

4. PATENT EXCLUSIONS THAT PROMOTE PUBLIC HEALTH OBJECTIVES

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Table of Contents

S.No.	Particular	Page No.
I	Introduction	1-4
II	Methods of Medical Treatment	5-43
A.	Introduction	5
B.	TRIPS and other Multilateral Treaties	11
C.	Europe and UK	12
D.	North American Region	24
E.	Australia and New Zealand	27
F.	Asia	31
G.	South America	37
H.	Africa and Middle East Region	40
III	'Ordre Public' and 'Morality'	43-73
A.	Introduction	43
B.	Important Concepts in Regards Article 27.2 of Trips	47
C.	International Organizations	49
D.	The European Patent Convention 2000	51
E.	Individual Countries	55

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I. INTRODUCTION

Amongst the various theories that exist today to explain the purport and rationale of the patent system, the most prevalent is the “incentive” or the “reward” theory.² In short, patents are rewards in the form of temporary monopolies granted to inventors who come up with new, inventive and useful ideas. The expectation is that the prospect of such rewards would incentivise inventors to come up with a higher rate of useful inventions, than would be the case without patents.

There is much debate on whether or not patents, in fact, foster a higher rate of new ideas, and if so, to what extent.³ More importantly, the issues are technology specific, and evidence that patents may help in an investment heavy industry such as pharmaceuticals may not be readily transposable to industries such as Information Technology and semiconductors. Further, there is also the issue of developing and least developed countries that are net importers of technology. The question is whether patent regimes promote technology transfer to these countries or whether they effectively curb the potential growth that these countries might have experienced, had they had the freedom to imitate and learn; freedoms that many of the developed countries enjoyed in the pre TRIPS era.⁴ For these countries, the potential use of patent eligibility exclusions is far more significant in driving national policy.

A brief survey of case law from developed economies would suggest a restricted reading of eligibility exclusions.⁵ However, developing countries such as India opt for a wide reading of such eligibility exclusions, reflecting their specific national priorities.⁶ Although we’ve categorised section 3(d) of the Indian Patents Act as an “impure” patent eligibility exclusion later in this chapter, it may help to consider this section for the purpose of this argument. Section 3(d) seeks to exclude a large number of similar chemical/pharmaceutical substances from patentability by providing that only those derivatives that demonstrate significantly enhanced efficacy would be patentable. This exclusion has been expensively interpreted by patent office and the courts: notably, the term ‘efficacy’ in the explanation to Section 3(d) of the Patents Act, 1970 has been interpreted in *Novartis AG & Another v. Union of India & Others*, 2007 4 MLJ 1153 at ¶ 13 to include only “therapeutic” efficacy, with the result that a number of derivatives that demonstrate non therapeutic

² W. Fisher, ‘Theories of intellectual property’, in *New Essays in the Legal and Political Theory of Property*, ed. S. R. Munzer (Cambridge University Press, Cambridge 2001), 168–200.

³ Bronwyn H. Hall ‘Patents and Patent policy’ 23(4) *Oxford Rev. Eco. Policy* 568 (2007).

⁴ Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law, Netherlands 2002), 46–7. Also see Lee G. Branstetter, ‘Do Stronger Patents Induce More Local Innovation?’, 7(2) *J. Int’l Econ L.* 359 (2004).

⁵ “As the discussion of European case law demonstrates, the legal definition of diagnostic methods does not reflect the true nature of a medical diagnosis. Modern diagnoses are rarely final and few occur without the aid of data and quantitative results from laboratory testing” See Tina Piper, *Commentary in response to ‘Are Patents for Methods of Medical Treatment contrary to the Ordre Public and Morality or ‘Generally Inconvenient?’*, 30 *J. Med. Ethics* 470 (2004), 476; See *Brucker/Non-invasive measurement T385/86* [1988] *EPOR* 357; See *Diagnostic methods G01/04* (2006) *OJEP* 334; See generally Cynthia M. Ho, ‘Patents, Patients and Public Policy: An Incomplete Intersection’, 33 *U.C. Davis L. Rev.* 601 (1999), 621.

⁶ Shamnad Basheer, ‘Policy-Style Reasoning in the Indian Patent Office’, 3 *IPQ* 309 (2005).

advantages such as heat stability etc are likely to be excluded.⁷

For developing countries, patent policies are not just about increasing the rate of innovation, but are to be calibrated to take into account concerns of “access” to technology goods. The question of access is most significant in the context of pharmaceuticals and public health.⁸ Therefore the patent regime cannot be hermetically sealed off from other public policy concerns such as health. Indeed, one often witnesses a conflict between patent rights on the one hand, and social values, public policies and fundamental rights on the other. The issue for most countries then is to balance out these competing and often conflicting concerns and devise a regime that would, while furthering innovation outcomes, also not erode important values such as health.

It is a truism that patents often cause price rises.⁹ A variety of tools exist to regulate such price rises and ensure affordable access to consumers, particularly in the context of drug patents and developing countries.

Indeed most such measures revolve around ex-post regulatory mechanisms such as compulsory licensing that help limit the impact of patents and in the process promote public health goals.¹⁰

This chapter seeks to evaluate the patent and public health interface from the point of view of ex-ante mechanisms i.e. ways in which countries have sought to limit the grant of patents to certain categories of subject matter in a bid to promote access to public health goods.

At a conceptual level and drawing from the patenting practices of most member states, one can draw a distinction between ‘patent eligibility’ and ‘patentability’.

‘Patent eligibility’ broadly refers to the requirement that a subject matter, for which a patent is sought, be inherently suitable for patent protection, in the sense of falling within the scope of subject matter that patent law prima facie exists to protect. The term ‘patentability’, on the other hand, refer to those set of principles that inform the requirements that must be satisfied for a patent eligible subject matter (i.e., an invention) to be granted a valid patent. Principally they are the requirements of novelty, inventiveness (non-obviousness), utility (industrial applicability) and sufficient description.¹¹

As noted by a commentator:

Analytically, this proposition exemplifies the familiar Aristotelian

⁷ Shammad Basheer & T. Prashant Reddy, ‘The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)’, 5(2) SCRIPTed 232 (2008), 244.

⁸ See generally ‘Holger Hestermeyer, Human Rights and the WTO: The case of Patents and Access to Medicines’, 14(6) Int. Trade Law & Reg 122 (2008).

⁹ Joseph Stiglitz, ‘Give prizes and not patents’ New Scientist, September 16, 2006, 21.

¹⁰ Carlos Correa, *Integrating Public Health Concerns into Patent Legislations in Developing Countries* South Centre Geneva 2000 page 93-109, available at <http://www.who.int/medicinedocs/fr/d/Jh2963e/6.html>. (Last visited on August 1, 2010).

¹¹ Justine Pila, ‘Bound Futures: Patent Law and Modern Biotechnology’, 9 Boston Univ. Journal of Science and Technology Law 326 (2003).

dichotomy between essence/kind on the one hand, and attributes/quality on the other, also reflected in other intellectual property laws. Thus, in copyright law, what qualifies as an artistic work (its 'essence' or 'kind') is analytically distinct from the question whether the work is 'original' or not (its 'attribute' or 'quality').¹²

In short, the term 'patent eligibility' or 'inherent patentability' denotes limitations in terms of the kind of 'subject matter' that would qualify for patent protection– this question is different from and often precedes the question of whether the said subject matter meets the 'patentability' criteria.

In most member countries, the principle of patent eligibility is embodied in the term 'invention' i.e. a poem, though new and useful, cannot be patented, since it is not an 'invention'.¹³ This is true with TRIPS as well, with Article 27.1 drawing a sharp distinction between patent eligibility and patentability, by its use of the term 'invention'. It reads as below:

In this chapter, we focus on the "patent eligibility" criteria that countries deploy in order to limit the scope of patents considered deleterious from the point of view of public health. Broadly, such exclusions include the following:

- i) Ordre public or morality¹⁴
- ii) Method of Medical Treatment¹⁵
- iii) Plant and Animal Varieties¹⁶
- iv) Discoveries¹⁷
- v) Second Medical use¹⁸
- vi) Combinations with no synergy¹⁹
- vii) Derivatives of chemical substances with no "efficacy"²⁰

Patent eligibility exclusions can be broadly divided into three broad classes:

- i) Exclusions that are based on "policy" considerations

¹² David Vaver, 'Invention in Patent Law: A Review and a Modest Proposal', 11 (3) Intl J Law and IT 287(2003). However, he cautions in a footnote that 'the distinction between kind and quality cannot be pressed too far. For example, one might fairly argue that novelty and non-obviousness are part of an invention's essence'. *Ibid.*

¹³ See Section 3(l) of Indian Patents Act which excludes 'a literary, dramatic, musical or artistic work...'. See also Article 52 (2) (b) of the European Patent Convention (EPC) which similarly excludes all 'aesthetic creations'.

¹⁴ Article 53(a) of the EPC.

¹⁵ Article 53(c) of the EPC.

¹⁶ Article 53(b) of the EPC.

¹⁷ Article 52(2)(a) of the EPC.

¹⁸ Section 3(d) of the Indian Patents Act.

¹⁹ Section 3(e) of the Indian Patents Act.

²⁰ Section 3(d) of the Indian Patents Act.

- ii) Exclusions that in some way that derive from the meaning of the term “invention”
- iii) Exclusions that encompass a heightened patentability standard or encapsulate a bright line patentability rule

The first 3 exclusions outlined above would fall within category (i). The next one (“discovery”) would fall within category (ii). And the last 3 would fall within category (iii).

However, we deal only with exclusions that fall within category (i). It is pertinent to note in this regard that the standing committee preliminary report on this issue provides as below:

“Since the mandate given to the International Bureau by the SCP was to prepare a preliminary study on the exclusions from patentable subject matter, in principle, this preliminary study focuses on subject matter which can be generally categorized as patentable subject matter (or inventions) but which is excluded from patent protection.”²¹

Even amongst category (i), we deal with only “methods of treatment” and ordre public or morality, since the category of higher life forms is being dealt with by another colleague (Denis Barbosa).

We deal with these two exclusions below and attempt to outline a framework for their assessment, taking into account their specific articulation within domestic regimes. While dealing with each of these exclusions, we also seek to highlight the intended ways in which they might further public health goals.

²¹ Standing Committee on the Law of Patents, 13th Session, Geneva, March 23 to 27, 2009, Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights, 7, ¶27.

II. METHODS OF MEDICAL TREATMENT

A. Introduction

Methods of medical treatment are excluded from patentability in a large number of countries today. The most commonly cited justification is that such patents are likely to fetter the freedom of physicians and prevent them from helping patients with the latest medical advances. To this extent, this exception best captures the tension between patent law and its innovation inducing rationale on the one hand, and concerns of public health on the other, where doctors must be free to administer the latest medical techniques without fear of patent infringement or incurring costs of licensing such inventions. As a commentator rightly notes:

*“Patenting of methods of medical treatment of human beings is, however, a complicated issue for it is not only based on patent law but also on medical law. Medical law has its origins in the Hippocratic Oath, and the goal is the preservation of human life. Since the goal of patent law is to encourage innovation by rewarding inventors, it is quite distinct from the goal of medical law. Thus, there is a public policy concern that in order to ensure the best possible health treatment, physicians must always be free in their choice of treatment.”*²²

The articulation of these competing concerns can also be found in various judicial pronouncements. Illustratively, Justice Jacob notes in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* that ‘The purpose of the limitation is... merely to keep patent law from interfering directly with what the doctor actually does to the patient.’²³

While some WTO member states had initially interpreted existing patentability criteria to oust new medical methods,²⁴ they later began to base such exclusions on stand alone ethical and public policy grounds. In other words, methods of medical treatment began to be seen more as a patent eligibility criterion stemming from public policy concerns rather than a patentability or an inherent patentability criterion.²⁵ It is pertinent to note that this historical development gives us reason to suspect that patentability criteria such as “utility” may take on the role of patent-eligibility criteria in some cases.²⁶

Europe is a good example in this regard. Article 52 (4) of the European Patent

²² O Mitnovetski & D Nicol, ‘Are patents for methods of medical treatment contrary to ordre public and morality or “generally inconvenient”’, 30 J. Med. Ethics 470(2004), 471.

²³ [1999] RPC 253 (Pat Ct) [51], aff’d in part [2001] RPC 1 (CA).

²⁴ Rainer Moufang, ‘Methods of Medical Treatment Under Patent Law’, 24 HC 18, 22, 24-25, 27 (1993).

²⁵ Justine Pila, ‘Methods of Medical Treatment within Australia and United Kingdom Patents Law’, 24(2) University of New South Wales Law Journal 420(2001).

²⁶ Sivaramjani Thambisetty, ‘Legal Transplants in Patent Law: Why Utility is the New Industrial Applicability. Jurimetrics’, *The Journal of Law, Science and Technology*, Fall 2008, LSE Legal Studies, Working Paper No. 6/2008, available at <http://ssrn.com/abstract=1111966>. (Last visited on August 11, 2010)

Convention (EPC) categorically excludes “methods of medical treatment” on the ground that such methods are not “susceptible of industrial application”.²⁷

Given that medicine is practiced for the most part within a “commercial” and perhaps “industrial” framework in a large number of countries, some scholars have questioned the logic of such a rationale.²⁸ However, others have maintained that there continues to be a distinction between the practice of a noble “profession” such as medicine and an “industry”.²⁹ For instance, Chris Wadlow categorically argues that historically the medical profession has never been regarded as trade or an industrial activity.³⁰ He provides the following justifications:

“...One of the distinguishing features of an organized profession is that its members are subject themselves to a higher code of practice and honour than mere tradesmen, exemplified in the case of medical practitioners by the so called Hippocratic oath... The proposition that medicine cannot simultaneously be a profession and an industry is consistent with the treatment of patentability of methods of diagnosis, surgery and therapy... In historical as opposed to functional terms the original European prohibition on patenting: “Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body”, (EPC Article 52(4)) may plausibly be understood as turning on the status of the professional practice of medicine (by both surgeons and physicians) rather than purely on utilitarian consideration that the day to day practice of medicine should be kept free from patent monopolies.”³¹

The EPC 2000 now excludes medical methods from patentability, without linking it up to the “industrial application” requirement.³² This suggests that the exclusion reflects a core public policy concern and is not tethered to conventional patentability criteria. However, countries such as Japan, Morocco and South African continue to exclude medical methods on the ground that such methods are not capable of industrial application.³³

²⁷ The EPC was signed in Munich in 1973 and came into effect in 1978. See Rudolf Kraßer, ‘Purpose and Limits of the Exclusion from Patentability of Medical Methods, Especially Diagnostic Methods’, cited in *Patents and Technological Progress in a Globalized World*, (Springer Heidelberg, 2009), 275-88.

²⁸ O Mitnovetski & D Nicol, *supra* n. 22.

²⁹ Chris Wadlow, ‘Regulatory Data Protection under TRIPS Article 39(3) and Article 10 bis of the Paris Convention: is there a doctor in the house?’, 4 IPQ 355 (2008) 378.

³⁰ *Ibid.*

³¹ Chris Wadlow, *supra* n. 29.

³² Article 52(4)/ 53(c) EPC 2000 of the European Patent Convention “*European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.*” See also Eddy D. Ventose, *In the Footsteps of the Framers of the European Patent Convention: Examining the Travaux Préparatoires*, 31(7) EIPR 353(2009).

³³ See *Examination Guidelines for Patents and Utility Models in Japan*, Part II-Chapter 2 (2002) which states: “Industrially Inapplicable Inventions: (1) Methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”. See also Rudolf Kraßer,

After the advent of the EPC, the UK's patent trajectory has largely mirrored the EPC position. However, prior to the EPC, UK courts based their method of medical treatment exclusion on what some commentators perceive to be an untenable legal foundation.³⁴

UK courts and the patent office rejected medical method patents on the ground that they were not "vendible" products³⁵ and therefore did not constitute a "manner of manufacture".³⁶ However, with the liquidation of the vendibility criterion from the patentability lexicon, the method of medical treatment exclusion could not be sustained on this ground anymore.³⁷ Courts therefore began to link up the exclusion to a want of "artificiality" or a lack of an essential economic character as required for an invention under the NRDC case³⁸ Later however, courts began to look for ways in which to tether this exclusion explicitly to "ethics" than any of the traditional patentability criteria. However, they shied away from explicitly articulating such an exclusion, preferring instead to leave the job to the legislature.³⁹

In *Eli Lilly & Co's Application*⁴⁰ the patents appeal tribunal noted that the exclusion is "technically anomalous and therefore illogical" and appears to "be based in ethics rather than logic". However, it also noted that "if there is to be a change of policy, which would appear to us to be sensible, this ought in our view to be effected by legislation rather than by interpretation".⁴¹ Two years later, the legislature did indicate its endorsement of this exclusion, albeit on the ground that it lacked "industrial application".⁴²

The Australian position tracked the UK position for the large part, with both countries influencing each other in their determination of the patentability of this controversial subject matter. At first, Australian courts rejected such methods as non-vendible products.⁴³ However, with NRDC⁴⁴ the objection gradually morphed

supra n. 27.

³⁴ Justine Pila, *supra* n. 25.

³⁵ *Re G.E.C.'s Application*, (1942) 60 RPC 1.

³⁶ Schering Case, [1971] R.P.C. 337.

³⁷ Anna Feros, 'Patentability of Methods of treatment', 23(2) EIPR 79 (2001) 80.

³⁸ William van Caenegem, 'The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' 13 Australian Intellectual Property Journal 41(2002), 47-8. The author herein discusses cases in Australia including *Anesthetic Supplies v. Rescare* where the Court applied the principles of *NRDC case* in an enquiry as to whether the claimed invention was an artificially created state of affairs providing economic utility to the society.

³⁹ Anna Feros, *supra* n. 37.

⁴⁰ [1975] RPC 438, 445 .

⁴¹ *Ibid.* See also *Upjohn Company (Robert's) Application* [1977] 1 RPC 94, where Russell J said that it was well established that a method of treatment of a human ailment with a known substance was not capable of being an invention under the Statute, and that if this should be changed, it should be done by Parliament.

⁴² See Section 4(2) **Patents Act 1977 (UK)** as per which "an invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application." However, the Patents Act has been amended in 2004 and Section 4A does not mention industrial application.

⁴³ Anna Feros, *supra* n. 25; The requirement that there be a "manner of manufacture" in the Statute

into one of “economics” and “artificiality”. Courts appeared to suggest that methods of treatment were “essentially non economic” in nature⁴⁵ and that they lacked the “artificiality” required of an invention.⁴⁶ Later, courts began to explicitly reject methods of treatment as generally “inconvenient” inventions under the statute of monopolies.⁴⁷ However, this was later reversed, with courts suggesting that there was no rational basis for holding such methods to be “generally inconvenient”.⁴⁸

In so far as the other European countries are concerned, almost all of them excluded medical methods on one ground or the other, till the time of the EPC and its intended harmonization of the laws of member countries. However, even after this harmonization drive and consequent pressures on individual EC member states to conform, the alleged rationale for exclusion appears slightly different in the different countries. Illustratively, while The United Kingdom, Germany, and France⁴⁹ appear to mirror the EPC in stating that methods as not industrially applicable, Denmark, Italy, and Sweden treat such methods as non-inventions, and Switzerland treats them as legal exceptions to patenting.⁵⁰

Germany might have been the only exception in this regard where, in the early 1900s, the German Patent Office granted a few patents for medical methods⁵¹. However, in 1904, the German Patent Office suggested that such patents could not be granted, since the statute did not envisage patent protection for the treatment of humans.⁵² More specifically, this and other future cases appeared to suggest that an industrially applicable invention could only be assumed to exist if raw material was mechanically or chemically treated or processed.⁵³

of Monopolies has been described as “the touchstone of patentability” and still is in force today in Australia, New Zealand, and Israel (Patents Act 1990 (Cth), 3 S 18 and schedule 1).

⁴⁴ *National Research Development Corp. v. Commissioner of Patents*, 102 CLR 252 (1959), [1960] ALR 114, [1961] RPC 134 (Full Ct. of the H.Ct., Austl.).

⁴⁵ O Mitnovetski & D Nicol, *supra* n. 22.

⁴⁶ Justine Pila, *supra* n. 25, 443. William van Caenegem, *supra* n. 38.

⁴⁷ Section 6 of the Statute of Monopolies, 1624 “...which others at the time of making such letters patent and grant shall not use, so as also they be not ... generally inconvenient.” See David Kell, ‘Expanding the Frontier of Patentability: Methods of Medical Treatment of the Human Body’, [1995] 4 EIPR 202, at 203 ; See also Todd Martin, ‘Patentability of Methods of Medical Treatment: A Comparative Study’, 82 J. Pat. & Trademark Off. Soc’y 381(2000), 411.

⁴⁸ See Federal Court decision in *Rescare v. Anaesthetic Supplies* (1992), confirmed methods of treating snoring and obstructive sleep apnoea were patentable subject matter. And *Bristol-Meyers Squibb v. Faulding* (2000), the Federal Court went on to hold a dosage regime for an anticancer drug as patentable subject matter.

⁴⁹ Even prior to the EPC, France and Italy excluded methods of treatment on the basis that they lacked industrial character. Contrast this with Switzerland and Austria which refused such patents on ethical grounds. See O Mitnovetski, D Nicol, *supra* n. 22.

⁵⁰ O Mitnovetski & D Nicol, *supra* n. 22.

⁵¹ These including a method of removing deeper stitches from wounds (German patent no 150666); a method for treating curvature of the human spine (German patent no 150699); a method of removing magnetised objects from the eye or another part of the body (German patent 155294), and a method of trans-illuminating parts of the body using x rays (German patent 156389). O Mitnovetski & D Nicol, *supra* n. 22.

⁵² Badewasser (1904) BlfPNZ 4.

⁵³ See Federal Supreme Court of September 26, 1967. BGHZ 313, (1968) GRUR 142. See also O

By 1990s, more than 80 countries, in Europe, Asia, Africa, North America, South America and Central America, exempted medical methods from patent protection.⁵⁴

The principal rationale for excluding medical methods in most countries appears to be one of “ethics”, namely that doctors must be free to use the latest medical methods to help patients. The exclusion also appears to be based in some countries on the notion that the medical profession cannot qualify as “industry” and therefore does not come within the proper scope of patentable subject matter.⁵⁵

Skeptics question these justifications by arguing that if the rationale is to help doctors use the latest medical technology in favour of patients, there is no reason why pharmaceutical drugs that are used in the course of treatment ought to be patentable. In other words, since such drugs are patentable and hospitals and patients routinely pay the patented price, they must do so with patented medical methods as well. This dilemma can be better understood if one considered the Bristol Meyer case in Australia, which involved the new use of a known substance to treat cancer.⁵⁶ The substance itself might have been patented initially and doctors might have paid the monopoly price to cure patients with this drug. With the discovery of a new use of the said drug, should a patent be disallowed only to permit doctors and patients to use it without payment of royalties. Although such new use claims are captured by the patentee as “method” claims, is this not as good as patenting a new drug. Why then should doctors and patients be free to use this new use of the drug without paying any royalties?⁵⁷

On the other hand, some argue that there is a significant distinction between a ‘drug’ and ‘a method of medical treatment’ administered to a patient. Drug development and its introduction into the market is a long and expensive journey which necessitates incentives in the form of patents.⁵⁸ In comparison, most medical methods are relatively inexpensive to discover and implement.⁵⁹

In this regard, it is pertinent to note the novel approach of the US, which is to permit such patents, but to prevent their enforcement by doctors and related healthcare professionals.⁶⁰ If the key issue is seen as one of freedom of doctors to deploy latest medical techniques to help patients, this approach might appear to be a more direct way of resolving the issue.

While the patenting of medical methods is seen as conflicting with “ethical” concerns in developed countries for the large part, in so far as developing countries are

Mitnovetski & D Nicol, *supra* n. 22.

