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# THE NEW INVENTION CREATION ACTIVITY BOUNDARY IN PATENT LAW

MARGO A. BAGLEY\*

## ABSTRACT

*This Essay identifies a new boundary in patent law—illegal or immoral invention creation activity—and explores the possible challenges and opportunities it may facilitate. The boundary currently is neither robust nor extensive, and whether and under what circumstances it should exist at all is open to debate.*

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\* Professor of Law, University of Virginia School of Law. I greatly appreciate the insights of Drs. Christian May, Dieter Schneider, and Doris Walter of the German Patent & Trademark Office, and the comments of Ken Abraham, Lori Andrews, Lillian BeVier, Rochelle Dreyfuss, Ed Kitch, Cynthia Ho, Chris Sprigman, Glen Robinson, Timothy Holbrook, Pam Samuelson, Joshua Sarnoff, Nadia Sawicki, Fred Schauer, Robin Feldman, and participants in workshops at University of Virginia School of Law, University of Pennsylvania Law School, Cardozo School of Law, William & Mary Law School, the Max Planck Institute for the History of Science, Drake University Law School, and the IP Scholar's Conference at Stanford University. Invaluable research assistance was provided by Kevin McNish, Sarah Wu, and the amazing research librarians of the University of Virginia Law Library.

## INTRODUCTION

Set in eighteenth-century France, author Patrick Suskind's novel *Perfume* tells the story of Jean-Baptiste Grenouille, a man who, from birth, had no personal body odor, which had the effect of alienating him from others.<sup>1</sup> Lacking a personal scent but having an unusually refined sense of smell, Grenouille, an inventor, became obsessed with developing the perfect perfume that would cause people to adore him. He succeeded in his quest. Unfortunately, his method of creating this compound was to murder young women and extract fragrance compounds from their bodies.

Fast-forward to the twenty-first century and imagine that Grenouille seeks a patent on his useful, novel, and nonobvious composition of matter. Should the fact that he murdered people in order to create the invention have any impact on his ability to obtain a patent or on the enforceability of any patent he does obtain?

Although this is a hypothetical question, an increasing number of countries are considering, in patentability determinations, past "bad" activities in creating inventive subject matter. Such inquiries traditionally have been irrelevant to an invention's ultimate patentability or to patent enforceability, but times are changing. This Essay, written in conjunction with a conference on boundaries in intellectual property law, identifies what is shaping up to be a new boundary in patent law: invention creation activity.<sup>2</sup>

As in real property determinations, patent law contains numerous boundaries, or limits, delineating the criteria for obtaining patent protection and for losing it. Unfortunately, patent law boundaries

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1. PATRICK SUSKIND, *PERFUME: THE STORY OF A MURDERER* (John E. Woods trans., 1986). Special thanks to Dr. Doris Walter for sharing this hypothetical.

2. Patent rights are territorial and differ in varying respects from country to country. In this Essay, I take a global view of patent law for the sake of simplicity, as well as to denote the impact that changes in the patent laws of one country can have on those of another. There currently are no meaningful efforts underway to begin incorporating invention creation activity inquiries into U.S. patent law; however, observable trends in other countries suggest it may be prudent to analyze the issues and opportunities such a boundary engenders.

tend to be difficult to ascertain<sup>3</sup> and are subject to both expansion<sup>4</sup> and contraction.<sup>5</sup>

Whereas patent law boundary *locations* may change, the boundaries themselves are quite stable. Subject matter, utility, novelty, nonobviousness, and others continue to be the basis for patent limits, and it is rare to see old boundaries eliminated or new boundaries created.<sup>6</sup> Yet it appears that a new boundary—*invention creation activity*—is being erected in patent law today.<sup>7</sup>

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3. Patent claim scope is a prime example. As explained by Professor Mark Lemley: [B]oth the physical and legal boundaries of real property are, in the main, clear. We can all find out what the boundaries of real property are, either by looking at physical fences or by going down to the county recorder's office and determining where the lines exist. We also have a good idea what the legal rules are with respect to property—physical intrusion is generally forbidden, and other kinds of intrusion generally aren't....

Neither "boundary" is clear in intellectual property law, however. It is difficult—and in many cases impossible—to know whether one is "trespassing" upon another's intellectual property right. In part this is a problem with defining the scope of the legal right in question. While courts sometimes talk about patent claims as defining the "metes and bounds" of the legal right, claims lack the certainty associated with real property deeds.... Not until the Federal Circuit rules on the meaning of any particular claim can the patent owner or its competitors know what is owned and what isn't.

Mark A. Lemley, Reply, *What's Different About Intellectual Property?*, 83 TEX. L. REV. 1097, 1100-01 (2005).

4. See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980) (expanding the patent-eligible subject matter boundary to include living matter); *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1377 (Fed. Cir. 1998) (expanding the patent-eligible subject matter boundary to include business methods).

5. See, e.g., *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (contracting the nonobviousness patentability requirement boundary); *In re Bilski*, 545 F.3d 943, 965-66 (Fed. Cir. 2008) (contracting the patent-eligible subject matter boundary in relation to non-computer-implemented mental methods).

6. The statutory nonobviousness boundary of 35 U.S.C. § 103 was added in the Patent Act of 1952 but was judicially created more than a century earlier. See generally John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1 (2007).

7. There is considerable consistency in patent law boundaries around the world, due in part to treaties such as the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which set minimum standards of protection that countries must provide for patents. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 127, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]. Nevertheless, countries may have additional, specific boundaries in their systems, such as the inequitable conduct boundary in the United States. See *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988); 37 C.F.R. § 1.56 (2008).

Recently, applicants for patents in places such as the countries of Europe, Japan, Peru, India, and Brazil have begun facing invention creation activity issues in relation to inventions involving human embryonic stem cells (raising morality concerns) and illegally obtained genetic resources.<sup>8</sup> New revisions to China's patent law include invention creation activity provisions as well.<sup>9</sup>

Traditionally, inventor/owner conduct has only been relevant, if at all, in two distinct time periods: (1) after the filing of an application, and (2) before patent issuance. Even then, such conduct is relevant only to patent enforceability, not validity, based on theories derived from the equitable doctrine of unclean hands.<sup>10</sup> For example, in the United States, doctrines such as inequitable conduct and prosecution laches can be asserted to bar enforcement of a patent based on misconduct of the patentee in prosecuting the application;<sup>11</sup> and after a patent issues, the doctrines of patent misuse, equitable estoppel, laches, and more may be invoked to bar enforceability based on patentee misconduct in enforcing the patent.<sup>12</sup>

<b>Pre-filing:</b>	<b>Post-Filing:</b>	<b>Post-Issuance:</b>
<b>Emerging restrictions?</b>	<b>Inequitable conduct Prosecution laches</b>	<b>Patent Misuse Estoppels</b>
_____	_____	_____

The idea of patent offices engaging in a similar inquiry for pre-application filing, invention creation conduct is new, but not completely surprising.<sup>13</sup> It is, perhaps, not a coincidence that inventions

8. See generally LeRoy Walters, *Human Embryonic Stem Cell Research: An Intercultural Perspective*, 14 KENNEDY INST. ETHICS J. 3 (2004).

9. See *infra* notes 22-26 and accompanying text.

10. See, e.g., *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945).

11. See, e.g., *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334 (Fed. Cir. 2008).

12. See, e.g., *Va. Panel Corp. v. MAC Panel Co.*, 133 F.3d 860 (Fed. Cir. 1997).

13. Of course, it is possible that random instances of such inquiries exist around the world that simply have not been cataloged. For example, Professor Shamnad Basheer has identified an Indian case in which invention creation activity served as a bar to patentability under a morality provision. He notes:

[T]here appears to be only one unreported instance of the use of this exception by the Indian Patent Office. The invention in this case related to medicinal

involving life forms comprise the current context in which invention creation activity questions are arising and that this is an area where utility patent protection was essentially unavailable thirty years ago, before the landmark *Diamond v. Chakrabarty*<sup>14</sup> decision. In *Chakrabarty*, the U.S. Supreme Court ruled that living matter, such as genetically modified bacteria, could qualify for patent protection, opening the floodgates to the patenting of morally controversial biotech inventions ranging from transgenic animals and plants, to genetic DNA sequences and human embryonic stem cell products.<sup>15</sup> Perhaps it was inevitable that expansions in the scope of patent-eligible subject matter would lead, in some countries at least, to a concomitant increase in restrictions on the patenting of such inventions or the enforceability of patents on such inventions.

