

**THE EUROPEAN PATENT CONVENTION:  
A MORAL ROADBLOCK TO  
BIOTECHNOLOGICAL INNOVATION  
IN EUROPE**

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The purpose of this Comment is to question the vehicle by which the European Patent Convention (EPC) regulates biotechnological innovation involving human cloning research, stem cell research, and other innovative subject matter to which special interest groups object on moral grounds.<sup>1</sup> The moral debate surrounding controversial biotechnology, on the other hand, is far beyond the scope of this paper.<sup>2</sup> To that end, this

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1. See Implementing Regulations to the Convention on the Grant of European Patents rule 23(d), Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended Dec. 9, 2004) [hereinafter EPC Regulations].

2. This Comment in no way condones, nor condemns the pursuit of human cloning. Mere mention of human cloning guarantees an emotionally-charged debate will ensue. Research goals and personal agendas often define the desired ends of scientific research. Therefore, this Comment humbly suggests that society exercise caution before discounting an entire field of research based merely upon the desired ends of a sect of researchers. Research leading to nuclear technology certainly affected unintended and

Comment takes no stance pertaining to the issue of the merit of legislative regulation of biotechnological research.<sup>3</sup> Instead, this Comment will focus on critiquing the validity of the legislative means employed by the European Patent Office (EPO) to achieve its desired end of moral regulation of biotechnology research.<sup>4</sup>

To provide sufficient background necessary to appreciate the recurring theme of irony in the remaining sections, some basic characteristics of a patent system must be highlighted. Patents do not grant any positive rights to anything, but instead grant a limited negative right to exclude others from exploiting the patented subject matter<sup>5</sup> resulting in the now-old adage that patents are merely roadblocks.<sup>6</sup> Considering the roadblock role of patents in connection with the fact that most patents today are granted for improvements upon previous—and often patented—technology,<sup>7</sup> the purpose of patent rights is quite clear: negative exclusionary rights.<sup>8</sup> Improvement patents, the most common type of patent, often sit within previously patented technology meaning the holder of an improvement

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undesirable results. However, one would be hardpressed to argue such research should have been inhibited by creating a disincentive for investment. In that vein, the mere fact that nuclear technology can be used in a manner inconsistent with public policy certainly does not mean it should be denied patent protection. Similarly, few would argue that a standard firearm should be denied patent protection merely because the firearm can be utilized to achieve immoral ends.

3. See *supra* note 1 and accompanying text.

4. See Convention on the Grant of European Patents art. 53(a)–(b), Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter EPC] (listing exceptions to patentability).

5. Jonathan Grossman, *Human Embryos, Patents, and the Thirteenth Amendment*, 55 U. KAN. L. REV. 731, 763–65 (2007).

6. See Peter Lee, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 688 (2004) (describing the roadblock function patents serve in scientific research); Michael A. Carrier, *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation*, 56 VAND. L. REV. 1047, 1064–65 (2003) (referring to patents as roadblocks).

7. Theon van Dijk, *Patent Height and Competition in Product Improvements*, 44 J. INDUS. ECON. 151, 152 (1996); Vincent P. Tassinari, *Complied Legislative History of 35 U.S.C. § 284: The Patent Compensation Statute*, 31 UWLA L. REV. 45, 63 (2000); see also Bureau of Nat'l Affairs, *FTC, DOJ Hold Hearing on Overlap, Conflict Between Antitrust Enforcement, Patent Law*, 7 ELECTRONIC COM. & L. REP. 138, 139 (2002) (asserting that improvement patents account for most patents today).

8. See *supra* note 6 and accompanying text.

patent may not even be able to exploit his or her own innovation.<sup>9</sup> Given this context in which a patent holder not only has no positive rights by way of his patent, but he may even be precluded from exploiting his innovation due to the nature of the patent, it would be absurd to contend that denial of a patent that grants very limited negative rights to its holder would discourage research into a particular technology.<sup>10</sup>

Section VI of this Comment will detail a case illustrating that patents, functioning as roadblocks, grant exclusionary rather than positive rights upon a patent holder.<sup>11</sup> The discussion will specifically touch upon a widely recognized concept that even if a patent issued for some unimaginable morally objectionable innovation, the most the holder could do with the patent is prevent others from exploiting the innovation.<sup>12</sup> Now that the fundamental purpose of a patent is clear, the critique of the morality provisions of the EPC can proceed.

### **'Ordre' of Comment**

This Comment will critique the logic behind relevant European Patent Office decisions, European directives, and EPC provisions, specifically Article 53(a) and Rule 23(d), that have shaped patent law in the European Union.<sup>13</sup> In that regard, Section I will analyze the opinions of advisors to the European Commission: The Group of Advisers on the Ethical Implications

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9. *See id.*

10. *See* discussion *infra* Part I.A (discussing in further detail the absurdity of exploiting the patent system to regulate morally objectionable research).

11. *See* discussion *infra* Part VI.B.

12. *See id.*; *supra* note 6 and accompanying text.

13. *See* EPC, *supra* note 4, art. 53(a) (stating that subject matter running counter to public policy or morality is excluded from patentability); EPC Regulations, *supra* note 1, rule 23(d) (setting forth per se exclusions from patentability and explicitly removing processes for cloning humans from subject matter which shall be eligible for patent protection). Pursuant to the Treaty on European Union, the term European Union will be used in the remainder of this Comment to refer to the European Community and the member states of the European Union. *See* Treaty on European Union art. A, 1992 O.J. (C 224) 1, 5.

of Biotechnology (GAEIB) and later The European Group on Ethics in Science and New Technologies (EGE).<sup>14</sup>

Following the analysis of advisory opinions, and the comparison of the resulting European Directive and governing EPC provisions with the previously analyzed advisory opinions, Section II will highlight the disconnect between the opinions and directives and discuss the fundamental misuse of the patent system as a regulatory mechanism in the field of biotechnology, as noted in the academic literature.<sup>15</sup> Section III will provide a comparative analysis of European and U.S. patent systems by way of a recently decided biotech case.<sup>16</sup> Section IV of this Comment will analyze a group of exemplary cases handled by the European Patent Office illustrating the EPC in action and providing a platform upon which further critique of EPO methodology is built.<sup>17</sup> Section V will analyze the purposes and intended functions of a patent system.<sup>18</sup>

This Comment will shift gears in Section VI, considering two special cases in which ingenious tactics were employed by special interest groups thus exposing the logical flaws discussed throughout this Comment and highlighting the debate surrounding biotech innovation in both the United States and Europe.<sup>19</sup>

Finally, Section VII will set forth logical and effective alternatives to the current EPC that would improve the

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14. See European Group on Ethics in Science and New Technologies, From the Group of Advisers on the Ethical Implications of Biotechnology to the European Group on Ethics in Science and New Technologies, [http://ec.europa.eu/european\\_group\\_ethics/archive/1998\\_2000/gceb\\_en.htm](http://ec.europa.eu/european_group_ethics/archive/1998_2000/gceb_en.htm) (last visited Nov. 19, 2007) (describing the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB), the first group of advisors assembled by the European Commission to advise them on the method by which biotechnology innovation should be protected). In 1997, by mandate of the European Commission, the group was adopted into the European Group on Ethics in Science and New Technologies (EGE). *Id.*

15. See discussion *infra* Part II.

16. See discussion *infra* Part III.A–B.

17. See *infra* Part IV.B–E.

18. See *infra* Part V.

19. See *infra* Part VI.A–B.

functioning of the EPC and enable the European Union to compete at a higher level in the field of biotechnological research while still addressing its moral and ethical concerns.<sup>20</sup>

### I. FROM WHENCE THEY CAME

This section will analyze the opinions upon which the current statutory patent law in the European Union is based.<sup>21</sup> Subsection A will provide a detailed analysis of advisory opinions promulgated by the legislature regarding the inclusion of moral inquiry in the patent system.<sup>22</sup> Subsection B will reveal a radical shift in the logic behind the advisory opinions.<sup>23</sup> Subsection C will report the stance taken in the academic literature regarding the debate surrounding the shift in EPC ideology.<sup>24</sup> Subsection D will compare the resulting directive enacted by the same legislature that drafted the opinion upon which the directive is based, as well as highlight some of the glaring differences.<sup>25</sup>

#### A. *In the Beginning, Logic Prevailed*

To understand the governing EPC provisions and the European Union directive at issue, the opinions upon which their drafters relied must first be analyzed.<sup>26</sup> In 1993, a group of advisors to the European Commission issued an opinion on the ethical implications of biotechnology.<sup>27</sup> The advisors clearly understood the fundamental purpose of the patent system: to protect.<sup>28</sup> However, the advisors did not stop there, but

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20. See *infra* Part VII.C.

21. See *infra* note 43 and accompanying text.

22. See EPC, *supra* note 4, art. 53.

23. See *infra* Part I.B.

24. See *infra* Part I.C.

25. See *infra* Part I.D.

26. See *id.*

27. *Opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission No. 3*, Sept. 30, 1993, available at [http://ec.europa.eu/european\\_group\\_ethics/docs/opinion3\\_en.pdf](http://ec.europa.eu/european_group_ethics/docs/opinion3_en.pdf) (last visited Nov. 19, 2007) [hereinafter *Opinion No. 3*].

