Second, it set detailed and mandatory harmonising standards of intellectual property law on the ownership of two major technologies: digital technology and, importantly, biotechnology²⁶

The struggle over the TRIPS agenda illustrates that even the economic logic of patenting regulation is less than neutral when political interest is included in the equation: a country's approach to the global harmonisation of patenting will be influenced by the strength or weakness of its competitive position in the international economy. For example, at the insistence of India, Argentina, Brazil, and Turkey, all of whom sought to protect their own industries, TRIPS contains a 10 year delay for the institution of pharmaceutical and agricultural chemical patent protection in developing countries.²⁷

In addition, the *Universal declaration on the human genome and human rights* in 1997 by the International Bioethics Committee (IBC) of the United Nations Educational and Cultural Organisation (UNESCO) initiated a global debate about the moral status of the human body and human life and their relationship to the market that is still gathering political speed in both bioethical and policy making circles worldwide.²⁸

At the conclusion of its 8th Session on 14th September 2001 the IBC adopted by consensus an *Advice on the patentability of the human genome* which states that 'there are strong ethical grounds for excluding the human genome from patentability' and further recommends 'that the WTO, in its review of the TRIPS Agreement, clarify that, in accordance with the provision of Article 27(2)1 (the morality clause), the human genome is not patentable on the basis of the public interest considerations set out therein, in particular, *ordre public*, morality and the protection of human life and health'.²⁹

Landmarks decisions of US SC allowing patenting: Micro-organisms-

²⁵ *Id.*

²⁶ Drahos P with Braithwaite, *Information feudalism: who owns the knowledge economy?* London: Earthscan (2002).

²⁷ Gitter, *supra* 17 at 4.

²⁸ B. Salter B, Bioethics and the global moral economy: the cultural politics of human embryonic stem cell science. Working Paper 3. Global Biopolitics Research Group. University of East Anglia, Norwich (2005).

²⁹ European Group on Ethics in Science and New Technologies, *Ethical aspects of patenting inventions involving human stem cells*. Opinion No 16. Brussels: European Commission (2002).

In *Diamond v. Chakrabarty*,³⁰ the Supreme Court held that genetically-altered bacteria were patentable subject matter. The Court relied on evidence that Congress intended section 101 of the Patent Act to be broadly construed, including a congressional report declaring that the provision encompassed "anything under the sun" made by human beings.³¹ According to the Court, Congress enacted two separate statutes governing plant patents to resolve special patent law questions related to plant patenting, rather than to override the exclusion of living things from section 101 of the Patent Act. 16 For the Court, the important distinction in determining patentable subject matter was "not between living and inanimate things, but between products of nature, whether living or not, and human made inventions."³² Accordingly, a microorganism produced by "human ingenuity and research" qualified as patentable subject matter. Although the government and certain amici argued in *Chakrabarty* that patenting living organisms would present substantial risks to society and the environment, the Court dismissed this material as irrelevant to its decision and more suitable for a congressional inquiry into the appropriate national policy governing genetic engineering activities.³³ The *Chakrabarty* ruling clearly established that microorganisms could be patented, but failed expressly to address the matter of higher life forms.

Higher Life forms-

*In re Allen*³⁴ provided the impetus for the new policy. The applicant in *Allen* sought a patent on a method of creating polyploid oysters,³⁵ and on the oysters themselves. The examiner rejected the application for two reasons: (1) the polyploid oysters were "living entities controlled by laws of nature" and thus not covered by section 101; and (2) the process of creating the oysters would have been obvious to a person of ordinary skill in the area. On appeal, the PTO Board of Appeals and Interferences (Board) reversed the first determination.³⁶

The Board interpreted *Chakrabarty* to require that any subject matter created by human beings could be patented. As long as the polyploid oysters failed to occur naturally, they could be patented under section 101 as new manufactures or compositions of matter. The

³⁰ 447 U.S. 303 (1980).

³¹ 447 U.S. 310-14 (1980). These statutes are the Plant Patent Act of 1930, 35 U.S.C. §§ 161-64 (1982) and the Plant Variety Protection Act of 1970, 7 U.S.C. §§ 2321-2583 (1982). See OFFICE OF TECHNOLOGY ASSESSMENT, IMPACTS OF APPLIED GENETICS: MICRO-ORGANISMS, PLANTS, AND ANIMALS 239-40 (1981).

³² *Id.* at 317. The Court also noted that a negative decision on patentability would fail to prevent continued genetic engineering research. *Id.*

³³ R Dresser, Ethical & Legal Issues in Patenting new animal life, 28 JURIMETRICS 399(1988).

³⁴ 33 Pat. Trademark & Copyright J. (BNA) No. 826, at 638 (April 20, 1987).

³⁵ The oysters possessed an extra set of chromosomes that allegedly would make them edible year-round. See Annas, Of Monkeys, Man, and Oysters, HASTINGS CENTER REPORT, at 20,21 Aug./Sept. 1987.

³⁶ *In re Allen*, 2 U.S.P.Q.2d (RNA) 1425 (P.T.O. Bd. App. & Int. 1987). The Board affirmed the denial on grounds that the oysters failed to meet the non-obviousness requirement.