Part I of this Essay describes the new boundary's appearance in relation to illegal and immoral invention creation activity, as well as its possible future extension to unethical activity such as that at issue in *Moore v. Regents of the University of California*.<sup>16</sup> Part II discusses potential issues and opportunities that the new boundary raises while also exposing its current fragility. The Essay ultimately concludes that invention creation activity is a new boundary whose contours bear watching and whose continued development, if there is any, should be cautious, incremental, and well-considered.

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powder prepared from skeletal remains of dead bodies dug up within a week of burial. Digging up graves for profit-oriented purposes was seen as highly objectionable by the patent office.

Posting of Shamnad Basheer to Spicy IP, Grave Diggers, "Immoral" Patents and the NBRA, <http://spicyipindia.blogspot.com/2008/07/grave-diggers-immoral-patents-and-nbra.html> (July 30, 2008, 20:30). However, I have found no evidence of systematic application of such a boundary in traditional patentability determinations.

14. 447 U.S. 303 (1980).

15. *Id.* at 309-10; see also Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 475-76 (2003).

16. 793 P.2d 479 (Cal. 1990).

## I. ILLEGAL, IMMORAL, AND UNETHICAL ACTIVITY IN INVENTION CREATION

Although questions of the illegality or morality of the *use* of an invention<sup>17</sup> have often come into play throughout history and up to the present time, there appears to be little precedent for considering the acts of *invention creation* in the determination of either patentability or patent enforceability.<sup>18</sup>

Until now. Recent legislative actions and judicial decisions in China, Europe, and beyond illustrate the emergence of the new invention creation activity boundary in relation to illegal and immoral conduct.

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17. For example, the prohibition on the patenting of inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon" is concerned with how the invention will be used, not how the invention was created. 42 U.S.C. § 2181 provides in relevant part:

(a) Denial of patent; revocation of prior patents

No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor.

(b) Denial of rights; revocation of prior rights

No patent hereafter granted shall confer any rights with respect to any invention or discovery to the extent that such invention or discovery is used in the utilization of special nuclear material or atomic energy in atomic weapons. Any rights conferred by any patent heretofore granted for any invention or discovery are revoked to the extent that such invention or discovery is so used, and just compensation shall be made therefor.

42 U.S.C. § 2181 (2006). For a discussion of the rejection of patents for inventions such as gambling machines and other devices used in deception or fraud, see Bagley, *supra* note 15, at 489.

18. Allegations of illegal activity in invention creation are not completely unknown to U.S. law. For example, in *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996), a defendant accused of patent infringement argued that the plaintiff had "misappropriated inventions, materials, people and information" from the University of California" and that the plaintiff should be barred from enforcing the patent under the doctrine of unclean hands. *Id.* at 1565. However, the court gave short shrift to this argument, finding the assertions to be without evidentiary support and outside the context of the lawsuit. *Id.* Also, in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), the court rejected assertions that a patent should be deemed unenforceable for inequitable conduct when the alleged bad behavior was noncompliance with National Institute of Health guidelines and misrepresentation of information in the patent application. *Id.* at 1569-71. The court deemed the misconduct immaterial to patentability, and there was no framing or consideration of the question as improper invention creation activity. *Id.*

*A. Illegal: Genetic Resources and Disclosure of Origin*

For several decades, interests in the United States and abroad have been concerned with intellectual property protection in China. Although China has often been criticized for having weak intellectual property laws and lax enforcement of those laws, in recent years the country has increased efforts to protect intellectual property and to encourage domestic entities to pursue the development and protection of intellectual property.<sup>19</sup> One result of this policy change is that the Chinese State Intellectual Property Office (SIPO) has seen an exponential increase in patent applications.<sup>20</sup> Despite having a patent statute since only 1984, China's SIPO has jumped from a position of relative obscurity to number three in the world in the number of utility patent applications received each year, and that number is climbing.<sup>21</sup> On December 27, 2008, China's top legislative body, the National People's Congress Standing Committee, passed the Third Amendment to the Chinese Patent Law, which went into effect October 1, 2009.<sup>22</sup> The Third Amendment includes a provision that would deny patentability to any invention created using genetic resources obtained in violation of Chinese law. The new Article 5 states:

No patent right shall be granted for any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to the public interest.

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19. See, e.g., OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2009 SPECIAL 301 REPORT 13-15 (2009), available at <http://www.ustr.gov/sites/default/files/Full%20Version%20of%20the%202009%20SPECIAL%20301%20REPORT.pdf>; Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (Jan. 26, 2009).

20. State Intellectual Prop. Office of the P.R.C., Applications for Three Kinds of Patents Received from Home and Abroad, 2000-2006 (June 11, 2007), [http://www.sipo.gov.cn/sipo\\_English/statistics/200804/t20080416\\_380894.html](http://www.sipo.gov.cn/sipo_English/statistics/200804/t20080416_380894.html).

21. WORLD INTELLECTUAL PROP. ORG., WORLD INTELLECTUAL PROPERTY INDICATORS 17 (2009), available at [http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/pdf/wipo\\_pub\\_941.pdf](http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/pdf/wipo_pub_941.pdf). In fact, China ranks number one when utility patent, utility model, and industrial applications are combined. *Id.* at 17, 48, 70. The United States, Japan, China, Korea, and the European Patent Office received the most applications in 2007. *Id.* at 17.

22. Yan Wenfeng, *NPC OKs New Patent Law*, CHINA REP.: INTELL. PROP., Dec. 31, 2008, [http://www.sipo.gov.cn/sipo\\_English/news/ChinaIPNews/2008/200904/P020090408579902833623.pdf](http://www.sipo.gov.cn/sipo_English/news/ChinaIPNews/2008/200904/P020090408579902833623.pdf) [hereinafter Chinese Patent Law].



No patent right shall be granted for any invention-creation which is completed on the basis of genetic resources of which the acquisition or use breaches the stipulations of related laws and regulations.<sup>23</sup>

Thus, for the first time under Chinese patent law, the revised draft introduces special measures to make violation of genetic resource acquisition laws in invention creation a basis for denying patentability or invalidating a patent.

The draft implementing guidelines for the new Act define genetic resources to include genetic material extracted from humans, animals, and plants, such as blood, genes, organs, and skin, if the invention relies on the "genetic functionality" of the material.<sup>24</sup>

In addition to Article 5, the revised Chinese Patent Act contains another provision related to genetic resource acquisition, Article 26, which states in part:

An applicant who files a patent application for an invention-creation completed on the basis of genetic resources shall in the patent application document indicate the direct and indirect source of the genetic resources; the applicant unable to indicate the original source of the genetic resource must provide an explanation.<sup>25</sup>

Article 26 thus requires applicants to disclose the country of origin of relevant genetic resources in addition to the direct supplier. Failure to supply the required information is a basis for

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23. EU-CHINA IPR2, EUROPEAN PATENT OFFICE, THIRD REVISION OF CHINA'S PATENT LAW: LEGAL TEXTS AND DOCUMENTS ON THE DRAFTING PROCESS 2006-2008, at 11 (2009), *available at* [http://www.ipr2.org/images/eu\\_patent\\_law-090805-7-final.pdf](http://www.ipr2.org/images/eu_patent_law-090805-7-final.pdf) [hereinafter CHINA'S PATENT LAW].

24. Amy Feng, Update on Patent Development of the Life Science Field in China, Address at the Second Beijing International Pharmaceutical and Chemical Intellectual Property Forum, at slide 17 (Aug. 6, 2009) (powerpoint slides, on file with author). Use of genetic functionality has yet to be defined. In a humorous bit of irony, at the same time that China's new patent law denies patentability to inventions created using illegal activity, the patent office in the Chinese province of Gansu recently issued rules to encourage prison inmates to apply for patents. Intellectual Prop. Prot. in China, Gansu Issues Rules To Urge Inmates To Apply for Patents (July 28, 2009), <http://www.chinaipr.gov.cn/Frontier/286288.shtml>.