28. See *id.* at 6 (asserting that the awarding of a patent does not grant a patentee any rights to perform or utilize the subject matter for which the patent is granted, but instead only grants the right to stop others from producing or utilizing that for which

proceeded a step further in pointing out what logically flows from the stated purpose of the patent system: (i) ethical and moral constraints placed upon the subject matter for which a patent is sought should be restricted to the advisory recitals of the directive issued by the European Commission, as opposed to the binding body of the directive itself;<sup>29</sup> and (ii) the regulation of research in specific morally or ethically sensitive areas should be affected by way of legislation governing such research as opposed to the patent system.<sup>30</sup> The advisors continued, after clearly articulating their position, in an attempt to lay to rest the widely held misconception that a relationship exists between cloning technology, patent law, and biodiversity.<sup>31</sup> The issue of biodiversity surfaced again as a central issue in the European Commission's objection to human cloning.<sup>32</sup> It is absurd that logical drafting, in reliance upon the clear recommendations of the advisory opinions discussed above, could result in directive provisions clearly taking the opposite position.<sup>33</sup> This logical gap is why this story does not end in 1993.<sup>34</sup>

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patent was granted); EPC, *supra* note 4, art. 64 (rights conferred upon a patentee by the grant of a European patent); *see also* 35 U.S.C. § 271 (2000 & Supp. IV 2004) (granting patent holders the right to stop third parties from infringing the patent).

29. *See* Opinion No. 3, *supra* note 27, § 2.2.2 (setting forth that moral and ethical constraints should be carried out in the language of the directive, but not in the binding body of the directive).

30. *See id.* § 2.2.1.

31. *See id.* § 2.2.5 (establishing that no link exists between biodiversity and the patent system). Thus, permitting an inference that, even if cloning contributed to a decrease in biodiversity, the patent system is not the appropriate vehicle to regulate that effect. *See id.*

32. *See Opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission No. 9*, § 1.13, May 28, 1997, available at [http://ec.europa.eu/european\\_group\\_ethics/docs/opinion9\\_en.pdf](http://ec.europa.eu/european_group_ethics/docs/opinion9_en.pdf) (last visited Nov. 19, 2007) [hereinafter Opinion No. 9] (raising the necessity of maintaining biodiversity as an objection to cloning).

33. *See infra* notes 45–46 and accompanying text.

34. *See* Council Directive 98/44/EC, *pmbl.*, para. 1–2, 4, 13, 1998 O.J. (L 213) 13 [hereinafter Directive 98/44] (illustrating the continuing need to balance the protection of advances in biotechnology with the concern for the moral implications of such development).

*B. Out of Right Field: A Radical Shift in Logic*

In 1997, a group of advisors identical in membership to the advisory group who three years earlier issued the clear and logical opinion discussed above issued a subsequent opinion in what can only be described as a momentary lapse of reason, or possibly a state of temporary amnesia.<sup>35</sup> Already, the waters were muddied as the advisory group began to backpedal on their previous opinion.<sup>36</sup> Within the three-year period between the two opinions, the patent system, in a conceptual sense, must have evolved from a system designed to do no more than protect an invention into a vehicle through which society's ethical and moral concerns could be imposed upon the subject matter for which patent protection is sought.<sup>37</sup>

*C. The World Reacts: Perspectives on the Ideological Shift*

A review of literature on this issue reveals a debate over the merits of integrating moral consideration into the patent system.<sup>38</sup> At least one relatively polarized article goes so far as to suggest modeling the U.S. patent system after that of the European Union.<sup>39</sup> Unlike the confusion espoused in the academic literature,<sup>40</sup> the advisory group to the European Commission clearly recognized the patent system as neither the

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35. *Compare* Opinion No. 9, *supra* note 32, § 2.10 (expressing how the condemnation of human cloning should be considered in the proposed Directive on legal protection of biotechnology), *with* Opinion No. 3, *supra* note 27, § 2.2.2 (setting forth that moral and ethical constraints should be carried out in the language of the directive, but not in the binding body of the directive).

36. *See supra* note 35.

37. *See id.*

38. *See, e.g.,* Margo Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 492 (2003) (citing the end of moral consideration in U.S. patent law); R. Stephen Crespi, *Patenting and Ethics—A Dubious Connection*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 31, 47 (2003) (describing the prospect of imposing moral considerations upon the patent system as highly contested).

39. *See* Dana Visser, *Who's Going to Stop Me From Patenting My Six—Legged Chicken? An Analysis of the Moral Utility Doctrine in the United States*, 46 WAYNE L. REV. 2067, 2085 (2000) (recommending that the U.S. model its patent system after the European system with respect to the imposition of moral and ethical consideration of subject matter).

40. *See supra* notes 38–39 and accompanying text.

appropriate—nor logical—vehicle for moral and ethical regulation of scientific research.<sup>41</sup> A proposition clear to the European Patent Office and European Commission is that any attempt to infuse any patent system with a moral or ethical requirement by way of a value-laden decision making process demonstrates a fundamental ignorance of the purpose and function of a patent.<sup>42</sup>

*D. Ideology Realized: A Directive is Not Advisory*

In 1998, the European Parliament and Council of the European Union enacted Directive 98/44/EC (Directive 98/44) which effectively converted the advisory opinions analyzed above into a legislative directive.<sup>43</sup> By enacting the directive, a problem immediately presented itself; both the logical content of the opinions were enacted along with the illogical portions of the opinions.<sup>44</sup> As a specific example, recital fourteen of Directive 98/44 contains language nearly mirroring that of advisory Opinion No. 3,<sup>45</sup> however the drafters ignored the immediately preceding statement they included in Opinion No. 3 cautioning that ethical constraints have no place in the directive beyond the recitals.<sup>46</sup> Rather than following the suggestion of the advisors

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41. Opinion No. 3, *supra* note 27, § 2.2.2–2.2.3.

42. *See* Directive 98/44, *supra* note 34, pmbl., para. 14 (stating that a patent does not grant any right to utilize the subject matter patented); Opinion No. 3, *supra* note 27, § 2.2.3 (advising that a patent carries with it no right to employ the innovation patented); Harvard/Onco-Mouse, 1991 E.P.O.R. 525, 526 (EPO (Examining Div.)) [hereinafter Harvard Oncomouse 1991] (holding that a patent does not grant the patentee the right to use his invention, just to stop others from using his invention).

43. *See* Directive 98/44, *supra* note 34, art. 15 (setting forth that the adopted directive is binding upon the member states of the European Union).

44. *See infra* notes 45–47.

45. *Compare* Directive 98/44, *supra* note 34, pmbl., para. 14 (stating a patent does not carry any right to utilize that which is patented, but merely the right to stop third parties from utilizing that which is patented), *with* Opinion No. 3, *supra* note 27, § 2.2.2 (stating a patent does not grant a right to use, but only to stop third parties from using the patented material).

46. *See* Opinion No. 3, *supra* note 27, § 2.2.2 (stating moral and ethical considerations should be addressed in the recitals as opposed to the binding body of the directive). *But see* Directive 98/44, *supra* note 34, art. 6 (setting forth such moral and ethical considerations in the binding body of the directive—in flagrant disregard for Opinion No. 3).

by addressing ethical and moral considerations in the recitals, the drafters placed their ethical and moral considerations squarely into the body of the directive.<sup>47</sup> The effect of placing the moral considerations into the body as opposed to the recitals was the forced implementation of the considerations into the patent laws of each member state rather than merely encouraging the member states to adopt alternative legislative means to achieve their respective moral agendas.<sup>48</sup> Why, if the drafters relied upon the advisory opinions, would the enacted directive deviate so flagrantly from the opinions upon which it was purportedly created?<sup>49</sup> The answer is likely that traditional notions of European moral and ethical conservatism trumped the desired policy of cultivating biotechnological investment in Europe.<sup>50</sup> Regardless of the reasons motivating the drafters, the European Patent Convention and Directive 98/44 both miss the mark in their attempt to regulate biotechnological research.<sup>51</sup> As discussed above, the purpose of granting patent rights and the process by which those rights are granted involves protecting innovation—certainly not discouraging investment in research to which special interest groups object on moral grounds.<sup>52</sup> The European Parliament's attempt to address the moral and ethical considerations of human cloning and other biotechnological research by way of the patent system smacks of Chaos Theory in that the insignificant change in an initial condition (i.e., exclusion of human cloning processes from patentability) is anticipated to have some significant desired result at some

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47. See Directive 98/44, *supra* note 34, art. 6 (codifying a per se exclusion from patentability of: (i) human cloning process; (ii) modification of germ line identity; and (iii) use of human embryos for industrial purposes).

48. See *id.* art. 15 (setting forth that member states must revise their respective patent laws to effect the provisions of the directive by July 30, 2000 at the risk of being sanctioned by the Council of the European Union).

49. See *supra* note 47 and accompanying text.

50. See Robin Beck Skarstad, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. PA. J. INT'L ECON. L. 353, 378, 383 (1999) (discussing Europe's conservatism and the negative consequences on Europe's drive to be more competitive in the field of biotechnology).

51. Compare Directive 98/44, *supra* note 34, art. 6, and EPC, *supra* note 4, art. 53(a)–(b), and EPC Regulations, *supra* note 1, rule 23(d), with *supra* note 6 and accompanying text.

52. See discussion *supra* Part I.A.

future point on an unrelated aspect of research (i.e., level of investment funding human cloning research).<sup>53</sup>

## II. PATENTLY ILLOGICAL OR AN UNFORTUNATE COMPROMISE

This section of the Comment will postulate upon the cause of disparity between the directive and the resulting statutory law.<sup>54</sup> Perhaps the most perverse notion, in light of perfect hindsight, is that Directive 98/44 was drafted by the European Parliament and the Council of the European Union in an attempt to encourage growth and investment in the biotechnology research sector of the European Union.<sup>55</sup> How then, one might ask, could the directive purporting to harmonize patent law in the European Union by displacing comparable national laws of each member state arguably affect the opposite result?<sup>56</sup> Commentators claim it was in the process of drafting the directive and in the goal of harmonizing the different laws of the many member states that such contradictions arose, and as a result, the effect of the directive was diminished.<sup>57</sup> However, a comparative analysis must be carried out to properly consider available alternatives to the EPC before one throws in the proverbial towel by taking the position that, regardless of the validity of exploiting the patent system to achieve the conservative agenda of the European Parliament, it remains the

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53. See Vincent Di Lorenzo, *Complexity and Legislative Signatures: Lending Discrimination Laws as a Test Case*, 12 J.L. & POL. 637, 640–41 (1996) (discussing the application of chaos theory to legislative decision making).