PTO Commissioner issued his notice the following week.³⁷ By granting inventors a limited monopoly on the patented invention, the law creates an economic incentive for inventors and their employers to bear the financial risks entailed in developing and commercializing an invention.³⁸ The incentive, it is hoped, will ultimately benefit the public by stimulating advancements in knowledge and technology that would otherwise be delayed or never occur.³⁹

LIFE PATENTS: THE INDIAN EXPERIENCE

The Indian Patents Act, 1970 governs patent protection in India. It has been gradually amended over 1999-2005 to suit India's international obligations under TRIPS. India has always maintained that '...patent rights should be exercised coherently with the objectives of mutual advantage of patent-holders and users of patented medicines, in a manner conducive to social and economic welfare and to the balance of rights and obligations.'⁴⁰ When India became a party to the WTO in 1995, in spite of strong civil society opposition,⁴¹ TRIPS was an indispensable part of the deal. The then national policy makers hoped that the overall gains made from greater links with the global trading community would more than upset any possible dangers of accepting a stricter IP regime.

Having contested to fully utilize its ten year transition period India has introduced three major amendments to the Patents Act, 1970. The first among these was the 1999 amendment which introduced exclusive marketing rights (EMRs)⁴² and established mailbox applications for patents for pharmaceuticals and agrochemicals from 1 January 1995. The next amendment came in 2002 which allowed for patents on microorganisms.⁴³ Even prior to this amendment, the judiciary had interpreted the patent regime under the unamended Patent Act to cover a patent on a living organism much to the displeasure of the Indian Patent Office. The Hon'ble High Court of Calcutta, in the matter of *Dimminaco A G v Controller of Patent Designs & Ors*⁴⁴ was approached by a Swiss company which had been inventions that fulfilled the

³⁷ The PTO has created a new category to accommodate the policy, namely: "Class 800 Multicellular Living Organisms and Unmodified Parts Thereof." See Jones, *Patenting of Invented Animals Okd*, L.A. Times, April 18, 1987, sec. 1, at 1,23.

³⁸ See Burch, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1147-48 (1987).

³⁹ Ref: Report from Hindustan times, as assessed on the 20th of October' 2014 at 4:00PM.

Id. at 1158.

⁴⁰ The objective of TRIPS, mentioned in Article 7, states: 'The protection and enforcement of intellectual property rights should contribute... to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare...'

⁴¹ Gopakumar K M, Mashelkar Committee Report: A Critique: V R Krishna Iyer, O Chinnappa Reddy, D A Desai & Rajinder Sachar, Peoples' Commission on GATT, Centre for Study of Global Trade System and Development (1996).

⁴² India's domestic patent law describes the EMR as the exclusive right to sell and distribute the substance or article concerned.

⁴³ Refer *Diamond v. Chakraborty* discussed earlier.

⁴⁴ 2002 IPLR 255 Cal.

patentability criteria when patent refused a process patent for preparation of a live vaccine for Bursitis. Even though there was no express or implied bar in the Indian Patent Act 1970, patents were traditionally granted only to non-living. process patent over a vaccine The Court observed that the term 'manufacture' had not been defined in the Act and consulted a variety of dictionary meanings to conclude that the process for manufacturing such a vaccine is new process and such new process was patentable under §544 read with §2(I)(i)45 of the Patent Act.

The PTO Commissioner issued his notice the following week.⁴⁵ By granting inventors a limited monopoly on the patented invention, the law creates an economic incentive for inventors and their employers to bear the financial risks entailed in developing and commercializing an invention.⁴⁶ The incentive, it is hoped, will ultimately benefit the public by stimulating advancements in knowledge and technology that would otherwise be delayed or never occur.⁴⁷

The Hon'ble Court relied on the vendibility test⁴⁸ to determine the question of patentability of a process. It concluded that since the claim process for patent leads to a vendible product, it is certainly a substance after going through the process of manufacture. Reference was also made to *M/s Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries station*⁴⁹ to clarify the other patentability requirements of newness and usefulness. The Court adopted a careful stance though many considered it a bold step, legalizing patentability of living matter in India even before a legislative amendment expressly provided for the same. Subsequently amendment in 2002 was made to change the definition of 'invention' and added the additional requirement of newness and usefulness. Another amendment was made in 2005 The 2005 amendment substituted new §3(d) for the existing section which limited the scope of patentability by excluding 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance.'⁵⁰

Conclusion

In summary, it is undeniable that there has been a crisis created by the existing patent law systems in developed countries whereby the heightened barriers to accessibility of knowledge

⁴⁵ The PTO has created a new category to accommodate the policy, namely: "Class 800 Multicellular Living Organisms and Unmodified Parts Thereof." See Jones, *Patenting of Invented Animals Okd*, L.A. Times, April 18, 1987, sec. 1, at 1,23.

⁴⁶ See Burch, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1147-48 (1987).

⁴⁷ *Id.* at 1158.

⁴⁸ The vendibility test is a test to check if the process results in the production of some vendible item, i.e.an item which can be transferred upon sale and purchase. The Court ultimately held that the process for creating a vaccine leads to a vendible product, even if the end product contains live material.

⁴⁹ AIR 1982 SC 1444.

⁵⁰ The Patents (Amendment) Act, 2005, www.patentoffice.nic.in/ipr/patent/patent_2005.pdf.

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and patented technologies are threatening to limit innovation rather than encourage it. There are also wide criticisms that the patent law system is morally impoverished because of its monopoly practices and disregard for the detrimental impact such practices have upon the poorer nations.

In the present age of globalisation, there needs to be a more globalised approach to thinking about intellectual property rights and the consequences it creates. Solutions will need to come from both within the patent system and outside of it because the patent law system in itself is not capable of bringing about enough change because the infrastructure of law is not able to accommodate morality in its totality.

In the long term, biotech and pharmaceutical companies need take up their moral responsibilities and adopt a view to operate with corporate social responsibility. Patent pooling should also be instituted into the patent system to improve the utility of the system. Overall, it requires the concerted efforts of the biotech industry and various governmental and non-governmental or aid organisations to resolve the crisis that the existing patent regime has created.