25. CHINA'S PATENT LAW, *supra* note 23, at 15.

rejecting claims in an application, but apparently not for invalidating an already issued patent.<sup>26</sup>

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26. Feng, *supra* note 24, at slide 17. Violating the new Chinese Patent Act only impacts patentability/validity. But the laws of some other countries go even further. For example, a Brazilian law regulating access to components of Brazilian genetic heritage contains a variety of penalties for violation of genetic resource laws in creating patentable inventions. Such penalties include: payment to the Federal Government of at least twenty percent of the gross income or royalties from commercializing or licensing the resulting product (benefit sharing), Medida Provisória No. 2.186-16, de 23 de agosto de 2001, D.O.U. de 24.08.2001, tit. VII, art. 26 (Brazil), available at [http://www.planalto.gov.br/ccivil\\_03/mpv/2186-16.htm](http://www.planalto.gov.br/ccivil_03/mpv/2186-16.htm); suspension or cancellation of the resulting patent, *id.* at tit. VIII, art. 30, and much more. Disclosure of the origin of genetic material used in creating an invention must be disclosed in the patent application, *id.* at tit. IX, art. 31.

India's Biodiversity Act has even stiffer penalties, such as imprisonment, while also allowing for retroactive permission and the imposition of benefit-sharing conditions. The law provides in part:

6. (1) No person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:

Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned.

....

(2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.

....

#### *Penalties*

55. (1) Whoever contravenes or attempts to contravene or abets the contravention of the provisions of section 3, section 4, or section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakhs such fine may be commensurate with the damage caused, or with both,

....

#### *Offences by Companies*

57. (1) Where an offence or contravention under this Act has been committed by a company, every person who at the same time the offence or contravention was committed was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence or contravention and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this subsection shall render any such person liable to any punishment provided in this Act, if he proves that the offence or contravention was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence or contravention.

These new provisions appear to be designed to address several concerns relating to biopiracy. "Biopiracy" has been defined as "[t]he patenting of plants, genes, and other biological products that are indigenous to a foreign country" without compensating the keepers of those resources and the holders of knowledge appropriated during ethnobiological research processes.<sup>27</sup> Many biodiversity-rich countries, like China, are changing their laws to deny patentability to inventions created with illegally acquired genetic resources.<sup>28</sup> Such countries include members of the Andean Community, Brazil, and India.<sup>29</sup> These countries and others also have been pressing in several multilateral fora for a new Disclosure of Origin (DOO) patentability requirement that would address benefit sharing and prior informed consent.<sup>30</sup> Such efforts are consistent with, and designed to give effect to, the Convention on Biological Diversity (CBD).<sup>31</sup> The CBD established that genetic resources are not the

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Biological Diversity Act 2002, No. 18 of 2003 (India), available at [http://www.nbaindia.org/act/act\\_english.htm](http://www.nbaindia.org/act/act_english.htm). The Act in Section 2 defines "biological resources" as including plants, animals and micro-organisms or parts thereof, their genetic material and by-products, but, unlike China, does not include human genetic material. *Id.*; see also Andean Community, Commission Decision 391: Common Regime on Access to Genetic Resources, Complementary Provisions (July 17, 1996), <http://www.sice.org/trade/JUNAC/decisiones/DEC391e.asp> ("The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.").

27. The Word Spy, <http://www.wordspy.com/words/biopiracy.asp> (last visited Oct. 17, 2009). For examples and discussions of perceived instances of biopiracy, see Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 COLO. J. INT'L ENVTL. L. & POL'Y 219, 227 (2008); Kaitlin Mara, *Indigenous Groups Express Concerns on IP Protection of Their Knowledge*, INTELL. PROP. WATCH, Mar. 3, 2008, <http://www.ip-watch.org/weblog/2008/03/03/indigenous-groups-express-concerns-on-ip-protection-of-their-knowledge/>.

28. It is argued that such provisions, relating only to inventions made with genetic materials, are in conflict with the TRIPS Agreement which, in Article 27, bars discrimination in patentability based on technology. See, e.g., Nuno Pires de Carvalho, *Requiring Disclosure of Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL'Y 371 (2000); Graham Dutfield, *Thinking Aloud on Disclosure of Origin* (Quaker United Nations Office, QUNO Occasional Paper 18, 2005); Thomas Moga, *Changing China's Patent Regime*, Butzel Long, <http://www.butzel.com/pdf/070601artAutoAlley.pdf> (last visited Oct. 17, 2009) (discussing possible tensions with TRIPS).

29. QUEEN MARY INTELLECTUAL PROP. INST., REPORT ON DISCLOSURE OF ORIGIN IN PATENT APPLICATIONS 52-55 (2004), available at [http://trade.ec.europa.eu/doclib/docs/2005/June/tradoc\\_123533.pdf](http://trade.ec.europa.eu/doclib/docs/2005/June/tradoc_123533.pdf) [hereinafter QUEEN MARY REPORT].

30. *Id.* at 5.

31. Comments by the Chinese SIPO on the 2006 draft revisions to patent law provide

common heritage of mankind, but rather are the property of sovereigns who should make access to them available under principles of prior informed consent (PIC) and access and benefit sharing (ABS).<sup>32</sup>

In July 2008, a group of World Trade Organization (WTO) member countries<sup>33</sup> introduced a proposed amendment to the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) that would address these issues as follows:

4. Members agree to amend the TRIPS Agreement to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge for which a definition will be agreed, in patent applications. Patent applications will not be processed without completion of the disclosure requirement.

5. Members agree to define the nature and extent of a reference to Prior Informed Consent and Access and Benefit Sharing.

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some insight into the motivations for Articles 5 and 26. After discussing CBD principles, the comments state:

Measures taken to protect China's genetic resource[s] at least include the following two aspects: one is to establish a management mechanism for genetic resource[s] through special legislation to prevent any person from obtaining China's genetic resource[s] without the approval of the relevant department and impose an administrative fine or even criminal punishment to the violator; and the other is to add relevant provisions to the Patent Law so as to stop the act of illegal obtaining or use of the genetic resource[s] based on which the creations are completed.

CHINA'S PATENT LAW, *supra* note 23, at 55.

32. Convention on Biological Diversity art. 15, June 5, 1992, 1760 U.N.T.S. 143, 152; see also Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 473 (2006). DDO regimes and proposals fall into three basic categories: (1) strong—mandatory disclosure accompanied by access and benefit sharing provisions, including proof of legal acquisition; (2) medium—mandatory disclosure only; and (3) weak—disclosure is simply “encouraged or even expected but not required.” QUEEN MARY REPORT, *supra* note 29, at 3. China, India, and Brazil's regimes all appear to fit in the “strong” category.

33. The sponsors were Albania, Brazil, China, Ecuador, the European Communities, India, Indonesia, the Kyrgyz Republic, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group, and the African Group. Trade Negotiations Committee, *Draft Modalities for TRIPS Related Issues*, TN/C/W/52 (July 19, 2008). These same countries also pushed for an amendment addressing protection of geographical indications of origin in tandem with this proposal. World Trade Organization, TRIPS: Geographical Indications, Background and the Current Situation, [http://www.wto.org/english/tratop\\_e/trips\\_e/gi\\_background\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/gi_background_e.htm) (last visited Oct. 19, 2009).

6. Text based negotiations shall be undertaken ... to implement the above. Additional elements ..., such as PIC and ABS as an integral part of the disclosure requirement and post-grant sanctions [such as invalidity or unenforceability], may also be raised and shall be considered in these negotiations.<sup>34</sup>

What factors are driving this effort? Sabrina Safrin posits that the expansion of patent subject matter to include genetic material initiated a chain reaction, leading to the desire among biodiversity-rich developing countries for second-generation property rights over sovereign resources used to create inventions.<sup>35</sup> As she explains:

Why, these [developing] countries asked, should individuals and companies from gene-poor developed countries obtain genetic material free of charge from gene-rich developing countries when they then patent these genes and at times sell them back to the country where the genetic material originated? Moreover, developing countries faced increasing pressure [from developed countries] to extend patent protection to man-made living organisms and their genetic material....

....

The key operating dynamic is that of a tit-for-tat. Namely, if developed countries assert and demand that developing countries recognize intellectual property rights over man-made living organisms and isolated and purified genetic sequences, then developing countries believe that they should also assert property interests over the raw genetic material that may contribute to the patented goods.<sup>36</sup>

The fact that emerging economies are taking the lead by incorporating genetic resource protection measures into their domestic laws suggests these issues will continue to be pushed in multilateral fora as well. As explained by Rochelle Dreyfuss:

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34. *Id.* The amendment did not pass and its future is uncertain, yet its introduction, and the continued focus on these issues by many countries, suggests this is an issue that is not going away any time soon.

