

2020

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### Recommended Citation

Shannon M. Patrick, *Can We Learn to Incentivize Morality?: A Discussion of Biotechnology on an International Level*, 34 Emory Int'l L. Rev. 859 (2020).

Available at: <https://scholarlycommons.law.emory.edu/eilr/vol34/iss3/4>

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# CAN WE LEARN TO INCENTIVIZE MORALITY?: A DISCUSSION OF BIOTECHNOLOGY ON AN INTERNATIONAL LEVEL

## INTRODUCTION

Four letters: A, T, C, and G. Those four letters represent the nucleic acids that build humans.<sup>1</sup> From the time we are conceived until the day that we die, those four letters control our life. We have altered fruits, and we have changed animals. What if *you* are next?

The technology is here, and it is happening. The question of whether we should alter the human genome is no longer something we can ignore because we lack the capabilities. Germline cells are the cells in the body that reproduce.<sup>2</sup> So, any changes to those cells are passed on to future generations.<sup>3</sup> CRISPR-Cas9 is a tool used to edit the genome in a “faster, cheaper, and more accurate” way than ever before.<sup>4</sup> It allows for the genetic manipulation of DNA. As a result of CRISPR-Cas9, the international community has had strong debates over the manipulation of germline cells.<sup>5</sup> Would the world tolerate genetically modified babies?

In 2018, the world welcomed Lulu and Nana into the world.<sup>6</sup> A scientist, He Jiankui, claims to have used the CRISPR technology to edit these two Chinese girls’ genomes to decrease their risk of contracting HIV.<sup>7</sup> The claim prompted serious uproar within the scientific community.<sup>8</sup> Jennifer Doudna, one of the biochemists who helped to develop the CRISPR technology, stated that “[t]his work is a break from the cautious and transparent approach of the global scientific community’s application of CRISPR-Cas9 for human germline

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<sup>1</sup> See generally Kristin Hendrickson, *Why Humans Need Nucleic Acids*, LIVESTRONG, <https://www.livestrong.com/article/383411-why-humans-need-nucleic-acids/> (last visited Feb. 11, 2019).

<sup>2</sup> *What is CRISPR-Cas9?*, YOUR GENOME (last updated Dec. 19, 2016), <https://www.yourgenome.org/facts/what-is-crispr-cas9>.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.* Previous genetic mutations were done through chemicals, radiation, or gene targeting. *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> He Jiankui, *About Lulu and Nana: Twin Girls Born Healthy After Gene Surgery As Single-Cell Embryos*, YOUTUBE (Nov. 25, 2018), [https://www.youtube.com/watch?time\\_continue=1&v=aezxaOn0efe](https://www.youtube.com/watch?time_continue=1&v=aezxaOn0efe).

<sup>7</sup> Ron Stein, *Chinese Scientist Says He’s First to Create Genetically Modified Babies Using CRISPR*, NPR (Nov. 26, 2018, 5:02 AM), <https://www.npr.org/sections/health-shots/2018/11/26/670752865/chinese-scientist-says-hes-first-to-genetically-edit-babies>.

<sup>8</sup> *Id.*

editing.”<sup>9</sup> But, is there a problem if it is just a small change to help prevent a deadly disease?

Editing the human genome in a way that can be passed down to subsequent generations has been considered off-limits until now.<sup>10</sup> There are two main rationales behind this historical restriction. First, even the smallest mistake in germline editing could have catastrophic effects on future generations as the change is passed down.<sup>11</sup> Second, even if we are able to ensure no mistakes are made, once we begin playing this game it “open[s] the door to ‘designer babies.’”<sup>12</sup> The consequences of using CRISPR-Cas9 in this manner raise concerns that germline editing is “an extremely premature and questionable experiment in creating genetically modified children” and that “this amounts to unethical and reckless experimentation on human beings, and a grave abuse of human rights.”<sup>13</sup> So we are concerned, and it is happening already. Is there anything we can do about it?