⁵⁴ Robert M. Portman, ‘Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress’, 4 U. Balt. Intell. Prop. L.J. 91 (1996), 118.

⁵⁵ Chris Wadlow, *supra* n. 29.

⁵⁶ William van Caenegem, *supra* n. 38.

⁵⁷ O Mitnovetski & D Nicol, *supra* n. 22.

⁵⁸ *Pfizer Inc v. Commissioner of Patents* [2005] 1 NZLR 362.

⁵⁹ Alexandra Simms, ‘The case against patenting methods of medical treatment’, 29(2) EIPR 43 (2007), 48.

⁶⁰ Cynthia M. Ho, *supra* n. 5, 606-8.

concerned, the concern is more in terms of affordable medicines and accessible healthcare.⁶¹ The report by the Commission on Intellectual Property Rights notes the importance of affordable healthcare particularly for developing countries:

“...IP rights are not conferred to deliver profits to industry except so that these can be used to deliver better healthcare in the long term. Such rights must therefore be closely monitored to ensure that they do actually promote healthcare objectives and, above all, are not responsible for preventing poor people in developing countries from obtaining healthcare.”⁶²

Indeed, a number of developing countries continue to stress the need for affordable availability of treatment methods both in their domestic IP formulation⁶³ and at various international policy making fora.⁶⁴ Recently, India protested against the seizure of generic drugs exported by Indian pharmaceutical companies to destinations abroad via the EU ports. India argued before the TRIPS Council that the widespread and repeated seizures, under the EC Regulation 1383, have an adverse systemic impact on the principle of universal access to medicines, national public health budgets, legitimate trade of generic medicines and also seriously impair the efforts of civil society organisations engaged in providing medicines and improving public health in the least developed parts of the world.⁶⁵

To this extent, the conflict between the standard patent rationale of incentivizing innovation on the one hand and that of fostering a more optimal public health outcome on the other is a starker one in the context of developing countries.⁶⁶ Further, given that many developing countries are net importers of technology, the importance of the incentivizing innovation rationale diminishes somewhat when compared with the access to medicines and affordable healthcare imperative. Having said this, it is important to appreciate that developing countries are not one monolithic block. Rather, the emergence of technologically proficient developing countries suggest that such countries might balance out the competing innovation and public health policies in ways that are different from other developing countries,

⁶¹ Tina Piper, *supra* n. 5.

⁶² Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, 2002, 35, available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf. (Last visited on August 11, 2010).

⁶³ Section 3(d) of the Indian Patent Act of 1970 excludes from patentability mere discovery of a known substance unless there is significant enhancement in the efficacy or a new use of a known substance. The legislative history indicates that this provision was introduced to prevent the phenomenon of ‘ever-greening’ and thereby addressing the issue of affordability of medicines. See also Shamnad Basheer & T. Prashant Reddy, ‘The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)’ 5(2) SCRIPTed 232(2008) 238.

⁶⁴ ‘Patents: Subject Matter and Patentability Requirements’, Chapter 17, CY564-Unctad, Volume 1, dated 29.11.2001, available at http://www.iprsonline.org/unctadictsd/docs/RB_2.17-2.26_Patents_update.pdf. (Last visited on July 5, 2010).

⁶⁵ Jonathan Lynn, ‘India, Brazil raise EU drug seizure issue at WTO’, Live Mint, 4 February 2009, available at <http://www.livemint.com/2009/02/04232721/India-Brazil-raise-EU-drug-se.html>. (Last visited on August 8, 2010).

⁶⁶ O Mitnovetski & D Nicol, *supra* n. 22.

particularly ones that qualify as least developed countries.⁶⁷

B. TRIPS and other Multilateral Treaties

Article 27.3(a) of the TRIPS agreement⁶⁸ excludes *methods* for the treatment of humans or animals from patentability. However, it makes clear that products or processes that are deployed during the course of medical treatment are patentable in their own right, since they do not amount to “methods of treatment” ipso facto.⁶⁹

As early as 1964, during the preliminary stages of the plan to introduce a European patent for the Common Market, the European Economic Community (EEC)'s working group on patents resolved to recognize the principle of the free exercise of the medical profession by means of a restriction on patentability.⁷⁰ This resulted in a proposal to exclude methods for treatment performed on the human or animal body from patentability. The proposal was later expanded to include methods of diagnosis, and in its final wording referred to ‘methods for treatment ... and diagnostic methods.’ In this form, it was presented to the Luxembourg Inter-Governmental Conference to establish a European System for the Grant of Patents.⁷¹ At this conference, in line with earlier proposals, a patent ban was instated that explicitly referred to human as well as veterinary medicine.⁷²

The Munich Diplomatic Conference, 1973⁷³ at which the European Patent convention was signed, advised against including methods for medical treatment as “non-inventions”, as they are “inventions” but merely lacked industrial applicability.⁷⁴ Thus came in the Article 52(4) of the 1973 EPC, which stipulated that surgical or therapeutic methods of treating the human or animal body and diagnostic methods carried out on the human or animal body are not industrially applicable inventions within the meaning of Article 52(1) EPC.

Today, a number of multinational treaties permit signatories to exclude methods of medical treatment from patentability. The *North American Free Trade Agreement* (NAFTA) Article 1709(3)(a) allows its members to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”⁷⁵

⁶⁷ Shamnad Basheer and Annalisa Primi, *Implementing Wipo's Development Agenda*, Jeremy DeBeer, ed., Wilfred Laurier University Press, 2009, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1289288. (Last visited on July 8, 2010).

⁶⁸ Article 27.3(a) defines Patentable Subject Matter, and states that ‘Members may also exclude from patentability: diagnostic, therapeutic and surgical methods for the treatment of humans or animals;..’

⁶⁹ O Mitnovetski & D Nicol, *supra* n. 22.

⁷⁰ Rudolf Kraßer, *supra* n. 27.

⁷¹ Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents (Luxembourg Conference) (1969 to 1972).

⁷² Rudolf Kraßer, *supra* n 27.

⁷³ Munich Diplomatic Conference for the setting up of a European system for the Grant of Patents, 1973 (Munich, 10 September to 6 October 1973).

⁷⁴ Rudolf Kraßer, *supra* n. 27.

⁷⁵ North American Free Trade Agreement, Dec. 17, 1992, Art. 1709, 3(a), 32 I.L.M. 605, 670-81.

Article 6(e) of the *Bangui Agreement*⁷⁶ as per its Annex I prohibits patents to be granted for methods for the treatment of the human or animal body by surgery or therapy, including diagnostic methods.⁷⁷

In so far as South America is concerned, Article 20 of the Andean Pact prohibits patents for diagnostic, therapeutic, and surgical methods for the treatment of humans or animals under clause (d).⁷⁸

At a more procedural level, the 1970 Patent Cooperation Treaty (PCT), Rule 39.1 specifies that a designated International Searching Authority is under no obligation to conduct patent searches relating to “methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.”⁷⁹

C. Europe

The European Patent Convention (EPC) categorically excludes “methods of medical and veterinary treatment” from patentability.⁸⁰ Such inventions are excluded to ensure that people who carry out medical or veterinary treatments are not inhibited by patents.

As noted earlier, prior to the EPC 2000, methods of medical and veterinary treatment were excluded on the basis that they were not capable of industrial application. Under the EPC 2000, however, this problematic deeming provision was done away with. Methods of treatment are now excluded directly, and presumably on the basis of ethical concerns with such patents.⁸¹ Article 53(c) EPC 2000 provides that ‘a patent shall not be granted for methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body’. Most EU member states have implemented this provision within their domestic regimes.⁸²

⁷⁶ The African Intellectual Property Organization (OAPI) was formed by the adoption of a new convention signed in Bangui on 2nd March 1977. The OAPI consists of sixteen west and Central African countries, namely; Benin, Burkina Faso, Cameroon, Central African Republic, Chad Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo. Patent law under the OAPI is dealt with under the Bangui Accord.

⁷⁷ Bangui Agreement, Annex I (1999).

⁷⁸ DECISION 486, Common Intellectual Property Regime (2000).

⁷⁹ Patent Cooperation Treaty (PCT), (Washington, 1970).

⁸⁰ D. Thums, ‘Patent Protection for Medical Treatment: A Distinction between Patent and Medical Law’ (1996) 27 *IIC* 423; G. Burch, ‘Ethical Considerations in the Patenting of Medical Processes’, 65 *Texas LR* 1139(1987).

⁸¹ Dr. Christian Keller, ‘European Patents on Diagnostic Methods: What are the Requirements and Perspectives for Applicants?’, [2005/2006] 2 *BSLR*, available at http://www.patentanwalt-landau.de/Publikationen/Diagnostic%20Methods_Keller.pdf. (Last visited on July 4, 2010). See also D. Seaborne Davies, ‘The Early History of the Patent Specification’, 50 *Law Quarterly Review* 86(1934), 102.

⁸² Illustratively, Section 4A of the 1977 Act in the UK mirrors Article 53(c) of the EPC.

Given that the substance of the exclusion remains the same (pre and post EPC 2000), the only difference being one of rationale/justification, case law interpreting the exclusion under EPC 1973 is still applicable.⁸³ In fact, the Enlarged Board of Appeal categorically mentioned that even after EPC 2000, the ‘actual legal position remains unchanged’.⁸⁴

1. Methods

As stated in the previous section, the exclusion is confined only to *methods* of medical and veterinary treatment. As such, it does not prevent the patenting of any products that are used during the course of such methods. Illustratively, drugs and medical devices can be patented in Europe, if they otherwise comply with patentability criteria.⁸⁵

2. Surgery, therapy, or diagnosis

For an invention to be excluded by Article 53(c), it must consist of a method of surgery, therapy, or diagnosis. In order to make this determination, tribunals had earlier focused on the skill and knowledge needed for a person to use the method in question. Thus, if an activity were to be carried out by or under the supervision of a doctor or a vet, exercising medical or veterinary skills, it was more likely to fall within the exclusion.⁸⁶ If the invention could be used by someone such as an engineer or a farmer with little or no medical expertise, it was more likely to fall outside the scope of the exclusion.

However, after the Enlarged Board of Appeal decision in *Diagnostic methods*⁸⁷, this approach is no longer relevant. The Board categorically held that the question of whether or not an invention falls within the exclusion is not dependent on *who* carries out the method in question. In its words:

‘whether or not a method is a diagnostic method within the meaning of [EPC 1973 Article 52(4); EPC 2000 Art 53(c)] should neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practiced by medicinal or non-medicinal support staff, the patient himself or herself or an automated system.’

Although these comments were made in relation to diagnostic methods, it is likely that the reasoning could also be applied to surgery and therapy.⁸⁸ Therefore, the only criterion now is that the “method” itself must qualify as surgery, therapy, or

⁸³ We’ve borrowed most of the European analysis from Brad Sherman’s excellent reference material that he sent as part of Phase I of this project. This is largely taken from a book he co-authored with Lionel Bentley. Bentley & Sherman, *Intellectual Property Law* (OUP New Delhi 2003).

⁸⁴ *Diagnostic methods* G01/04 (2006) OJEP0 334, 360 (EBA).

⁸⁵ *Visx v. Nidek* [1999] FSR 405, 465.

⁸⁶ *Cygnus/Device and method for sampling substances*, T964/99 (2002) OJEP0 4, 17. The invention was excluded under EPC Art. 52(4).

⁸⁷ G01/04 (2006) OJEP0 334 (EBA).; See also Sven J.R. Bostyn, ‘No Contact with the Human Body Please! Patentability of Diagnostic Method Inventions after G01/04’, EIPR 238(2007).

⁸⁸ Applied in *Australian National University/Method and apparatus for early detection of glaucoma*, T1197/02; See also *Beth Israel Hospital Association/Non-invasive method for diagnosing Alzheimer’s disease in a patient*, T143/04.

diagnosis, and one does need to determine as to who the “performer” of the said method is. However, the skill and knowledge needed to perform an invention may provide a useful indication.⁸⁹

i) Surgery: ‘Surgery’ has been defined as the branch ‘of medicine concerned with the healing of disease, accidental injury or bodily defects by operating on the living body’. It is said to include both ‘conservative (non-invasive) procedures (such as vaginal hysterectomy, laser surgery to shrink tumors, dermatological procedures, Lasik eye surgery) and the far more numerous operative (invasive) procedures using instruments’.

In recent years, there appears to have evolved two approaches, albeit inconsistent ones, to the way that surgery is defined. While one approach is to focus on the *nature* of the physical intervention, the other is to concentrate on the *purpose* of the intervention. Under the first and oldest approach, tribunals have looked at the nature of the intervention and asked if this would qualify as ‘surgery’. This approach is endorsed by the EPO Guidelines which state that surgery is defined by ‘the nature of the treatment rather than the purpose’.⁹⁰ It has also been applied in a series of decisions by the Technical Board of Appeal at the EPO.⁹¹ It is also the approach that has been adopted in the UK.⁹²

Lately, the EPO has moved beyond the *nature* of the intervention and focused on the *purpose* of the invention in question i.e. whether the physical intervention ‘is suitable for maintaining or restoring health, the physical integrity of the physical well being of a person or animal’.⁹³ The Enlarged Board of Appeal held (albeit in

⁸⁹ *Wellcome/Pigs I*, T116/85 [1988] EPOR 1.

⁹⁰ *Medi-Physics*, G1/07 of 15 February 2010 provided guidelines on the exception to patentability on methods for treatment of the body by surgery. The context of this decision relates to methods for MRI imaging of lung and heart vasculature. It has been questioned whether the presence of a single surgical step in a multi-step method excludes the surgical step from patentability. The present decision makes it clear that a method is excluded from patentability if it involves at least one method step for treatment of a body by surgery or therapy. The decision emphasizes that it is the nature of the intervention that is decisive in defining surgery, and not the purpose. When determining its nature, a guiding factor may be the complexity of the invasive step, including the required medical expertise and the health risks involved.

⁹¹ *Shell/Blood flow*, T182/90 [1994] EPOR 320, 323 (the presence of a surgical step in a multi-step method for treatment of the human or animal body normally confers a surgical character on that method); See also *Baxter International Inc.*, T329/94 (1998) OJEP 241 (focused on the use of surgical instruments).

⁹² *Occidental Petroleum’s Application* BL O/35/84 (A method of embryo implantation which required the intervention of a surgeon or veterinary surgeon was held to be a surgical method, regardless of its purpose). See also *Allen’s Application* BL O/59/92 (It is wrong to assume that a method which did not necessarily require a surgeon could not be considered to be surgery. A physical intervention which requires the medical skills of, for example, a nurse, could still be regarded as surgery. Thus the nature of the method and performer are important in determining whether the method is a surgery).

⁹³ *BrainLAB AG*, T0542/06 decided on 10.10.2007, available at <http://legal.european-patent-office.org/dg3/pdf/t060542eu1.pdf>. (Last visited on July 05, 2010) [A method for visualizing procedural guidelines for a medical procedure in which a medical instrument is shown in an image representation of a body portion including the area in which a medical procedure is to be carried out is patentable and does not fall under the exception. The method for visualizing procedural guidelines

obiter) that surgery ‘includes any physical intervention on the human or animal body in which maintaining the life and health of the subject is of paramount importance’.⁹⁴

On the basis of the above proposition, tribunals have held that processes whose end-result is the death of living beings under treatment, either deliberately or incidentally, fall outside the ambit of the exception.⁹⁵

In a similar vein, in the *General Hospital* decision⁹⁶, the Technical Board of Appeal held that surgical treatment is that which aims at curing. On this basis, it was held that methods which were ‘neither clearly suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well being of human beings or animals’ fell outside the exclusion in Article 53(c) EPC 2000.

The above framework has led to the exclusion of a number of “cosmetic” surgeries from the scope of Article 53. Illustratively, the Board concluded that an application that related to ‘methods for hair-removal using optical radiation’ (effectively applying optical radiation to a selected wavelength to damage the hairs and follicles without causing significant damage to the skin) was not excluded from patentability. While the invention involved ‘a non-intentional physical intervention which [was] to be regarded as a surgical operation’, it was not ‘potentially suitable for maintaining or restoring the health, physical integrity, or physical well-being of a person or animal’. The purpose of the application was to improve the aesthetic appearance of the person treated rather than to cure the underlying malady. As such the Board held that the application did not fall within the remit of Article 53(c).⁹⁷

Applying a similar logic, the Board also said that tattooing and piercing, whose only possible object was to beautify the human or animal body, would not fall foul of EPC 2000 Art 53(c). However, the tribunals drew a distinction between cosmetic surgeries that were only intended to beautify and those that intended to restore bodily integrity.⁹⁸ Therefore, methods relating to breast enlargement or nose reconstructions which were meant to restore the physical integrity of the body following, for example, breast cancer or a car accident were held to be non patentable.⁹⁹

The nature of the conflict between the two lines of decisions at the EPO was recognized by the Technical Board of Appeal in *Medi-Physics*,¹⁰⁰ where the question

does not have a surgical character because it is not suitable or potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of a human being or animal, or to prevent diseases].

⁹⁴ *Diagnostic methods*, G01/04 (2006) OJEP0 334 (EBA).

⁹⁵ *Georgetown University/Pericardial access*, T35/99 (2000) OJEP0 447, 451.

⁹⁶ *General Hospital Corp/Hair removal method* T 383/03 (2005) OJEP0 159.

⁹⁷ *Ibid.*

⁹⁸ See also *Thermage*, T1172/03 decided on 04.05.2005 [The application of electromagnetic energy through the skin surface of the body to a collagen-containing tissue site, in order to achieve controlled contraction of collagen and skin tightening. The method, though cosmetic, is suitable for maintaining or restoring the health, the physical integrity and the physical well being of a human being].

⁹⁹ *General Hospital Corp/Hair removal method* T 383/03 (2005) OJEP0 159.

¹⁰⁰ *Medi-Physics/Treatment by Surgery* T992/03 (2007) OJEP0 557.

of the proper approach to be followed was referred to the Enlarged Board for consideration. In so doing, the Technical Board raised the familiar complaint of purpose-bound tests, namely that the same physical activity may be used for different purposes. Thus the injection of a medicament (such as Botox) for treating a disease would be excluded, whereas the injection of the same medicament for the purpose of reducing wrinkles would not (on the basis that it would be carried out for cosmetic rather than curative reasons). In this context, the operation of the exclusion will depend on the *motive of the person administering the drug*. However, when the decision was referred to the Enlarged Board for consideration, it held that it was important to focus on the nature of the activity itself, rather than on the type of person who delivers the activity and what their motive may have been.¹⁰¹

In the above-mentioned case of *Medi-Physics*, the applicant, Medi Physics Inc, filed an application relating to medical imaging of the heart or lungs which involved injecting or inhaling Xenon 129. The Examining Division rejected the application on the basis that the injection of the Xenon 129 amounted to a surgical step and that the invention concerned a diagnostic method. On appeal the Technical Board of Appeal held that the invention was not a diagnostic method, but on the subject of injecting the Xenon 129, it referred the case to the Enlarged Board. The Enlarged Board had to answer the question: *“Is a claimed imaging method for a diagnostic purpose which comprises or encompasses a step consisting of a physical intervention practised on the human or animal body, to be excluded from patent protection as ‘a method of treatment of the human or animal body by surgery’ pursuant to article 53(c) EPC if such a step does not per se aim at maintaining life and health?”*

The EBA concluded that the claimed imaging method was excluded from patentability under Article 53(c) EPC 2000 due to the fact that the invasive (injection) step was required, irrespective of whether the purpose was diagnostic or not. The Board clearly stated that the purpose of the method is irrelevant – the exclusion is *not* limited to therapeutic or reconstructive surgery. Instead, surgery is defined by the nature of the method, and in particular the level of skill required and risk incurred, not the ultimate purpose of the procedure.

(ii) Therapy: ‘Therapy’ has been interpreted broadly as the curing of a disease or the correction of a malfunction of the human or animal body.¹⁰² It also includes prophylactic treatments with a view to maintaining health by preventing ill effects that would otherwise arise.¹⁰³ On the basis that pregnancy and lice infestation are not “diseases”, inventions for methods of treatment that prevented pregnancies and removed lice were not caught by the exclusion.¹⁰⁴ However, a method of immunizing against coccidiosis¹⁰⁵ and a method of controlling mange in pigs¹⁰⁶ were held to

¹⁰¹ *Kononklijke Philips Electronics T09/04* (Unpublished); See also *Maquet Critical Care T1102/02* (Unpublished).

¹⁰² *Michigan State University, T0866/01* decided on 11.05.2005 [Application of a medicament ‘for providing euthanasia in lower mammals’ cannot be considered a therapeutic method].

¹⁰³ *Duphar/Pigs II, T19/86* [1988] EPOR 241.

¹⁰⁴ *Salimen/Pigs III, T58/87* [1989] EPOR 125.

¹⁰⁵ *Unilever (Davis’ Application)* [1983] RPC 219.

¹⁰⁶ *Wellcome/Pigs I, T116/85* [1988] EPOR 1.

relate to diseases and, as such, were excluded as methods of treatment by therapy. The exclusion of therapeutic methods applies irrespective of whether the disease or bodily malfunction that the invention seeks to prevent or cure is internal or external, and whether or not it is a temporary or a permanent infliction. It also applies irrespective of the origin of the pain, discomfort or incapacity that the therapy seeks to remedy.¹⁰⁷ While an invention may interact with or relate to a human or animal body, it will only be excluded if it is classified as a form of treatment on the body. In line with this, the Technical Board of Appeal held¹⁰⁸ that ‘a method and apparatus for preventing piglets from suffocating’ by blowing hot air under a mother pig to discourage piglets from going under her was patentable. While the invention protected the body, it was still patentable because the method was not treating any malfunction the body of the piglet and hence could not be classified as therapy.

Here again, “cosmetic” methods are excluded. In other words, while a method that leads to weight loss for the purpose of curing or preventing obesity would not be patentable, a method for weight loss that is undertaken for cosmetic purposes does not fall within the scope of the exclusion.¹⁰⁹ However, if a method was to have both potential uses (weight loss for obesity and for cosmetic purposes) and the claim in the patent merely recites the intent, the said method is not excluded from the ambit of the exception. If the cosmetic use of the method is only expressed in the claim as a mere intention of the person using the method. Thus, the method of skin resurfacing, being both surgical (requiring application of electromagnetic energy through the skin surface) and therapeutic (i.e. application on the face or neck for reconstructive purposes) is excluded from patent. The cosmetic use of these methods is only expressed in the claim as a *mere intention of the applicant*, a feature which is only reflected in the mind of the person carrying out the claimed invention. This is a subjective, non-technical feature which is not relevant for the assessment of patentability.¹¹⁰

(iii) Diagnostic Methods: The nature and scope of the exclusion of diagnostic methods was clarified to a large extent by the decision of the Enlarged Board of Appeal in *Diagnostic methods*.¹¹¹ In this decision, the Enlarged Board held that methods of diagnosis typically consist of four subsidiary steps . These are:

- (1) Examination: involving the collection of data (recording the case history),
- (2) Comparison: comparing this data with normal values,
- (3) Identification: identifying any significant deviation from the norm (i.e. symptom), and
- (4) Diagnosis: the ‘deductive medical or veterinary decision phase’ where the

¹⁰⁷ *Rorer/Dysmenorrhoea*, T81/84 (1988) OJEP0 207.

¹⁰⁸ *Salimen/Pigs III*, *supra* n. 104.; See also *Thompson/Cornea*, T24/91 [1996] EPOR 19.

¹⁰⁹ *Du Pont/Appetite suppressant*, T144/83 (1986) OJEP0 301 (A cosmetic method is patentable unless it inevitably has a therapeutic effect. It was therefore possible to patent a method of dieting involving suppression of appetite, since the effect would not necessarily have been positive).

¹¹⁰ *Thermage*, *supra* n. 98. See also *Mobil Oil III*, 1990 OJEP0 93.