35. Sabrina Safrin, *Chain Reaction: How Property Begets Property*, 82 NOTRE DAME L. REV. 1917, 1917 (2007) (arguing that the Court's decision in *Chakrabarty* initiated this expansion).

36. *Id.* at 1928, 1931 (citations omitted).

[E]merging economies such as India, Brazil, and China, may well hold the key to the future.... [T]hese countries have a thick legal and political culture and can ably defend their domestic legislation in international circles. As emerging economies move into a leadership position in establishing new practices ... they are sure to challenge the preeminent role of the North in setting world norms for intellectual property protection.<sup>37</sup>

An interesting question raised by DOO and illegal acquisition provisions that deny patentability for violations of genetic resource acquisition laws in order to allow for benefit sharing is how such laws actually contribute to the reallocation of and sharing in the benefits of such inventions. If the patent claims are invalid or unenforceable, one would expect revenue from the patent to be negatively impacted. The Brazilian provisional law and Indian Biological Diversity Act both allow the government to share in the financial benefits from the invention and do not mandate patent invalidity or unenforceability.<sup>38</sup> China's approach apparently does not mandate benefit sharing; however, future implementing guidelines for the new Act may include such a requirement.

Under the Demsetzian view that private property rights arise to allow parties to internalize externalities,<sup>39</sup> it is not surprising that individuals and groups that provide access to and conservation of genetic resources and associated traditional knowledge might also wish to share in internalizing some of the benefits to which they

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37. Rochelle Dreyfuss, *The Role of India, China, Brazil and Other Emerging Economies in Establishing Access Norms for Intellectual Property and Intellectual Property Lawmaking* 2-3 (Inst. for Int'l Law and Justice, Working Paper No. 09-53, 2009), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1442785](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1442785). Comments on the revised Chinese patent act by SIPO are quite explicit on this point:

In recent years, developing countries have repeatedly advocated the ... formation of international regulations for the protection of genetic resources in the World Trade Organization, the World Intellectual Property Organization and other international organizations. However, these efforts have made little headway due to the obstruction of developed countries.... [I]t is of necessity for China to use the practice of relevant developing countries for reference and carry out the protection of genetic resource through legislation in the country.

CHINA'S PATENT LAW, *supra* note 23, at 55.

38. See *supra* note 26 and accompanying text.

39. See Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 348 (1967).

have contributed.<sup>40</sup> Yet not all groups are financially motivated. Some groups are primarily motivated by concerns regarding control and overexploitation of the genetic resources in their region.<sup>41</sup> The creation of a statutory DOO requirement for genetic materials and traditional knowledge, along with a statutory provision denying patentability to inventions made with illegally-obtained genetic resources, represents one means for allowing possibly aggrieved parties to determine if a law was broken by the inventor and if a claim for relief is justified.

Outside of the context of genetic resources and traditional knowledge, there are, of course, a variety of other scenarios in which the patentability of an invention could be compromised if the illegality of invention creation activity were made a patentability criteria. For example, the use of fetal tissue obtained from a partial birth abortion performed in violation of the Partial Birth Abortion Ban Act,<sup>42</sup> using plants or wildlife removed from a U.S. national park without authorization,<sup>43</sup> the falsification of data to obtain a federal grant,<sup>44</sup> or even engaging in patent infringement are all illegal activities that could result in invention creation.

Determining which illegal activities are sufficiently egregious to warrant censure through the patent system, with the concomitant risk to the patent incentive, would be a complicated undertaking. Moreover, issues of proximate cause between the illegal activity and the creation of the invention (for example, a researcher being ticketed for speeding on the way to her laboratory), as well as whether the violation of laws in one country should impact patent-

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40. Although, as Professor Safrin notes, the profit motive can only partially explain the actions of developing countries in this area as cost-benefit analyses appear to be missing from the discussion. Safrin, *supra* note 35, at 1931.

41. Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919, 955 (1996) ("The goal is not simply to receive money in exchange for access to knowledge and resources, but to control whether, and how, such knowledge is commercialized, while also leaving it available for noncommercial uses.").

42. See *Gonzales v. Carhart*, 550 U.S. 124, 168 (2007) (upholding the constitutionality of the Partial Birth Abortion Act).

43. See 36 C.F.R. § 2.1(a)(1) (2009).

44. See, e.g., Findings of Scientific Misconduct, 74 Fed. Reg. 4201, 4201-02 (Jan. 23, 2009) (notice) (barring MIT researcher from receiving federal funds for falsifying data in multiple immunology projects).

ability in another, would also require resolution.<sup>45</sup> Nevertheless, although determining that an activity is illegal can be difficult, that complexity pales in comparison with determining morally unacceptable activities.

### *B. Immoral: Destruction of Human Embryos*

Much illegal activity can be considered a subset of immoral activity as it is generally considered to be “wrong” to break the law.<sup>46</sup> Thus, murder and theft are not only illegal activities, they are also immoral activities.

The patent laws of many countries contain provisions allowing for the denial of a patent to an invention whose exploitation or publication would violate public order or morality.<sup>47</sup> Such provisions facially apply only to consideration of the use of, or at most the nature of, an invention. However, the controversy over human embryonic stem cell patents in Europe provides an interesting example in which legal activities involved in creating an invention that is not otherwise objectionable still render that invention unpatentable for moral reasons.<sup>48</sup>

The Convention on the Grant of European Patents, better known as the European Patent Convention or EPC, contains substantive and procedural requirements for obtaining a European patent valid in all thirty-four member countries and four extension states, with

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45. An example might be a violation of the genetic resource acquisition laws in China, or developing a therapy in Israel by using human embryonic stem cells for cloning purposes, which is against Israeli law. The Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law, 1998, S.H. 47 (Isr.). An analysis of such issues is beyond the scope of this Essay but will, hopefully, be addressed in future work.

46. Of course, there are exceptions to that rule. As one blogger notes:

Everytime you willfully break a law you are willfully breaking law itself. Only in a small way, but you are. This doesn't mean there is a never a reason to do so, if the law demands you round up Jews to be killed, you can break that law accepting that the devaluation of law is a consequence (and regretting that consequence) whilst still recognising that the cost is worth it.

When You Break the Law You Vote for Anarchy, <http://proudyoungreactionary.blogspot.com/2008/03/when-you-break-law-you-vote-for-anarchy.html> (Mar. 21, 2008) (blog is no longer active).

47. In fact, TRIPS explicitly allows WTO member countries to exclude such inventions from patentability. TRIPS Agreement, *supra* note 7, art. 27(2).

48. See *infra* notes 61-71 and accompanying text.



only a single application.<sup>49</sup> It also contains an express morality-based patent eligibility bar. EPC Article 53 states that:

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.<sup>50</sup>

Article 53(a) not only provides a basis for European Patent Office (EPO) examiners to reject a patent application, but any member of the public can lodge an opposition to the grant of a patent on this or one of several other patentability bases at any time within nine months of the EPO decision to issue the patent.<sup>51</sup> The Patent Act of

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49. See European Patent Office, How To Apply for a European Patent, [http://www.european-patent-office.org/gr\\_index.htm](http://www.european-patent-office.org/gr_index.htm) (last visited Oct. 17, 2009). The European patent is treated as a national patent in each member country. See Convention on the Grant of European Patents (European Patent Convention) arts. 1-3, Oct. 5, 1973, 1065 U.N.T.S. 199, available at <http://www.epo.org/patents/law/legal-texts/epc.html> [hereinafter EPC]; Commission of the European Communities, *Proposal for a Council Regulation on the Community Patent*, at 4, COM (200) 412 final (Jan. 8, 2000), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0412:FIN:EN:PDF> [hereinafter Proposal]. Applicants can still seek patent protection in individual EPC member countries exclusively or concurrently; however, only one patent (national or European) will ultimately be maintained. See European Patent Office, Frequently Asked Questions, <http://www.epo.org/help/faq.html> (last visited Oct. 17, 2009).