Let us take it one step further. What if the scientists who edit embryos want to protect their creation and process with a patent? A patent is a legal protection for a product of human ingenuity.<sup>14</sup> A patent owner gains a property right to an invention from the government in exchange for certain disclosures.<sup>15</sup> The patentee secures the right to exclude others from “making, selling, offering to sell, using, or importing the invention” during the patent term.<sup>16</sup> If we allow patents on edited embryos and the human genome we give someone a property right over part of a human being.<sup>17</sup>

This controversy is just one of many that infiltrates the discussion of biotechnology, but those who create and invest in biotechnology want rights that will be protected.<sup>18</sup> Biotechnology involves “techniques for using the properties

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<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* (quoting Jeffery Kahn and Marcy Darnovsky).

<sup>14</sup> JANICE M. MUELLER, *PATENT LAW* 8 (Wolters Kluwer 5<sup>th</sup> ed. 2016).

<sup>15</sup> Jon Schuchardt, *Basic Patent Law: II. Patents as Exclusive Rights*, DILWORTH IP (Feb. 18, 2013), <https://www.dilworthip.com/basic-patent-law-ii-patents-as-exclusive-rights/>.

<sup>16</sup> 35 U.S.C. § 154 (2018).

<sup>17</sup> *See generally* DAVID KOEPSSELL, *WHO OWNS YOU?: THE CORPORATE GOLD-RUSH TO PATENT YOUR GENES 1* (Michael Boylan ed., 2009) (“Now, thanks to creative interpretations and applications of patent laws, parts of living things can be owned. Patents have been issued, in surprisingly large numbers, on the essential building blocks of multiple life-forms, including humans—including you.”).

<sup>18</sup> *Biotechnology Patents at the EPO*, EUROPEAN PATENT OFFICE, <https://www.epo.org/news-issues/issues/biotechnology-patents.html> (last visited Sept. 22, 2018) (biotech patents represent roughly 4% of the applications received by the European Patent Office).

of living things to make products or services.”<sup>19</sup> The field and the desire for patent protection are not new phenomena; they go back more than two hundred years.<sup>20</sup> As the biotechnology industry flourished, society craved the benefits of the technology without always anticipating the prospective consequences.<sup>21</sup>

Patent protections are not transnational because patents are territorial and only valid in the jurisdiction(s) of grant or registration specified by national law.<sup>22</sup> In formulating a way to cope with any moral concerns, each jurisdiction opted for an individualized approach.<sup>23</sup> Thus, when a scientist goes to the local patent office and wants to patent the methods of editing embryos and the edited embryos themselves, the grant of a patent will depend in part on where the scientist files the patent application.

No global patent exists today.<sup>24</sup> Despite that truth, moral concerns are not constrained by the jurisdictional borders of patent laws.<sup>25</sup> Globalization facilitated the swift spread of technology internationally.<sup>26</sup> In responding to the technological dissemination, one country may decide that moral concerns outweigh the benefits of patenting a particular biotechnology, but that unilateral action is insufficient to phase out the fears on an international level because of the limited reach of patent rights. The patent right serves as a reward for genuine innovation and an incentive to continue innovating.<sup>27</sup> Unless the actors across the international community decide that giving such a reward is not worth the risk of facing the morality concerns then, an inventor can simply choose to patent

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<sup>19</sup> Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT’L L.J. 47, 47 n.1 (2001).

<sup>20</sup> *Biotechnology Patents at the EPO*, *supra* note 18.

<sup>21</sup> See generally Sang Yup Lee, *Biotechnology: What It Is and How It’s About to Change Our Lives*, WORLD ECONOMIC FORUM (Dec. 20, 2016), <https://www.weforum.org/agenda/2016/12/what-is-biotechnology-how-will-it-change-our-lives/>.

<sup>22</sup> GUIDES TO INFORMATION SOURCES, INFORMATION SOURCES IN PATENTS 59 (C.P. Auger ed., Bowker Saur 1992). While many countries have their own national patent offices, there are regional patent offices such as the European Patent Office and the African Regional Intellectual Property Organization. See generally ARIPO, <http://www.aripo.org> (last visited Feb. 4, 2019); EPO, <https://www.epo.org/index.html> (last visited Feb. 4, 2019).