¹¹¹ *Diagnostic Methods*, G01/04 (2006) OJEP0 334.

diagnosis for curative purposes is made (which represents a purely intellectual or non-technical exercise).

A key issue that the Enlarged Board was forced to contend with was whether to fall within the exclusion an application only needed to include the fourth ‘deductive stage’ (broad interpretation), or whether it had to include all four stages (narrow interpretation). Drawing on a range of factors, the Enlarged Board adopted the broad interpretation and said that to fall within the exclusion, *all* four steps needed to be present in an invention. (In so doing the Enlarged Board overturned the Technical Board’s decision of *Cygnus*¹¹² and reinstated the earlier decision of *Bruker/Non-invasive measurement*¹¹³). The Board also said that no distinction should be drawn between the essential method steps that have a diagnostic character and non-essential steps that do not.¹¹⁴

Under the Boards framework, a distinction is now drawn between the act of making a diagnosis (which involves the interpretation of data to reach a conclusion) and methods of data acquisition or data processing (the results of which may subsequently be used in diagnosis). If an invention only provides interim or preliminary results (data or information), the invention will not be excluded from patent protection by Article 53(c). Put differently, the exclusion will only apply where an invention makes it immediately possible to decide on a particular course of medical treatment (i.e. the curative step representing the deductive medical decision phase).¹¹⁵ As a result, a method of taking a sample or determining internal temperature or pH would not in itself identify a condition and as such would not be classified as diagnostic method.¹¹⁶

The current interpretation of Article 53 means that many diagnostic methods will no longer be caught by the exclusion, despite the express language of the EPC 2000. It also means that common diagnostic procedures practised on the human body, such as percussion or palpitation, could, in principle, be patented because they do not constitute a complete “diagnosis”. The reasoning of the Enlarged Board has been

¹¹² *Cygnus/Device and method for sampling substances*, T964/99 [2002] OJEP 4, 13. The invention, which monitored sugar levels from the skin thus avoiding the need for the pricking of fingers to collect blood, did not involve all the steps in medical diagnosis (it only provided information used to make a diagnosis). The Board rejected *Bruker* and held that the patent was a method of medical diagnosis and as such was excluded from patentability. Drawing upon the French text of the EPC, the Board in *Cygnus* said that the EPC ‘does not favour an interpretation limiting the exception to patentability encompassing all steps required for reaching a medical diagnosis. Instead the Board said that ‘any medical activity concerning the gathering of information in the course of establishing a diagnosis qualifies as a diagnostic method.’

¹¹³ *Bruker/Non-invasive measurement* T385/86 [1988] EPOR 357, ¶ 3.2–3.4 (for an invention to be classified as a non-patentable diagnostic method, *all* of the different steps had to present).

¹¹⁴ *Diagnostic methods* G01/04 (2006) OJEP 334, 356 (EBA).

¹¹⁵ *Exergen Corporation*, T1255/06 decided on 23.10.2008 [A radiation detector for tympanic temperature measurement i.e. ear temperature detector only defines the data acquisition steps (the temperature of the body) which can be used in a diagnostic method. It does not define the features relating to the diagnosis for curative purposes *stricto sensu*].

¹¹⁶ This is also consistent with the earlier UK Office practice prior to *Cygnus* (T964/99 (2002) OJEP 4), which followed *Bruker* (T385/86 [1988] EPOR 357) and the decision under the 1949 Act in *Bio-Digital Sciences Application*, [1973] RPC 668.

applied in a subsequent decision¹¹⁷ which concerned methods for magnetic resonance imaging. On the basis that the invention only led to the *acquisition of data*, it was held that the invention was not a diagnostic method as defined in Article 53(c) EPC 2000.

Commentators have critiqued what they perceive to be a whittling down of the method of treatment exception, by defining terms such as diagnosis in a very limited way:

*“As the discussion of European case law demonstrates, the legal definition of diagnostic methods does not reflect the true nature of a medical diagnosis. Modern diagnoses are rarely final and few occur without the aid of data and quantitative results from laboratory testing”.*¹¹⁸

Treatment on or in the body- The “method of treatment” exclusion articulated in Article 53 only applies to methods that are practised on or in the human or animal body i.e. the exclusion does not apply to methods practised on substances that are removed from the body. Illustratively, the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded. Similarly, operations that occur at a cellular level (such as the incorporation of an oncogene into the fertilized egg of an animal) are not performed on or in the body.¹¹⁹ In contrast, a treatment of blood by dialysis, where the blood is returned to the same body, would be excluded from patentability.¹²⁰

In *Aerocrine AB*,¹²¹ the European Board of Appeal determined the patentability of a method for ascertaining the current lung function of a human subject. The method comprised of measuring the endogenous nitrogen monoxide content and/or the time of its distribution during one or more exhalation phases in a sample of exhaled air. Since measuring is of a technical nature, it had to be evaluated whether or not it is practiced on the human body. The Board categorically stated that:

“It results from the feature ‘measuring... during one or more exhalation phases’ that the presence of the human subject and its connection to the device is necessary even if the measuring was to be performed on exhaled air removed from the body. The condition ‘practised on the human body’ is therefore satisfied in the present situation”.

As stated earlier, diagnostic methods typically consist of a number of steps, all of which must be present if an application is to fall within the ambit of the exclusion. While this framework is essential to determining whether something amounts to a diagnostic method and is therefore excluded, the converse appears to apply when determining if a diagnostic method is practised on or in the human or animal body.

¹¹⁷ *Medi-Physics/Treatment by Surgery* T992/03 (2007) OJEP0 557, 563.

¹¹⁸ Tina Piper, *supra* n. 5.

¹¹⁹ *Harvard/Onco-mouse* (2003) OJEP0 473, 491 (OD). It clarified that ‘the incorporation of the oncogene into the genome is a method which is neither surgical nor therapeutic nor diagnostic in nature’.

¹²⁰ EPO Guidelines, C-IV, 4.8. See *Baxter/Blood extraction method*, T329/94 [1998] EPOR 363, 367.

¹²¹ *Aerocrine AB*, T0125/02 decided on 23.05.2006.

The reason for this is that some of the stages in a diagnostic method (particularly the final 'deductive phase') are intellectual exercises: they are carried out in the mind of the medical or veterinary practitioner. To get around the problems that this might pose, the Enlarged Board of Appeal held that the requirement that the invention be 'practised on or in the human or animal body' is only to be considered in relation to method steps of a technical nature. 'Thus, it does not apply to the diagnosis for curative purposes *stricto sensu*, i.e. the deductive decision phase, which as a purely intellectual exercise cannot be practiced on the human or animal body'.¹²²

Direct treatment- In order for a patent to fall within the therapeutic method exclusion, it is necessary to show that the invention constitutes a *direct treatment by therapy*. This means, for example, that while the programming of a pacemaker to control the way it uses energy undoubtedly has an indirect effect on the human body, it was held to be more concerned with improving an apparatus, rather than health.¹²³ While it is difficult to draw the line between direct and indirect effects, a patent is more likely to fall within the exclusion if it can be shown that there is a 'corresponding functional link' between the invention and human or animal health. That is, a method does not fall within Article 53(c) 'if there is no functional link and hence no physical causality between its constituent steps carried out in relation to a therapy device and the therapeutic effect produced on that body by that device'.¹²⁴ Similarly, it has been held that to fall within the exclusion, the invention must target a particular illness or disease, and also provide a 'defined, real treatment' of a pathological condition.¹²⁵

Two or more uses- So long as an application has a use which falls within the scope of Article 53(c) it will be excluded. This is the case even if the invention has other uses that do not fall within the exclusion. Thus, an application for a method of cleaning plaque from human teeth which had both an (excluded) therapeutic effect and a (non-excluded) cosmetic effect was excluded from patentability by Article 53(c) EPC 2000 on the basis that the application claimed a therapeutic treatment.¹²⁶ While the presence of a surgical step in a multi-step method of the treatment of the human or animal body normally confers a surgical character on the method, there may be some cases where this is not the case.¹²⁷ On the basis that methods that have a destructive purpose do not fall within the aim of section 4A/Article 53(c) surgery is limited to processes that give 'priority to maintaining life or health of the human or animal body on which they are performed'.¹²⁸ As such, a process that has as its end result the death of a living thing (either deliberately or incidentally) will not be caught by the exclusion: even if the process involves a surgical step. Similarly, the fact that a chemical product has both a cosmetic and a therapeutic effect when used

¹²² *Diagnostic methods*, G01/04 (2006) OJEP0 334.

¹²³ *Ela Medical*, T789/96 (2002) OJEP0 364, 369.

¹²⁴ *Siemens*, T245/87 (1989) OJEP0, 171.

¹²⁵ *Eli Lilly/Serotonin receptor*, T241/95 (2001) OJEP0 103, 109.

¹²⁶ *ICI/Cleaning plaque*, T209/86 (1992) OJEP0 414.

¹²⁷ *See-Shell/Blood flow*, T182/90 [1994] EPOR, 320; EPO Guidelines C-IV, 4.3.

¹²⁸ *Georgetown University/Pericardial access*, T35/99 [2000] OJEP0 447, 451. This is in contrast to processes whose end result is the death of living things 'under treatment' either deliberately or incidentally.

to treat the human or animal body does not render the cosmetic treatment unpatentable¹²⁹.

Limits- While Article 53(c) imposes important limits on the types of medical and veterinary inventions that may be patented, it would be wrong to assume that all medical and veterinary inventions are excluded from the scope of patent protection. The reason for this is that the potential scope of the exclusion is restricted by the fact that it must be read in light of Article 54(5).¹³⁰

These provisions have been construed in such a way that they permit the patenting of uses of known substances for the manufacture of a medicament for the treatment of a particular disease. However, these so-called *Swiss claim* patents are beyond the scope of this exception.¹³¹

The Enlarged Board of Appeal decision in *KOS life sciences*¹³² further clarified the question, where it is already known to use a particular medicament to treat a particular illness, whether this known medicament can be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness. In other words, is it possible to patent the same medicament for the same illness, used in a different way? Replying in the negative the EBA has recently held in G02/08¹³³ that second medical use claims in the Swiss-type format are no longer allowable before the EPO. Thus, it is not allowed to patent the same medicament for the same illness, used in a different way.

As Article 54(5) only applies to medical methods which use substances or compositions, the exclusion of methods of medical and veterinary treatment still applies where apparatuses and objects are used. However, Swiss-type claims aiming at the use of surgical instruments were rejected by the Technical Boards. The residual scope of the exclusion was reaffirmed by the Appeal Board of the EPO when it resisted attempts to extend the scope of Article 54(5) beyond the use of substances and compositions to include the surgical use of an instrument.¹³⁴

¹²⁹ *General Hospital Corp/Hair removal method* T 383/03 (2005) OJEP0 159, 162.

¹³⁰ Article 54(5) states that 'the provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.'

¹³¹ In *Eisai*, G0005/83, the EPO accepted that Art 54(5) by relaxing the usual novelty rules enables the inventor of a first medical use to obtain purpose-limited product protection for a known substance or composition. But for second and subsequent medical uses it held that Art 54(5) no longer applies. The prior identification of any medical use is enough to invoke the proviso.

¹³² *KOS Life Sciences/Dosage Regimen*, T1319/04 (2009) OJEP0 36.

¹³³ *KOS Life Sciences*, G02/08 of February 19, 2010.

¹³⁴ *CODMAN/Second surgical use*, T 227/91 (1994) OJEP0 491 held that second medical use claims to surgical instruments were not allowed on the grounds that 'a surgical use of an instrument is not analogous to a therapeutic use... since the former is not consumed in the application and could be repeatedly used for the same or even for other purposes'.

United Kingdom :

Historically, the UK excluded methods of treatment from the scope of patentability on the ground that such methods were not “vendible products”¹³⁵ and therefore did not amount to a “manner of manufacture”. In *C & W’s Application*¹³⁶ a method of extracting lead from human bodies was held ineligible for patent protection because of its lack of association with the manufacture or sale of a ‘commercial product’. Later development was seen in the form of the *NRDC* case¹³⁷ from Australia, involving a method of using a known chemical substance to help remove weeds from crop areas without affecting the crops themselves. The court effectively repudiated the “vendibility” test and noted that in order to be patentable, the claimed invention must:¹³⁸

- i) provide a material advantage
- ii) be of value within an economic field of endeavor.
- iii) must belong to practical rather than the fine arts
- iv) must possess as its end result an artificial effect or a discernible artificial state of affairs.

Based on the above, the court held that the claimed method of eradicating weeds was patentable since it consisted of an artificially created state of affairs discernible by observing the growth of weeds and crops sown on the land, and it is of tremendous economic value.¹³⁹

Drawing on the *NRDC* principles outlined above, commentators suggest that methods of treatment of the human body would be excluded on the grounds of their “essentially non-economic” nature and the fact they lacked the “artificiality” required of inventions.¹⁴⁰

In line with the above decision, UK courts and the patent office began to base their exclusion of medical methods on the fact that such claims lacked the “artificiality” required of inventions.¹⁴¹

This reason was first articulated in *Swift & Company’s Application*¹⁴² in respect of a method of treating live animals, and was adapted during the 1960s to support the exclusion in relation to humans as well.¹⁴³ Thus in *Neva Corporation’s Application*¹⁴⁴

¹³⁵ *Re G.E.C.’s Application*, (1942) 60 RPC 1

¹³⁶ *C & W’s Application*, (1914) 31 RPC 235.

¹³⁷ *NRDC* (1959) 102 CLR 252.

¹³⁸ *Ibid*, 275.

¹³⁹ A.L. Monotti ‘The Scope of Manner of Manufacture Under the Patents Act 1990 (Cth) after Grant v. Commissioner of Patents’ 34 Fed. L. Rev. 461(2006), 465, available at <http://ssrn.com/abstract=1091281>. (Last visited on August 5, 2010).

¹⁴⁰ William van Caenegem, *supra* n. 38. See also *CCOM Pty Ltd v. Jiejing Pty Ltd.* (1994) 51 FCR 260. See also Justine Pila, *supra* n. 25, 441.

¹⁴¹ Justine Pila, *supra* n. 25.

¹⁴² *Swift & Company’s Application*, [1961] RPC 129.

¹⁴³ *Puharich and Lawrence’s Application*, [1965] RPC 395.

a method of inducing a state of reduced awareness in humans (and animals) by means of sounds generated by a known apparatus was held to be an unpatentable method of medical treatment on the ground that its utility depended upon the reception and interaction of the sounds with the human brain, therefore lacking any “artificiality” of invention.¹⁴⁵

Pursuant to the advent of the EPC 1973 and the EPC 1990, the UK amended its law to be in consonance with these multilateral instruments. And UK courts have, for the most part, rendered decisions that are largely in conformity with the EU courts understanding of the method of medical treatment exclusion.

Illustratively, the approach adopted by the Enlarged Board in *Diagnostic methods* has been followed by the UK Intellectual Property Office. The Enlarged Board in the decision noted that the criterion “practised on the human body” was to be considered only in respect of method steps of a technical nature. It also pointed out that steps involved in diagnosis such as comparison of data were non-technical in character as they are performed outside the body¹⁴⁶. A method performed on the body which does not enable a disease to be identified, but which may be of value in diagnosis (i.e. only for acquisition of data) is therefore not excluded under Section 4A(1) of the 1977 Act in UK since the amendment in 2004 adopts the EPC position. For example, a method of imaging using CT scanning¹⁴⁷, a method of measuring blood glucose¹⁴⁸ and a method of assessing tissue viability by measuring total haemoglobin, oxygen saturation and hydration¹⁴⁹ were all considered to provide only intermediate results which did not enable a diagnosis to be made. Indeed, UK courts have also stressed on limiting the reach of this exclusion on the basis of its alleged rationale. In *Bristol-Myers Squibb Co v Baker Norton Inc*, Jacob J held:¹⁵⁰

“[T]he limited purpose of the [s 4(2)] exception ... is not so broad as to allow doctors using whatever they feel they need to treat patients. If that were the purpose then one would not allow patents for medicines or medical implements at all. The purpose of the limitation is much narrower, merely *to keep patent law from interfering directly with what the doctor actually does to the patient*. Patent monopolies are permitted to control what he administers to, or the implements he uses on, the patient. The thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research

¹⁴⁴ *Neva Corporation's Application*, [1968] RPC 481.

¹⁴⁵ This was consistent with *London Rubber Industries Ltd's Patent*, [1968] RPC 31 where a method of controlling female ovulation through the prescribed oral administration of known hormones was refused a patent on the ground, implicitly, that the utility of such method depended upon the physiological response of the person treated and for this reason fell outside the realm of useful arts in which inventions exist.

¹⁴⁶ Eddy D. Ventose, ‘Patent protection for diagnostic methods under the European Patent Convention’, 38(8) IIC 884(2007), 897.

¹⁴⁷ *Kononklijke Philips Electronics*, T09/04.

¹⁴⁸ *Albott Laboratories*, T 330/03 (Unpublished).

¹⁴⁹ *National Research Council of Canada*, T 41/04 (Unpublished).

¹⁵⁰ *Bristol-Myers Squibb Co v Baker Norton Inc*, [1999] RPC 253.

incentive, then there is no reason to suppose that that would not apply also to methods of treatment” (emphasis added).¹⁵¹

However, there are some minor differences between the interpretations proffered by the EU and the UK courts. Illustratively, as the UK Intellectual Property Office Guidelines for medical inventions note, the approach as outlined in the *General Hospital* decision that methods which were ‘neither clearly suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well being of human beings or animals’ fell outside the exclusion in Article 53(c) EPC 2000, is out-of-step with British practice. Following the 1983 UK decision of *Unilever (Davis’ Application)* which in *obiter* mentioned that claims to a method of surgery should be refused, *regardless of their purpose*, the UK Intellectual Property Office has decided not to follow the EPO in this regard.¹⁵²

D. North American Region: United States

In the United States, patents on medical procedures were not allowed until 1954. The earliest case in this regard was *Morton v. New York Eye Infirmary*¹⁵³, in which a patent for a procedure of administering ether to surgical patients as an anaesthetic was disallowed on grounds of lack of novelty and obviousness. Although this case seemed to have been decided on traditional patentability criterion, it was perceived as establishing more generally that medical procedures were unpatentable subject matter.¹⁵⁴ In *Ex parte Brinkerhoff*¹⁵⁵, *Morton* was relied upon by the Patent Office Board of Appeals which went on to hold that ‘methods or modes of treatment of physicians of certain diseases are not patentable’ on the rationale that ‘to grant a patent for a particular method of treatment would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired result in all cases’.¹⁵⁶

However, in *Ex parte Scherer*¹⁵⁷, while allowing a patent on a method of injecting medicine by a pressure jet, the Board overruled its decision in *Brinkerhoff* and held that medical or surgical processes or methods were patentable since they constituted a ‘useful process’ under § 101 of the United States Code.¹⁵⁸

¹⁵¹ The Enlarged Board of the EPO reiterates a similar philosophy noting that the exclusion “helps to achieve the socio-ethical and public health goal that ‘medical and veterinary practitioners should be free to take the actions they consider suited to diagnose illness by means of investigative methods.’” See *Diagnostic methods* G01/04 (2006) OJEP 334.

¹⁵² *Unilever (Davis’ Application)* [1983] RPC 219: ‘.....surgery can be curative of the disease or diseased conditions, or prophylactic, that is, preventative of diseased conditions, as for example, where an appendix or tonsils may be removed before any diseased condition starts up, and surgery may even be cosmetic without being curative or preventative. Any method of surgical treatment, whether it is curative, prophylactic or cosmetic, is not patentable.’

¹⁵³ 17 F. Cas. 879 (C.C.S.D.N.Y. 1862).

¹⁵⁴ Cynthia M. Ho, *supra* n. 5, 611.

¹⁵⁵ 24 Off. Gaz. Pat. 349 (Comm’r Pat. Off. 1883).

¹⁵⁶ *Ibid.*

¹⁵⁷ 103 U.S.P.Q. (BNA) 107 (Pat. Off. Bd. App. 1954).

¹⁵⁸ *Ibid.*, 109.

35 U.S.C. § 101 of the United States Code states that any process, machine, manufacture and composition of matter is patentable, if it is new and useful, subject to conditions of Title 35.¹⁵⁹

In a controversial case, Dr Samuel Pallin, the owner of a patented method relating to the performance of cataract surgery without sutures. sued others that were using his method. Given that almost half of all cataract procedures performed in the United States involved Dr. Pallin's technique, several associations of physician's protested the enforcement of this patent and lobbied for legislative change in this regard.¹⁶⁰

Responding to this uproar created by Dr Pallin's patent, the US government brought in a specific defense in favour of medical practitioners using patented methods through the *Omnibus Consolidated Appropriations Act*.¹⁶¹ As a result of this act, Section 287(c)(1) now provides that:

"With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of section 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.¹⁶²

35 U.S.C. § 287(c)(2)(A) however provides for an exception from the above rule by stipulating that the defense will not apply to a patented machine, item of manufacture, or composition of matter, biotechnological patents, and importantly, patented uses of a composition of matter..¹⁶³In short, although the US grants patents to medical methods, they curtail the scope of such patents by providing an express defences in favour of medical practitioners that use such methods.¹⁶⁴ To this extent, the treatment of medical method patents by the US is perhaps unique.

Canada- There is no specific statutory bar to the patenting of medical methods in Canada. The issue has been left largely to the courts, which have held that methods

¹⁵⁹ "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title". Section 101, Title 35.

¹⁶⁰ *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995). See also Wendy W. Yang, Note, 'Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion From Patentability', 1 B.U. J. Sci. & Tech. L. 5 (1995).

¹⁶¹ The Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, 110 Stat. 3009 (1996).

¹⁶² The term 'Medical activities' is defined in 35 USC 287(c)(2)(A) as "the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent".

¹⁶³ Todd Martin, *supra* n. 47, 403.

¹⁶⁴ In February 2010, the Secretary's Advisory Committee on Genetics, Health, and Society has recommended that this exemption be extended to medical practitioners providing gene testing. SACGHS, *Revised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, 2010.

of medical treatment are considered inherently unpatentable.¹⁶⁵ To be considered a method of medical treatment, the method should cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity such as by physiotherapy or surgery.¹⁶⁶

As with other common law jurisdictions, Canadian courts have also confirmed that while methods of using surgical instruments are inherently unpatentable,¹⁶⁷ the instruments/apparatuses designed to perform surgeries are themselves patentable.¹⁶⁸

In *Tennessee Eastman Co. v. Commissioner of Patents*¹⁶⁹, the leading case on the point, the Canadian Supreme Court was faced with the patentability of an alleged invention relating to "a new use for esters of a-cyanoacrylic acid and more particularly to a surgical method of joining tissue surfaces through the use of such esters as adhesives". This claim had been rejected by the patent examiner on the ground that it was directed towards a method of surgical treatment. While upholding the decision of the patent office, Justice Kerr relied extensively on the *NRDC* decision.¹⁷⁰ And held in pertinent part that the claimed invention did not fall within the field of the manual or productive arts nor did it, when applied to the human body, produce a result in relation to trade, commerce or industry or a result that was "essentially economic". The method related essentially to the professional field of surgery and medical treatment of the human body, even although it could be applied, at times, by persons not within that field.

In so far as methods of diagnosis are concerned, courts have held that methods of testing not relating to any step of actual treatment or vital function of the body, have been held to be patentable.¹⁷¹ This appears similar to the EU position, where the meaning of "diagnosis" has been considerably narrowed to permit wider patenting of such methods.

Courts have held that prophylactic methods of treatment are unpatentable,¹⁷² as are methods for reducing nicotine cravings, and cleaning teeth.¹⁷³ To this extent, Canadian courts appear to take a different line than the EU authorities by holding

¹⁶⁵ *Tennessee Eastman Co. v. Commissioner of Patents*, 8 C.P.R. (2d) 202 (1972) (S.C.C., Can.).