54. See discussion *supra* Part I.A–D.

55. See Directive 98/44, *supra* note 34, pmbl., para. 1 (stating the purpose of the directive as encouraging research in biotechnology through cultivation and protection of innovation in an attempt to attain a competitive edge in the rapidly expanding industry).

56. See *id.* art. 15 (directing EU member states to revise their respective national patent law in accord with the directive); see also Skarstad, *supra* note 50, at 383–84 (postulating that innovation in biotechnology that is excluded from patentability in the European Union will simply move elsewhere).

57. See Lydia Nenow, *To Patent Or Not To Patent: The European Union's New Biotech Directive*, 23 HOUS. J. INT'L L. 569, 590–92 (2001) (detailing the long and arduous ratification process through which legislation, such as Directive 98/44, must pass to become binding upon European Union member states); 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, 9–10, 40 (2001) (describing the challenges meeting the drafters of Directive 98/44).

best method of harmonization available in such a vastly complex situation as the European Union.<sup>58</sup>

### III. A CASE FOR COMPARISON

This section of the Comment will provide a specific case offering insight into the differences between a patent system employing moral inquiry and a patent system vehemently opposed to moral regulation of patentable subject matter.

#### A. *European Patent Convention in Action*

As one of the most often cited cases in the literature when discussing the state of biotechnology patent eligibility, the Harvard Oncomouse case provides an excellent example for comparison of the U.S. and European patent systems.<sup>59</sup> The Harvard Oncomouse was a transgenic mammal with a genetically engineered propensity to develop cancer at an increased rate when exposed to carcinogens.<sup>60</sup> In Europe, the Examining Division of the European Patent Office, on the first round, refused to grant the patent, and it was subsequently appealed to the Opposition Division.<sup>61</sup> The European Patent Office's Board of Technical Appeals ruled that the Examining Division should consider morality in accord with the EPC in deciding whether to grant the patent, and remanded the case to the Examining Division for further consideration.<sup>62</sup> Upon reconsideration, the Examining Division granted the patent in 1992 after weighing the potential suffering of the animal against

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58. See Gitter, *supra* note 57, at 3 (discussing the various viewpoints on the most effective way to utilize the patent system to regulate ethical and moral standards).

59. See Harvard/Onco-Mouse, 1990 E.P.O.R. 4 (EPO (Examining Div.)) [hereinafter Harvard Oncomouse 1989] (setting forth the European approach on the patentability of the Oncomouse); see also Gitter, *supra* note 57, at 26–27 (reviewing the history of the Harvard Oncomouse case).

60. See Harvard Oncomouse 1989, *supra* note 59, at 6 (setting forth technical specifications of the claimed invention).

61. See also Harvard/Onco-Mouse, 1990 E.P.O.R. 501 (EPO (Technical Bd. App.)) (ruling on the opposition filed in the European Patent Office).

62. *Id.* at 510–13.

the benefit to mankind.<sup>63</sup> Oppositions were subsequently filed,<sup>64</sup> and moral opposition continues to date as some Europeans refuse to look beyond their morally and ethically conservative view of biotechnological innovation.<sup>65</sup> Despite being forced to employ what is commonly referred to as the utilitarian doctrine,<sup>66</sup> the Examining Division held in favor of those seeking patent protection stating that the mere possibility that an invention could be used in a manner inconsistent with public policy does not itself foreclose that innovation from patent protection.<sup>67</sup>

### B. USPTO: A Different Story

Meanwhile, in the United States the Harvard Oncomouse patent process proceeded very differently.<sup>68</sup> The patent for the Harvard Oncomouse was granted upon first submission in 1988.<sup>69</sup> While the Harvard Oncomouse example, as a comparison of each nation's respective process, is not the most drastic illustration of the differences between the European and U.S. patent systems, comparison of the two highlights the inconsistencies and drawbacks associated with the imposition of inherently subjective and abstract concepts of morality upon the patent system.<sup>70</sup> The inconsistencies between the Examining

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63. Harvard Oncomouse 1991, *supra* note 42.

64. Harvard/Onco-Mouse, 2005 E.P.O.R. 271, 280 (EPO (Technical Bd. App.)) [hereinafter Harvard Oncomouse 2005].

65. *See generally id.* (serving as the latest example of a long string of appeals in opposition of the patent).

66. *See* Visser, *supra* note 39, at 2084–85 (describing moral inquiry in the patent process as the moral utility doctrine).

67. *See* Gitter, *supra* note 57, at 29 (citing Harvard/Onco-Mouse, 1991 E.P.O.R. 525, 528 (EPO (Examining Division))); *see also Bioethics and Patent Law: The Case of the Oncomouse*, WIPO MAGAZINE, June 2006, at 16, available at [http://www.wipo.int/edocs/pubdocs/en/2006/wipo\\_pub\\_121\\_2006\\_3.pdf](http://www.wipo.int/edocs/pubdocs/en/2006/wipo_pub_121_2006_3.pdf) (last visited Nov. 19, 2007) [hereinafter *Bioethics and Patent Law*] (discussing the process of obtaining and defending the Harvard Oncomouse patent).

68. *See Bioethics and Patent Law*, *supra* note 67, at 16 (outlining the relatively simple process by which the Harvard Oncomouse patent was obtained in the United States).

69. *Id.*

70. *Compare id.* (illustrating the predictability and ease with which the Oncomouse was patented in the United States), *with* Harvard Oncomouse 2005, *supra*

Division and the Technical Board of Appeals of the European Patent Office raise the question: if morality simply means conforming to objective standards of conduct in the European Union, how did two groups of the same judicial body come up with opposite rulings?<sup>71</sup> Lack of objectivity is one of the fundamental problems with imposing a value-laden requirement upon a patent system.<sup>72</sup> The moral inquiry is not welcomed by some at the European Patent Office as illustrated by the comments in *Harvard Oncomouse* 1991.<sup>73</sup>

### C. A Consequence of Two Different Patent Systems

The patent system in the European Union is simply unpredictable and inconsistent, as illustrated in the *Harvard Oncomouse* case.<sup>74</sup> The unpredictability produces two undesired results: (i) the patentability of a particular innovation is not always clear at the outset; and (ii) even if a patent is ultimately issued, the onslaught of opposition litigation that will surely ensue (assuming the patent subject matter is controversial) results in prohibitive defensive litigation costs.<sup>75</sup>

## IV. EXEMPLARY CASE LAW AND CONFOUNDING MORAL BLUNDERS

This section of the Comment will analyze several biotechnology patent cases decided by the European Patent Office to provide a broader cross section of the European Patent Convention in application. In subsection A, the *Oncomouse* case will be critiqued in greater depth and the tests that resulted

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note 64, at 271–82 (demonstrating the unpredictability and excessive litigation that results from using subjective standards as a basis for evaluating patentability of technology).

71. See *Nenow*, *supra* note 57, at 585 (explaining that no definition exists in the EPC for *ordre public* or morality leaving the European Patent Office with the value-laden requirement of conformity with European standards of conduct).

72. See *id.* at 597 (discussing the difficulty in remaining objective when applying the moral rules of the patent system).

73. See *Harvard Oncomouse* 1991, *supra* note 42, at 588 (explaining that the Examining Division made an exception in making a statement on morality because it does not ordinarily address morality issues regarding the question of patenting animals).

74. See discussion *supra* Part III.A.

75. See *supra* note 70 and accompanying text.

from the case will be considered.<sup>76</sup> Furthermore, the debate arising in that case regarding retroactive application of amended law is discussed.<sup>77</sup> Subsection B will analyze another recent case currently pending in the European Patent Office.<sup>78</sup> The analysis will reveal a fundamental confusion among the courts regarding rules for constructing statutory provisions.<sup>79</sup> Subsection C will set forth an analysis of a case recently decided in the European Patent Office.<sup>80</sup> The case of the Edinburgh patent provides a view of just how far the regulatory moral inquiry can reach into the subject matter for which patent protection is sought.<sup>81</sup> In subsections D and E this Comment will shift to an analysis of the function of the patent system prior to introduction of the broadened moral inquiry provisions of Directive 98/44.<sup>82</sup> Subsection F will conclude the analysis with a compact summary distilling the tests and lessons learned from the cases analyzed.<sup>83</sup> Finally, subsection G will provide ideas for a direction the European Patent Office may wish to take based upon the lessons learned in the cases analyzed in section IV.<sup>84</sup>

#### A. *Harvard Oncomouse: Another Look*

A prime example of the confusion and inconsistency resulting from subjective and illogical patent legislation is provided by the case of the Harvard Oncomouse.<sup>85</sup> As discussed

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76. See *infra* Part IV.A.