<sup>23</sup> Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 494 (2003) (discussing the diversity of approaches that can result from “localized cultural norms and political structures”) [hereinafter *Patent First, Ask Questions Later*].

<sup>24</sup> GUIDES TO INFORMATION SOURCES, *supra* note 22, at 59.

<sup>25</sup> Murphy, *supra* note 19, at 47 (2001) (“genetically modified organisms could be developed and released into the global environment”).

<sup>26</sup> Aqib Aslam et al., *Globalization Helps Spread Knowledge and Technology Across Borders*, IMFBLOG (Apr. 9, 2018), <https://blogs.imf.org/2018/04/09/globalization-helps-spread-knowledge-and-technology-across-borders/>.

<sup>27</sup> Margo A. Bagley, *Stem Cells, Cloning and Patents: What’s Morality Got to Do with It*, 39 NEW ENG. L. REV. 501, 504–05 (2005) (describing how patent rights are “designed to promote the progress of science and useful arts by rewarding innovation with temporary exclusivity”) [hereinafter *Stem Cells, Cloning and Patents*].

their invention in a jurisdiction without heightened morality considerations. The worldwide development of biotechnology fosters the need to revisit how morality and patent laws can work together if society determines that an invention is not worth the risk.

This Comment argues that the time has come to incorporate morality concerns into patent deliberations so that society has a mechanism should it decide a technology should not be pursued. First, this Comment will examine some of the moral concerns behind biotechnology and why these concerns are important on an international level. Second, it will discuss how the United States and Europe have approached patenting biotechnology through their national patent systems, with a focus on cases that relate to humans. Finally, this Comment will propose a solution that involves a new international recommendation that will affect how national and regional patent office's approach morality both individually and as part of the international community.

## I. A DISCUSSION OF MORALITY CONCERNS

The discovery of DNA by Watson and Crick in 1953 laid the groundwork for an impressive new field of technology—biotechnology.<sup>28</sup> In the 1970s, when biotechnology really came into its own, the general public feared that the classic story of genetically modified humans in *Brave New World* would become a reality.<sup>29</sup> Because these new technologies exploit biological processes, the field faces tough moral concerns.<sup>30</sup> These moral issues include scientists concerns about human safety, clashes with religion, and animal cruelty.<sup>31</sup>

The moral issues surrounding biotechnology are particularly important in the face of patent protection.<sup>32</sup> It is important to understand that not all biotechnology carries moral unease.<sup>33</sup> In fact, the field has the potential to improve the life and health of everyone on the planet,<sup>34</sup> but the fact remains that a patent on the human genome would give someone a property right in a part of

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<sup>28</sup> *The Francis Crick Papers: The Discovery of the Double Helix, 1951–1953*, NIH, <https://profiles.nlm.nih.gov/spotlight/sc/feature/doublehelix> (last visited Apr. 14, 2020).

<sup>29</sup> William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 195 (1990) (citing *Researcher Warns of Brave New World of Genetics*, K. C. TIMES, Mar. 31, 1978, at 1) [hereinafter *Patenting Medical Technology*].

<sup>30</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 494.

<sup>31</sup> *Patenting Medical Technology*, *supra* note 29, at 294–95.

<sup>32</sup> See Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002) (UK).

<sup>33</sup> *Patenting Medical Technology*, *supra* note 29, at 295.

<sup>34</sup> *Id.*

a human being.<sup>35</sup> Despite being less concerning to some people, a patent on any biological process gives a person ownership over some lifeform. Society needs a venue for their opinions about the future of this type of innovation to be recognized.

Scientific abilities have far surpassed the ability to use biological processes with technology.<sup>36</sup> Therefore, the question for the society is not “can we?” The question is “should we?” And if so, where do we draw the line? Finally, who makes these decisions? These questions are not limited in the way that patent rights are limited, but rather, affect a number of different countries and even have the potential to affect all living beings.<sup>37</sup> It is within these questions that the moral objections to biotechnology lie.