¹⁶⁶ *Axcan Pharma Inc. v. Pharmascience Inc.* [2006] F.C. 527; 50 C.P.R. (4th) 321. See also Chapter 17, *Manual of Patent Office Practice*, available at [http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/2009-01-01chapitre17-chapter17-eng.pdf/\\$file/2009-01-01chapitre17-chapter17-eng.pdf](http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/2009-01-01chapitre17-chapter17-eng.pdf/$file/2009-01-01chapitre17-chapter17-eng.pdf). (Last visited on August 5, 2010).

¹⁶⁷ Stephen B. Garland, 'Methods of Medical Treatment Revisited', *Patent World*, August, 1997, 7-8.

¹⁶⁸ *Merck & Co. v. Apotex Inc.*, [1995] 2 F.C. 723; 60 C.P.R. (3d) 356; 180 N.R. 373 (C.A.). See also *Visx, Inc. v. Nidek Co.*, 72 C.P.R. (3d) 19 (1996) (Can.).

¹⁶⁹ *Tennessee Eastman Co. v. Commissioner of Patents*, *supra* n. 165.

¹⁷⁰ Section 2(d) of the Canadian Patents Act defines invention as "invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."

¹⁷¹ David Vaver, *Intellectual Property Law*, *Essential of Canadian Law*, 130(1997); See also *Re Application for patent of Goldenberg*, 22 C.P.R. 159 (1988) (Can. Comm'r Pat.).

¹⁷² *Re Application of Ackerman*, 105 C.P.O.R. 14-xviii (1977) (Can.).

¹⁷³ *Re Application of Revici*, 71 C.P.R. (2d) 285 (1981) (Can. Comm'r Pat.); *Imperial Chemical Ltd. v. Commissioner of Patents*, 9 C.P.R. (3d) 289 (FCA) (1986) (Can. Fed. Ct.).

that claims on methods that achieve a cosmetic result are patentable.¹⁷⁴

As per the Manual of Patent Office Practice of the Canadian Patent Office that arise from the Office's interpretation of the *Patent Act*, *Patent Rules* and jurisprudence "*the methods that involve performing surgery on the human or animal body are excluded, whether the effect of the surgery is therapeutic or not. Methods that involve the excision of tissue, organ, or tumour samples from the body are considered to be forms of surgery, and are excluded regardless of their reproducibility. The removal of fluids from the body such as by needle or cannula is not of itself surgery.*"¹⁷⁵

Mexico- Article 19 (VII)¹⁷⁶ of the Industrial Property Law in Mexico states that methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals shall not be considered as "inventions". Thus such methods are not patentable under the Mexican Law.

E. Australia and New Zealand

Australia- Section 18 of the Patent Act, 1990¹⁷⁷ provides that an invention is patentable, if it is a "manner of manufacture" within the meaning of section 6 of the Statute of Monopolies¹⁷⁸. The Act does not expressly prohibit patents on medical methods. For a great number of years, the courts followed the English courts' understanding of "manner of manufacture" and held that only a "vendible product" would constitute a "manner of manufacture". Since methods of medical treatment were not vendible products, they could not be patented.¹⁷⁹

In the NRDC Case,¹⁸⁰ the court shifted the analysis away from a pure "vendible product" test to a more general manner of manufacture test; asking if the process or product is "*... a proper subject of the letters patent according to the principles which have been developed for the application of Section 6 of the Statute of Monopolies.*"¹⁸¹

The court noted that in order to clear the requirements of the test under the NRDC Case, the subject matter must be useful, provide a material advantage, and be of

¹⁷⁴ Chapter 12, *Manual of Patent Office Practice (MPOP)*, available at <http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr02212.html>. (Last visited on August 1, 2010).

¹⁷⁵ *Ibid.*

¹⁷⁶ **Article 19 (Mexico):** The following shall not be considered inventions for the purposes of this Law:...VII. methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals.

¹⁷⁷ **Section 18 (Australia): Patentable inventions:** (1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies;...

¹⁷⁸ **Section 6** of the Statute of Monopolies, 1624 provides that no declaration contained in the statute shall extend: " ... to any letters patent and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm to the true and first inventor and inventors ...which others at the time of making such letters patent and grant shall not use, so as also they be not ... generally inconvenient;"

¹⁷⁹ William van Caenegem, *supra* n. 38.

¹⁸⁰ *National Research Development Corp. v. Commissioner of Patents*, 102 CLR 252 (1959), (Full Ct. of the H.Ct., Austl.).

¹⁸¹ *Ibid.*, 269.

value within the economic field of endeavor.¹⁸² The court also noted in passing the "apparent" need to exclude methods of treatment of the human body on the grounds of their "essentially non-economic" nature.¹⁸³

Subsequently, in *Joos v. Commissioner of Patents*¹⁸⁴, the High Court of Australia narrowed the scope of the exclusion of methods of treatment of the human body by confining the exclusion to methods of preventing or alleviating diseases, malfunctions or incapacities.¹⁸⁵ The invention in question in this case was a 'process for improving the strength and elasticity of keratinous material'. The Court held that mere application of a substance to the human body did not qualify as 'treatment'. Explaining this concept further, it was held by Barwick, C.J.:

"To be treatment in the relevant sense, it seems to me that the purpose of the application to the body whether of a substance or a process must be the arrest or cure of a disease or diseased condition or the correction of some malfunction or amelioration of some incapacity or disability."¹⁸⁶

On this basis, the court drew a distinction between cosmetic processes and therapeutic processes, noting that a cosmetic process of strengthening hair and nails had no relation to a method of treatment of a disease, malfunction, disability or incapacity of the human body and the cosmetic process for improving the strength and elasticity of human hair and nails was patentable subject matter.¹⁸⁷ The court also concluded that the medical field was as economic as any other, implicitly rejecting the vendible product test or the "essentially economic nature" test as controlling.¹⁸⁸ However, it did not fully clarify whether or not patents for medical methods involving surgery etc could continue to be excluded on the ground that it was "generally inconvenient".¹⁸⁹

This position was clarified in *Anaesthetic Supplies Pty Ltd v Rescare Ltd*,¹⁹⁰ where the court held that a method of medical treatment could not be considered as generally inconvenient. It noted that although Parliament had the opportunity to exclude methods of treating the human body when it enacted the 1990 Act, it chose not to do so.¹⁹¹ Rather, it merely excluded human beings and biological processes to generate human beings from the scope of patentability.¹⁹² It must be borne in mind that the EU explicitly legislated to exclude medical methods from patentability in 1973 and the UK followed suit in 1977.

¹⁸² *Ibid*, 275.

¹⁸³ *Ibid*.

¹⁸⁴ *Joos v. Commissioner of Patents*, 126 CLR 611 (1972) (Austl.).

¹⁸⁵ David Kell, *supra* n. 47, 203.

¹⁸⁶ *Joos v. Commissioner of Patents*, *supra* n. 184, 619

¹⁸⁷ *Joos v. Commissioner of Patents*, *supra* n. 184, 623

¹⁸⁸ *Joos v. Commissioner of Patents*, *supra* n. 184, 618.

¹⁸⁹ David Kell, *supra* n. 47, 236.

¹⁹⁰ (1994) 50 FCR 1 (Rescare) ¶ 77.

¹⁹¹ Todd Martin, *supra* n. 47, 411.

¹⁹² Todd Martin, *supra* n. 47.

The *Anaesthetic Supplies* position was endorsed in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*¹⁹³, where the *Federal Court of Australia* dealt with patents claiming a method of administering Pacil-taxel (a naturally occurring compound from the Pacific Yew Tree) for the treatment of cancer. While the Court upheld the invalidity of the Patent on grounds of lacking novelty, it nevertheless concluded that methods of medical treatment were patentable subject matter.¹⁹⁴ The Court held that it was difficult to justify the distinction between patentability of a product for treating the human body and a method of treatment.¹⁹⁵ It further held that the legislative history in Australia favoured the grant of patents for methods of medical treatment.¹⁹⁶

Although the ruling of the Court in both *Anaesthetic Supplies* and *Bristol-Myers* may be considered *obiter dicta* according to some commentators, it is still widely considered as the law of the land now.¹⁹⁷

Australia is therefore one of the few countries that grants patents over medical methods. It tracks the US position in this regard, except that while the US recognizes an express defense that saves doctors and others who use patented medical methods, Australia does not.

New Zealand- The Patent Act of 1953 in New Zealand does not contain any statutory exclusion from patentability of medical methods like those prevalent in Canada and Australia.¹⁹⁸ Further the Courts in New Zealand have historically conformed with English decisions and held that a method of treatment of human illness or disease does not qualify for the grant of a patent, since it does not meet the requirement of 'manner of manufacture' under the definition of 'invention' in Section 2.¹⁹⁹

In the *Wellcome case*, an application for a new method of treating meningeal leukemia in the brain by using known compounds was refused by the Assistant Commissioner of Patents as not coming within the scope of an invention under Section 2 of the Patents Act 1953.²⁰⁰ This was reversed by the Supreme Court, which held that there was no basis in law or otherwise for excluding medical methods.²⁰¹ In his decision, CJ Davison elaborated as follows:

¹⁹³ [2000] FCA 316 (22nd March, 2000).

¹⁹⁴ Todd M. Martin, 'New Appellate Decision Clarifies Australian Law Concerning Patentability of Methods of Medical Treatment', 82 J. Pat. & Trademark Off. Soc'y 645(2000).

¹⁹⁵ *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*, [2000] FCA 316 (22nd March, 2000), ¶ 15.

¹⁹⁶ *Ibid*, ¶ 16.

¹⁹⁷ Todd M. Martin, *supra* n. 193, 648.

¹⁹⁸ "Invention" means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture. See Section 2 of the Patents Act 1953 (New Zealand).

¹⁹⁹ *Swift & Company's Application*, [1960] NZLR 775, [1961] RPC 129, [[[1962] RPC 37 (D.C.) (N.Z. H.C. (formally S.Ct.); *Wellcome Foundation v. Commissioner of Patents* 1983 NZLR 385. Courts placed reliance on *Schering A.G.'s Application* [1971] RPC 337; *Upjohn Co. (Robert's) Application* [1977] RPC 185. Tom Syddall, 'Method of Treatment Claims and Patent Law Reform in New Zealand', CIPA Journal, June, 423(1996).

²⁰⁰ *Wellcome Foundation v. Commissioner of Patents* [1983] NZLR 385.

²⁰¹ *Ibid*.

“ Is there any justification in law or in logic to say that simply because, on the one hand, substances produce a cosmetic result or a functional result as opposed to a curative result, the one is patentable and the other is not? I think not. The Court must now take a realistic view of this matter in light of current scientific developments. The law must meet the need of the age.”²⁰²

This decision was in turn reversed by the New Zealand Court of Appeals which categorically held that a patent may not be granted for a method of treating a disease or illness in humans.²⁰³ The basis for the decision appears to be that English Courts have held under legislation similar to that in New Zealand that a method of treatment of a human being is not patentable. Further according to Somers J. there was no New Zealand or Australian case that has held the contrary.²⁰⁴ The Court of Appeals stated that a shift in the law which favours grant of a monopoly for such medical methods was the prerogative of the Parliament.²⁰⁵

In 1999, the Court of Appeals in the *PHARMAC case*²⁰⁶ found that a method of medical treatment fell within the definition of the term "invention," but such claims may be properly prohibited on policy or ethical grounds. The Court suggested that to permit claims to extend to the method of treatment using the compound or composition would require the patentee to submit a disclaimer of any right to sue the practitioner in order to ensure that there is no interference with the medical practitioner's diagnosis and treatment of patients. In a subsequent case of *Pfizer Inc v. Commissioner of Patents*²⁰⁷, Pfizer submitted such a disclaimer to the Court and argued that this was consistent with the *PHARMAC case*. However, the Court categorically stated that the observation in the *PHARMAC case* with regard to submission of a disclaimer was directed to the Legislature and officials considering reform proposals and was not an indication to impose such a requirement in future cases.²⁰⁸ Following the decision in *Bristol-Myers Squibb Co. v Baker Norton Pharmaceuticals Inc.*²⁰⁹, the Court has held that claims drafted in the Swiss format may be rejected if they also relate to the mode of administration, dosage or frequency of dosage.

The medical treatment exclusion has been recently challenged by Pfizer Inc. before the Court of Appeal.²¹⁰ Pfizer Inc's applications related to methods of medical treatment of psychotic disorders using a new compound. The appellants argued that the amendments to the Patents Act of 1953 introduced in 1994 for the purposes of implementation of the TRIPS Agreement intentionally omitted the medical treatment exclusion.²¹¹ They also relied on proposals for reforms in other

²⁰² *Wellcome Foundation v. Commissioner of Patents* [1979] 2 NZLR 591, 621.

²⁰³ *Wellcome Foundation v. Commissioner of Patents, supra* n. 201.

²⁰⁴ *Wellcome Foundation v. Commissioner of Patents, supra* n. 201, 404.

²⁰⁵ *Wellcome Foundation v. Commissioner of Patents, supra* n. 201, 397.

²⁰⁶ *Pharmaceutical Management Agency Ltd v. The Commissioner of Patents and Others* [2002] 2 NZLR 529.

²⁰⁷ *Pfizer Inc v. Commissioner of Patents, supra* n. 58.

²⁰⁸ *Pfizer Inc v. Commissioner of Patents, supra* n. 58, 380.

²⁰⁹ [2001] RPC 1.

²¹⁰ *Pfizer Inc v. Commissioner of Patents* [2005] 1 NZLR 362.

²¹¹ There were several amendments to the Patents Act of 1953 in 1994 but none of them were on

jurisdictions. The Court of Appeal unequivocally held that the medical treatment exclusion was still the governing law and that its omission from the amendments implementing the TRIPS Agreement did not indicate an intention by the Parliament that the medical exclusion no longer applied. As far as the argument relating to reforms was concerned, the Court held that any change in policy in this regard was a matter for the legislature and not for the courts.

F. Asia

Japan- Section 29 of Japanese Patent Law deals with the patentability of inventions.²¹² Section 29(1) states that an invention must be industrially applicable in order to be patentable. Part II of the Examination Guidelines for Patent and Utility Model under Section 2.1 of the Act lays down that a method of medical treatment is not industrially applicable.²¹³ The term medical treatment includes surgery, therapy and diagnostic methods.²¹⁴ Methods for treatment of samples that have been removed from the human body and methods of gathering information from them are not considered methods of treatment and are therefore not excluded from patentability. On the other hand, if the sample is returned to the human body, it is a medical method and is therefore excluded from patentability.²¹⁵

Methods for treatment of the human body by surgery include surgical operations and drawing blood (for tissue culture, dialysis etc), cosmetic methods for surgical operations whose purpose is not therapeutic or diagnostic (for plastic surgery, cosmetic make-over etc) and preparatory treatment for surgery, such as anesthetic treatment. These methods are industrially inapplicable and therefore not patentable.

Methods for treating the human body by therapy include the following: (i) methods of giving or injecting medicine, or giving physical treatment to a patient for cure or restraint of a disease; (ii) methods of implanting substitute organs such as artificial internal organs or artificial limbs; (iii) methods of preventing a disease ²¹⁶and methods of treatment for the maintenance of physical health and (iv) Preparatory methods of treatment by therapy or methods for nursing associated with the

exclusions from patentability. For instance, Section 17(1) as it stood originally empowered the Commissioner to decline registration if it appeared to him that the invention in respect of which the patent application was made would be "contrary to law or morality". The provision was amended in 1994 so that it now applies only where the use of the invention in respect of which the application is made would be "contrary to morality". See also WIPO, New Zealand Patents Act No. 122 (Amendment), 1994, available at http://www.wipo.int/clea/en/text_html.jsp?lang=EN&id=3322. (Last visited on August 8, 2010).

²¹² **Section 29 (Japan): Patentability of inventions:** (1) Any person who has made an invention which is industrially applicable may obtain a patent...

²¹³ **Section 2.1 (Japan): Industrially Inapplicable Inventions:** (1) Methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body. *Examination guidelines for patents and utility models in Japan-Part II-Chapter 2*

²¹⁴ *Ibid.*

²¹⁵ *Revised Japanese Patent Law and Examination Guidelines-Part II-Chapter 1, Sections 2.1.1.3 and 4.2.4.*

²¹⁶ *Ibid.* Methods for preventing diseases can be both therapeutic and diagnostic. For example, in Japan, Toyohari acupuncture is a therapeutic means of preventing diseases as well as maintaining health. A patent on these methods is not allowed.

treatment.

These methods are not patentable as they are industrially inapplicable. Diagnostic methods means methods of gathering different kinds of data by measuring structures or functions of each organ in the human body by physicians (or persons directed by them) for the medical purposes such as detecting diseases or recognizing or judging the physical condition of the human body, or methods of judging the condition of diseases based on the said data.²¹⁷ These include: (i) methods of measuring the shape or size of internal organs or the conditions of the interior or exterior of the human body for the medical purposes of detecting diseases or recognizing or judging the physical condition of the human body and (ii) preparatory methods for diagnosis. It is to be noted that methods per se for measuring structures or functions of the human body whose purposes are other than medical ones such as detecting diseases or recognizing or judging the physical condition of the human body are not deemed as “methods for treatment of the human body by diagnostic methods.”

India- Section 3 of India’s Patent Act, 1970 lists out all non patentable subject matter.

Section 3(i) excludes from patentability *“any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products”*.

This provision rules out the patentability of methods used for the treatment of not only human beings, but also animals and plants. The word “treatment” is quite broad and includes “medicinal”, “surgical”, “prophylactic”, “curative” or any “other treatment”. This exclusion is therefore of broad scope. Till date, it has not been interpreted by Indian courts. However, the Indian patent office has interpreted it on various occasions as outlined below.

In *Benitec Australia Ltd.’s* patent application²¹⁸ the claim was relating to a method of *repressing, delaying or otherwise reducing the expression* of a target gene in a vertebrate cell by introducing one or more dispersed nucleic acid molecules. The Patent Examiner in this case held that “...for Section 3(i) to apply, all three criteria listed therein must be present and satisfied. Thus, what is involved must be:

- (a) Any process for the medicinal, surgical, curative, prophylactic [diagnostic therapeutic] or other treatment;
- (b) The process or the treatment should be directed to either live human being or live animals; and
- (c) The process or the treatment should such as to render either the human beings or animals free of disease or possessed of increased economic value for themselves or their products.

²¹⁷ *Examination guidelines for patents and utility models in Japan-Part II-Chapter 2.*

²¹⁸ Patent Application No. IN/PCT/2000/00169/DEL decided on 31.03.2010.

Even if one of the criteria were absent, Section 3(i) cannot apply.”²¹⁹

It was held that the claimed invention did not satisfy any of the above mentioned criteria and was therefore not excluded under Section 3(i) of the Act.

In *Lalit Mahajan's* patent application,²²⁰ the issue was whether ‘a device for detection of antibodies to HIV and p24 antigen of HIV in human serum or plasma’ was excluded under Section 3(i). The opponents argued that the Applicant had camouflaged the diagnostic aspect of the device. The Patent Examiner observed that the invention in question was a device and not a diagnostic or therapeutic process/method. As a result, the ground raised by the opponent was not sustainable and Section 3(i) was found to be inapplicable. This view was consistent with a previous decision finding the exclusion inapplicable in case of a device for the rapid detection of presence of IgG and IgM antibodies against dengue viral antigens in a sample (human serum) for a diagnostic purpose.²²¹

Applicants have attempted to by-pass the exclusion by drafting their claims in the forms of products or kits camouflaging the essence of the invention. In *Christoph Von Mandach's* patent application²²², the claimed invention was a method for the correct application of orthodontic fastening parts such as buttons, hooks, eyelets or brackets onto teeth. Subsequently, after objections in the First Examination Report, the claims were amended and worded as ‘a kit comprising an orthodontic fastening part, a protector, and an applicator’ with descriptions of each of the components. It was held that the description mainly referred to the method for the correct application of orthodontic fastening parts and was therefore not an invention under section 3(i).

Similarly, in *M/s. Applied Research Systems Ars Holding, Netherland's* patent application²²³ the issue was whether the claim relating to a ‘kit for the treatment of infertility in women comprising multiple doses of FSH ...’ could be excluded under Section 3(i). The Patent Examiner concluded that the said invention was merely a method of medical treatment in the guise of the claimed kit (a product), and was not patentable under Section 3(i).

In some cases applicants have even attempted to overcome the patent eligibility threshold under Section 3(i) by elaborately drafting the claim as one dealing with a process for preparing pharmaceutical compositions, ala Swiss claim style. In *Tissuegene Inc.'s* patent application the claim was ‘a method of preparing a pharmaceutical composition which has an ability to generate or regenerate bone at a bone defect site comprising:

- a. insertion of a gene encoding a protein belonging to TGF-B (Transforming Growth Factor-B) super family having bone regeneration function into a vector operatively linked to a promoter, and
- b. transfecting or transducing a population of mammalian fibroblasts,

²¹⁹ *Ibid*, 2.

²²⁰ Patent Application No. 693/KOL/2007 decided on 11.01.2010.

²²¹ Patent Application No. 2484/DEL/2007 decided on 24.07.2009.

²²² Patent Application No. 2003/CHENP/2004 decided on 23.04.2010.

²²³ Patent Application No. 404/MUMNP/2005 decided on 28.09.2007.

chondrocytes or bone progenitor cells in vitro with said recombinant vector of step a.”

It was held that what was being claimed as a method of preparing a pharmaceutical composition was only a method of treating the connective tissue of a patient in vitro and producing modified connective tissue for re-introducing it into the patient body for generation of bone in vivo. The claim was amended to deliberately restrict the subject matter to a method for obtaining modified connective tissue as a method of preparing pharmaceutical composition described in step (a) and (b), which was an attempt to disguise the content of the invention which in reality was a method of treatment.

However, in a matter dealing with the enhancement of therapeutic efficacy, the patent office has held that claims such as improvement of insolubility reducing toxicity and improving of crossing blood brain barrier are not as such excluded under Section 3(i).²²⁴ The Examiner accepted the argument of the Applicants who submitted that enhancement of therapeutic qualities did not amount to a method of treatment.

There is considerable debate as to whether the invitro methods of diagnosis are covered within the ambit of the exclusion under Section 3(i). In *M/s Becton Dickinson and Company's* patent application²²⁵, the Applicants filed for a patent application titled as 'Diagnosis of Sepsis or SIRS using Biomarker profiles' which was amended during prosecution of the application as an 'Invitro method of determining the status of sepsis using biomarker profiles.' The Examiner of Patents and Designs recommended that certain claims are not allowable under the provisions of Section 3(i) of the Patents Act. The claims were amended but the Examiner raised an objection against the first 31 claims. Claims 32-5 being product claims which were novel, inventive and industrially applicable were allowed. During the hearing, the agent for the Applicants argued that the patent manual provides that methods of diagnosis performed on tissues or fluids which have been permanently removed from the body are not excluded under Section 3(i) of the Patents Act. As per the manual, 'Body' should be taken to mean living body. The agent for the Applicant argued that while the status of sepsis in an individual is a 'diagnostic method', such diagnosis is taking place outside the body *i.e.* by an invitro method which as per the guidelines issued by the Patent Office is not excluded by Section 3(i) of the Act.

The Examiner however concluded from the plain reading of the claims and the express admission by the agent for the Applicant that the alleged invention is a diagnostic method. It was also held that Section 3(i) of the Patents Act prohibits any diagnostic method irrespective of whether it is invitro or invivo. It was clarified that the patent manual refers to a diagnostic method performed on tissues or fluids which have been permanently removed from the body. As far as the present invention was concerned, the samples collected are for the diagnosis of a living

²²⁴ *M/s Signature R&D Holdings LLC's Patent Application*, Patent Application No. 942/DELNP/2006 decided on 1.05.2009.