50. EPC, *supra* note 49, art. 53(a), at 80. The proviso in Article 53(a) means that illegality of the invention (that is, of its use) in a Contracting State cannot alone provide the basis for a denial of patentability, although perhaps illegality under a supranational treaty such as the European Convention on Human Rights could suffice. According to the EPO Guidelines, one of the rationales for the proviso was that "a product could still be manufactured under a European patent for export to States in which its use is not prohibited." Amanda Warren-Jones, *Finding a "Common Morality Codex" for Biotech – A Question of Substance*, 39 INT'L REV. INTELL. PROP. & COMPETITION L. 638, 655 (2008) (quoting EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE Part C-IV, para. 3.1 (2001)); see DERYCK BEYLEVELD & ROGER BROWNSWORD, MICE, MORALITY AND PATENTS 72 (1993) ("[T]he European Convention on Human Rights is not law or regulation in (meaning within) the Contracting States, but constitutes some part of the constitutional framework by which the Contracting States constitute an emerging unified legal order ... [thus] the fact that something is regulated against is sometimes sufficient for the Examiners to declare it to be immoral.").

51. See EPC, *supra* note 49, art. 99, at 124; *id.* art. 100. The United States has no comparable post-grant proceeding allowing for public intervention in the issuance of a patent, as reexamination is a much more limited tool. See 35 U.S.C. § 603 (2006). Moreover, as established by the Court of Appeals for the Federal Circuit in *Animal Legal Defense Fund v.*

Japan contains a similar provision in section 32: "inventions liable to contravene public order, morality or public health shall not be patented."<sup>52</sup> Both of these provisions facially focus on issues associated with the nature of the invention and its use, not on how it was created.

In 1998, the European Union (EU) adopted a Biotechnology Directive designed to harmonize the patent eligibility of biotechnology-related subject matter in the EU member states.<sup>53</sup> In drafting the directive, the European Parliament and Council had two primary goals. The first was to clarify and harmonize the legal protection of biotech inventions in the region to increase investment in biotechnology research.<sup>54</sup> For years, the EU had lagged behind the United States and Japan in biotechnology, a deficit attributed, at least in part, to insufficient and inconsistent patent rights.<sup>55</sup> The second goal was to preserve the right of EU member states to consider moral questions in determining patent-eligible subject matter, as they had been able to do under EPC Article 53(a).<sup>56</sup>

Article 6, paragraph 1 of the European Union Biotechnology Directive essentially restates the EPC Article 53(a) position that "[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality."<sup>57</sup> Paragraph 2 of Article 6 then takes the further step of providing an explicit, nonexclusive list of subject matter that would be considered

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*Quigg*, members of the public also lack standing to challenge the validity of a patent in court. See 932 F.2d 920, 924-25 (Fed. Cir. 1991).

52. Tokkyo Ho [Patent Law of Japan], Law No. 121 of 1959, amended by Law No. 220 of 1999, art. 32, translated in [http://www.wipo.int/clea/docs\\_new/pdf/en/jp/jp036en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/jp/jp036en.pdf). Besides all of the EPC member states and Japan, the patent laws of several other countries contain such morality-based provisions, including China. See, e.g., Chinese Patent Law, *supra* note 22, at 295.

53. Council Directive 98/44, 1998 O.J. (L 213) 13 (EC).

54. *Id.*

55. See, e.g., David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 FORDHAM INT'L L.J. 990, 991 (1993) (characterizing Europe's competitive disadvantage in the biotech industry as "approaching perilous dimensions").

56. See Council Directive 98/44, *supra* note 53, ¶¶ 36-40, at 16; see also Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1, 2 (2001) (describing controversy surrounding adoption of the Directive).

57. Council Directive 98/44, *supra* note 53, art. 6, ¶ 1, at 18.

contrary to *ordre public* or morality.<sup>58</sup> Such unpatentable subject matter includes processes for cloning human beings, processes for modifying the germline identity of human beings, uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals likely to cause the animal suffering without any substantial medical benefit.<sup>59</sup>

The European Patent Office, although not an arm of the EU, voluntarily complied with the directive by amending the EPC implementing regulations.<sup>60</sup> In particular, Rule 23d<sup>61</sup> entitled “Exceptions to Patentability” further delineates EPC Article 53(a)’s *ordre public* and morality provisions, providing:

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.<sup>62</sup>

In April 2006, questions regarding the rejection of the Wisconsin Alumni Research Foundation’s (WARF) patent application relating to such stem cell products were referred to the EPO Enlarged Board

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58. *Id.* ¶ 2, at 18-19.

59. *Id.*

60. See European Patent Office, *Revision of the European Patent Convention (EPC 2000) Synoptic Presentation EPC 1973/2000—Part II: The Implementing Regulations*, O.J. E.P.O. 1 (Spec. Ed. May 1, 2007). All EU members are members of the European Patent Organization.

61. Rule 23d is now rule 28(c) as a result of renumbering to implement EPC 2000. *Id.* at 42-43.

62. *Id.* at 43. The EPO has cited Rule 23d(c) in rejections of patent applications claiming products created through the destruction of human embryos to obtain embryonic stem cells. See, e.g., Press Release, European Patent Office, “Edinburgh” Patent Limited After European Patent Office Opposition Hearing (July 24, 2002), <http://www.epo.org/about-us/press/releases/archive/2002/24072002.html>.

of Appeals to provide clarification on the parameters of the Rule 23d exceptions.<sup>63</sup>

In the WARF case, the EPO Examining Division rejected certain claims in WARF's European application under EPC Rule 23d(c) in conjunction with EPC Article 53(a).<sup>64</sup> The rejected claims, which were directed to, among other things, cell cultures comprising primate embryonic stem cells and methods of maintaining such cell cultures, were deemed to violate the prohibitions because they required the use and destruction of human embryos as starting material.<sup>65</sup>

The examiners considered it irrelevant that the claimed subject matter related to cell cultures and not to a method of producing the cell cultures because the only way to obtain the cell cultures was through destruction of a human embryo.<sup>66</sup> WARF appealed the decision to the EPO Board of Appeals that, because of the importance of the issue, referred four questions to the Enlarged Board of Appeals (EBOA) for decision. The EBOA heard oral arguments in June of 2008 on the following questions:

1. Does r.23d(c) [now 28(c)] EPC apply to an application filed before the entry into force of the rule?
2. If the answer to question 1 is yes, does r.23d(c) [now 28(c)] EPC forbid the patenting of claims directed to products ... which ... at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?
3. If the answer to question 1 or 2 is no, does art. 53(a) EPC forbid patenting such claims?
4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without ... the destruction of human embryos (here: e.g. derivation from available human embryonic cell lines)?<sup>67</sup>

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63. See Case T1374/04, WARF/Stem cells, [2006] E.P.O.R. 31, 2006 WL 1994709, at \*349 (Technical Bd. of App. Apr. 7, 2006).

64. *Id.* at \*333.

65. *Id.*

66. *Id.* at \*334.

67. Case G2/06, WARF/stem cells, [2009] E.P.O.R. 15, 2008 WL 5725561, at \*131 (Enlarged Bd. App. Nov. 25, 2008).

In a November 2008 decision the EBOA answered “yes” to questions 1 and 2 (negating the need to answer question 3) and “no” to question 4, thus agreeing with the rejection of WARF’s human embryonic stem cell culture claims.<sup>68</sup> The EBOA began by interpreting the Rule 23d(c) prohibition in the context of EPC Article 53(a) and Article 27(2) of TRIPS, which contain similar wording, and noted that “[t]he forbidden exploitation must be something contravening the underlying legal principles of all contracting states.”<sup>69</sup> In considering the various arguments for and against allowing patenting of the claim, the EBOA broadly construed both the implementing rule and the concept of “invention,” noting that “[a] claimed new and inventive product must first be made before it can be used. Such making is the ordinary way commercially to exploit the claimed invention and falls within the monopoly granted.”<sup>70</sup> The EBOA ultimately concluded, considering the intentions of the legislators, that “it is not the fact of the patenting itself that is considered to be against *ordre public* or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts.”<sup>71</sup>

Although WARF apparently did not seek a patent on the cell cultures in Japan, the Japanese Patent Office (JPO) also has denied patents on claims involving human embryonic stem cell-derived inventions in some cases.<sup>72</sup> Moreover, the Examination Guidelines

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68. *Id.* at \*144.