77. See *id.*

78. See *infra* Part IV.B.

79. See *id.*

80. See *infra* Part IV.C.

81. See *id.*

82. See *infra* Part IV.D–E.

83. See *infra* Part IV.F.

84. See *infra* Part IV.G.

85. See Bart Swinkels, *Oncomouse Case Puts EPC Rules to the Test*, MANAGING INTELL. PROP., Nov. 2005, at 98, 98–99 (discussing the enactment and subsequent application of EPC Rule 23(d) during the pendency of the Oncomouse opposition proceedings, the inconsistent decisions and the court's digression into voluminous pontifications upon morality seemingly unrelated to the case at hand); see generally Harvard Oncomouse 2005, *supra* note 64, at 311–25 (discussing the EPO's initial determination that moral scrutiny of subject matter was inappropriate, then later reopening the issue following enactment of Rule 23(d)).

above, Harvard College developed a mouse employing transgenic manipulation that exhibited a heightened susceptibility to carcinogens.<sup>86</sup> The development represented an extremely valuable, perhaps indispensable, animal model for use in cancer research.<sup>87</sup> Despite rejection of Harvard's initial patent application regarding the Oncomouse on grounds unrelated to this Comment,<sup>88</sup> the European Patent Office ultimately granted patent protection.<sup>89</sup> However, as discussed above, oppositions were continuously filed throughout the life of the patent, culminating in proceedings carried out subsequent to the enactment of Directive 98/44 and the corollary promulgation of Rule 23(d).<sup>90</sup> The court's inquiry, based upon the freshly minted legislation as applied to the now ancient facts of the case,<sup>91</sup> found the patent claims too broad and, as a consolation prize, upheld the patent with newly imposed restrictive language.<sup>92</sup> The court swiftly disposed of arguments advanced by the patent proprietors labeling the application of rules promulgated during pendency of the proceedings as retroactive and unfair.<sup>93</sup> In the opinion drafted by the European Patent Office, subjective arguments were repeatedly identified and rejected.<sup>94</sup> However, the white elephant in the room, as acknowledged by the decision makers themselves, was perhaps the most striking subjective

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86. See *Harvard Oncomouse 2005*, *supra* note 64, at 278–85 (detailing the background and history of the case).

87. See *Bioethics and the Patent Law*, *supra* note 67, at 16 (describing the Oncomouse as extremely important in the field of cancer research).

88. See *Harvard Oncomouse 2005*, *supra* note 64, at 330–40 (discussing provisions 53(a) and 83 of the EPC invalidating certain claims in Harvard's application).

89. See *id.* at 278–81 (detailing the initial rejection and subsequent grant of the Oncomouse patent application).

90. See Swinkels, *supra* note 85 (tiptoeing around the sticky issue of the legality of applying Rule 23(d) to the Oncomouse case).

91. *Harvard Oncomouse 2005*, *supra* note 64, at 312.

92. See *Harvard Oncomouse 2005*, *supra* note 64, at 324–27 (outlining the court's logic and reasoning resulting in the determination that the test of morality imposed by EPC 53(a) and interpreted according to EPC Rule 23(d) was satisfied if and only if the patent claims were restricted to mice as a specific subgroup of rodents).

93. See *id.* at 311–15 (setting forth a seemingly systematic, but systemically flawed analysis of interpretation versus amendment).

94. *Id.* at 313–14.

inquiry: the language of EPC Article 53(a).<sup>95</sup> While the court maintains that only one test, commonly referred to as the utilitarian test,<sup>96</sup> is to be employed to govern “real” Article 53(a) objections,<sup>97</sup> the court sets forth a new and simpler test for what it labels as “Rule 23(d)-type” Article 53(a) objections.<sup>98</sup> In the latter case, the court weighs any likely animal suffering against any likely substantial medical benefit in a fashion similar to a “real” Article 53(a) objection<sup>99</sup>—but with a twist.<sup>100</sup> Perhaps the European Patent Office originally intended to include the final ruling upholding Harvard University’s patent along with the notice of the patent’s expiration as a postage cost reduction measure, but, excuses for delayed timing aside, the Harvard Oncomouse Case timeline smacks of a pregnancy test providing its user with a definitive result in about nine months.

In comparison, the Harvard Oncomouse case experienced a very different fate in the hands of the U.S. Patent Office.<sup>101</sup> The case experienced yet another fate in Canada where, in a surprising lapse of logic and common sense, the Canadian court rejected the patent after determining that higher life forms were not merely compositions of matter like their lower life form relatives.<sup>102</sup>

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95. See *id.* at 323 (describing the moral inquiry, or what the court labels as a “real” Article 53(a) objection, as “careful weighing up” of the utility of an invention to society and placing this inquiry on a pedestal as beyond reproach and an accurate, yet flexible, barometer of the prevailing moral conscience of the times).

96. See *Bioethics and Patent Law*, *supra* note 67, at 16 (defining utilitarian balancing test and describing the courts use of the test in the Oncomouse Case).

97. See *Harvard Oncomouse 2005*, *supra* note 64, at 322 (defining “real” Article 53(a) objections as analyzing the effects of employing the invention).

98. See *id.* (defining “Rule 23(d)-type” Article 53(a) objections as fitting an invention into one of the Rule 23(d) per se excluded categories).

99. See *id.* (describing the two tests in a similar fashion, but labeling their effects as different).

100. See *id.* (detailing differences between tests employed for “real” Article 53(a) objections as opposed to “Rule 23(d)-type” Article 53(a) objections).

101. See *Bioethics and Patent Law*, *supra* note 67, at 16 (reporting the Harvard Oncomouse patent was granted to the broadest possible mammalian group, excluding only humans).

102. See *id.* at 17 (outlining the circumstances surrounding Canada’s rejection of the Oncomouse patent application).

As a parting gift, the European Patent Office provides one more contradiction to quibble over that is beyond the scope of this Comment but still warrants honorable mention.<sup>103</sup> The contradiction inherent in disallowing evidence of former, but not current, public sentiment toward an invention on one hand while on the other hand allowing newly promulgated legislation, no doubt arising from the very sentiment which was disallowed, is confounding.<sup>104</sup> The contradiction discussed above sounds the recurring theme of the European Patent Office's persistent inconsistent employment of moral inquiry in their patent system.

*B. WARF/Stem Cells Case: Exiting the Cloud of Confusion?*

A more recent, but perhaps less poignant, example of confusion resulting from patent legislation based upon flawed logic is provided by the WARF/Stem Cells case.<sup>105</sup> The WARF/Stem Cells Case is about the application of the Rule 23(d) per se exclusion of utilizing human embryos for industrial or commercial purposes.<sup>106</sup> The conflict arises from attempts to determine the intent behind the rule because a narrow interpretation of the rule would only apply to methods for physical utilization of human embryos, while a broad interpretation would apply additionally to downstream uses of cells harvested from human embryos.<sup>107</sup> What may be the greatest contribution of the WARF/Stem Cells decision to the European patent community is the court's surprising moment of clarity—setting forth that the European Patent Office is not to be regarded as the omnipotent being holding a magical moral

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103. Compare Harvard Oncomouse 2005, *supra* note 64, at 324 (stating that evidence of public sentiment toward the invention in question is inadmissible to the extent that such evidence arises after the priority filing date) with Harvard Oncomouse 2005, *supra* note 64, at 315 (setting forth that new changes in law occurring after the priority filing date, but before disposition of the case will come to bear on the proceedings).

104. See *supra* note 103.

105. WARF/Stem Cells, 2006 E.P.O.R. 331 (EPO (Technical Bd. App.)) [hereinafter WARF].

106. *Id.* at 336.

107. See *id.* at 335 (describing the determination of the proper interpretation of Rule 23(d) as the main issue in the case).

compass with which it will separate all that is morally right from wrong.<sup>108</sup> Subsequent to waxing lyrical upon the European Patent Office's modest functions, the court proceeds to embark upon an inquiry into the moral underpinnings of the 98/44 Directive.<sup>109</sup> Despite the court's clear and concise creation of what it later promoted as an objective test for a patently subjective inquiry in the Oncomouse Case, subsequent decisions continue to stumble upon the illogical language of Article 53(a) as applied via Rule 23(d) and exemplified in WARF.<sup>110</sup> Appeal after appeal and inquiry after inquiry attempt to delve into the mindset of the drafters of Directive 98/44.<sup>111</sup> The WARF/Stem Cells case is still pending,<sup>112</sup> and one question sent up on appeal is how broadly one should interpret the relevant provisions of the EPC.<sup>113</sup> The Enlarged Board of Appeals may choose to interpret Rule 23(d) in either a broad or narrow fashion.<sup>114</sup> The inquiry will require a fair bit of subjective speculation in order to create the façade that the European Patent Office has propagated an objective test.<sup>115</sup> However, can an objective test be objective if it is based almost entirely upon subjective data and speculation?<sup>116</sup> The entire ball of subjective inquiry wax is

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108. *See id.* at 337 (setting forth that the EPO is not concerned with moral righteousness but instead with granting patents).

109. *See Crespi, supra* note 38, at 574 (detailing the roadmap for inquiry by the enlarged board of appeals).

110. *See WARF, supra* note 105, at 336 (illustrating the difficulty in interpreting the intent of the legislature in enacting Directive 98/44); Harvard Oncomouse 2005, *supra* note 64, at 290; *see also* Crespi, *supra* note 38, at 574 (discussing the confusion created by the lack of a clear legislative intent in enacting Directive 98/44).

111. *See supra* note 108.

112. *See* WARF/Stem Cells, Interlocutory Decision, 2007 Official J. EPO 303, 303–55 (EPO (Technical Bd. App. Apr. 7, 2007)), <http://www.epo.org/patents/law/legal-texts/journal/2007/05.html>; Crespi, *supra* note 38, at 572–73 (reviewing pending cases in the European Patent Office).

113. *See Crespi, supra* note 38, at 574 (discussing the interpretation options facing the enlarged board of appeals in deciding WARF/Stem Cells).

114. *Id.* at 573–74.

115. *See id.* at 574 (concluding that at least one interpretation may prevent a decision from being rendered base upon the EPC rather than pure speculation).