In its most basic form, morality is defined as “the rightness, or wrongness of an action.”<sup>38</sup> We each individually determine which actions we consider to be right or wrong. The subjective nature of morality creates issues for legal determinations because morality can depend on the person, the place, or the time an issue is considered. Humans are constantly changing over time, leading to society’s viewpoint changing.<sup>39</sup> People can de-sensitize themselves to information or shift their viewpoints based on inherent selfishness.<sup>40</sup> For these reasons, specific legislation creates its own issues because it confines a moral determination to an ever-changing landscape of convictions.<sup>41</sup>

Biotech patents tend to generate one of two main moral objections “(1) objections to a patent based on concerns about the morality of practicing the patent’s underlying subject matter . . . , [and] (2) objections to a patent based on concerns regarding the morality of allowing anyone to limit the practice of the patent’s underlying subject matter.”<sup>42</sup> Both objections cover different concerns about the biotech industry, and both are equally important in an overall discussion of morality and biotechnology.

Morally controversial objections that are directly concerned with inventions underlying subject matter include objections to human cloning or animal

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<sup>35</sup> See generally KOEPEL, *supra* note 17, at 1.

<sup>36</sup> See generally Edward Teller, *Science and Morality*, 280 SCIENCE 1200, 1200–01 (1998).

<sup>37</sup> See generally *Patent First, Ask Questions Later*, *supra* note 23, at 494.

<sup>38</sup> *Id.* at 475 (citing WEBSTER’S NEW WORLD DICTIONARY AND THESAURUS 402 (MacMillan 1996)).

<sup>39</sup> *Stem Cells, Cloning and Patents*, *supra* note 27, at 502.

<sup>40</sup> *Id.*

<sup>41</sup> See *id.* (pointing out that specific legislation also creates problems because of the growth of technology).

<sup>42</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 475, 495 (“Biotechnology is an area in which many morally questionable inventions are generated”).

chimeras.<sup>43</sup> These types of inventions create a host of concerns among societies because they involve changing the fundamental nature of a living creature to create something new, or copied. The objections towards a patent's underlying subject matter can stem from a variety of different sources or concerns.

Usually, people consider the concerns around human DNA first because that directly affects them. For human DNA specifically, concerns work around the fact that each nucleotide sequence is responsible for "our individual traits."<sup>44</sup> Beyond that, DNA is directly responsible for building what we see when we look in the mirror. Patenting human DNA has already been prohibited in a variety of countries.<sup>45</sup> However, at least in the United States, an inventor can still obtain a patent over cDNA.<sup>46</sup> Although the court found a difference between cDNA and DNA, from a scientific perspective both forms of DNA occur in the body and are necessary for development.<sup>47</sup>

People struggle with biotech inventions that either use or change human DNA because in the simplest of explanations, DNA builds humans—you, me, and everyone around us.<sup>48</sup> One Pew Research Center study shows that even as of 2018, 27% of adults believe that changing a baby's gene to treat a serious disease or condition takes technology too far.<sup>49</sup> If the technology needs to be tested on human embryos the numbers drastically increase, with 65% finding that this use takes medical technology too far.<sup>50</sup> As is typical when discussing morality, these statistics change based on religiosity, gender, and familiarity.<sup>51</sup> Importantly, almost half of the adults interviewed believed that gene editing would lead to an increase in inequality, science being used in morally

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<sup>43</sup> See *id.* at 490 (defining chimera as "creatures made, in theory, by blending human cells with those of various animals such as mice, chimpanzees, pigs, or baboons").

<sup>44</sup> KOEPSSELL, *supra* note 17, at 22, 24.

<sup>45</sup> See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

<sup>46</sup> *Id.* The segments of DNA that code for RNA are called "exons." The non-coding regions are called "introns." The difference between cDNA and DNA is that cDNA "contains only the exons that occur in DNA, omitting the intervening introns." *Id.*

<sup>47</sup> See Megan Krench, *New Supreme Court Decision Rules That cDNA Is Patentable What It Means for Research and Genetic Testing*, SCI. AM. (Jul. 9, 2013), <https://blogs.scientificamerican.com/guest-blog/new-supreme-court-decision-rules-that-cdna-is-patentable-what-it-means-for-research-and-genetic-testing/>.