²²⁵ Patent Application No. 1200/CHENP/2005 decided on 17.07.2007.

individual and not for the identification of a substance from the permanently removed tissue or fluid. Hence, the subject matter was disallowed under Section 3(i). Similarly, the argument that the test is conducted invitro and hence is patent eligible was rejected in M/s. University of Reading's patent application.²²⁶ The claim, a method relating to identifying the possible occurrence of 'Pre-eclampsia' in pregnant ladies by determining the level of neurokinin B was held to be a diagnostic method.

However, it must be noted that in *Benitec Australia Ltd.*'s patent application, one of the reasons for inapplicability of Section 3(i) was the fact that the cell subjected to treatment had been removed from the vertebrate. This might perhaps suggest that the distinction between invitro and in vivo forms of treatment is discarded only in cases dealing with diagnostic methods.

The phrase 'other treatment' in Section 3(i) has also generated controversy regarding inclusion of cosmetic intervention. In *M/s. Galderma Research and Development S.N.C.*'s patent application²²⁷ the claim involved was "a method of improving the appearance of the body or hair, which comprises the application to the body or hair of a cosmetic agent comprising a compound as defined in the claims". The Examiner held that the above claim fell within Section 3(i) as it involved treatment of skin using the cosmetic agent.²²⁸

Allied questions dealing with whether lifestyle disorders can be considered as a 'disease' are equally pertinent to an enquiry under this provision. In a patent application dealing with 'a method of discovering compounds suitable for the treatment and or prophylaxis of obesity...', the Patent Examiner concluded that it is a method of diagnosis and treatment and hence not patentable under Section 3(i).²²⁹

Based on all the above, it would appear that the Indian Patent Office interprets the method of medical treatment exclusion in a wider manner than the EPO and UK patent office/courts, consequently excluding a larger number of such inventions from patentability.

China- Chapter II of the Patent Law of the People's Republic of China deals with the requirements for the grant of a patent. It states that, in order to be patentable, an invention must possess the characteristics of novelty, inventiveness and usefulness or practical applicability. Article 25 of the same chapter provides the list of subjects excluded from patentability. Clause (3)²³⁰ states that no patent right shall be granted for a method of diagnosis or for the treatment of diseases. Thus Chinese patent law provides a broad ban on patentability of such methods.

²²⁶ Patent Application No. IN/PCT/2002/593/DEL decided on 31.3.2010.

²²⁷ Patent Application No. 2196/DELNP/2003 decided on 31.03.2010.

²²⁸ It is interesting to note that the High Court of Australia in *Joos v. Commissioner of Patents*, [1973] RPC 59 has allowed patent claims relating to a process for improving the strength and elasticity of human hair and finger nails. The rationale being that purely cosmetic processes are not covered by the exclusion dealing with processes relating to treatment of humans or animals.

²²⁹ Patent Application No. 195/MUMNP/2003 decided on 18.05.2006.

²³⁰ **Article 25 (China):** For any of the following, no patent right shall be granted:...(3) Methods for the diagnosis or treatment of diseases.

Indonesia- Chapter II of the Patents Act, 2001 in Indonesia enlists the scope of patents i.e. it provides the criterion for an invention to be patentable and non-patentable. Article 7 of this chapter states the inventions for which patent shall not be granted. Clause (b) of Article 7²³¹ provides that a patent shall not be granted to an invention of a method of examination, treatment, medical care, and/or surgery which may be applied on human beings and/or animals. This provision therefore, expressly excludes a patent being granted in respect of such methods.

Malaysia- Part IV of the Malaysian Patents Act, 1983 deals with patentability of inventions. It provides that an invention must possess the basic requirements of patentability i.e. novelty, inventive step and industrial application. Section 13 provides a list of non-patentable inventions; Clause (d)²³² of this section provides that methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body are not patentable. However, the proviso to this clause states that this exclusion from patent shall not apply to any products used in such methods. Therefore, this Act expressly excludes such methods from patents but expressly includes the products used therein.

Pakistan- Chapter III of the Patents Ordinance 2000 of Pakistan lays down patentability criteria. Article 7 states that any invention is patentable in Pakistan if it new, involves an inventive step and is capable of industrial application. Article 7(4) provides a list of non patentable inventions; Clause (c)²³³ of this Article states that a patent shall not be granted for diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Therefore, such methods are expressly excluded from patents in Pakistan.

Philippines- The Philippines has a very exhaustive Intellectual Property Code. Part II of this Code deals with patents. Chapter II of this Part provides that any technical solution of a problem which is new, involves an inventive step and is industrially applicable shall be patentable. Section 22 which falls under the same chapter provides a list of non-patentable inventions. Clause 22.3²³⁴ expressly excludes from patents methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. However, the same clause also states that this provision shall not apply to products and composition for use in any of these methods.

²³¹ **Article 7 (Indonesia):** Patent shall not be granted to an invention of:.... **(b)** a method of examination, treatment, medical care, and/or surgery which may be applied on human beings and/or animals.

²³² **Section 13 (Malaysia): Non-patentable inventions:** (1) Notwithstanding the fact that they may be inventions within the meaning of section 12, the following shall not be patentable:.... **(d)** methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body:

Provided that this paragraph shall not apply to products used in any such methods.

²³³ **Article 7(4) (Pakistan):** A patent shall not be granted:....**(c)** for diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

²³⁴ **Section 22 (Philippines): Non-Patentable Inventions:** The following shall be excluded from patent protection:....**22.3** Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods.

South Korea- The Patents Act of South Korea does not expressly exclude methods of treatment from patentability.

Thailand- Chapter II of the Patent Act of Thailand deals with patents for inventions. Part I of the chapter spells out patentability criteria i.e. novelty, non-obviousness, inventive step and capability for industrial application. Section 9 of the chapter provides a list of non patentable subject matter; Clause (4) of the section states that a patent shall not be granted for methods of diagnosis, treatment or cure of human and animal diseases. Methods of treatment or cure would include surgical, therapeutic and diagnostic methods.

G. South America

South American legal systems are best understood when divided into three zones: the Mercosur area, the Andean Pact area, and jurisdictions not aligned to any of these. Mercosur does not have a common IP regimen, and however somewhat interconnected, the legal systems remain national. The Andean pact influences the basic IP legal system of countries under the Pact (Bolivia, Colombia, Ecuador, and Peru). Ancillary domestic provisions may be added as supplementary law. However, Andean law prevails over such domestic law. Thus, countries may provide enhanced protection under their domestic laws, but the minimum standards are laid by the Andean supranational law. Also, any domestic law in violation of Andean law is invalid.

Laws regarding countries in each of these three regions are discussed hereunder.

COUNTRIES IN THE MERCOSUR AREA

Brazil- Article 10 of Brazilian patent law²³⁵ provides a list of items which shall not be considered inventions or utility models, and are therefore non-patentable. Clause VIII of this article provides that techniques and methods for operations or surgery or methods for therapy or diagnosis applied to human or animal body are not considered inventions and are therefore non-patentable.

Argentina- In Argentina, Article 4 of the Patent Law 24.481 stipulates that all inventions that are new, inventive and subject to industrial application are patentable. Article 6 lists out non patentable subject matter; clause (e) of this Article²³⁶ provides that surgery treatment, therapeutic or diagnosis methods, applicable to the human body and regarding animals are not considered inventions and therefore cannot be patented.

²³⁵ **Article 10 (Brazil):** The following shall not be considered inventions or utility models:.... **VIII** - techniques and methods for operations or surgery or methods for therapy or diagnosis applied to human or animal body.

²³⁶ **ARTICULO 6 (Argentina):** No se considerarán invenciones para los efectos de esta ley:.... **(e)** Los métodos de tratamiento quirúrgico, terapéutico o de diagnóstico aplicables al cuerpo humano y los relativos a animales.

Paraguay- Paraguay Patent law (1.630/00) grants patents to all new, inventive and useful inventions. Under Article 4²³⁷ of this law, certain items are not considered inventions; clause (e) of this Article states that diagnosis, therapeutic and surgery (for people and animal treatments) is not invention, hence not patentable.

Uruguay- Uruguay Patent Law provides that new products and procedures that imply an inventive activity and are subject to industrial application are patentable.²³⁸ Article 14 of the Law²³⁹ which provides a list of items that are deemed not patentable inventions includes “diagnosis, therapeutic and surgical methods for the treatment of persons or animals”.

COUNTRIES OUTSIDE MERCOSUR: ANDEAN REGION

As stated earlier, countries in this region have adopted the Common Intellectual Property Regime. As per Article 14 of this Common Regime,²⁴⁰ goods and process patents shall be granted for inventions that are new, involve an inventive step and are industrially applicable. Article 20 provides a list of inventions that shall not be patentable. Clause (d) of the article²⁴¹ states that inventions in respect of diagnostic, therapeutic, and surgical methods for the treatment of humans or animals are excluded from patents. Therefore, it is to be noted here, that the Common IP Regime of the Andean expressly excludes such methods from being patented, and not from the definition of invention itself. Therefore, this specific exclusion follows the TRIPs Article 27 standards, not the also Mercosur trend of deeming it not an invention.

The specific domestic laws of each of the countries in the Andean Region are discussed hereunder:

Ecuador- Patent Law of Ecuador provides that all inventions satisfying novelty, technical and industrial utility shall be patentable. However, certain inventions stated under Article 126 of the Law²⁴² are expressly excluded from patents. Clause

²³⁷ **Ley 1.630/00 (Paraguay):** Artículo 4°.- De las materias excluidas como invención. No se considerarán invenciones, entre otros, los siguientes: a) los simples descubrimientos, las teorías científicas y los métodos matemáticos; b) las creaciones puramente estéticas; c) los esquemas, planes, principios o métodos económicos, de negocios, de anuncios o de publicidad y los referidos a actividades puramente mentales o intelectuales o a materia de juego; d) los programas de computación aisladamente considerados; e) los métodos de diagnósticos, terapéuticos, quirúrgicos para el tratamiento de personas o animales; y, f) las diferentes formas de reproducir informaciones.”

²³⁸ **Article 8 (Uruguay):** New inventions of products or proceedings entailing an inventive activity and having industrial applicability are deemed patentable inventions.

²³⁹ **Article 14 (Uruguay):** The following are not deemed patentable inventions: Diagnosis, therapeutic and surgical methods for the treatment of persons or animals; those inventions contrary to public order, socially accepted manners, public health, population nutrition, security and environment.

²⁴⁰ **Article 14 (Andean Rules):** The Member Countries shall grant patents for inventions, whether goods or processes, in all areas of technology, that are new, involve an inventive step, and are industrially applicable.

²⁴¹ **Article 20 (Andean Rules):** The following shall not be patentable:....(d) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.

²⁴² **Article 126 (Ecuador):** Se excluye de la patentabilidad expresamente:....(b) Los métodos de

(b) states that the methods of diagnostic, therapeutic and surgical treatment of humans and animals are not patentable. Even though being inventions satisfying the general patentability requirements, patents are denied to inventions in these areas.

Bolivia- Bolivia Industrial Property Law of 1916 provides the same criteria for patenting as under the Common Regime. Bolivian domestic law remains supplementary and subject to the Andean rules. There are no provisions under Bolivian domestic law pertaining to specific exclusions regarding diagnostic, therapeutic and surgical methods for treatment of humans and animals. Therefore, it follows the Common Regime of the Andean Region.

Peru- Peru is also essentially ruled by the Andean rules. It also has its domestic law of 2009 as edited by the Free Trade Agreement with the United States. The new legal environment in respect of methods of surgery, therapy and diagnosis for treatment of humans and animals does not diverge from the Andean text.

Colombia- Colombia applies the Andean Common Intellectual Property Regime.

OTHER COUNTRIES IN SOUTH AMERICA

Venezuela- Venezuela withdrew from the Andean pact in 2006, having been a member since 1973. It has now subject to the 1955 law on Industrial Property. Venezuelan law demands as requirements of patentability the following: absolute novelty; inventive step and industrial applicability. For this reason methods of treatment for human beings or animals, including diagnostic, therapeutic and surgical methods, are excluded from patentability in Venezuela according to Article 20(d) of the Patent Law. It is considered that such methods are not susceptible of industrial application and therefore do not fulfill the fundamental requirements of patentability.

Chile- The Chilean IP statute was amended in 2006 in order to assimilate new international obligations. Article 32 states that patents are obtainable for all inventions that are new, non obvious and capable of industrial application. Chilean law excludes diagnostic, therapeutic and surgical methods for treatment of humans and animals from the definition of invention, and not from patentability. Article 37 of the Law states that surgical, diagnostic and therapeutic methods for human or animal body are not considered inventions, discoveries or abstract knowledge, thus not patentable. However, products intended to implement these methods are patentable.

H. Africa and Middle East Region

Most African and Middle East countries exclude methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods. However, **Nigeria** is an exception and does not exclude methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

Regional Treaty: The African Intellectual Property Organization (OAPI) was formed by the adoption of a new convention signed in Bangui on 2nd March 1977. The OAPI consists of sixteen west and Central African countries, namely; Benin, Burkina Faso, Cameroon, Central African Republic, Chad Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, and Togo. Patent law under the OAPI is dealt with under the Bangui Accord.²⁴³ Article 6(e) of the Bangui Agreement prohibits patents to be granted for methods for the treatment of the human or animal body by surgery or therapy, including diagnostic methods.²⁴⁴

Bahrain- Article 3(A)(3) of Bahrain's patent law prohibits the grant of patents for diagnostic, therapeutic, and surgical methods necessary for the treatment of humans and animals. The provisions also clearly states that it shall not apply to products used in any of these methods.²⁴⁵

Ethiopia- Article 4(1)(e) of the Proclamation²⁴⁶ states that methods for the treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body shall not be patentable. But Article 4 (2) states that sub-article 4 (1)(e) shall not apply to products for use in any of the methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body.

Ghana- As per section 1(3)(d) of Ghana's Patent Law of 1992, methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods are not regarded as inventions. This provision also states that the exclusion shall not apply to products for use in any of these methods.²⁴⁷

Kenya- Section 21(3)(c) of the Industrial Property Act 2001 excludes methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods from patent protection. Sub clause (e) also provides that public health related methods of use or uses of any molecule or other substance whatsoever used for the prevention or treatment of any disease which the Minister responsible for

²⁴³ Article 1 Annex 1: Patents, Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic) 24 February 1999.

²⁴⁴ Bangui Agreement, Annex I.

²⁴⁵ Bahrain Law No. 1 of 2004 in Respect of Patents and Utility Models, as amended by Law No. 14 of 2006.

²⁴⁶ Ethiopian Proclamation No. 123/1995 concerning Inventions, Minor Inventions and Industrial Designs.

²⁴⁷ **Article 1 (Ghana):** (1)The following shall not be regarded as inventions within the meaning of subsection (1) of this section – (.....) **(d)** methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods; this provision shall not apply to products for use in any of these methods.

matters relating to health may designate as a serious health hazard or as a life threatening disease are not regarded as inventions and are excluded from patent protection.²⁴⁸

Lebanon- The patenting of methods of medical diagnosis or treatment related to humans or animals is prohibited as per Article 3(3) of the Law pertaining to Patents, 2000,²⁴⁹ but not products or utilities for use in such methods.²⁵⁰

Mozambique- Section 30(1)(g) of the Industrial Property Code prohibits patents for methods of surgical, therapeutic or diagnostic treatment applicable to the human body or animals, although the products, substances or compositions used in any of such methods are patentable.²⁵¹

Tunisia- Chapter I of the Tunisian Patent Law deals with patentable inventions. Article 2(d) of this chapter²⁵² does not consider methods of therapeutic and surgical treatment of the human body or of animals and diagnostic methods applied to the human body or to animals as “inventions” to be patentable. The section does not apply to preparations or in particular to products and compositions used for the purposes of the application of any such method.²⁵³

Uganda- section 7(2)(d) of the Patent Law of Uganda²⁵⁴ does not regard methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods as “inventions”. However, the exclusion does not apply to products for use in any of these methods.²⁵⁵

Morocco and South Africa- It is interesting to note that Morocco and South Africa deem methods of medical treatment as being incapable of industrial application. Article 25 of Morocco’s Industrial Property Law²⁵⁶ does not regard *methods of surgical or therapeutic treatment of the human or animal body and diagnostic*

²⁴⁸ **Article 21 (Kenya): (3)** The following shall not be regarded as inventions and shall be excluded from patent protection – (.....) **(c)** methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practised in relation thereto, except products for use in any such methods;.....**(e)** public health related methods of use or uses of any molecule or other substance whatsoever used for the prevention or treatment of any disease which the Minister responsible for matters relating to health may designate as a serious health hazard or as a life threatening disease.

²⁴⁹ **Article 3 (Lebanon):** A patent is not to be granted to:....**(3)** Methods of medical diagnosis or treatment related to humans or animals but not products or utilities for use in such methods.

²⁵⁰ Law pertaining to Patents, Law No. 240 of 7 August 2000.

²⁵¹ *Mozambique Industrial Property Code Decree No. 04/2006 of 12th April 2006.*

²⁵² **Article 2 (Tunisia):** The following in particular shall not be considered inventions within the meaning of the first paragraph of this Article.... **(d)** methods of therapeutic and surgical treatment of the human body or of animals and diagnostic methods applied to the human body or to animals; these provisions shall not apply to preparations or in particular to products and compositions used for the purposes of the application of any such method.

²⁵³ Law No. 2000-84 of August 24, 2000, on Patents.

²⁵⁴ **Article 7 (Uganda): (2)** The following shall not be regarded as inventions.... **(4)** methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods, but the restriction under this paragraph shall not apply to products for use in any of these methods.

²⁵⁵ Patents Act Cap 216 of the Law of Uganda.

²⁵⁶ Law No. 17-97 Concerning Protection of Industrial Property (Dahir No. 1-00-91 of 15 February 2000 (9 Kaada 1420)).

methods practiced on human beings or animals as inventions capable of industrial application within the meaning of Article 22.

Article 25(11) of the South African Patent Act²⁵⁷ states that an invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body shall be deemed as not being capable of being used or applied in trade or industry or agriculture. Article 25 (12)²⁵⁸ however exempts products consisting of a substance or composition capable of being used or applied in trade or industry or agriculture from the scope of the above exception.²⁵⁹

Some of the African and Middle Eastern countries exclude methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods, without expressly mentioning the patentability of the products used for these methods. However, owing to Article 27.3 (a) of TRIPS, it is clear that related products do not fall within the ambit:

Algeria- As per Article 7(4) of the Algerian Ordinance, methods of treating the human or animal body by surgery or therapy and diagnostic methods are not inventions and hence not patentable.²⁶⁰

Egypt- Article 2(3)²⁶¹ prohibits granting of patents for diagnostic, therapeutic and surgical methods for humans and animals.²⁶²

Jordan- Article 4 of Jordanian patent law²⁶³ does not allow the granting of patents for diagnostic, therapeutic and surgical methods for humans and animals.²⁶⁴

Qatar- Article 4(c) of Qatar's Patent Law²⁶⁵ prohibits patenting of diagnostic, therapeutic and surgical methods for the treatment of humans or animals.²⁶⁶

²⁵⁷ **Article 25 (South Africa): Patentable Invention: (11)** An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture.

²⁵⁸ **Article 25(12) (South Africa):** Subsection (11) shall not prevent a product consisting of a substance or composition being deemed to be capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method.

²⁵⁹ South Africa Patents Act 57 of 1978.

²⁶⁰ Algerian Ordinance No. 03-07 on Patents (19 Jomada El Oula 1424 corresponding to July 19, 2003), as approved by Law No. 03-19 on Patents (of 9 Ramadhan 1424 corresponding to November 4, 2003).

²⁶¹ **Article 2 (Egypt):** Patents shall not be granted for.... **(3)** Diagnostic, therapeutic and surgical methods for humans and animals.

²⁶² Egypt Law on the Protection of Intellectual Property Rights (Law No. 82), adopted on 3 June 2002.

²⁶³ **Article 4 (Jordan):** A patent shall not be granted in the following cases:....**(D)** Diagnostic, therapeutic and surgical methods necessary for the treatment of humans or animals.

²⁶⁴ Patents of Invention Law No. 32 of 1999, as amended by Temporary Law No. 71 of 2001.

²⁶⁵ **Article 4 (Qatar):** Subject to the law hereby, patentability shall not include.... **(c)** diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

²⁶⁶ Patents' Law, issued under Decree Law No (30) for the Year 2006 to Issue Patents' Law.

III. THE ORDRE PUBLIC AND MORALITY EXCLUSIONS

A. Introduction

The 'ordre public' and 'morality' exclusions to patentability, are both terms filled with inherent ambiguity since the scope of their application is largely dependent on the local cultures and practices of member states. In terms of the historical underpinnings of this exclusion, there is very little academic literature available. Any debate on the inclusion of morality in determining the patentability of a subject-matter will mirror the law and morality debate that has dogged the scholars of jurisprudence especially in the last century. The essential question in this debate is whether law is a reflection of morality or whether law can be divorced from morality. The positivist school of law would argue that law has to be divorced from morality and instead based on the rules of logic and reason.²⁶⁷ The school of natural law on the other hand would argue that the law necessarily reflects the morals of society and that it cannot be based solely on rules of reason and logic.²⁶⁸

In the context of patent law therefore the positivist would argue that an invention should be granted a patent as long as it is novel, inventive and displays an industrial application and that morality, unless well-defined in terms of the law, should have no role to play in the decision to grant or withhold a patent. The school of natural law would present a diametrically opposite argument stating that an invention which offends society's morals should not be granted a patent regardless of whether it fulfills the standard patentability criteria. The reason for this being the natural school of law's fundamental premise that law is a reflection of morals and something that offends the morality of society cannot possibly be given a legal character. While this is of course an over-simplification of the highly nuanced debate between scholars of jurisprudence, it does capture the bare essence of the debate on the inclusion of the morality dimension within the patentability criteria of Article 27 of the Agreement related to the Trade Related Intellectual Property rights (TRIPs).

Article 27.2 of TRIPs allows countries to exclude from patentability those inventions which may offend the morality or *ordre public* of its populace. The proviso, which states that such an exclusion cannot be made merely because the exploitation of the invention in question is prohibited by their law, ensures that the conclusion of morality has to be based not only on the law but also certain extraneous factors, such as the morality of society, which in itself is not clearly defined within the TRIPs agreement itself. The reason to not provide precise definitions was deliberate since TRIPs was only meant to provide a minimum standards with adequate flexibility for member states.²⁶⁹

²⁶⁷ See generally P.J. Fitzgerald (ed.), *Salmond on Jurisprudence*, (Universal law Publishing, New Delhi 1966).

²⁶⁸ *Ibid.*

²⁶⁹ In a speech by Mr. Maran, the Indian Minister of Commerce, while introducing the Patent (Amendment) Act, 2002 which was aimed at making Indian patent law TRIPs compliant, he stated and quite rightly that "We are all aware that the text of the TRIPs is a masterpiece of ambiguity, couched in the language of diplomatic compromise, resulting in a verbal tight-rope walk, with a prose remarkably elastic and capable of being stretched all the way to Geneva.", available at

While most of the TRIPs debates have seen a tension between the developing and developed world, the Article 27.2 debate is unique for the contrast and differences that it brings out amongst the developed countries themselves. The debate highlighted above in the context of natural law and positive law is probably best captured in the contrast between the approaches adopted by the United States of America and the European Union.