69. *Id.* at \*133. Interestingly, the Board noted that, as there was no constitutional tradition common to member states nor international treaty stating that a pre-fourteen day embryo should not be used for stem cell research, there was “no reason to forbid patenting of a use involving extracting some cells from a pre-embryo.” *Id.* This language suggests that the violation of a common constitutional tradition or international treaty could be the basis for denial of patentability under the EPC—illegal activity barring patentability.

70. *Id.* at \*141.

71. *Id.* at \*142.

72. Yoichi Yoshizawa, Comparative Analysis on Patentability of Human Embryonic Stem Cells 49-54 (Sept. 11, 2006) (unpublished LL.M. IP thesis, Munich Intellectual Property Law Center) (on file with author). However, a more recent commentary suggests this view may be changing and that the JPO is open to patenting human embryonic stem cell inventions. Koichi Sumikura, *The Issues Surrounding Patent Protection for Human-Embryonic Stem Cells and Therapeutic Cloning in Japan*, 13 MPI STUD. ON INTEL. PROP., COMPETITION & TAX L. 111, 115-16 (2009). Also, the JPO has issued the world’s first patent on induced pluripotent stem cells, based on the reprogramming of adult stem cells. See Ben Jones, *First Pluripotent Stem Cell Patent Granted in Japan*, BIONEWS, Sept. 22, 2008, <http://www.bionews>.

for Article 5 of the current Chinese Patent Act, which provides that inventions incompatible with the law, social morality, or public interest shall not be patented, list as unpatentable human embryonic stem cells and processes to prepare them, as well as the human body at all stages of development.<sup>73</sup>

Patent offices are not alone in invoking this morality-based invention creation activity boundary. In December 2006, the German Federal Patent Court (GFPC) partially revoked claims in a German patent to Dr. Oliver Brüstle on similar grounds to the EPO Enlarged Board of Appeals.<sup>74</sup> The GFPC ruled that claims to stem cells and methods for producing them that could involve the destruction of human embryos violated the *ordre public* and morality provision of the German Patent Act.<sup>75</sup>

These decisions likely do not express a broad view regarding the relevance of invention creation activity to patentability outside of their specific contexts.<sup>76</sup> Nevertheless, they do show that immoral conduct, as defined by appropriate legislative bodies, in invention creation can be the basis for denial of patentability under certain circumstances.

### *C. Where the Boundary Isn't: Unethical Invention Creation Activity and Beyond*

Morality and ethics are two words that are often used interchangeably. "Morality" is derived from the Latin word *moralis*,

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org.uk/page\_13516.asp?hlight=Japan.

73. Tang Guangliang, *Patentability of Research Results in Connection with Human-Embryonic Stem Cells, Especially with the So-Called Therapeutic Cloning-Chinese Points of View*, 13 MPI STUD. ON INTEL. PROP., COMPETITION & TAX L. 68-69 (2009).

74. Martin Grund et al., *Patentability of Human Embryonic Stem Cells—German Federal Patent Court*, 8 BIO-SCI. L. REV. 104, 104-05 (2007).

75. *Id.* at 104. Interestingly, the research that yielded the claimed inventions was legal in Germany and was in fact funded in part by the German government. *Id.* at 105.

76. For example, in *Howard Florey/Relaxin v. Fraktion der Grünen im Europäischen Parlament*, App. No. 83307553.4, [1995] E.P.O.R. 541, 1994 WL 1062472, at \*542 (Opposition Div. Dec. 8, 1994), several groups filed an opposition in the EPO to the issuance of a gene patent for the hormone Relaxin. *Id.* at 544. The case included an (unsuccessful) argument targeted at invention creation activity. The opponents argued that the patent would offend Article 53(a) because, among other things, it involved taking tissue from a pregnant woman, thus offending human dignity. *Id.* at 550.

which relates to custom or manner.<sup>77</sup> "Ethics" is derived from the Greek word *ethos*, which relates to moral character or custom.<sup>78</sup> Thus there is some similarity and overlap in the meaning of these words, as they both deal with custom or behavior.<sup>79</sup> One contextual distinction that can be made between the two words, and which will be used for the purposes of this Essay, relates to standards. We can think of immoral behavior as violating particular societal standards of behavior and unethical conduct as violating particular group standards of behavior. Though there do not appear to be any instances of patents being invalidated or held unenforceable based solely on unethical, as opposed to illegal and/or immoral, invention creation activity as defined in this Essay, whether such invalidation or refusal to enforce should occur is a question worth considering.

Formal and informal ethical norms and notions of commercial morality can be found in various industry groups. In fact, in the trade secret arena, which provides the primary alternative to patent protection, the violation of such norms can form the basis for misappropriation liability.<sup>80</sup> For example, in a case involving proprietary seed corn, the Eighth Circuit upheld a finding of trade secret misappropriation when the defendant used improper means to obtain samples of the plaintiff's corn and used the samples to develop competing products.<sup>81</sup> The court explained that "by labeling certain wrongful, if not actually otherwise illegal, acts 'improper,' trade secret law plays an important role in regulating commercial behavior.... Our analysis is consistent with the stated purposes of

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77. THE OXFORD ENGLISH DICTIONARY 1070, 1080 (2d ed. 1989).

78. *Id.* at 421.

79. One commentator characterizes the differences this way:

The moral sphere encompasses acts that are momentous rather than trivial, that affect others as much as or more than the agent, that subject the agent to blame or punishment if he chooses incorrectly, and that are a matter of conscience. Narrowly defined, ethical questions are general and theoretical; moral questions are specific, practical, and something else—this "something else" varies from case to case.

CARL WELLMAN, *MORALS AND ETHICS*, at xvi-xvii (1975).

80. See, e.g., *E.I. duPont deNemours & Co. v. Christopher*, 431 F.2d 1012, 1015 (5th Cir. 1970). Such notions are also present to some degree in trademark and unfair competition law. See, e.g., *Lanham Trademark Act*, 15 U.S.C. § 1125 (2006); *RESTATEMENT (THIRD) OF UNFAIR COMPETITION* § 2 cmt. a (1995).

81. *Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226, 1228 (8th Cir. 1994).

trade secret protection: (1) maintaining commercial morality, and (2) encouraging innovation.”<sup>82</sup>

While encouraging innovation is a well-accepted goal of patent law, maintaining commercial morality is not. Nevertheless, notions regarding ethical conduct could be relevant in the context of patents. Because of their specialized training, professionals, such as doctors, lawyers, and engineers, have additional moral obligations, often reflected in codes of conduct, beyond those of ordinary laymen. One area in which the issue of unethical invention creation activity could easily arise is in relation to informed consent. Medical researchers are obligated under a number of professional creeds to obtain the informed consent of their human research subjects. For example, the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (Helsinki Declaration) was designed to provide guidance to physicians and “other participants in medical research involving human subjects” including those conducting “research on identifiable human material and data,” and provides in part:

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights....

....

24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail.... The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.... After ensuring that the subject has understood the information, the physician ... must then seek the potential subject’s freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.<sup>83</sup>

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82. *Id.* at 1238 n.42 (citation omitted).

83. WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 1-3 (2008), *available at* <http://www.wma.net/e/policy/pdf/17c.pdf>. In the United States, the American Medical Association’s Code



The Helsinki Declaration is explicitly referenced in a European Union directive covering the conduct of clinical trials on medicinal products for human use, which grounds the conduct of such trials in "the protection of human rights and the dignity of the human being."<sup>84</sup>

A famous U.S. case involving unethical invention creation activity is *Moore v. Regents of the University of California*.<sup>85</sup> In *Moore*, a patient sued his former physician and his physician's employer for using cells extracted from Moore's body to create and patent cell lines that then provided considerable revenue to the physician and the patent assignee, the University of California.<sup>86</sup> Moore alleged that the physician, Dr. Golde, had failed to disclose his economic interest in Moore's tissues before obtaining consent to remove them. Moore also charged the defendants with conversion of his personal property, his body tissue.