<sup>48</sup> KOEPSSELL, *supra* note 17, at 24.

<sup>49</sup> Cary Funk & Meg Hefferon, *Public Views of Gene Editing for Babies Depend on How It Would Be Used*, PEW RESEARCH CENTER (July 26, 2018), <http://www.pewinternet.org/2018/07/26/public-views-of-gene-editing-for-babies-depend-on-how-it-would-be-used/>.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* Those who tend to be more accepting of gene editing for babies tend to be men, the less religious, and the more familiar with gene editing. *Id.*

unacceptable ways, and technology being utilized before science reaches a full understanding of gene editing's effects.<sup>52</sup>

The prevalence of religious beliefs regarding the creation of life and conception contribute to some moral patenting concerns.<sup>53</sup> Creation of life constitutes a central component to several religious constituencies.<sup>54</sup> To fully address such moral concerns, it might be necessary to ask more existential questions about what people want science to achieve and if there should be any limits to innovation.<sup>55</sup> Unfortunately, even those questions are predicated on more complex philosophical questions. The idea that these questions about life, science, and its limits are answerable is a fallacy, and yet some decisions would need to be made in order to effect any change. To respond adequately to these inquiries would require a decision maker. If that authority is given to a legislative body then the international community would be required to pick which legislative body's decision to abide by.<sup>56</sup> Even if an agreement could be made regarding who would field these questions, there would never be agreement as to the response. Morality is not static and rightness or wrongness is a belief not a fact.<sup>57</sup> It would be erroneous to presume society as a whole could ever come to a definitive conclusion on a belief.<sup>58</sup> There is no one right answer. Yet, if people determined that they want to prevent controversial biotechnology from disseminating across the globe there has to be a general consensus on at least some of the most prominent and vital concerns facing us today.

The second moral objection to patents deals with limiting rights of use by the general public due to patent rights.<sup>59</sup> A patent on a medical procedure brings this type of moral objection to light because the right to exclude means that

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<sup>52</sup> *Id.*

<sup>53</sup> Drew Endy & Laurie Zoloth, *Should We Synthesize a Human Genome*, COSMOS (May 12, 2016), <https://cosmosmagazine.com/society/should-we-synthesize-a-human-genome>.

<sup>54</sup> *Id.*; see also David E. Anderson, *Religious Leaders Question Genetic Engineering*, UPI (Nov. 13, 1987), <https://www.upi.com/Archives/1987/11/13/Religious-leaders-question-genetic-engineering/3966563778000/> (“[r]everence for all life created by God may be eroded by subtle economic pressures to view animal life as if it were an industrial product invented and manufactured by humans”).

<sup>55</sup> See generally *Regulating and Patenting Transgenic Animals: Hearings Before the Subcomm. On Courts, Civil Liberties and the Administration of Justice of the House Comm. On the Judiciary*, 100th Cong. 396, 405 (1987) (statement of Rabbi Michael Berenbaum, Scholar-in-Residence, Religious Action Center of Reform Judaism) (noting the importance of asking “what are the limits of scientific knowledge and what are its frontiers. Should there be constraints on scientific experimentation . . .”).

<sup>56</sup> See generally *Stem Cells, Cloning and Patents*, *supra* note 27, at 507.

<sup>57</sup> See *id.* at 502.

<sup>58</sup> See generally *Patent First, Ask Questions Later*, *supra* note 23, at 536 (discussing how there is a “lack of consensus on when life begins for human embryos and fetuses used for research purposes” and this supports having Congress making a decision as to its patent eligibility).

<sup>59</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 495.

doctors cannot use the procedure to help their patients.<sup>60</sup> Ultimately, the patient would suffer.