116. The test set forth in the Oncomouse presumably can only be carried out after determining the parameters of the test which are in turn derived from the statute, which are in turn based upon interpretation of said statute. *See id.* at 573–74 (detailing the

the result of: (i) the attempt of legislators to distill the complex idea of morality into the few examples set forth in the Rule 23(d) per se exclusions from patentability;<sup>117</sup> and (ii) the mere concept of a judicial body applying a few lines of statutory text to a set of facts and, through the miracle of legal inquiry, deciding if a given technology offends such abstract concepts as morality or *ordre public*.<sup>118</sup> To illustrate that the confusion inflicted upon the European Patent process by subjective EPC provisions is not merely endemic to an isolated case, more case law is considered below.

*C. Edinburgh: How Far is Too Far?*

In the case of the Edinburgh patent, as in the WARF/Stem Cells case, patentability hinged upon broad versus narrow construction of Rule 23(d).<sup>119</sup> The Edinburgh patent claims a method of keeping cells separate during the culture process, but incidentally, the patent also describes various sources of raw material cells.<sup>120</sup> The conflict arises in this case due to the fact embryonic stem cells are referenced as a potential cell source.<sup>121</sup> Once again, the intent of the legislators must be subjectively determined via speculation to resolve the ambiguity and confusion inherent in the few isolated examples of morally objectionable technologies or uses thereof provided in the Rule 23 recitations.<sup>122</sup> The court in the case of the Edinburgh patent took an unprecedented step, one that has been rejected by subsequent courts.<sup>123</sup> The Edinburgh court decided a broad interpretation of Rule 23(d) was necessary to avoid being

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court's roadmap of determining the parameters of applying Rule 23(d) and Article 53(a) via interpretation of the meaning of Directive 98/44).

117. EPC Regulations, *supra* note 1, rule 23(d).

118. *See supra* note 71 and accompanying text; Crespi, *supra* note 38, at 573–74 (discussing the effect of the language in EPC Rule 23(d)).

119. *See Crespi, supra* note 38, at 572 (discussing the facts of the case and the unpublished opinion of the Opposition Division of the European Patent Office).

120. *Id.*

121. *Id.*

122. EPC Regulations, *supra* note 1, rule 23(d).

123. *See WARF, supra* note 105, at 337 (discussing the argument presented by the court in the Edinburgh case claiming that a narrow interpretation of Rule 23(d) is illogical as the provision would thus be cumulative of other provisions of Rule 23).

cumulative of other Rule 23 provisions and applied 23(d) accordingly.<sup>124</sup> But even after stretching Rule 23(d) to its logical limits—tainting any conceivable downstream use of products derived from the industrial or commercial use of human embryos—the court was forced to uphold the patent.<sup>125</sup> With all the confusion swirling around the interpretation of Rule 23 and the ensuing subjective speculation into legislative intent, the court missed the ball: the patent simply did not claim anything prohibited or even remotely addressed by the widest possible interpretation of Rule 23(d).<sup>126</sup> Much has been discussed above regarding the logical flaws inherent in Rule 23's distilled embodiments of moral indicators;<sup>127</sup> which leads one to query into European patent law prior to Directive 98/44. As a useful commentary on the convoluted state of the recent applications of Article 53(a), the next two cases illustrate the way things were prior to the 98/44 Directive.<sup>128</sup>

*D. Howard Florey / Relaxin: The Way We Were*

There was a simpler time in European patent law when logic ruled and common sense abounded, and that time was prior to Directive 98/44.<sup>129</sup> The European Patent Office, prior to the biotech directive of 1998, had quite a different image of moral inquiry as it pertains to the realm of granting patent protection.<sup>130</sup> The original understanding and application of Article 53(a) by the EPO resulted in rare moral objection and a still rarer denial of patent protection on such grounds.<sup>131</sup> In the Relaxin case, the moral opposition was vehemently rejected and characterized as the result of a fundamental misunderstanding

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124. *Id.*

125. *Id.*

126. *Id.* at 331–49.

127. *See supra* notes 110–13, 122–25 and accompanying text.

128. *See infra* Part IV.D–E.

129. *See, e.g.,* Howard Florey/Relaxin, 1995 E.P.O.R. 541, 549–50 (EPO (Opposition Div.)) [hereinafter Relaxin] (stating with clarity and conviction the common sense with which Article 53(a) is to be applied).

130. *See id.* at 550–51 (“[N]o moral distinction can be seen in principle between the patenting of genes on the one hand and other human substances on the other . . .”).

131. *Id.* at 549.

of the function of the patent system and the effect of obtaining patent protection within a particular subject matter.<sup>132</sup> In this case, mysteriously missing is any critique of legislative intent or subjective inquiry into broad or narrow construction of per se exclusions.<sup>133</sup> Despite swift disposition of the idea, the idea serves as an indicator of the convoluted and illogical inquiries to be carried out in the near future.<sup>134</sup> The court addressed, but quickly disposed of, the idea of a population survey to take the pulse, if you will, of the community to determine public sentiment or abhorrence toward the granting of a patent.<sup>135</sup> What should baffle the reader of this Comment is how a group of respected scholars could logically leap from stating that a patent does not confer the right to a technology to stating that public abhorrence could in any way invalidate a patent claim.<sup>136</sup> The idea that public resistance against propagation of a technology could somehow affect a bar against conferring: (i) what is in effect no right to utilize the subject matter; and (ii) only the right to preclude the exploitation of the protected technology by others is contradictory in and of itself.<sup>137</sup> However, as illustrated in the cases discussed above, this type of contradictory logic should be preferable to the litany of confusion and convoluted subjective inquiry to follow Directive 98/44.<sup>138</sup> There is one additional case to analyze in completing the picture of where we were and how we got to where we are.

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132. *Id.* at 550–53 (rejecting opponent’s arguments and upholding the patent).

133. *See id.* (stating that no critique of legislative intent is found, and, of course, no critique of exclusions exists, as no exclusions were present at this time in the EPC).

134. *See id.* at 552–53 (discussing the possibility of a population survey admissible as evidence or some form of barometer of public sentiment harbored in relation to a technology).

135. Relaxin, *supra* note 129, at 552–53.

136. *Id.*

137. *See supra* note 6 and accompanying text (describing the roadblock function of a patent).

138. *See discussion supra* Parts III.A, IV.A (outlining the confusion surrounding the Harvard Oncomouse case).

*E. Plant Genetic Systems: Pinnacle of Understanding?*

In the final case examined in this Comment, a number of gems of knowledge emerge, but their luster has gone unnoticed beyond the confines of this case.<sup>139</sup> First, and perhaps the most striking statement, given the context of this Comment, is the court's proclamation that ambiguities and flawed logic in the existing statute do not necessitate—or even permit—the court to remedy that which is to be created by the legislature.<sup>140</sup> In other words, if the legislature passes ineffective or illogical legislation, it is not up to the judiciary to rectify it or attempt to apply it in a manner which makes sense of the statute.<sup>141</sup> This pearl of wisdom could go a long way to making sense of the current situation but is an entire school of inquiry unto itself and beyond the scope of this paper.<sup>142</sup> Rather than stopping there, the court continues to point out just what it perceives as flaws in the then-current statutory law.<sup>143</sup> Indeed, the court recognized the subjectivity involved in the moral evaluation of technologies for which patent protection was sought.<sup>144</sup> The court even ventured as far as to state: (i) Europe never agreed upon a single definition of morality, nor *ordre public*, as recognized by the drafters of the EPC; and (ii) morality is defined solely within the culture of European society.<sup>145</sup> It is truly amazing that the court openly recognizes the fallacy of basing legislation upon a definition that neither exists in the legislation itself, and even worse, that does not exist at all.<sup>146</sup> As a parting gift, and

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139. Plant Genetic Systems/Glutamine Synthetase Inhibitors, 1995 E.P.O.R. 357 (EPO (Technical Bd. App.)) [hereinafter Plant Genetic Systems].

140. *Id.* at 373.

141. See Keenan D. Kmiec, *The Origin and Current Meanings of "Judicial Activism"*, 92 CAL. L. REV. 1441, 1447 (2004) (discussing what is commonly known as judicial activism and espousing the idea that members of the judiciary should never surpass their interpretive function).

142. See *supra* notes 140–41 and accompanying text.

143. See Crespi, *supra* note 38, at 570 (discussing the court's opinion of the inadequacies of Article 53(a) and thus why it could not be applied in accordance with opponent's arguments).

144. *Id.*

145. Plant Genetic Systems, *supra* note 139, at 366.

146. See Nenow, *supra* note 57, at 585 (pointing out that there simply is no definition for *ordre public* and certainly only amorphous concepts of morality).

considering the veritable bomb the court just dropped on the EPC, the court sets forth a standard and some principles by which moral objections to patent application may be evaluated.<sup>147</sup> The court declares that because patentable subject matter is to be construed broadly according to the historical documentation upon which the EPC drafters relied, one may presume the exceptions to patentability must be construed narrowly.<sup>148</sup> Furthermore, the court stated that “under Article 53(a) EPC, inventions the exploitation of which is *not* in conformity with the conventional standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.”<sup>149</sup> This test of course is not, by any stretch of the imagination, objective, but on a continuum of objectivity, it is far less subjective than the tests employed to decipher the reach of the Rule 23 per se exclusions.<sup>150</sup> In the Plant Genetic Systems case, the court holds consistently with other courts, both past and future, by rejecting survey polls as a barometer of public sentiment towards the subject matter for which patent protection is sought.<sup>151</sup> The court even goes so far as to reject polls, even assuming their accuracy and reliability, in reflecting widespread dissent or abhorrence concerning the subject matter because such dissent or abhorrence is not itself reflective of morality.<sup>152</sup> The Plant Genetic Systems case reflects the state of mind prior to the enactment of Directive 98/44 and the ensuing amendments to the EPC, and the time period in which Relaxin and its progeny was decided exhibited a better and more thorough understanding of the patent system.<sup>153</sup> The cases discussed above tell a dizzying story and that story will be pieced together in the following section.