While the United States of America never had a morality requirement in its statutory patent law, such a requirement was carved out by the judiciary under the guise of a moral utility requirement.²⁷⁰ For over 200 hundred years the moral utility requirement was rarely used either by the USPTO or the judiciary. The only exception was in the case of inventions related to gambling devices, wherein the USPTO was regularly rejecting patenting applications on the grounds that some of these inventions lacked 'moral utility' since they could be used for the purposes of gambling.²⁷¹ However even these rejections came to an end in 1977 when the USPTO decided that a patent for an invention that could be used for gambling was no more or no less immoral than for an invention such a gun which may end up being used in murders.²⁷² Thus, for over 200 years this morality doctrine was rarely invoked. However, in the late nineties, with researchers and scientists pushing biotechnology to its limits by filing admittedly controversial patent applications, the USPTO has invoked the moral utility doctrine to draw the line for future patent applicants and at one point even issued an official communication reiterating the moral utility doctrine and its willingness to use it.²⁷³ While rejecting a patent application related to human/animal chimeric embryos, the USPTO did not invoke the moral utility doctrine but it did in part base its actions on the U.S. Constitution. The reference to the Constitution was widely interpreted as meaning a reference to the 13th amendment to the U.S. Constitution – i.e. the right against servitude or slavery.²⁷⁴ The U.S. Courts however have been critical of the USPTO's reiteration of the morality utility doctrine since according to them it is the legislature and not the executive which can define the boundaries of a nations' morality.²⁷⁵ It must however be clarified that the USPTO's rejection on the basis of the moral utility doctrine is confined to a few, rare patent applications like the human/animal chimeric embryos and the predominant U.S. approach towards controversial technologies is to 'patent first and ask questions later'.²⁷⁶

http://commerce.nic.in/writereaddata/publications/wto_may2002.pdf. (Last visited August 5, 2010).

²⁷⁰ *Lowell v. Lewis*, 15 Fed. Cas. 1018, 1019 (C.C.D. Mass. 1817); Article 53 of EPC, 2000.

²⁷¹ *Nat'l Automatic Device Co. v. Lloyd*, 40 F.89, 89-90 (C.C.N.D.III, 1889), *Schultze v. Hotz*, 83 F.448,449 (C.C.N.D. Cal 1897), *Reliance Novelty Co. v. Dworzek*, 80 F. 902, 903 (C.C.N.D. Cal. 1897). See also Robert B. Morrill, Brian Ogonowsky, 7(6) Gam. L. Rev. 411 (2003)..

²⁷² *Ex-parte Murphy*, 200 U.S.P.Q. (BNA) 801 (Bd. Pat App. & Int. 1977).

²⁷³ Media Advisory, U.S. Patent and Trademark Office, 'Facts on Patenting Life Forms Having a Relationship to Humans' (Apr. 1, 1998), <http://www.uspto.gov/news/pr/1998/98-06.jsp>.

²⁷⁴ Cynthia M. Ho, 'Splicing Morality & Patent Law: Issues arising from mixing Mice and Men', 2 Wash. U. J. L & Pol'y 247 (2000), 251.

²⁷⁵ *Infra* n. 321.

²⁷⁶ See generally Margo A. Bagley, 'Patent first, ask questions later: Morality and Biotechnology in Patent Law', 45 Wm. & Mary L. Rev. 469 (2003).

The European Union on the other hand has adopted a more pro-active approach toward the questions of 'morality' and 'ordre public' while granting patents. This is evidenced by the fact that the European Patent Convention has had the 'morality' and *ordre public* requirement in its law since its very inception in the year 1973.²⁷⁷ One of the interesting distinctions between the morality exclusion in TRIPS and the EPC is that while TRIPS allows member countries to incorporate this exclusion at their discretion, the EPC mandatorily requires all member countries to provide for a morality & 'ordre public' exclusion.²⁷⁸ When the EPO started receiving an increased number of biotechnology patent applications the E.U. responded by issuing the Biotech Directive – 98/44/EC which clearly defined those biotechnological inventions that would be deemed unpatentable in Europe. Although the exclusion under 98/44/EC has not been articulated in the language of morality, it was a result of the debates in Europe over the morality of patenting certain biotechnology inventions derived from the destruction of human embryos or manipulation of genetic structures. It is interesting to note that even within the EU there was opposition to the adoption of the Biotech Directive. The Kingdom of Netherlands for instance attempted to oppose the Directive and in fact it unsuccessfully approached the European Court of Justice in this regard.²⁷⁹ Therefore unlike the U.S., the E.U. prefers to ask questions first before deciding to grant controversial patents. However, as explained above, even within the E.U., the decision to ban patents on grounds of morality was not unanimous.

The most vibrant public debates regarding the morality and *ordre public* exclusion have been confined mostly to the economies of the developed worlds i.e. the United States and the European Union. To date, the E.U. is probably the only signatory to the TRIPs agreement to have had extensive judicial interpretation of these doctrines. The rest of the world, despite having an *ordre public* and morality exclusions have rarely invoked the morality doctrine to reject a patent application. Part of the reason could be the fact that the biotechnology industries and market of these countries is yet to advance to the stage of the United States or European Union because of which innovators are not even filing such controversial patent applications in these countries.

Scientists in the developed countries are pushing the boundaries of known science in a manner which sometimes conflicts with the religious and political ideals of the populations of those countries. To that extent the 'ordre public' and 'morality' debate in developed countries is not really centered on increasing access to medicines in a manner likely to benefit public health. The only country in which 'ordre public' and morality exclusion to patent law has been invoked in the context of public health is India. The one decision on these lines is however pending appeal before the Supreme Court which should likely deliver a judgment within a year.

In other countries like Australia and Canada where there is no statutory 'morality'

²⁷⁷ See generally European Patent Convention (1973).

²⁷⁸ Article 53 of the EPC starts off by stating that “*European patents shall not be granted in respect of.....*”

²⁷⁹ C-377/98 before the European Court of Justice.

exclusion to patentability there have been isolated calls for such an exclusion. In the *Oncomouse* case, where the question was essentially of 'morality' in other jurisdictions, the Canadian Supreme Court managed to deny a patent by distinguishing between 'higher life forms' and 'lower life forms'.²⁸⁰ Despite the Commissioner of Patents deciding to invoke a public policy doctrine to dismiss the patent application the Canadian Supreme Court refused to uphold the decision on the grounds that the Canadian Parliament had not included such an exclusion despite having multiple opportunities to consider the same.²⁸¹

In countries like Japan and New Zealand, both of which have statutory morality exclusions to patentability, controversial patents like the WARF patents for inventions related to human and animal embryos have been granted.²⁸² Part of the reason for this seems to be the reluctance of the national patent offices in these countries to be drawn into the 'morality' debate. This is a phenomena affecting most patent offices world wide and for good reason. Morality is a question of public policy, which can be decided only by the representatives of the people. The most competent arbiters of morality, if at all there is somebody, are the legislators who are elected by citizens of a country and not appointed bureaucrats, who have neither the mandate nor the expertise to make judgments on the basis of morality. In this respect it is only the EU, which by specifically codifying its moral concerns, regarding the use and patenting of embryos, into the EPC, has succeeded in providing a reasonable and successful basis for prohibiting certain types of patents related to the biotechnology field. By codifying a country's morality into its patent legislation, the patent office is required to apply only the law and not make judgments of morality. The best manner therefore to apply the Article 27.2. exclusion, is to insist on codification of the country's moral concerns into a legislation.

Some Muslim countries like Qatar and Morocco base their morality judgments on religious beliefs which in turn are codified in Sharia law or the Quran. These countries may therefore be in a better position to articulate their moral concerns, than secular countries which depend on their legislatures to define the prevalent morality.

One of the problems with continuing to have 'morality' as a criteria, for patentability is the fact that several inventions will have multiple uses of which only one may be immoral. For example although alcoholic beverages may be considered immoral in several countries, including India²⁸³, certain types of alcohol have vital medical

²⁸⁰ *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 (Can.).

²⁸¹ *Ibid.*

²⁸² *Infra* n. 316.

²⁸³ For example Article 47 of the Indian Constitution (a Directive Principle of State Policy), requires that "the state shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health". Article 47 however is part of a Directive Principle of State Policy and belongs to a Chapter in the Indian Constitution which is not justiciable before a Court of Law. Some Indian states like Gujarat have codified this constitutional provision into legislations and have therefore prohibited the consumption of alcohol within its boundaries. It follows therefore that even production of alcohol within Gujarat's boundaries is prohibited.

applications. This was the same scenario with the gambling machine patents in the U.S.A., all of which could have been used for several other applications, with gambling being only one of the options especially since gambling is a crime based on the state of mind and intention of the person so carrying out the Act. Therefore prohibiting the patenting of certain inventions on the grounds of morality is a double edged sword and needs to be exercised carefully.

While banning patents on the grounds of morality is bound to affect funding for certain kinds of research, such a ban in no ways guarantees the end to such research. It may then be asked as to what purpose such a ban on patenting would serve. The answer is simple – it sends out a political message reiterating that civilized society finds it against public policy and democratic norms to allow for ownership and monopolies over certain inventions, no matter how beneficial they may prove to mankind in the long run.²⁸⁴ Such an exclusion is meant to remind society and its inventors that the 'means' matter as much as the 'ends' that are sought to be achieved.

B. Important Concepts in Regards Article 27.2 of Trips

(1) Scope of Article 27.2 – The 'ordre public' & 'morality' exclusion

Article 27.2 of TRIPs states that *Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*

The 'ordre public' or 'morality' exclusion of Art. 27.2 is one of the grounds to exclude subject matter from the purview of the TRIPs agreement. The phrase 'ordre public' is derived from French Law and is a term that is not easy to translate into English.²⁸⁵ According to one interpretation, the phrase “expresses concerns about matters threatening the social structures which tie a society together i.e. matters that threaten the structure of civil society as such.”²⁸⁶ 'Morality' on the other hand is defined as “degree of conformity of an idea to moral principles”²⁸⁷. Being reflective of the then prevailing principles of a society, it is a relatively subjective standard. 'In other words, given that the definition of both, 'ordre public' and 'morality', depends on the socio-cultural, religious values of individual member states, it is not possible to provide a objective definition of the same. The only well defined, aspects of this exclusion, are explained in the latter half of Art. 27.2, as those inventions, the commercial exploitation of which has to be necessarily banned in order to protect human, animal or plant life or the environment. Art. 27.2 also makes it clear that

²⁸⁴ *Supra* n. 276, 545.

²⁸⁵ UNCTAD – ICTSD, *Resource Book on TRIPs and Development*, (Cambridge University Press, New York 2005), 375.

²⁸⁶ *Ibid*

²⁸⁷ Frank Abate (ed.), *The Oxford American Dictionary of Current English*, (Oxford University Press, 1999), available at <http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry=t21.e19923>. (Last visited on August 11, 2010).

'such exclusion' cannot be allowed 'merely' due to the fact that an existing law of a member state prohibits exploitation of the invention in question. This proviso is necessary since most inventions can have a dual purpose of which only one purpose maybe illegal and prohibited. The legality or illegality of the purpose itself is defined in terms of the *mens rea* or mental intent of the person carrying out the Act. For example while a gun could be used to kill a person, the context of the killing i.e. murder or self defence can be established only in a court of law and while the use of a gun for murder is prohibited by the law, the use of a gun for self-defence is legal.

(2) 'Commercial exploitation': It is a moot question as to whether Article 27.2 can be invoked only in those circumstances when the commercial exploitation of the invention, sought to be excluded, is expressly banned by the laws of the member states. A literal reading of Article 27.2, especially the phrase, 'the prevention within their territory of the commercial exploitation' seems to indicate that a member state can invoke the exclusions under Art. 27.2 only when the member state in question has banned, under its laws, even the commercial exploitation/sale of the invention. According to one authority this exclusion cannot be invoked, if the invention itself may be sold or distributed in the member state, which seeks to ban the patenting of the same.²⁸⁸

Other authorities however argue that an explicit legal ban on the commercial exploitation of the invention is not necessary in order to exclude the invention from the list of patent-able subject matter under Art. 27.2. Instead, it is argued that Article 27.2 "does not require an actual *ban* of the commercialization as a condition for exclusions; only the *necessity* of such a ban is required."²⁸⁹ Therefore according to this interpretation, a member state need not establish that a ban on commercial exploitation actually exists but instead, it would suffice for such a member state to argue that a ban on commercial exploitation is a necessity in light of the prevailing circumstances in the member country.²⁹⁰ These authorities support their argument on the basis of the qualification that exists in the latter half of Article 27.2 - "*such exclusion is not made merely because the exploitation is prohibited by their law*". This qualification requires an objective assessment of the exclusions independent of the existing prohibitions in the law. While this interpretation does seem plausible on a literal reading of the provision, it would seem impractical to exclude an invention from being patented, despite there being no legal bar against commercially exploiting the invention.

(3) 'State Practice': As is obvious from the above explanation, a state cannot simply prohibit the patenting of all pharmaceutical products on the grounds that it offends the 'morality' and 'ordre public' of its citizens, while allowing for the commercial exploitation of such pharmaceutical products by its citizens. According to one authority, it may be possible to invoke the Article 27.2 exception in those

²⁸⁸ *Infra* n. 291, 12-13.

²⁸⁹ Dan Leskien & Michael Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System' (Issues in Genetic Resources No. 6 June 1997), International Plant Genetic Resources Institute.

²⁹⁰ *Ibid.*

circumstances wherein all developing countries decide to suspend the patentability of certain pharmaceutical products on the ground of *ordre public* and morality.²⁹¹ Such a collective suspension would lead to the creation of a new state practice. However, according to the above cited authority, in order to circumvent the 'commercial exploitation' requirement of Art. 27.2, the exploitation of the pharmaceutical products in question would have to be on a not-for-profit basis.²⁹² This possible theory is however qualified with the caveat that it is speculative and depends to a large extent on the future interpretation of Article 7 & 8 of TRIPs.²⁹³

(4) Patent Office as an 'arbiter' of morality: One of the main issues with vesting patent offices with the power to determine the 'morality' of an invention is that 'morality' is essentially a question of policy and since the patent office consists of bureaucrats who are appointed and not elected, they do not have the necessary mandate to make exclusions based on the grounds of 'morality'. Further since patent examiners are generally scientists or engineers who have degrees in science and engineering and not 'morality' they would be not be adequately trained or qualified to make judgments on the 'morality' of an invention.²⁹⁴ The controversy surrounding the EPO patent oppositions on the grounds of 'morality' and the EPO's and the NZPO's reluctance to get drawn into 'morality' based debates is further proof of the fact that patent offices are probably not the best forums to decide morality.²⁹⁵ In the context of biotechnology inventions in the U.S., one scholar has opined the following: *"Because the patenting of morally controversial biotech research involves such serious, deeply felt issues, the patenting decision must not be left, as it currently is, to scientists pushing the frontiers of technology, motivated by factors beyond public comment and scrutiny. No one person is competent to decide and resolve these moral issues and determine what the limits should be. Difficult though the task may be, Congress, through legislation, is the only actor competent to clarify the limits of patentable subject matter and the extent to which moral issues should be considered in patentability determinations, if at all."*²⁹⁶ Therefore the best manner to exploit this TRIPs exclusion is to legislate on it through the legislature, preferably on the lines of the E.U Biotech Directive i.e. technology specific legislation.

C. International Organizations

(1) African Intellectual Property Organization (OAPI)

The African Intellectual Property Organization also known as the Organisation Africaine de la Propriété Intellectuelle (OAPI) finds its legal basis in Article 19 of the Paris Convention, which reserves the rights of individual member states to enter

²⁹¹ Carlos Correa, 'Integrating Public Health Concerns into Patent Legislation in Developing Countries', South Centre, Geneva, 2000, 11, available at <http://www.who.int/medicinedocs/fr/d/Jh2963e/6.html>. (Last visited on August 1, 2010).

²⁹² *Ibid*, 13.

²⁹³ *Ibid*, 15.

²⁹⁴ Cynthia M. Ho, *supra* n. 274, 283.

²⁹⁵ Benjamin D. Enerson, 'Protecting society from patently offensive inventions: The risk of reviving the moral utility doctrine', 89 Cornell L. Rev. 685 (2004), 709.

²⁹⁶ Margo Bagley, *supra* n. 276, 546.

into specific agreements with each other as long as these agreements do not specifically contradict the Convention itself. On this basis 16 African member states came together in order to form a single body, the OAPI, which would in turn act as the national patent rights authority for each of them. The members of the OAPI, which are mainly French speaking countries, are as follows: Benin, Burkina Faso, Cameroon, Central Africa, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, Togo. The current patent law of this organization is governed by the Bangui Agreement, which was adopted by the member states on 2nd March, 1977.

Article 6 of the Bangui Agreement deals with the subject of "Non-Patentable Subject Matter". In pertinent part it states that, "Patents shall not be granted for inventions the exploitation of which is contrary to public policy and morality, provided that the exploitation of the invention shall not be considered contrary to public policy or morality merely because it is prohibited by law or regulation". Article 6 of the Bangui Agreement therefore fully exploits the exclusions granted under Article 27.2 TRIPs. In fact the Article 6 exclusion is slightly broader than the exclusion in Article 27.2 since it uses only the word 'exploitation' and not 'commercial exploitation'.

(2) African Regional Intellectual Property Organization (ARIPO)

While OAPI is an organization of primarily French speaking African nations, the African Regional Intellectual Property Organization (ARIPO) is an organization of primarily English speaking African nations. The organization was established in 1976 through the Lusaka Agreement and it aims at harmonizing the intellectual property legislations of all its member states. ARIPO is also authorized to grant and administer patents on behalf of its member states. The principle protocol dealing with patents is the Harare Protocol, which was adopted on December 10th 1982 and amended subsequently in the following years. The following members of ARIPO are signatories to the Harare Protocol – Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Uganda, United Republic of Tanzania, Zambia or Zimbabwe.

Section 3 of the Protocol deals with patentability criteria etc. In particular Section 3(10) of the Protocol states in no uncertain terms that, "*Inventions for which patents are granted by the Office shall be new, shall involve an inventive step and shall be industrially applicable.*" This protocol however does not fully exploit the exclusions provided under Article 27.2 of TRIPs, in the sense that it does not exclude an invention from being patented on the grounds that the exploitation of the patent is against *ordre public* and morality.

(3) Andean Pact

The Andean Pact is a supranational legislation, which provides the basic IP legal system to the countries under the Pact (Bolivia, Colombia, Ecuador, and Peru). The Andean Pact suggests only the minimal levels of protection that is required. Member States are free to add ancillary domestic provisions to the existing rules in the Treaty. Some of the member states like Colombia have relinquished the right to provide for an independent domestic legislation. Yet other countries like Venezuela

in 2008 have abandoned the Pact and instead revived its 1955 IP domestic law. Decision 486 of the Commission of the Andean Community is the law, which prescribes the minimum patentability criteria for the contracting states. Article 20 of this Decision also specifies the grounds on which an invention may be excluded from patent protection. As per Art. 20 (a), those inventions, the commercial exploitation of which is required to be prevented in order to protect 'public ordre' or morality, provided that such exclusion is not made merely because the exploitation is prohibited or regulated by a legal or administrative provision. Interestingly the Andean Pact divorces into a separate provision (Art. 20(b), the Article 27.2 qualification, of including within the definition of 'ordre public' or 'morality', any prohibition that is necessary "to protect human, animal or plant life or health or to avoid serious prejudice to the environment". Since Article 27.2 has effectively been split into two distinct provisions by the Andean Pact the 'ordre public' and morality requirements of Article 20(a) will have to be determined independently of the criteria in Article 20(b).

D. The European Patent Convention 2000

Article 53(a) of the European Patent Convention 2000 provides that European patents '*shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "ordre public" or morality*' and that '*such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting states*'. Rule 28 of EPC 2000 which corresponds to Article 53 of EPC, 2000 states the following:

Rule 28 Exceptions to patentability : Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) 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.

(1) The Onco-Mouse decision: The scope of the morality exclusion under Article 53(a) of the EPC was first debated in the 1989 *Onco-Mouse* decision. The subject matter of this patent application filed in 1985, were mice which had been genetically modified to carry an activated oncogene, by researchers at Harvard, to make them more susceptible to cancer. The object of the invention was to use these mice for cancer research. At the stage of examination of the patent application, the Examining Division of the European Patent Office did not apply the 'morality' exclusion under Article 53(a) on the grounds that it was not staffed with people qualified to make judgments on morality. It rejected the application on the grounds that animal

varieties were not patentable under the EPC.²⁹⁷ On appeal however, the Technical Board of Appeal considered it necessary to apply the 'morality' exclusion under Article 53(a). The Technical Board of Appeal was of the view that genetically modifying a mammal to ensure it developed cancer was highly problematic, since such genetic modifications and the resultant cancer would necessarily cause suffering to the animal.²⁹⁸ The Board of Appeal therefore remitted the application to the Examining Division with instructions that while considering morality, the patent office should balance the invention's utility to mankind with the suffering caused to animals and the possible risk to the environment. In line with the Board of Appeal's instructions, the Board held the genetically modified mouse to be patentable on the grounds that cancer research was to the benefit of humanity.²⁹⁹ While considering the suffering caused to mice the Examining Division reasoned that cancer research would take place anyway and that it would require the sourcing of several mice to locate the ones which had 'naturally' developed cancer; the invention under consideration however benefited mice since it would reduce the large number of mice that would have otherwise been sourced and subsequently destroyed by laboratories for cancer research. Based on this utilitarian framework, the EPO therefore went ahead to grant a patent for the genetically modified mouse.

(2) The Upjohn case: In this case, a pharmaceutical company had filed a patent application covering a mouse into which a gene had been introduced so as to cause the mouse to lose its hair. The EPO applied the same utilitarian test that it had developed in the Onco-mouse case but with different results. After balancing the benefits of the invention in experiments to cure hair loss, as against the harm suffered by the mice, the EPO came to the conclusion that the invention was immoral and would therefore not be patentable.³⁰⁰

(3) The Plant Genetic Systems Case:³⁰¹ In this case, the patent which was granted for a genetically engineered plant which rendered the plants resistant to herbicide, was opposed by Greenpeace on the grounds that such an invention was inherently immoral and also that it created risks to the environment. Applying the utilitarian approach, formulated in the Onco-Mouse case, Greenpeace argued for the possible risks to be balanced against the benefits likely to accrue from the invention. The Opposition Division of the European Patent Office refused to consider the patent on the basis of the utilitarian theory developed in the Onco-Mouse case on the grounds that they were primarily concerned with the technical aspect of the invention and that they were not competent or qualified to decide ethical issues. Instead, the Opposition Division held that the 'ordre public' & 'morality' exclusion would be invoked only in those cases where the invention was regarded to be so outrageous that there was an overwhelming consensus that no patent should be granted for the same. The EPO therefore required that a certain threshold be crossed before the application of the morality test. With this decision the EPO considerably narrowed

²⁹⁷ [1989] OJEP 451 (Exam.)

²⁹⁸ *Harvard/Onco-mouse*, T19/90 (1990) OJEP 490 (TBA).

²⁹⁹ *Harvard/Onco-mouse*, T19/90 (1991) EPOR 525 (Exam).

³⁰⁰ *Independent* (2 Feb. 1992).

³⁰¹ [1993] 24 IIC 618.

the application of the *morality* in the patent system. The decision of the Opposition Division was appealed to the Technical Board of Appeal. While dismissing the appeal the Board of Appeal held that although the morality provision is to be considered normally it should not be disregarded by the patent office even in those cases where it is difficult to judge whether the claimed subject matter would offend 'ordre public' and morality.

(4) The Relaxin case: In this case, the Howard Florey's Institute was granted a patent for the DNA sequences of a naturally occurring substance, which is obtained from the human ovary and which relaxes the uterus during child birth.³⁰² This patent was opposed by the Green Party on three grounds: (i) That the use of pregnancy for profiteering was offensive to human dignity; (ii) that the applicant was involved in patenting life itself and that the same was intrinsically immoral; and (iii) such patenting was equivalent to slavery. The EPO rejected these objections on the grounds that the tissue that was used in the research was donated during the course of necessary gynaecological operations and therefore did not offend 'human dignity'. Moreover, the EPO held the DNA to be a 'chemical substance which carries genetic code' and not 'life'. The 'slavery' analogy was also shot down by the EPO on the grounds that the opponents had failed to appreciate the true nature of patent right which did not grant a monopoly over life but simply a right to prevent others from practising the same invention.