While denying that Moore had a property interest in tissue removed from his body, the Supreme Court of California did find that a physician has a fiduciary duty to disclose any personal and economic interest in research matters unrelated to the patient's treatment that may affect the physician's judgment regarding such treatment. The court concluded that Dr. Golde had such an interest in Moore's cells at the time he was treating Moore and that Dr. Golde had breached his fiduciary duty by failing to disclose his interest to Moore.<sup>87</sup>

If the patent laws allowed lack of informed consent in invention creation to be a basis for patent invalidity or patent unen-

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of Medical Ethics is the professional code accepted by virtually all state medical societies and physician licensing bodies. See ETHICS AND QUALITY OF CARE: REPORT OF THE AMERICAN MEDICAL ASSOCIATION AND THE FEDERATION OF STATE MEDICAL BOARDS 3 (1995), [http://www.fsmb.org/pdf/1995\\_grpol\\_Ethics\\_and\\_Quality\\_of\\_Care.pdf](http://www.fsmb.org/pdf/1995_grpol_Ethics_and_Quality_of_Care.pdf).

84. Council Directive 2001/20, 2001 O.J. (L121) 34 (EC).

85. 793 P.2d 479 (Cal. 1990).

86. *Id.* at 479-83. Moore was also required to expend considerable time and money in traveling across state lines to meet with the physician over a period of several years, during which time the physician negotiated a \$15 million contract with a pharmaceutical company to develop Moore's cell line. See LORI ANDREWS & DOROTHY NELKIN, BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE 1 (2001).

87. *Moore*, 793 P.2d at 497. Two other recent cases involving similar issues of control over donated human biological material and consent agreements are *Washington University v. Catalona*, 490 F.3d 667 (8th Cir. 2007), and *Greenberg v. Miami Children's Hospital Research Institute*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

forceability, then Dr. Golde's patent in *Moore* could have been affected because the *Moore* court held that the duty of informed consent had been violated.<sup>88</sup>

Allowing violations of professional ethical codes during the creation of an invention to affect patentability or patent enforceability is, in some respects, perhaps even less justifiable than considering illegal or immoral conduct. Professionals are under a duty to be aware of the ethical standards of their calling. But to conclude that these standards should be relevant when the professional is acting in the role of an inventor is a rather large step. Why should the patents of professionals be subject to greater uncertainty than patents obtained by other types of inventors? As one commentator notes:

Ethics is the most daunting of subjects in professional practice of any description; most likely because it often seems to be the most amorphous and most arbitrary body of rules of all the practicing professional concepts. Moreover, many ... of the rules of professional ethics seem to have only the most attenuated relationship to socio-religious behavior codes.

....

For example: ... (1) It may not be "immoral" for a lawyer to form a law partnership with a non-lawyer; but, as of 2002, it was a breach of Bar professional ethics in almost every jurisdiction.<sup>89</sup>

Casting too broad and undefined a net over unethical activity could exacerbate the uncertainty already associated with patents to untenable levels.<sup>90</sup> A more prudent approach might be to codify specific ethical breaches on which there is widespread unanimity as bases for patent unenforceability. For example, a physician's failure to obtain informed consent or a researcher using data from publicly condemned experiments, such as those performed by the Nazis, could form bases for patent unenforceability, unless rediscovered in an

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88. *Moore*, 793 P.2d at 497. However, it seemingly would not have made much, if any, financial difference for Moore himself unless the court imposed some type of constructive trust on the patent in Moore's favor.

89. BETTE KESTER CONRAD, *THE TAO OF LEGAL ETHICS* 7, 13 (2003).

90. See JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* 9 (2008) (arguing that poor notice in patents can create a disincentive for innovation).

ethical way.<sup>91</sup> Yet even these seemingly straightforward prescriptions could be fraught with difficulty in implementation due, for example, to variations in what is required for adequate informed consent under a particular set of circumstances. In the *Washington University v. Catalona* case alone, the Eighth Circuit noted that fifteen different versions of consent forms were used for six different research studies.<sup>92</sup> Furthermore, state laws on informed consent govern the area implicating federalism concerns as discussed below.

## II. THE INVENTION CREATION ACTIVITY BOUNDARY: CONTOURS AND CONCERNS

At a sufficiently high level of abstraction, the above examples point to a new invention creation boundary in patent law. However, none of the examples illustrating the new boundary reflect an explicit focus on the idea of creating liability for invention creation activity per se. Rather, in each situation there is a more specific, primary concern. In the WARF case, the concern relates to uses of human embryos for industrial purposes. In the efforts to tie violations of laws regarding access to genetic resources to patentability, the main concerns seem to be complying with the CBD and creating a mechanism by which governments and indigenous groups can be adequately compensated for their contributions to lucrative, otherwise proprietary developments. Consequently, these scenarios may not be evidence of a trend towards expansive penalties for invention creation misconduct; rather, the creation of such penalties may be an indirect and unintended effect of efforts to facilitate a different

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91. Jeffrey H. Barker, *Human Experimentation and the Double Facelessness of a Merciless Epoch*, 25 N.Y.U. REV. L. & SOC. CHANGE 603, 604 (1999). There is a fair amount of disagreement regarding whether the Nazi data should be used. As one researcher who has chosen to use Nazi-generated hypothermia data states, "I don't want to have to use this data, but there is no other and will be no other in an ethical world." Kristine Moe, *Should the Nazi Research Data Be Cited?*, HASTINGS CENTER REP., Dec. 1984, at 5, 5 (quoting researcher John S. Hayward of the University of Victoria in British Columbia).

92. 1490 F.3d 667, 671 n.3 (8th Cir. 2007).

policy.<sup>93</sup> Nevertheless, it is worth considering some of the possible impacts and opportunities the new boundary could create.

At least two different groups could benefit from a new invention creation activity boundary: First, alleged infringers, who might be able to challenge the enforceability of a relevant patent. Second, an inventor's victims, pursuing a form of justice for injuries sustained as a result of the invention creation process such as, for example, indigenous groups seeking imposition of a constructive trust or other compensation for traditional knowledge misappropriation.

But there are also potential losers, even beyond the inventors, if invention creation activity is considered in patentability or patent enforceability analyses. For example, an innocent patent assignee might be unaware of any irregularities in invention creation conduct despite the exercise of due diligence. A failure to ensure protections for such parties could raise the uncertainty surrounding patent rights significantly. On the other hand, such uncertainty already exists for assignees under the doctrine of inequitable conduct. If a society chooses to penalize invention creation misconduct in order to discourage such activity and avoid the possibility of "patent laundering," the innocent assignee might just have to suffer.

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93. For example, the very same EU Biotech Directive that provided the basis for creation of an immoral invention creation activity boundary in the EPO explicitly declines to impose penalties for failing to disclose the origin of genetic resources:

If an invention is based on biological material of plant or animal origin ... the patent application should ... include information on the geographical origin of such material[;] ... this is *without prejudice* to the processing of patent applications or the *validity of rights* arising from granted patents.

Council Directive 98/44, 1998 O.J. (L 213) 15 (EC) (emphasis added). Moreover, some countries, such as Norway, require DOO but penalize noncompliance outside of the patent system. Section 8(b) of the Norway Patent Act provides in part:

If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from the national law in the providing country that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained....

....

Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

Lov om Patenter [Patents Act] (2008) (Nor.), *translated in* [http://www.patentstyret.no/upload/Filarkiv/regelverk/Norwegian\\_Patents\\_Act.pdf](http://www.patentstyret.no/upload/Filarkiv/regelverk/Norwegian_Patents_Act.pdf).

The presence of equitable doctrines relating to pre-patent issuance and post-patent issuance inventor/owner activity in patent law supports the concept of considering pre-patent filing activity in the equities of patent enforcement. The mere fact that remedies for inappropriate invention creation activity already exist outside of the patent system does not mean that such activity should be irrelevant to patentability or patent enforceability. Such opportunities for dual relief are already present in the patent system and outside of it. For example, declarations submitted to the U.S. Patent and Trademark Office (USPTO) under 37 C.F.R. § 1.68 are submitted under penalty of perjury. Thus, if false statements are made in such documents, they would provide a basis for the patent to be unenforceable due to inequitable conduct even though a separate criminal penalty for perjury would also be applicable.<sup>94</sup>

Analogies also can be found in other areas of U.S. law where "bad" activity impacts property rights. For example, property forfeiture statutes allow the government to seize houses and other property that have been used in the conduct of illegal activity such as drug trafficking,<sup>95</sup> and "murderous heirs" have been denied estates to which they would otherwise have been entitled.<sup>96</sup> Also, under "Son of Sam" statutes, criminals have been deprived of the economic fruits of their crimes. And in copyright law, creators of derivative works who use the work of another without authorization are not entitled to a copyright in any part of the work in which material is used unlawfully.<sup>97</sup> Though none of these analogies perfectly matches the context under discussion, they do suggest that

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94. See 37 C.F.R. § 1.68 (2009), which provides:

Any document to be filed in the Patent and Trademark Office and which is required by any law, rule, or other regulation to be under oath may be subscribed to by a written declaration. Such declaration may be used in lieu of the oath otherwise required, if, and only if, the declarant is on the same document, warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon.