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147. See Plant Genetic Systems, *supra* note 139, at 367 (discussing the breadth with which exceptions to patentability need be construed); Crespi, *supra* note 38, at 570 (describing the court’s test for morality in conjunction with Article 53(a)).

148. Plant Genetic Systems, *supra* note 139, at 367.

149. *Id.* at 366.

150. See EPC, *supra* note 4, rule 23(d) (listing EPC Rule 23(d) per se exclusions).

151. See Plant Genetic Systems, *supra* note 139, at 369 (labeling opinion polls as “[in]sufficient criterion for establishing that the said subject-matter is contrary to ‘ordre public’ or morality”).

152. *Id.*

153. See discussion *supra* Part IV.D.

*F. What Does It All Mean?*

It may appear daunting at first to dig through the lines of text and attempt to glean from them a coherent sense of where things stand, but the cases analyzed in the sections above fit quite nicely into one of two categories: (i) how things are,<sup>154</sup> or (ii) how things ought to be.<sup>155</sup>

*1. How Things Are*

As discussed at length above, a convoluted heap of speculation and subjective inquiry followed the amendments to the EPC enacting Directive 98/44.<sup>156</sup> *Oncomouse*, as one of the cases in that heap, teaches that two types of moral objection may now be made regarding Article 53(a).<sup>157</sup> Furthermore, *Oncomouse* sets forth two slightly different tests depending upon the type of Article 53(a) moral objection made.<sup>158</sup> If the subject matter fits into one of the Rule 23 per se exclusions, animal suffering or environmental risk will be weighed against likely substantial benefit depending upon the degree of correlation between the two.<sup>159</sup> However, if the objection is raised concerning subject matter not fitting into one of the Rule 23 per se exclusions, then factors other than the likely substantial benefit will be considered, including anything beneficial to mankind.<sup>160</sup> As discussed above, the *Edinburgh* and *WARF/Stem Cells* cases illustrate a serious caveat to the *Oncomouse* standards.<sup>161</sup> Namely, they provide two examples of the subjective inquiry the courts will embark upon to determine just how broad, or narrow, the Rule 23 exclusions will be construed by traveling beyond the subject matter claimed and either up or down stream from the subject matter in an effort to

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154. *See infra* Part IV.F.i.

155. *See infra* Part IV.F.ii.

156. *See* discussion *supra* Part IV.A–E.

157. *See* *Harvard Oncomouse 2005*, *supra* note 64, at 316, 321–22 (stating that the two types of objections are Rule 23d(d) objections and “real” Article 53(a) objections).

158. *See id.* at 316.

159. *See id.* (setting forth the standard for Rule 23(d)-type Article 53(a) objections).

160. *See id.* (setting forth the standard for real Article 53(a) objections).

161. *See* discussion *supra* Part IV.B–C.

avoid granting patent protection for anything that may, at any time-past or future, necessitate violation of a Rule 23 per se exclusion.<sup>162</sup> The case law analyzed above stands for more than a survey of recent cases; amassing and analyzing the cases reveals a disturbing trend towards greater subjectivity, thus exposing the proprietor of a patent that any one interest group deems particularly objectionable to a higher degree of risk in seeking patent protection.<sup>163</sup> Such a pessimistic assessment may lead one to pine for the days of yore—and possibly for good cause—despite the futility of such an exercise.

## 2. *How Things Ought To Be*

A category of case law analyzed in greater detail above espouses a more logical approach to disposing of moral inquiry in the context of the patent system.<sup>164</sup> Two illustrative cases discussed *supra* represent this relatively objective pursuit in assessing moral objections raised against patent applications.<sup>165</sup> During the time preceding the addition of Rule 23 to the EPC, the courts were all too ready to admit the fallacy of moral inquiry in the patent process and readily recognized the conspicuous omission of any guidelines existing in the EPC to launch such an inquiry.<sup>166</sup> While recognizing the shortcomings of the EPC with respect to guiding the courts in the moral inquiry raised by special interest groups, the court did attempt to set forth a test:

[U]nder Article 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally-

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162. *See id.*

163. *See* discussion *supra* Part IV.A–D.

164. *See* discussion *supra* Part IV.D–E.

165. *See id.* (discussing cases decided prior to Directive 98/44 and the logic involved behind those decisions); Relaxin, *supra* note 129; Plant Genetic Systems, *supra* note 139.

166. *See* discussion *supra* Part IV.A–E (referencing the courts in stating: (i) moral objections were rarely raised and even more rarely successful; (ii) no definition of morality or *ordre public* existed in the EPC; (iii) that morality was embedded in European culture; and (iv) evidence of widespread dissent regarding a patent application on moral grounds is inadmissible).

accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.<sup>167</sup>

Furthermore, the courts stated that exceptions to patentability must be construed narrowly<sup>168</sup> and should only prevent a patent from issuing for subject matter that would “universally be regarded as outrageous.”<sup>169</sup> This line of reasoning rejecting most, if not all, moral inquiry is a fair representation of how things ought to be.

### G. *Where Do We Go From Here?*

Several alternatives and improvements to the existing European Patent Office procedure are detailed below, but can we ever effectively turn back the clock? The answer to that question may be “no,” unless there is a logical alternative to stare decisis.<sup>170</sup> However, we can work to reverse the downward spiral towards subjectivity that is currently forming.<sup>171</sup> By the time the reversion is complete, the concept of moral inquiry may be too wellingrained in the EPC to be removed in totality, but objectivity will slowly weed out subjectivity because increased objectivity in the moral assessment process should yield fewer objections; as fewer will succeed, and thus fewer will be raised.<sup>172</sup> This hopeful thinking may be idealistic, but that characteristic is not logically sufficient grounds to abandon the pursuit towards objectivity.

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167. See *Harvard Oncomouse 2005*, *supra* note 64, at 322 (citing *Plant Genetic Systems*, *supra* note 139, at 366).

168. See *id.* at 317–18 (discussing construction of patent statute and exceptions thereto).

169. See *Relaxin*, *supra* note 129, at 549 (addressing the moral objection raised against an mRNA isolation procedure).

170. See *Kmeic*, *supra* note 141, at 1447 (discussing no logical alternative to stare decisis currently exists).

171. See *supra* Part IV.F.i (discussing the disturbing trend towards subjectivity in the recent cases decided under Rule 23 EPC).

172. This commonplace logic is akin to a negative feedback inhibition loop. See Stephen T. Abedon, Associate Professor, Ohio State University Mansfield, Supplemental Lecture (Feb. 6, 2007), <http://www.mansfield.ohio-state.edu/~sabedon/biol1045.htm> (describing what a negative feedback inhibition loop is).

## V. BEST LAID PLANS

As mentioned above, the intended purpose and proposed functions of the patent system in the European Community and beyond may shed light on the inherent logical flaw of permitting moral inquiry to enter the patent process.<sup>173</sup> First, Subsection A will present historical perspective regarding the purpose of a patent.<sup>174</sup> Subsection B will present evidence of the purpose and proposed function of a patent system as declared by the European Patent Office itself.<sup>175</sup> Subsection C will tie in the direction the patent system has taken over the last half century with why this divergence took place.<sup>176</sup>

A. *Why Patent in the First Place?*

Several historic commentators have promoted the patent system as means by which: (i) intellectual property may be protected;<sup>177</sup> (ii) incentive to invest in research is created;<sup>178</sup> (iii) information is publicly-shared, thus permitting—perhaps even encouraging—improvements upon existing technology.<sup>179</sup> Therefore, one may conclude from the historical perspectives on the purpose of a patent system that a patent is primarily made available to create an additional incentive to invest in research, thus promoting innovation.<sup>180</sup> Mysteriously absent from every discussion of the policy behind a patent system is any mention of exploiting the patent system to regulate the subject matter for

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173. See *supra* notes 6–7 and accompanying text.

174. See *infra* Part V.A.

175. See *infra* Part V.B.

176. See *infra* Part V.C.

177. See Nenow, *supra* note 57, at 580 (citing ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS 712 (Edwin Cannan ed., Random House 1937)).

178. See Skarstad, *supra* note 50, at 357 (citing David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 86–87 (1995)).

179. See Gitter, *supra* note 57, at 8 (discussing process by which patents stimulate biotechnical innovation).

180. See *id.*

which patent protection is sought.<sup>181</sup> The absence of mention of regulation creates a presumption that a regulatory function was never intended—nor foreseen.

*B. What Does the European Patent Office Think?*

With the many claims that patent systems create such great incentives and protections,<sup>182</sup> one may question what exactly a patent does. The European Patent Office, through its court of law, discussed just that topic when it stated rather clearly that a patent bestows upon its holder absolutely no direct right but instead only grants the patent holder a roadblock for a limited period of time.<sup>183</sup> With the same breath however, one must note that the European Patent Office is a combined effort of several European nations.<sup>184</sup> That characteristic of the European Patent Office undoubtedly led to the inclusion of the following provision in the European Patent Convention:

European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that state. . . .<sup>185</sup>

In an effort to promote harmonization of patent law across the European community, the European Patent Office was apparently forced to protect the integrity of each nation's respective patent laws.<sup>186</sup> In view of the analysis above, one may conclude that the European Patent Office and the member states of the European Community view the patent system as a

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181. See *supra* notes 177–78 (maintaining that the patent system is not used to regulate patentable subject matter beyond ensuring that such subject matter is novel, etc.).