(5) The Transgenic Animals decision: The scope of the 'morality' exclusion in Article 53(a) was once again considered by the Technical Board of Appeal (EPO) in its 2006 *Transgenic Animals* decision. In this appeal against the Order of the Opposition Division in the year 2003, the Technical Board of Appeal was required to consider whether the patent could stand in an amended form to cover all transgenic rodents, i.e. genetically modified rodents could be excluded from patentability under the morality requirements of Article 53.³⁰³

In its decision, the Technical Board of Appeal ruled that the words 'contrary to *ordre public* or morality' in Article 53 of the EPC was not concerned with either the morality of the process of genetically manipulating a mouse nor with the technique of such manipulation. Instead, the Technical Board of Appeal stressed that the 'morality' provision of Article 53 was concerned with the morality of *exploiting* such a genetically modified organism or the method to carry out such genetic manipulation³⁰⁴. The Board further confirmed that the utilitarian approach laid down by the Opposition Division in the 1991 Onco-mouse decision (T 19/90) was the correct approach to be taken by the Court while deciding the suitability of bringing the invention under the 'morality' requirement of Article 53 EPC.

The Board however rejected the amendment aimed at covering all rodents on the grounds of EPC 2000 Rule 28 which clearly states that under Article 53A, European Patents shall not be granted in respect of biotechnological inventions which in particular concern the following - (I) process for cloning humans (ii) processes for

³⁰² *Howard Florey/Relaxin*, T74/91 [1995] EPOR 541 (Op. Div.).

³⁰³ *Harvard/Onco-mouse*, [2003] OJEP 473 (Opposition Division).

³⁰⁴ *Harvard/Transgenic Animals*, T 315/03 (2006) OJEP 15, 29 (TBA).

modifying the germ line genetic identify of human being (iii) uses of human embryos for industrial or commercial process and (iv) process for modifying the genetic identity of animals which are likely to cause them suffering without any corresponding medical benefit to man or animal and also causes animals resulting from such processes. The applicant's main request claiming 'transgenic rodents', (which meant claiming all animals within the taxonomic order *Rodentia*), was rejected on the basis of the balancing test in this Rule, since the applicants failed to show the medical benefits of conducting such tests on the entire taxonomic order, instead of only mice. The claims with respect to only 'mice' however survived the original utilitarian test since the applicants were able to demonstrate increased medical benefits vis-à-vis mice.

(6) The 'University of Edinburgh's human embryo patent': In the year 2002, the University of Edinburgh was granted a patent for an invention in the field of development biology. The patent in question "described a method of using genetic engineering to isolate stem cells – including embryonic stem cells – from more differentiated cells in a cell culture in order to obtain pure cell cultures."³⁰⁵ The patent was challenged by the Governments of Germany, Italy and the Netherlands along with the German branch of Greenpeace, on the grounds that such an invention was against 'ordre public' and morality. On concluding the hearings, the Opposition Division at the EPO held that the University of Edinburgh's controversial human embryo patent did not comply with EPC 2000 Rule 28(c) and Article 53(a) of the EPC 2000.³⁰⁶

(7) The Wisconsin Alumni Research Foundation (WARF) case:³⁰⁷ The question that arose in this case was whether or not human embryonic stem cell (HESC)s were patentable or not. While the EPO had been granting patents for stem cell research, the issue with the HESCs was that the method of extraction inevitably led to the destruction of the human embryo. As already discussed, Article 53(a) prohibited the grant of patents for those inventions which were against 'ordre public' & morality, while Rule 28(c) specifically prohibited the patenting of human embryos for industrial or commercial purposes. The patent application was therefore rejected by the EPO on these grounds. On appeal to the EPO Technical Board of Appeal (TBA), given the significance of the matter, the Board of Appeal referred the matter to an

³⁰⁵ The 'Edinburgh' patent is European patent No. EP 0695351, with the title "Isolation, selection and propagation of animal transgenic stem cells", available at <http://www.epo.org/about-us/press/releases/archive/2002/18972002.html>. (Last visited on August 11, 2010).

³⁰⁶ Patent EP 695351, granted by EPO Dec. 1999. See EPO press release, 'Edinburgh patent limited after European Patent Office opposition hearing' (24 Jul. 2002). Rule 28 reads as follows: **Exceptions to patentability** : Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) 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.

³⁰⁷ *Wisconsin Alumni Research Foundation*, Case G 0002/06, Eur. Patent Off., 23-26 (Nov. 25, 2008), (2009) 5 OJEP 306.

Enlarged Board of Appeals (EBoA). The EBoA issued its ruling in November 2008 in which it refused to allow WARF's patent for the HESCs to proceed as the same was against "the public order and morality requirements of Article 53(a) & Rule 28(c) of the EPC 2000." The EBoA was partly guided by the Biotech Directive of the E.U. which incorporates ethical considerations into the patentability analysis.³⁰⁸

(8) Eurasian Patent Convention: This treaty is administered by the Eurasian Patent Organization (EAPO). The members of the EAPO are mainly former members states of the USSR and include the following: Turkmenistan, Republic of Belarus, Republic of Tajikistan, Russian Federation, the Republic of Azerbaijan, Republic of Kazakhstan, the Krygyz Republic, the Republic of Moldova, Georgia, Ukraine and Republic of Armenia. It must be observed that not all of these countries are signatories to TRIPs. Some of these countries like the Russian Federation are only observers and not signatories to the WTO and its ancillary treaties. The main aim of this convention is to create a single patent system for all the member states in order to avoid duplication of resources. The Eurasian Patent Convention does not provide for any exclusion from patenting on the grounds of 'ordre public' or 'morality'.

E. Individual Countries

(1) Albania

Albania is a member of the European Patent Convention (EPC) and is governed by a patent law which is referred to as the Committee of Science and Technology Order, No. 1707, of December 29, 2008, Rules for Patents. Article 6 of this legislation contains an elaborate exclusion from patentability on the grounds of public order and morality. Article 6(1) states that patents shall not be granted to inventions, the commercial exploitation of which would be contrary to public order, morality or public health and human life. This provision of law further clarifies that such exploitation may be deemed to be so contrary even if it has not been so banned expressly by law or regulation. The legislation therefore vests in the patent office a wide discretion to decide when exploitation of an invention is offensive to public order, morality or health. Clause 6 further incorporates provisions of the E.U. Biotech Directive 98/44/EC, by specifically prohibiting "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." Albanian patent law therefore appears to exploit the scope of the exclusion under Article 27.2 of TRIPs.

³⁰⁸ "Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;" Clause 42 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July, 1998 on the legal protection of biotechnological inventions.

(2) Armenia

The relevant patent legislation of Armenia is the Industrial Property Law, 2008. Article 10 of this legislation lists all the exceptions to patentability. Of particular relevance to this paper is Article 10(2): *Inventions, the exploitation of which contradicts the public interests, morality, philanthropy principles shall not be subject to legal protection.* The nature of the exclusion under Article 10(2) of the relevant Armenian law, especially the 'philanthropy' principle, *prima facie*, seems to be much broader than the exclusion under Article 27.2 of TRIPs.

(3) Argentina

The relevant patent legislation of Argentina is Law No. 24. 481 enacted in the year 1995 and amended subsequently. Article 7 of the same law, deems unpatentable, the inventions whose exploitation in the Argentinean territory should be prevented so as to protect public good or morality, the health or life of persons or animals, the conservation of plants or the avoidance of serious damage to the environment. Although similarly worded to Article 27.2 of TRIPs this provision does not state that the exploitation of the invention has to be of a commercial nature.

(4) Australia

The relevant patent legislation of Australia is the Patents Act, 1990, as consolidated in 2010. The Australian legislation does not incorporate an express 'ordre public & morality' exclusion as envisaged by Article 27.2 of TRIPs. This legislation however does stipulate that "human beings, and the biological processes for their generation, are not patentable inventions". In essence these are exclusions to patentability which can be defended on the basis of the basis of the 'ordre public' and 'morality' exclusions of Article 27.2 of TRIPs.

(5) Bahrain

The relevant patent legislation of Bahrain is Law No. 1 of 2004 in Respect of Patents and Utility Models, as amended by Law No. 14 of 2006. Under Article 3 of this law the Kingdom of Bahrain may prohibit the patenting of any inventions the commercial exploitation of which is imperative for the protection of public order or principles of morality; including the protection of humans life or health or that of animals or plants or to avert causing serious harm to the environment.

(6) Bangladesh

The relevant patent legislation of Bangladesh is the Patent & Designs Act, 1911. This legislation does not provide for the 'ordre public' or morality exclusion from patent law. In this sense Bangladesh is not fully exploiting the exclusions that are found in Article 27.2 of TRIP.

(7) Belize

The relevant patent legislation of Belize is the Patents Act, Chapter 253 (revised edition 2000). As per Article 12(3)(a) of this legislation a patent shall not be granted for an invention, the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such refusal shall not be based solely on the grounds that the commercial exploitation of such an invention is prohibited by a law in force in Belize.

(8) Bolivia

The relevant patent legislation in Bolivia is the Industrial Property Law, 1912. According to Article 3 of this law, patents can be denied to inventions the exploitation of which would be contrary to law, public safety, or decency or morality. This provision therefore adequately exploits the exclusion under Article 27.2. Although Article 27.2 does not expressly include the term 'decency', the same can be read into the undefined terms of 'morality' / 'ordre public'.

(9) Brazil

The relevant patent legislation in Brazil is Law No. 9.279/96. Article 18 of this legislation states that any invention contrary to morality, decency or public safety, order and public health shall be excluded from the scope of patentable subject matter. Article 18(II) further goes on to prohibit the patenting of all or part of living things even though they may have satisfied the requirements of patentability and were not mere discoveries. Although this provision does not expressly use the words 'ordre public' or 'morality' the scope of the provision essentially takes shelter under the Art. 27.2 heading of 'morality'.

(10) Bulgaria

The relevant patent legislation of Bulgaria, a member of the EPC, is a legislation which was originally promulgated in the State Gazette in the year 1993 and consequently amended in the years 1993, 1996, 1998, 1999, 2002 & 2007. As per Article 7 of this legislation a patent shall not be granted for inventions the commercial use of which would be contrary to 'social order or morality', including "*(a) methods of cloning human beings; (b) methods of altering the genetic identity of human embryo; (c) use of human embryos for industrial or commercial purposes; (d) methods of modifying the genetic identity of animals, where this may cause them suffering without any substantial use from a medical point of view for humans or animals, as well as animals obtained by such methods;*". Thus, Article 7, in effect incorporates the E.U. Directive on Biotechnology – 98/44/EC.

(11) Cambodia

The relevant patent legislation of Cambodia is the 'Patents & Utility Models & Industrial Designs, law of 2003'. Article 9 of this legislation states that inventions, the commercial exploitation of which would be contrary to public order or morality or prohibited by law would not be patentable under the legislation. This provision therefore adequately exploits the scope of the 'ordre public' or 'morality' exclusion available in Article 27.2 of TRIPS.

(12) Canada

The relevant Canadian patent legislation is the Patents Act, 1985 as amended several times over the last decades. This legislation does not provide for any specific 'ordre public'/morality exclusion from patentability. In the controversial *Oncomouse* decision the Commissioner of Patents turned down the patent application for the Harvard Oncomouse. This invention basically involved injecting cancer cells into mice so as to enable the cancer to develop within them in a manner which would be useful for animal carcinogenic studies. The Commissioner of Patents initially rejected the patent application on grounds of public policy. The Canadian Supreme Court while overturning the decision of the appeals court³⁰⁹ held that the 'public policy' could not be grounds for rejecting a patent since Parliament did not incorporate an 'ordre public' or 'morality' exception into the Patent Act despite having an opportunity to do so while it was amending the Patent Act to make it compatible with TRIPS and NAFTA, both of which provide for such an exclusion.³¹⁰ As a result 'ordre public' and morality as a grounds of exclusion to patentability have no basis in Canadian law.

(13) Chile

The relevant, revised patent legislation in Chile is law no: 19.039, 2005 (Establishing the Rules Applicable to Industrial Titles and the Protection of Industrial Property Rights). Article 38 of this law excludes from the definition of patentable subject matter those inventions, the commercial exploitation of which must be necessarily prevented in order to protect public order, state security, morals & decency, the health or life of people or animals, or to preserve plants or the environment, provided that the exclusion is not made for the sole reason that a legal or administrative provision exists prohibiting or regulating that exploitation. The provision therefore adequately exploits the exclusion under Article 27.2 of TRIPs.

(14) China

The relevant patent legislation in China is 'The Patent Law of the People's Republic of China', 2000 as amended in the subsequent years. Article 5 of this legislation states that no patent right shall be granted for any invention that contravenes any law or social moral or that is detrimental to public interest. Unlike Article 27.2 of TRIPS which states that an exclusion shall not be made simply for the reason that its exploitation is prohibited by the law, this Chinese legislation allows for excluding protection merely on the grounds that the invention contravenes any law. Further unlike Article 27.2 of TRIPs the Chinese exclusion does not seem to require the exploitation to be of a 'commercial' nature. The Chinese State Intellectual Property Office (SIPO) gives some examples of few such inventions which are not patentable³¹¹: (1) Processes for cloning human beings and human beings being cloned (2) Processes for modifying the germ line identity of human beings (3) Uses

³⁰⁹ *President and Fellows of Harvard College v. Commissioner of Patents*, Federal Court of Canada, File: T-275-96; April 21, 1998.

³¹⁰ *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 (Can.), available at <http://www.canlii.org/en/ca/scc/doc/2002/2002scc76/2002scc76.html>. (Last visited on August 11, 2010).

³¹¹ Melissa Wetkowski, 'Unfitting: Gene patent limitations too tight for United States' biotechnology innovation and growth in light of international patenting policies', 16 Sw. J. Int'l L. 181 (2010), 196.

of human embryos for industrial or commercial purposes (4) Processes for modifying the genetic identity of animals, which are likely to cause them suffering without any substantial medical benefit to human and animal, and also animals resulting from such processes. These guidelines virtually mirror the European law on the point.

(15) Colombia

This country follows the Andean Rules with no domestic legislation supplementing it and therefore automatically has the same exclusions that exist under the Andean Pact.

(16) Croatia

The relevant patent legislation in Croatia is the 'Patent Act and Amending Patent Act and Act on Amendments to the Patent'. Article 7 of this legislation states that inventions shall be considered un-patentable where their commercial exploitation would be contrary to public order or morality. In addition to this, Article 7 also incorporates the E.U. Biotech Directive 98/44/EC by expressly prohibiting the process for cloning human beings, process for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes and also 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.

(17) Cyprus

The relevant patent legislation of Cyprus is the Patent Law of 1998. Article 5 of this legislation states that a patent shall not be granted in respect of an invention the publication or exploitation of which would be contrary to public order or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. This provision does not state that the exploitation is required to be of a commercial nature.

(18) Czech Republic

The relevant patent legislation of the Czech Republic is the Law No. 527/1990 of Coll., Act on Inventions, Industrial Designs and Rationalisation Proposals, as amended by the Law No. 519/1991 of Coll. Via an Amendment Act dated 2000, Section 4 (a) was amended to introduce an exclusion to patentability on the grounds of 'ordre public' and 'morality'. In pertinent part the exclusion reads as follows: "inventions, the exploitation of which would be contrary to public order or morality; this fact may not be concluded merely because the exploitation of the invention is prohibited by law". This provision does not state that the exploitation is required to be of a commercial nature.

(19) Denmark

The relevant patent legislation of Denmark is the Patents Act as amended over several years. Section 1(b) of the legislation states that patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to *ordre public* or morality provided that an exploitation shall not be deemed to be so contrary merely because the exploitation is prohibited by law or administrative regulation. This legislation additionally incorporates the E.U. Biotech Directive –

98/44/EC – in Article 1(b) therefore banning the patenting of all processes for cloning human beings, processes for modifying the germ line, the use of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals, which process may cause them harm that is not proportional to the benefit to mankind.

(20) Ecuador

The relevant patent legislation in Ecuador is Codificación 2006-013. According to Article 126 of this law patents are to be denied to inventions, the commercial exploitation of which must be prevented as necessary to protect morality. Patents are also denied on absolute grounds to inventions, the commercial exploitation of which must be prevented as necessary to protect public order including to protect the health or life of humans or animals or plant life or to prevent serious damage to the environment or ecosystem.

(21) Egypt

The relevant patent legislation in Egypt is the Law on the Protection of Intellectual Property Rights (Law No. 82) which was adopted on 3 June 2002. Under Article 2 of this law patents shall not be granted for inventions whose exploitation is likely to be contrary to public order or morality, or prejudicial to the environment, human, animal or plant life and health. This provision does not state that the 'exploitation' is required to be of a commercial nature.

(22) Estonia

Estonia is a member of the EPC. The relevant patent legislation in Estonia is the Patent Act, 1994 as amended consequently in the years 2000, 2001, 2002, 2003 & 2004. Section 7 of this legislation lists all the inventions that are deemed to be 'unpatentable inventions'. Included in Clause (1)(1) of this provision are any inventions which are contrary to public order and morality. This provision does not state that the 'exploitation' is required to be of a commercial nature. In addition, Section 7 of this legislation also incorporates the E.U. Biotech Directive 98/44/EC, which prohibits the patenting of all processes for cloning human beings, processes for modifying the germ line, the use of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals, which process may cause them harm that is not proportional to the benefit to mankind.

(23) Ethiopia

The relevant patent legislation in Ethiopia is titled 'Proclamation No. 123/1995 concerning Inventions, Minor Inventions and Industrial Designs'. Section I, Article 4(a) of this legislation deems any invention contrary to public order or morality as unpatentable.

(24) France

France is a member of the EPC. The relevant patent legislation in France is Book VI of the Intellectual Property Code – 'Protection of Inventions and Technical Knowledge'. As per Article L611-17 of this Code 'Inventions shall be considered unpatentable where their commercial exploitation would be inconsistent to public policy or morality, however such inconsistency may not emanate from a prohibition by law or regulation.' In addition to this exclusion, France has also incorporated the

E.U. Biotech Directive 98/44/EC and has thereby prohibited processes for cloning human being, modifying germ-line identity, use of human embryos, partial sequences of a gene, animal varieties, essential biological processes for the production of plants and animals, processing for modifying the genetic identity of animals which are likely to cause them suffering without substantial benefit to man or animal.

(25) Finland

Finland is a member of the EPC. The relevant patent legislation in Finland is the Patents Act, No. 550 of December 15, 1967 as amended subsequently over the years with the last amendment in the year 2006. Section 1(b) of Chapter I of this legislation states that patents shall not be granted for inventions the commercial exploitation of which would be contrary to ordre public or morality provided that the commercial exploitation may not be considered to be contrary to ordre public or morality merely because it is prohibited by law or regulation. In addition to this exclusion Finland has also incorporated the E.U. Biotech Directive 98/44/EC thereby expressly prohibiting a range of inventions related to the field of biotechnology.

(26) Germany

Germany is a member of the EPC. The relevant patent legislation in Germany is the Patentgesetz (Patent Law) or the Patent Act of December 16 as last amended by the law of 31st July, 2009. As per Section 2 of this legislation, inventions whose commercial exploitation would be contrary to public order or morality, would be unpatentable, provided however that such patenting shall not be unpatentable solely due to the fact that the exploitation is prohibited by law or regulation. This legislation also incorporates the E.U. Biotech Directive 98/44/EC thereby expressly prohibiting a range of inventions relating to the field of biotechnology such as human cloning, the use of embryos for commercial or industrial purposes, the modification of genetic identity of human beings, the modification of the genetic identity of animals in those cases where such modification does not cause substantial medical benefits to man or animal kind.

(27) Georgia

The relevant patent legislation in Georgia was adopted on the 4th of February, 1999 adopted on the 25th of May, 1999. As per Section 17 of this legislation a patent is not granted for an invention the commercial exploitation of which may cause inhuman, immoral and/or anti-social action.

(28) Ghana

Ghana is a member of ARIPO. The relevant patent legislation of Ghana is the Patent Law, 1992, PNDCL, No. 305A. As per Section 6 of this legislation 'a patent shall be obtained in respect of an invention the exploitation of which is prohibited by law, except where the prohibition relates to public order or morality.' Unlike Article 27.2 of TRIPs this provision does not require the exploitation to be of a commercial nature.

(29) Guyana

The relevant patent legislation of Guyana is the Patent and Designs Act, 1973. This legislation does not provide for an *ordre public* or morality exclusion to patentability.

(30) Greece

Greece is a member of the EPC. The relevant patent legislation in Greece is the 'Law on Technology Transfer, Inventions and Technical Innovation as amended in subsequent years. Section 8 of the law states that patents shall not be granted in cases where the inventions, the publication or exploitation of which would be contrary to *ordre public* or morality. This provision does not require the exploitation to be commercial in nature. Additionally Section 8 also prohibits the patenting of plant or animal varieties or biological processes for the production of plants or animals. Greece has also incorporated the E.U. Biotech Directive – 98/44/EC through Presidential Decree No. 321/2001. As already explained above this Directive prohibits the patenting of inventions relating to the field of biotechnology such as human cloning, the use of embryos for commercial or industrial purposes, the modification of genetic identity of human beings, the modification of the genetic identity of animals in those cases where such modification does not cause substantial medical benefits to man or animal kind.

(31) Hungary

Hungary is a member of the EPC. The relevant patent legislation in Hungary is the 'Law No. XXXIII of 1995 on the Protection of Inventions by Patents'. Article 6 of this legislation states that no patent protection may be granted for an invention if the publication or exploitation thereof would be contrary to public policy or morality; exploitation may not be regarded as contrary to public policy merely because it is prohibited by law or regulation. In addition to this provision Hungary has also incorporated the E.U. Biotech Directive 98/44/EC via Act XXXIX of 2002. As a result of this Directive Hungarian law prohibits the patenting of inventions relating to the field of biotechnology such as human cloning, the use of embryos for commercial or industrial purposes, the modification of genetic identity of human beings, the modification of the genetic identity of animals in those cases where such modification does not cause substantial medical benefits to man or animal kind.

(32) Iceland

Iceland is a member of the EPC. The relevant patent legislation in Iceland is the Patents Act, 1991 as amended in the year 1993, 1996 etc. Section 1, Part I of this legislation states that a patent shall not be granted for inventions the use of which would be contrary to morality or public order. In addition the plant or animal varieties or essentially biological processes for the production of plants or animals are considered to be unpatentable. Additionally, Iceland has enacted a legislation implementing the E.U. Biotech Directive 98/44/EC on the 11th of May, 2004. As a result of this Directive Iceland now prohibits the patenting of inventions relating to the field of biotechnology such as human cloning, the use of embryos for commercial or industrial purposes, the modification of genetic identity of human beings, the modification of the genetic identity of animals in those cases where such modification does not cause substantial medical benefits to man or animal kind.

(33) India

Section 3(b) of the Patent Act, 1970 states that the following shall not be considered inventions:

(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment

The Draft Patent Office Manual, 2008, which is only indicative and not binding on the examiner cites the following examples to indicate the kinds of inventions which may be prohibited by Section 3(b):³¹²

- a. Any device, apparatus or machine or method for committing theft/burglary,*
- b. Any machine or method for counterfeiting of currency notes,*
- c. Any device or method for gambling*
- d. Inventions, the established or intended use or commercial exploitation of which is found to be injurious to public, animal or plant life or health, such as, a method of adulteration of food.*
- e. An invention, the present or intended use of which is likely to violate the well accepted and settled social, cultural, legal norms of morality, e.g. method of cloning*
- f. An invention, the primary or proposed use of which would disturb the public order e.g. a device for house-breaking.*
- g. Terminator gene technology*

So far there has been few reported cases in India, wherein the patent office or the judiciary have denied a patent on grounds of Section 3(b) of the Patent Act, 1970. In one unreported decision of the patent office, a patent was denied to an invention related to medicinal powder prepared from skeletal remains of dead bodies dug up within a week of burial on the grounds that digging up graves for profit-oriented purposes was immoral.³¹³ The one case which was widely reported was the case of *Novartis AG v. UoI & Ors.*³¹⁴. The IPAB (Intellectual Property Appellate Board) in this case denied Novartis a patent on grounds of excessive pricing i.e. the anti cancer drug, Gleevec that was sought to be patented was priced very highly in India and

³¹² Indian Patent Office, *Draft Manual of Patent Practice and Procedure*, (2008), 56, available at http://ipindia.nic.in/ipr/patent/DraftPatent_Manual_2008.pdf. (Last visited on August 11, 2010).