95. See, e.g., *United States v. James Daniel Good Real Prop.*, 510 U.S. 43, 46-47 (1993) (requiring that the Government afford the owner due process before such seizure).

96. See *Riggs v. Palmer*, 22 N.E. 188 (N.Y. 1889).

97. See 17 U.S.C. § 103(a) (2006). Moreover, physicians have lost their licenses to practice medicine after committing an offense involving "moral turpitude" such as filing a fraudulent tax return. See *In re Kindschi*, 319 P.2d 824, 825-27 (Wash. 1958).

considering illegal invention creation activity in patent enforceability analyses is not completely anomalous.<sup>98</sup>

Moreover, as explained by the Supreme Court in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*<sup>99</sup>: “[O]ne’s misconduct need not necessarily have been of such a nature as to be punishable as a crime .... [A]ny willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim by the chancellor.”<sup>100</sup> The Court further noted the important public interest at stake:

[Patents] ... are matters concerning far more than the interests of the adverse parties. The possession and assertion of patent rights are “issues of great moment to the public.” A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the “Progress of Science and useful Arts.” At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies *spring from backgrounds free from fraud or other inequitable conduct* and that such monopolies are kept within their legitimate scope.<sup>101</sup>

While the Supreme Court is undoubtedly correct on this point, there are other issues at stake. Patents provide important incentives for inventors to engage in activity that results in socially beneficial knowledge and products. However, the costs of obtaining patent protection are significant and increasing, and the uncertainty surrounding the real value of issued patents can be a deterrent to obtaining patent protection. Any proposal creating

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98. Suppression of evidence gathered in violation of the Constitution presents similar issues. See *Wong Sun v. United States*, 371 U.S. 471, 488 (1963) (“[T]he more apt question in such a case is ‘whether, granting establishment of the primary illegality, the evidence to which instant objection is made has been come at by exploitation of that illegality or instead by means sufficiently distinguishable to be purged of the primary taint.’” (quoting *JOHN MACARTHUR MAGUIRE, EVIDENCE OF GUILT* 221 (1959))).

99. 324 U.S. 806 (1945).

100. *Id.* at 815.

101. *Id.* at 815-16 (emphasis added).

liability for invention creation activity potentially could be seen as a further disincentive to engage in the patent process because of the added uncertainty it would create in relation to patent enforcement.

Also, with compensation for many types of illegal or unethical invention creation activity available outside of the patent system,<sup>102</sup> injecting such a new inquiry into the already complex patent arena may in some cases be redundant and in others simply unwise.<sup>103</sup>

In the United States, federalism concerns also would be relevant to this issue. The right to exclude granted to a patentee is a right granted under the federal patent laws.<sup>104</sup> If, for example, the illegal invention creation activity is theft, it normally would be defined by state law and those standards and definitions can vary from state to state.<sup>105</sup> Although the prohibition of a federal statute cannot be "set at naught" by a state statute,<sup>106</sup> it is possible for state statutes to impact federal rights. In fact, some federal statutes by definition require recourse to state law to ascertain their parameters.<sup>107</sup>

Patent law is, at base, utilitarian and was designed to effectuate the constitutional object of "promoting the progress of ... the useful arts" by granting an exclusive right, for a limited time, to inventors for their discoveries.<sup>108</sup> The lure of patent exclusivity can be a strong incentive for the creation of new products and processes and their disclosure for the advancement of knowledge and the benefit of society at large. But that incentive can be diminished significantly if the rights granted by a patent are not seen as commensurate with the expense and inconvenience involved in obtaining the right, and

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102. For example, compensation may be available in civil damages suits for tortious conduct.

103. See F. Scott Kieff, *Patents for Environmentalists*, 9 WASH. U. J.L. & POL'Y 307, 317-18 (2002) (suggesting that biodiversity custodians who do not receive a share of patent profits despite their contributions to patented inventions be compensated through ordinary market and political mechanisms outside of the patent system).

104. See 35 U.S.C. § 271(a) (2006).

105. See, e.g., *United States v. Corona-Sanchez*, 291 F.3d 1201, 1202, 1207 (9th Cir. 2001) (analyzing whether a California state conviction for petty theft constitutes an aggravated felony under federal law, and noting that "[t]he language of the California theft statute is unique among the states").

106. See *Leo Feist, Inc. v. Young*, 138 F.2d 972, 975 (7th Cir. 1943).

107. See generally Wayne A. Logan, *Contingent Constitutionalism: State and Local Criminal Laws and the Applicability of Federal Constitutional Rights*, 51 WM. & MARY L. REV. 143 (2009).

108. U.S. CONST. art. I, § 8, cl. 8.

if enforcement of the right is hindered by a lack of legal clarity and certainty.

In a recent book, James Bessen and Michael Meurer argue that, in many technology areas, patents now provide a disincentive to innovation because of their poor boundaries, which provide insufficient notice to third parties of what the patents cover.<sup>109</sup> As a result, the authors assert that patents are not really working as property-based incentives. For example, they note that:

By the late 1990s the risk of patent litigation for public firms outside of the chemical and pharmaceutical industries exceeded the profits derived from patents. This means that patents likely provided a net disincentive for innovation for the firms who fund the lion's share of industrial R&D; that is, patents tax R&D.<sup>110</sup>

Thus, they contend, the risk of patent litigation has increased because the metes and bounds of the property right are unclear and their enforceability value uncertain. There are, unfortunately, many culprits in the patent system responsible for that uncertainty and lack of clarity. A few examples include claim construction (determining what the claims mean), nonobviousness, application of the doctrine of equivalents, and the standard for determining if a patentee engaged in inequitable conduct in procuring a patent. Moreover, after a patent issues, broader claims may be added to it for a period of up to two years, or a continuation application could remain on file in the USPTO to which further claims could be added for an even longer period. These are just a few of the many areas of uncertainty currently associated with patents. Creating liability within the patent system for inappropriate invention creation activity would exacerbate this existing uncertainty and could be expected, at least in the short term, to further erode patent value.

A truly daunting question is how a court, legislature, or patent office is to determine which activities are sufficiently egregious to warrant denial of a patent or patent unenforceability. Of course, the major challenge with employing morality or ethical standards in the patent realm is the fluidity and context specificity of moral and ethical behavior. Societal standards vary over time and place with

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109. BESSEN & MEURER, *supra* note 90, at 62.

110. *Id.* at 144.



different societies having different conceptions of right or wrong behavior. Likewise, different groups have differing ethical standards of behavior that also may change over time. Without sufficient constraints, inquiring into the morality or ethics of invention creation activity could encompass vast vistas of behavior and cast an untenable level of uncertainty over the patent right. These issues do not mean that liability for egregious invention creation activity should not be imposed. However, they do suggest that such inquiries might work best, and with the least negative impact on incentives, where such consensus has been achieved that positive law codification of the standard takes place, such as is seen in the European Union Biotechnology Directive definitions of immoral inventions and the patent laws of countries such as China, India, and Brazil.

### CONCLUSION

The human embryonic stem cell cases and the genetic resources acquisition provisions are examples of a new invention creation activity boundary in patent law. On one level, the creation of such a boundary is intuitively appealing; no one wants a Grenouille to profit from his crime in any way. However, the patent system's historical lack of concern with the legality or the morality of invention creation conduct is consistent with its utilitarian focus. A reevaluation of the wisdom and fairness of this approach seems timely, especially in view of the expansion in patent-eligible subject matter and continuing concerns invoked by the patenting of genetic material.

Nevertheless, perhaps the slow evolution of categories of patent-impacting invention creation activity misconduct is appropriate considering the potential impact on the patent incentive and the lack of consensus on standards of ethical and moral behavior and on the extent to which illegal behavior should influence the patent realm. The creation of this new boundary in patent law holds the promise of both benefits and hazards. If development of this new boundary occurs at all, prudence counsels in favor of it being cautious, incremental, and well-considered.