182. See discussion *supra* Part V.B.

183. See Harvard Oncomouse 1991, *supra* note 42, at 526–27 (setting forth basic principles of patent law).

184. See Gitter, *supra* note 57, at 3–4 (discussing the complex attempt to harmonize European patent law).

185. See EPC, *supra* note 4, art. 2(2) (addressing the purpose of the European Patent Convention).

186. See *id.* (creating the presumption that inclusion of the provision cited was not accidental, but instead necessary for adoption of the convention by member states).

system of indirect—as opposed to direct—rights while working within the constraints of a multinational framework.<sup>187</sup>

*C. What Happened: A New Direction for the Patent System*

Perhaps the analysis in Section B sheds some light on the regulatory direction the European Patent Office has taken in an increasing fashion over the last decade symbolized by the enactment of Directive 98/44 in 1998 by the European Community thus imposing increased moral restraint upon the patent system over that reflected in the initial draft.<sup>188</sup> One may question why a system promoted as a means to protect intellectual property and stimulate innovation would be exploited to morally regulate research.<sup>189</sup> Perhaps the answer lies in the character of the European Patent Convention as a tool for harmonizing patent law across an entire community of nations.<sup>190</sup> Perhaps indirect means for morally regulating scientific research (e.g., a patent system) are easier to enact within a multinational framework than direct legislation.<sup>191</sup> Regardless of the motivation behind the EPC and enactment of Directive 98/44, it is undeniable that the European patent system is a significant departure from the fundamental principles of the patent system as set forth by Adam Smith<sup>192</sup> and others.<sup>193</sup>

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187. *See id.* (declaring that all members of the European Community will be bound by the EPC).

188. *See* Directive 98/44, *supra* note 34, art. 6 (setting forth that if commercial exploitation of an invention would “be contrary to *ordre public* or morality,” it would be unpatentable).

189. *See id.* (outlining types of unpatentable subject matter).

190. *See supra* notes 185–86 and accompanying text.

191. *See* Nenow, *supra* note 57, at 590–92 (describing the complex dance that passing legislation in the European Community entails).

192. *See supra* note 177 and accompanying text.

193. *Compare* Gitter, *supra* note 57, at 8 (describing the purposes of the patent system as protecting intellectual property and stimulating innovation), *and* Skarstad, *supra* note 50, at 378, 383–84 (describing the need to protect patent inventor’s profits to help stimulate innovation), *with* Directive 98/44, *supra* note 34, art. 6 (setting forth explicit moral regulations on patentable subject matter).

## VI. MINOTAURS, CHIMERAS, AND INGENIOUS STRATEGY

Given the purposes of the patent process discussed above, one must question the tactics employed by the European Patent Office in attempting to indirectly regulate the morality of scientific research through the patent system.<sup>194</sup> However, what if instead of employing legal scholarship to bring the debate into an open forum, a group of scholars attempted to bring the absurdity to light through practice?<sup>195</sup> Furthermore, what if an interest group attempted to utilize the morality provisions to affect what can only be described as a consequence the European Patent Office never intended?<sup>196</sup> The above questions form the thrust of this section starting with the Subsection A analysis of the Minotaur case about a mythical creature, the creation of which was the subject of a patent application in an attempt to expose the fundamental misuse of the patent system as a regulatory tool.<sup>197</sup> Subsection B will detail the ingenious strategy employed by a special interest group to inhibit the proliferation of a technology to which it is staunchly opposed.<sup>198</sup> Subsection C will analyze the commentary created by absurd cases and the changes in patent law for which the cases cry out.<sup>199</sup>

A. *50% Man, 50% Bull, 0% Patentable*

At first blush, the idea of patenting a Greek mythological character may seem absurd.<sup>200</sup> However, the two critics of biotechnology that filed the application to patent the creation of just such a creature intended to make a point in the context of the major strides in the field of biotechnology.<sup>201</sup> The U.S.

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194. See Gitter, *supra* note 57, at 9–13 (discussing the widespread debate regarding the EPC's morality provisions and regulation of patentable subject matter).

195. See *infra* Part VI.A–B.

196. See *id.*

197. See *infra* Part VI.A (discussing the Minotaur case).

198. See *infra* Part VI.B (discussing the tactics employed by anti-abortion groups).

199. See *infra* Part VI.A–C.

200. See John Travis, *Patenting the Minotaur?*, SCI. NEWS, May 9, 1998, at 299 (reporting the filing of a patent application claiming the mythical creature).

201. See *id.* (describing the act as a preemptive move to stimulate public policy debate regarding what the law should be regarding human animal chimeras).

Patent Office made a preemptive move of their own in issuing a media statement indicating they would not issue a patent for a minotaur.<sup>202</sup> While the U.S. Patent Office rejected the patent without a statutory basis,<sup>203</sup> Europe has several statutory bars against patenting nearly any form of life<sup>204</sup> despite declarations against a general ban on patenting living material.<sup>205</sup> The concept of patenting human animal chimeras is not nearly as far fetched as it may appear, as patents have already been issued for mammal-mammal chimeras.<sup>206</sup> The act of thumbing one's nose at the U.S. Patent Office was not accidental, and the meaning of such a critique of the lack of decisiveness with regards to patenting humans is discussed in greater detail below in Subsection C.

The issue of human chimeras is not exclusively a U.S. problem—despite the idea that Europe should be able to deal swiftly with any application for patent protection of such subject matter.<sup>207</sup> European Patent #380646 has raised more than one eyebrow at the European Patent Office.<sup>208</sup> Despite the fact the patent does not claim a process resulting in a human chimera,

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202. See Bratislav Stankovic, *Patenting the Minotaur*, 12 RICH. J.L. & TECH. 5, para. 5 (2005) (citing Donald J. Quigg, Statement by Assistant Secretary and Commissioner of Patents and Trademarks, *Patent and Trademark Office Notice: Animals-Patentability*, 1077 O.G. TM 24 (1987)).

203. See *id.* (noting the absence of a statutory bar to patenting a human animal chimera in the United States).

204. See *id.* (citing EPC prohibitions against patenting the human body in any stage of development, against patenting processes for modifying the germ line identity of human beings, and against patenting uses of embryos for specific applications as probable bars to patenting a minotaur).

205. See EPC, *supra* note 4, art. 53(b) (“[T]his provision does not apply to microbiological processes or the products thereof.”).

206. See Valerie J. Philips, *Half-Human Creatures, Plants & Indigenous Peoples: Musings On Ramifications Of Western Notions Of Intellectual Property and The Newman-Rifkin Attempt To Patent A Theoretical Half-Human Creature*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 383, 388 (2005) (discussing how close at hand the human animal chimera scene may be).

207. Bagley, *supra* note 38, at 501–03, 517–24.

208. See *PM: Biotech Firm Embroiled in Row* (ABC radio broadcast Nov. 21, 2000), available at <http://www.abc.net.au/pm/stories/s215002.htm> (discussing the debate over the patent claiming a process by which human and animal DNA is mixed together to immortalize embryonic stem cells in furtherance of Leukemia Inhibitory Factor research).

the mere fact that the technology could one day be utilized to achieve such ends caused Greenpeace to jockey their opposition to center stage at the European Patent Office.<sup>209</sup> At the risk of sounding redundant, failure to enact clear, concise and logical patent statutes combined with a concurrent absence of legislation regulating biotechnology can be attributed as the cause of the hotly contested debate taking place over the Minotaur.<sup>210</sup>

*B. Patenting on Abortion Technology: If You Can't Beat 'Em, Join 'Em*

What may first appear to be an oxymoron is in fact an ingenious strategy employed by activists who, after realizing that patents are merely roadblocks used to block others from exploiting protected technology, exploited patent law in furtherance of their own cause.<sup>211</sup> The European Patent Office obviously has much to learn from the anti-abortion activists who illustrated how well they understand the purpose of a patent: to block others.<sup>212</sup> Furthermore, the absurd result of the anti-abortion cases indicates that such a hotly contested concept cannot be appropriately addressed by indirect means, that is, through the patent system.

*C. What Good Can Come of the Minotaur?*

The case of the Minotaur and the cases of anti-abortion activists obtaining patents on abortion technology provide a poignant commentary on the state of morality in patent law.<sup>213</sup> That commentary establishes that: (i) the mass populace recognizes that biotechnological innovation has severe

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209. *See id.* (describing Greenpeace's opposition to the patent as more of an argument with the EPO over what Greenpeace previously perceived to be a nod and wink from the EPO regarding prohibiting patents on life).

210. *See supra* note 201 and accompanying text (discussing causes and motivations behind the filing of the Minotaur application).

211. *See* John R. Thomas, *Liberty and Property in the Patent Law*, 39 HOUS. L. REV. 569, 581–83 (2005) (discussing cases in which anti-abortion groups hold patents to abortion technology in order to preempt their use in abortion procedures).

212. *Id.*

213. *See supra* Part VI.A–B.

implications for society; (ii) such innovation should not occur unbridled; (iii) regulation should result from direct legislation as opposed to indirect methods;<sup>214</sup> and (iv) should regulation not be properly enacted, the patent system is open to unintended influence and consequence.<sup>215</sup>

#### VII. IF YOU CAN'T SAY ANYTHING NICE, DON'T SAY ANYTHING AT ALL

The old adage rings true, even in legal scholarship. However, in this forum, the saying requires the following revision: criticism is cheap unless it is constructive. This section of the Comment will recap areas of the EPC requiring improved functionality. Some suggestions will be offered that may cure those dysfunctional aspects of the EPC.