³¹³ Shammad Basheer, 'Grave Diggers, Immoral Patents & the NBRA', July 30, 2008, available at <http://spicyipindia.blogspot.com/2008/07/grave-diggers-immoral-patents-and-nbra.html> (Last visited on August 11, 2010).

³¹⁴ M.P. No. 1 to 5 /2007 in TA/1 to 5 /2007/PT/CH. (IPAB), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>. (Last visited on August 11, 2010).

was out of the reach of the common man. In pertinent part, the IPAB held: *“in our view[the drug] is too unaffordable to the poor cancer patients in India. Thus, we also observe that a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well. Considering all the circumstances of the appeals before us, we observe that the Appellant’s alleged invention won’t be worthy of a reward of any product patent on the basis of its impugned application for not only for not satisfying the requirement of section 3(d) of the Act, but also for its possible disastrous consequences on such grant as stated above, which also is being attracted by the provisions of section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which could create public disorder among other things.”*

It is important to note that the patent was denied on the grounds of “public order” and not morality. This case is currently pending appeal before the Supreme Court of India.

(34) Indonesia

The relevant patent legislation in Indonesia is the Patent Law as amended by law No. 14 on August 1, 2001. Article 7 of this law states that a patent shall not be granted to an invention whose publication and use or implementation contravenes the prevailing rules and regulations, religious morality, public order or ethics.

(35) Italy

Italy is a member of the EPC. The relevant patent legislation in Italy is the 2005 Italian Industrial Property Code. Italy has adopted the E.U. Biotech Directive – 98/44/EC through an Act of Parliament and effective from 11th of March, 2006.

(36) Ireland

Ireland is a member of the EPC. The relevant patent legislation in Ireland is the Patents, Act 1992, as amended subsequently. Section 10 of this legislation states that a patent shall not be granted in respect of “an invention the publication or exploitation of which would be contrary to public order or morality, provided that the exploitation shall not be deemed to be so contrary only because it is prohibited by law.” Unlike Art. 27.2 of TRIPs this provision does not require that the exploitation be commercial in nature. Additionally Ireland too has incorporated the E.U. Biotech Directive – 98/44/EC via 'The European Communities (Legal Protection of Biotechnological Inventions) Regulations, 2000 (S.I. No. 247 of 2000)' and given effect to it in 30th July, 2000. These regulations elaborate in great detail the biotechnological inventions that are deemed unpatentable under Irish law.

(37) Japan

The relevant patent legislation in Japan is the Patent Law (Law No. 121 of 13 April 1959, as last amended by Law No. 79 of 4 June 2004). Article 32 of this legislation states that inventions liable to contravene public order, morality or public health shall not be patented notwithstanding the fact that the invention would have otherwise passed the patentability criteria laid down in Article 29 of the same legislation.

(38) Jordan

The relevant patent legislation in Jordan is the Patents of Invention Law No. 32 of 1999 as amended by Temporary Law No. 71 of 2001. Article 4(2) of this legislation states that inventions the exploitation of which would be contrary to public order or morality may be excluded from patent protection. This legislation also prohibits the patenting of inventions, the prevention of its commercial exploitation, is necessary to protect life and health of humans, animals, or plants or to avoid serious prejudices to the environment. A proviso to both provisions states that the exclusion of protection is not made merely because the invention's exploitation is prohibited by other legislation in force.

(39) Kenya

The relevant patent legislation in Kenya is the Industrial Property Act No. 3 of 2001. As per Article 26(b) of this legislation those inventions contrary to public order, morality, public health and safety, principles of humanity and environmental conservation are not patentable. Unlike Article 27.2 of TRIPS this provision does not have a 'commercial exploitation' requirement.

(40) Latvia

Latvia is a member of the EPC. The relevant patent legislation in Latvia is the Patent Act, 2007. Article 9 of this legislation excludes from patentability those inventions which offend the morality of society. In addition Latvia has also incorporated the E.U. Biotech Directive 98/44/E through a legislation which came into effect from the 29th of December, 2005.

(41) Malaysia

The relevant patent legislation in Malaysia is Act No. 291 of 1983 as amended several times later, the latest amendment being in the year 2006. Section 31 of this legislation was amended in 2000 via Amendment Act A1088 to exclude from the purview of patentability those inventions, the exploitation of which would be contrary to public order or morality. In regards the 'public order' and 'morality' exploitation the Patent Office Manual states that the purpose of this provision is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive or immoral behaviour. As an illustration the manual cites the example of a letter-bomb as one of the inventions that would be excluded from the purview of this legislation. The Manual also assures that this provision is likely to be invoked in rare and extreme cases. A 'fair test' according to the Manual would be whether or not the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.

(42) Mexico

Mexico, a state which is a signatory to the North American Free Trade Treaty (NAFTA), does provide for an exclusion to patentability on the grounds of public order and morality. The relevant patent legislation in Mexico is the Industrial Property Law. Article 4 of the Industrial Property Law denies patent protection to any inventions in order to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the

environment, provided that the exclusion is not based solely on the ground that the law prohibits commercial exploitation of the subject matter of the patent within its territory.

(43) Morocco

The relevant patent legislation in Morocco is the Morocco Industrial Property Act, Act No. 17-97 (Feb. 9th 2000). As per Article 24(a) of this legislation, inventions that are contrary to public order and morality are not eligible for patent protection. In the opinion of one authority 'morality' and 'public order' must be interpreted in a broad sense as taught under Islam in accordance with the Koran.³¹⁵

(44) Mozambique

The relevant patent legislation in Mozambique is the Industrial Property Code Decree No. 04/2006 of 12th April, 2006. As per Art. 30 of this legislation inventions which are contrary to morality, *bonos mores*, public safety, public order and public health are excluded from patent protection. Unlike Article 27.2 this provision does not require that the exploitation of the invention be of a 'commercial nature'.

(45) Netherlands

Netherlands is a member of the EPC. The relevant patent legislation in Netherlands is the Patents Act, 1995 as amended in subsequent years. As per Article 3 of this legislation no patents shall be issued for inventions the publication or exploitation of which would be contrary to public order or morality. In regards the E.U. Biotech Directive – 98/44/EC, the Kingdom of Netherlands initially brought a case C-377/98 before the European Court of Justice arguing against the adoption of the directive. The ECJ however did not entertain Netherland's plea. As a result Netherlands did enact a legislation on the 11th of November, 2004 to incorporate the E.U. Biotech Directive. As per this legislation Netherlands will have to restrict the patentability of certain inventions related to the field of biotechnology.

(46) New Zealand

The relevant patent legislation in New Zealand is the Patents Act, 1953 as amended during the subsequent years. Under Section 17(1) the Commissioner of Patents may reject a patent application on the grounds that the invention claimed by it would be contrary to law or morality. An interesting decision in which Section 17 came into play was that of the Assistant Commissioner's in the case of the patent application filed by the Wisconsin Alumni Research Foundation and Wicell Research Institute Inc, Decision of the Assistant Commissioner.³¹⁶ At issue in this case were two patent applications: (i) NZ 532170 – filed in the name of Wisconsin Alumni Research Foundation (WARF) claiming a method for inducing primate stem cells to differentiate; & (ii) NZ 535243 – filed in the name of Wicell Research Institute (WRI) claiming a method for inducing primate stem cells to differentiate. Both applications were rejected by the Examiner on the grounds of Section 17(1). Both Parties appealed to the Assistant Commissioner against the orders of the examiner. The applicants targetted the application of the 'morality' requirement, primarily on the

³¹⁵ Tshimanga Kongolo, 'Morocco's Patent System and its International Connection', 42 IDEA J. L. & Tech. 181 (2002), 185.

³¹⁶ P22/2007

grounds that there was absolutely no definition of morality either in the legislation or in the form of judicial precedent therefore making it impossible to judge the standards for the same.³¹⁷ The applicants then referred to the common definitions of 'morality' and convincingly established before the Asst. Commissioner that the methods claimed by them in their patent applications did not offend these definitions of morality, since these methods were not "diametrically opposed to behaviour which New Zealand society believes to be right conduct, that belief being deeply rooted in our culture." The Assistant Commissioner agreed with these contentions after considering domestic legislation on the issue of research into stem cells and embryos. The Asst. Commissioner noted that although such research was strictly controlled by the Government it was not completely prohibited. As a result both applications were deemed not contrary to the morality and *ordre public* of New Zealand and were therefore allowed by the New Zealand Patent Office.

(47) Nigeria

The relevant patent legislation in Nigeria is the Patents and Designs Act, Chapter 344, Law of the Federation of Nigeria, 1990. As per Section 1(4) of this law patents "cannot be validly obtained in respect of inventions the publication or exploitation of which would be contrary to public order or morality (it being understood for the purposes of this paragraph that the exploitation of an invention is not contrary to public order or morality merely because its exploitation is prohibited by law)." Unlike Article 27.2 of TRIPs this provision does not require the exploitation to be of a commercial nature.

(48) Norway

Norway is a member of the EPC. The relevant patent legislation in Norway is the 'Lov om patenter' (Act No. 9 of December 15, 1967 on patents). As per Section 1(b) of this legislation inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality. An explanation to the section states that exploitation shall not be deemed so contrary merely because it is prohibited by law or regulation. Additionally Norway has also incorporated the E.U. Biotech Directive - 98/44/EC through a Parliamentary legislation in the year 2003 and which came into force on 01.02.2004. As a result certain inventions pertaining to the biotechnology sector are not patentable.

(49) Pakistan

The relevant patent legislation in Pakistan is the Patent Ordinance, 2000. Section 7(4) of this legislation excludes from the patentability criteria any invention the commercial exploitation of which would be need to be prohibited in order to protect the "*ordre public*" or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by any law for the time being in force.

³¹⁷ Julie Ballance & Fiona Pringle, 'Morality & Patentability - stem cell patents in New Zealand', available at

<http://www.baldwins.com/morality-and-patentability-stem-cell-patents-in-new-zealand/>. (Last visited on August 11, 2010).

(50) Paraguay

The relevant patent legislation in Paraguay is Law No. 1.630/00. According to Article 5 of this law invention whose commercial exploitation should be necessarily prevented to protect public order or morals, protecting health, peoples or animals lives, avoid damages to the environment, are excluded from patent protection.

(51) Peru

After the revocation of Peru's prior intellectual property legislation in the year 2008, the country has essentially been ruled by the Andean Pact. There have been further amendments as a result of the Free Trade Agreement (FTA) with the United States of America. As discussed earlier in this report the Andean Pact does provide for an exclusion to patentability on the basis of the 'ordre public' and morality.

(52) Philippines

The relevant patent legislation of the Philippines is the Intellectual Property Code (Republic Act No. 8293). Section 22(6) of this legislation excludes from the definition of patentable subject matter any invention which is contrary to public order or morality. Unlike Article 27 of TRIPs this legislation does not specify whether the exploitation of the invention should be commercial or not.

(53) Poland

Poland is a member of the EPC. The relevant patent legislation in Peru is the Industrial Property Law (Journal of Laws of 2003, No 119, text 1117 and of 2004, No 33 text 286). As per Article 29 of this Code "patents shall not be granted for inventions whose exploitation would be contrary to public order or morality" provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law. Unlike Article 27.2 of TRIPs this provision does not require the exploitation in question to be of a commercial nature. Additionally Poland has incorporated the E.U. Biotech Directive 98/44/EC via statutory amendment in the year 2000 which was effective from the year 2002. As a result Poland now prohibits a range of inventions pertaining to the field of biotechnology.

(54) Portugal

Portugal is a member of the EPC. The relevant patent legislation in Portugal is the Industrial Property (No. 36/2003) Code as subsequently amended in the following years. Article 21, of the consolidated code, expressly states that "inventions whose commercial exploitation is against the law or contrary to public policy, public health or morality are not patentable and their exploitation may not be considered as such due to the simple fact that is forbidden by law or regulation." Additionally Portugal has also incorporated the E.U. Biotech Directive - 98/44/EC - into its law via a Parliamentary amendment in the year 2002. This amendment came into force in the year 2003.

(55) Qatar

The relevant patent legislation in Qatar is the 'Patents' Law' (Decree Law No. 12 for the year 2003). This law was enforced only from the year 2006 through decree law no: 30 for the year 2006. Article of Qatar's main patent legislation states that patents shall not be granted for inventions that are "contradicting with the provisions of Islamic Sharia' (Law), violating the public order, ethics or national security." The

wording of this provision may be broader than the TRIPS enclosure since *firstly* unlike Article 27.2 of TRIPs the Qatari provision does not have a 'commercial exploitation' qualification. *Secondly* Islamic Sharia law is a large body of law with multiple interpretations.

(56) Romania

Romania is a member of the EPC. The relevant patent legislation in Romania is the Patent Law No 64/1991 as amended in the subsequent years. According to Section 12, Chapter II of this legislation "Inventions contrary to morality or public policy shall not be patentable". Unlike Article 27.2 of TRIPs this provision does not have a qualifying requirement of 'commercial exploitation'. Additionally Romania has amended its Patent Law No. 64/1991 via Law No. 203/2002 of 19th April, 2002 with the purpose of incorporating the E.U. Biotech Directive – 98/44/EC. As a result a number of inventions in the biotechnology sector are now prohibited under Romanian law.

(57) Serbia

Although Serbia is not currently a member of the EPC it has been invited to accede to the same. The relevant patent legislation in Serbia is Patents Law, 2004. As per Article 7 of this legislation patent protection shall not be granted in respect of "inventions the commercial use of which would be contrary to *ordre public* or morality." The proviso states that use of an invention shall not be considered contrary to *ordre public* or morality merely because it is prohibited by law or any other regulation. Although Serbia is not a member of EPC, the language of Article 7 prohibiting the patenting of human embryos etc. is similar if not identical to the language used in E.U. Biotech Directive (98/44/EC).

(58) Slovak Republic

Slovakia is a Member of the EPC. The relevant patent legislation in Slovakia is the Industrial Property (Inventions Designs), Law, 27/11/1980, No. 527. As per Section 4 of this legislation patents shall not be granted in respect of "inventions contrary to public interest, particularly the principles of humanity and morality." Additionally the Slovak Republic has also amended its law in 2001 to incorporate the E.U. Biotech Directive 98/44/EC. As a result certain inventions related to the field of biotechnology are un-patentable.

(59) Slovenia

Slovenia is a member of the EPC. The relevant patent legislation in Slovenia is the Industrial Property Law 2001. Article 11 of this legislation states that a patent shall not be granted for "inventions the exploitation of which would be contrary to public order or morality". Unlike Article 27.2 of TRIPs this legislation does not require the 'exploitation' to be of a commercial nature. Additionally Slovenia has also incorporated the E.U. Biotech Directive 98/44/EC into its national law via a statutory amendment published on 18th of August, 2003. This amendment came into force in the year 2003. As a result a range of inventions related to the biotechnology field are now prohibited in Slovenia.

(60) Singapore

The relevant patent legislation in Singapore is the Patents Act, (No. 24 of 2001) as subsequently revised in the years 1995, 2002 & 2005. As per Section 13(2) of this legislation, “an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour is not a patentable invention”. Section 13(3) clarifies that behaviour shall not be regarded as offensive, immoral or anti-social only because it is prohibited by any law in force in Singapore.

(61) South Africa

The relevant patent legislation in South Africa is the Patents Act, 1978. As per Section 24(4)(a) of this law patents cannot be granted for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour. Unlike Article 27.2 of TRIPs this legislation does not require the exploitation to be of a commercial nature.

(62) South Korea

The relevant patent legislation in South Korea is the Patents Act, 1978 as amended in the subsequent years. As per Section 25(4)(a) of this legislation a patent shall not be granted “for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour.” Unlike Article 27.2 of TRIPs this legislation does not require the exploitation to be of a commercial nature.

(63) Spain

Spain is a member of the EPC. The relevant patent legislation in Spain is the Patents (Utility Models), Law, 1986. As per Section 5(1)(a) of this legislation “inventions whose publication or working would be contrary to public order or morality” cannot be the subject-matter of a patent. Additionally Spain has incorporated the E.U. Biotech Directive – 98/44/EC – through Law No. 10/2002 of 29th April, 2002. As a result a certain range of biotechnological inventions are unpatentable subject-matter in Spain.

(64) Suriname

This country applies the patent legislation in force in Netherlands.

(65) Sweden

Sweden is a member of the EPC. The relevant patent legislation in Sweden is the Patents Act, 1967, as amended in the subsequent years. As per Section 1 of this legislation patents may not be granted to “inventions the use of which would be contrary to morality or public order”. Sweden also adopted the E.U. Biotech Directive through an Act of Parliament on the 1st of May, 2004. As a result a range of inventions related to the biotechnology field are unpatentable.

(66) Switzerland

Switzerland is a member of the EPC. The relevant patent legislation in Switzerland is the 'Federal Law on Patents for Inventions, 1954'. Article 2 of this legislation defines the inventions that are excluded from patentability. As per sub-section (a), “inventions the implementation of which would be contrary to public order or

morality would not be patentable". Unlike Article 27.2 of TRIPs this provision does not elaborate on whether the 'implementation' is required to be of a commercial nature or not.

(67) Thailand

The relevant patent legislation in Thailand is the Patent Act B.E. 2522 (1979). As per Section 9 of this legislation, inventions contrary to public order, morality, health or welfare are not patentable. Unlike Article 27.2 of TRIPs this provision does not have a 'commercial exploitation' qualification.

(68) Tunisia

The relevant patent legislation in Tunisia is the Law No. 2000-84 of August 24, 2000, on Patents. Section 3 of this legislation states that a patent may not be issued for "inventions the publication or implementation of which would be contrary to morality, public policy, public health or the protection of the environment". Unlike Article 27.2 of TRIPs this provision does not seem to require a 'commercial exploitation' requirement.

(69) Turkey

Turkey is a member of the EPC. The relevant patent legislation in Turkey is the Decree-Law No. 551 on the Protection of Patent Rights, 1995. Section 6 of this legislation states that patents shall not be granted for inventions related to "subject matter contrary to public policy or generally accepted standards of morality". Unlike Article 27.2 of TRIPs this provision does not seem to require a 'commercial exploitation' requirement.

(70) Uganda

The relevant patent legislation in Uganda is the Patents Act, 1993. This legislation does not provide for an exclusion based on 'ordre public' and 'morality'.

(71) United Kingdom

The United Kingdom is a member of the EPC. The relevant patent legislation is the Patents, Act, 1977. Section 1(3) of this legislation states that "a patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality". Section 1(4) of the same legislation clarifies that exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force. The United Kingdom has also incorporated the E.U. Biotech Directive in stages thereby deeming certain inventions pertaining to the field of biotechnology as unpatentable.

(72) United States

The patenting system in the U.S.A. is rather unique in the sense that is one of the few countries in the world to provide for the right to patent in the constitution itself. The U.S. Patent Act is the legislation which regulates this constitutional right. Unlike most other national patent law legislations, the U.S. Patent Act does not exclude inventions on the grounds of 'ordre public' & 'morality'. However, this is not to say that the U.S.A. has not witnessed any of morality related debates with respect to the scope of patentable subject matter allowed by its patent law.

The 1817 case of *Lowell v. Lewis*³¹⁸ was the first to lay down the judicial doctrine of beneficial utility. Interpreting the 'utility' requirement in the old Patent Act of 1790, it was held by the *Lowell* Court that an otherwise patentable invention would be unpatentable if it is "*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. But if the invention steers wide of these objections, whether it be more or less useful is a circumstance very material to the interests of the patentee, but of no importance to the public.*"

To this extent, it is important to appreciate that "utility" itself becomes a patent eligibility criteria, as opposed to a patentability criteria.

Subsequently in the 1960 case of in *Re Nelson*³¹⁹, the *Lowell* dicta was once again reiterated by the United States Court of Customs & Appeals. In pertinent portion the Board held that "*The word 'useful' is not supposed to be used, for the purpose of establishing general utility as the test of a sufficiency of invention to support a patent. It had been held, upon the use of the same word in the old patent act of 1793, that it was used merely in contradistinction to what is frivolous or mischievous to society. This term was held to be satisfied, if the alleged invention was capable of use, and was not injurious to the well-being, good policy or sound morals of society.*"

In a 1991 decision³²⁰ of the 2nd Federal Circuit Court cited the above two precedents to interpret the utility requirement of Section 101 of the Patent Act to include the possible moral implications of an invention on society. In pertinent part the Court held that "*Section 101 has also been interpreted to exclude inventions deemed to be immoral, such as (until 1977) gambling machines, or devices deemed to be scientifically impossible, such as perpetual motion machines.*"

In the year 1998, the United States Patents & Trademarks Office (USPTO), in response to a patent application for animal-human hybrids (chimera), issued an office statement, citing the decisions in the *Lowell's* and *Tol-o-Matic* cases, indicating that "*inventions directed towards human/non-human chimeras could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.*"³²¹ The USPTO therefore attempted to bring in the 'morality' aspect under the existing 'utility' requirement in Section 101 of the U.S. Patent Act.

A subsequent 1999 decision of the United States Court of Appeals for the Federal Circuit urged a broader interpretation of the utility requirement under Section 101, arguing that the USPTO and Courts should refrain from acting as arbiters of what

³¹⁸ 15 Fed. Cas. 1018, 1019 (C.C.D. Mass. 1817).

³¹⁹ 126 U.S.P.Q. 242.

³²⁰ *Tol-O-Matic, Inc. v. Proma Product-und Marketing Gesellschaft M.b.H.*, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991).

³²¹ Media Advisory, U.S. Patent and Trademark Office, 'Facts on Patenting Life Forms Having a Relationship to Humans' (Apr. 1, 1998), <http://www.uspto.gov/news/pr/1998/98-06.jsp>.

exactly constitutes fair practices.³²² In pertinent portion it was held that “*The requirement of “utility” in patent law is not a directive to the Patent and Trademark Office or the courts to serve as arbiters of deceptive trade practices. Other agencies, such as the Federal Trade Commission and the Food and Drug Administration, are assigned the task of protecting consumers from fraud and deception in the sale of food products.*”³²³

It is relevant to point out that although this Court refers to the precedents in *Lowell*, *Nelson & Tol-o-Matic* cases, it does not explicitly over-rule any of the above cases. Having said that, it is also pertinent to point out that none of these three cases actually applied the 'morality' requirement to invalidate the patents that were being challenged before their courts.

It should however be noted that despite the extensive political debate on the morality of stem-cell research and the temporary ban on U.S. Government funding for such research, the U.S.P.T.O. has been granting patents for such inventions since the first such grant to the Wisconsin Alumni Research Foundation (WARF) in the year 1998.³²⁴

(73) Uruguay

The relevant patent legislation in Uruguay is Law No. 17.164 (Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs). According to Article 14 of this law, inventions contrary to public order, manners, public health, population nutrition and safety of environment are unpatentable. Unlike Article 27.2 of TRIPs this provision does not carry a qualification of 'commercial exploitation'.

[Annex V follows]

³²² *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F. 3D 1364, 1368 (Fed. Cir. 1999).

³²³ *Ibid.*

³²⁴ Recently in April, 2010 three of WARF's patents were invalidated. These were however invalidated on the grounds of obviousness and not morality. See <http://www.news-medical.net/news/20100504/USPTO-rejects-WARFs-stem-cell-patent-claims.aspx>. (Last visited on August 11, 2010).