Subsection A will provide a restatement of where the EPC used to be.<sup>216</sup> Subsection B will recap the current state of the EPC regarding moral inquiry.<sup>217</sup> Finally, Subsection C will set forth perspectives on one direction the EPC could take.<sup>218</sup>

##### A. *The Good Old Days: Prior to Enactment of Directive 98/44*

As discussed in greater detail above, the European Patent Office, prior to enactment of Directive 98/44, took a relatively consistent stance on issues of moral inquiry in the patent process: rarely raised and even more rarely successful.<sup>219</sup> The European Patent Office furthermore admitted that no true definition for morality or *ordre public* existed in Europe.<sup>220</sup> The court at one point properly understood its own role in the patent process: to apply patent law as legislated by the legislature and not to attempt to rectify logical inadequacies by reading

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214. See Margo A. Bagely, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 533 (2003) (setting forth several reasons why Congress is best suited to regulate biotechnological research as opposed to the U.S. Patent Office).

215. See discussion *supra* Part VI.A–B.

216. See *infra* Part VII.A.

217. See *infra* Part VII.B.

218. See *infra* Part VII.C.

219. See discussion *supra* Parts IV.B, IV.D.

220. See *supra* note 147 and accompanying text.

language into the law and practically inventing legislative intent behind the law.<sup>221</sup> Only two basic principles governed morality prior to Directive 98/44: (i) exceptions to patentability were to be narrowly construed;<sup>222</sup> and (ii) subject matter for which a patent was sought should not “universally be regarded as outrageous.”<sup>223</sup> As analyzed above, several advisory opinions issued from the European parliament attempted to shape how the European Community would deal with the rising issue of biotechnological innovation and patent protection.<sup>224</sup> It is debatable whether the resulting Directive accurately reflected what the drafters of the opinions intended, but the result is a confounded mess of subjective inquiry.<sup>225</sup>

*B. Post-Directive 98/44 Enactment: Cloud of Confusion*

According to the case law analyzed above, it appears a new test arises from every case considered on moral grounds by the European Patent Office.<sup>226</sup> Beyond the multiplicity of tests for what appear to be similar moral objections, the court proclaimed that multiple objections are now possible based upon the same EPC provision due to the enactment of Directive 98/44 and the subsequent addition of Rule 23(d) EPC.<sup>227</sup> The broadening of exceptions from patentability flies in the very face of the court’s earlier statement of the principle that subject matter to be excluded from patentability is to be interpreted narrowly.<sup>228</sup> One may argue that, by providing examples of subject matter against morality, Directive 98/44 attempted to narrow the exceptions to patentable subject matter.<sup>229</sup> If that argument could be made with a straight face, the retort would point to the convoluted messes referred to as the WARF/Stem Cells case and the

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221. See *supra* notes 140–41 and accompanying text.

222. See *supra* note 162 and accompanying text.

223. See *supra* note 169 and accompanying text.

224. See *supra* Part I.A–B.

225. See discussion *supra* Part IV.A–E.

226. See discussion *supra* Part IV.A–C.

227. See *supra* notes 159–60 and accompanying text.

228. See *Harvard Oncomouse 2005*, *supra* note 64, at 317–18 (discussing Rule 23(d) and relevant case law).

229. Directive 98/44, *supra* note 34, art. 6.

Edinburgh Patent case.<sup>230</sup> The dispute was simply moved from defining subject matter that runs counter to morality to how far the subject matter examples provided can be stretched.<sup>231</sup>

Where does that leave us regarding moral objections to biotechnology patents in the European Patent Office? The tests provided in the Oncomouse case do resemble a roadmap, but their extremely subjective nature result in what may be an unacceptably high degree of risk.<sup>232</sup> The repeated statement by the European Patent Office indicating that each case will be reviewed in and of itself<sup>233</sup> is a mixed blessing at best.<sup>234</sup> So, as the current landscape lies before us, what is to be done?

### C. *Calling for a Return to Normalcy*

One might argue that the days of yore appear simpler because everything was simpler then. That is not entirely true.<sup>235</sup> Biotechnological innovation and genetic research are by no means recent developments.<sup>236</sup> The shift in ideology from objectivity to a more subjective approach to patent prosecution in the European community occurred in the late 1990's.<sup>237</sup> Subject matter for which patent protection is sought does grow increasingly complex over time, but as the Minotaur and

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230. See discussion *supra* Part IV.B–C.

231. Compare *Relaxin*, *supra* note 129, at 553 (approving a human gene patent pre-Directive 98/44 because it did not offend “widely accepted moral standards of behaviour,” nor could the court find a “clear consensus . . . that patenting human genes . . . is immoral.”), with *Crespi*, *supra* note 38, at 573–75 (discussing the Enlarged Board of Appeals options in the WARF/Stem Cell case concerning broad or narrow interpretations of Rule 23(d)).

232. See *supra* notes 96–100 and accompanying text.

233. See *Harvard Oncomouse 2005*, *supra* note 64, at 316–23 (discussing the balancing test used to determine the morality of an invention on a case-by-case basis).

234. See *id.* (showing that the mere process of a case-by-case analysis is subjective; logic dictates that the level of predictability decreases as subjectivity increases).

235. Compare *Harvard Oncomouse 2005*, *supra* note 64, at 279 (discussing transgenic eukaryotic animals), with *Plant Genetic Systems*, *supra* note 139, at 360–61 (discussing development of plants resistant to herbicide), and *Relaxin*, *supra* note 129, at 547–48 (discussing human H2-relaxin).

236. See generally *A History of the Human Genome Project*, 291 *SCI.* 1195 (2001) (describing the history of the Human Genome Project dating back to 1953 until complete genomes were mapped in 2001).

237. See discussion *supra* Part I.B.

anti-abortion activist examples above illustrate, society will not sit by and wait for the courts to continue their evolution toward increasingly subjective and less predictable case-by-case analyses and tests.<sup>238</sup> The most objective and efficient patent policy would be similar to that of the U.S. regime: patentable subject matter includes “anything under the sun that is made by man.”<sup>239</sup> Legislators are clearly in the best position to draft and shape patent law,<sup>240</sup> as they are better representatives of the populace than is the judiciary.<sup>241</sup> However, what must be accomplished (if reliance is placed solely upon legislation) is the drafting of clear and logically founded legislation. The European Parliament<sup>242</sup> and the United States<sup>243</sup> have both failed in this regard. Clearly, a forum must be established in which a public debate may take place on the future of the patent system, forms of biotechnology upon which the European Patent Office wishes to place their seal of approval in the form of patent protection, and the methods by which morality is to either be maintained or removed from the patent system. Europe’s system is far more complex than that of the United States, as the European system functions to serve a group of diverse nations with equally diverse moral codes.<sup>244</sup> As discussed above, the attempt to harmonize the European Community conservative moral agenda through exploitation of the patent system may be the root cause of the current Pandora’s Box of subjective inquiry and the hotly

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238. See *supra* Part VI.

239. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing S. Rep. No. 1979 (1952); H.R. Rep. No. 1923 (1952)) (interpreting congressional documents reflecting the intent of Congress in drafting current U.S. patent law).

240. Bagley, *supra* note 38, at 533.

241. See *id.* (citing Dwight R. Lee, *Politics, Power, Ideology, and the Power of Public Choice*, 74 VA. L. REV. 191, 196 (1988); Daniel A. Farber & Philip P. Frickey, *The Jurisprudence of Public Choice*, 65 TEX. L. REV. 873, 926 (1987)).

242. Skarstad, *supra* note 50, at 383.

243. See *Stankovic*, *supra* note 202, para. 8–10 (reporting the U.S. Patent Office relied rather vaguely upon unspecified language of the U.S. Constitution in denying a patent claim for a human-animal chimera, or Minotaur).

244. See *supra* notes 50, 57 and accompanying text (discussing the complexity facing legislators in the European Community).

contested debate surrounding patents on biotechnological innovation.<sup>245</sup>

One type of proposal worth noting may provide a solution to a good deal of the current chaotic state of moral inquiry in the European Patent Office regarding cell source.<sup>246</sup> Claudio Germinario's concept of focusing on a "prohibited step" permits the court to employ an inquiry into patentability with a fixed scope, thus obtaining a certain amount of objectivity.<sup>247</sup> While Germinario's concept may be limited in the circumstances to which it applies, if the legislature actively seeks to return to a state of objectivity, the test is proof that society can begin to work towards objectivity.<sup>248</sup>

### VIII. CONCLUSION

Whether or not biotechnological innovation such as human cloning research should be regulated in a moral sense is not an easy question to answer, and the answer will be different for different societies. However, what must be recognized is that there are proper and improper methods to regulate research, and indirect methods such as denying patent protection for subject matter deemed objectionable is ineffective and the equivalent to opening Pandora's Box. This paper stands for the proposition that regulations, such as EPC Article 53(a) and Rule 23(d) governing the morality of subject matter for which patent protection is sought, be retired from their regulatory function, and instead, the ideals behind them be enacted through direct

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245. See discussion *supra* Parts I.B–C, IV.

246. See Crespi, *supra* note 38, at 572 (citing Claudio Germinario, *The Value of Life*, 163 *PATENT WORLD* 16–18 (2004)).

247. See *id.* at 572–73 (explaining that the "prohibited step" should be excluded when considering the morality of a patented invention if the prohibited material is available from many other sources).

248. See *id.* (espousing the consideration of an objective viewpoint in the case of patenting human embryonic cells).

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legislative means. Patents are roadblocks, and roadblocks are extremely inefficient regulatory mechanisms, specifically when attempting to regulate such amorphous concepts as morality.

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