It is human nature to value one's own health. Everybody wants to survive and to do this we have to invest in our own health. If patents on medical procedures take away a person's ability to be treated for certain diseases, then arguably patents take away the option to obtain the optimal level of health.<sup>61</sup> At least in the United States, there is no constitutional right to health. Even without its status as a fundamental right, the right to health is in some measure aspirational.<sup>62</sup> There are glaring issues of right and wrong when we develop new technology or processes but cannot effectively use them to "improve life conditions and health" for all.<sup>63</sup>

Biotech investors who invest their money behind these medical procedures want patent protection.<sup>64</sup> The biggest industries that have come out of the last sixty years, including the biotech industry, grew with the help of patents.<sup>65</sup> The Biotechnology Innovation Organization, the leading industry trade organization representing biotechnology, refers to patents as the "lifeblood of the biotechnology industry."<sup>66</sup> Some even suggest that "investments in the biotech industry are based entirely on patents."<sup>67</sup> If moral considerations play such a big role that patents are denied, society could end up suffering as well.<sup>68</sup> Without

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<sup>60</sup> *Id.* at 499.

<sup>61</sup> See generally Beata Gocyk-Farber, Note, *Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics*, 18 CARDOZO L. REV. 1527, 1544–46 (1997). Beyond a patent holder's ability to refuse to license their invention, a patient's restricted access to a medical procedure can be due to a spike in price due to the monopoly given to the patent holder which can ultimately leave the patient without access. *Id.* at 1544–45.

<sup>62</sup> *Human Rights and Health*, WORLD HEALTH ORGANIZATION (Dec. 29, 2017), <https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health> ("[t]he right to health is one of a set of internationally agreed human rights standards").

<sup>63</sup> Eduardo Missoni & Guglielmo Foffani, *Nanotechnologies and Challenges for Global Health*, 3 STUD. ETHICS L. & TECH. 1, 1 (2009).

<sup>64</sup> See Ronald Rosenber, *Call to Ban Gene Patents Stirs Industry Fears*, BOSTON GLOBE, May 19, 1995, at 39.

<sup>65</sup> Marshall Phelps, Response, *Do Patents Really Promote Innovation? A Response to the Economist*, N.Y. TIMES (Sept. 16, 2015, 2:42 PM), <https://www.forbes.com/sites/marshallphelps/2015/09/16/do-patents-really-promote-innovation-a-response-to-the-economist/#7dc67f941921>.

<sup>66</sup> *Area of Focus*, BIOTECHNOLOGY INNOVATION ORG., <https://www.bio.org/bio-areas-focus> (last visited Oct. 27, 2018).

<sup>67</sup> Matthew Herper, *New Patent Law Would Trash Disease Cures*, FORBES (Mar. 24, 2015, 11:02 AM), <https://www.forbes.com/sites/matthewherper/2015/03/24/new-patent-law-would-trash-disease-cures/#389a5cd24d5f>.

<sup>68</sup> See also *Patent First, Ask Questions Later*, *supra* note 23, at 536 (patent legislation could "[reduce] discoveries and innovations in certain biotech areas of inquiry, a consequence which cannot be dismissed lightly").

investments in the biotech industry, society closes itself off to improving health and life for all.

Not surprisingly, many doctors strongly object to patents on medical treatments that inhibit their ability to treat their patients.<sup>69</sup> Doctors serve people for a living. The medical profession is built on philanthropic values and altruistic motives.<sup>70</sup> Bringing economics and the right to exclude others into the medical field commercializes a profession founded in the interest of greater good for the public.<sup>71</sup> Historically, for the medical community, a better alternative to commercializing medicine was to “set free a pack of ravening wolves in a community” because commercialization would lead to “physicians and pharmacists . . . [degenerating] into quacks and charlatans . . . [who] take shameful advantage of the community for gain.”<sup>72</sup> The American Medical Association (AMA) has even taken a stand in the discussion. The AMA condemns the patenting of medical procedures because of the ethical duty to share medical information.<sup>73</sup>

That such views may be held by doctors and other medical professionals is not all that unexpected due to their field of choice but also due to the status of health as a fundamental right.<sup>74</sup> The International Covenant on Economic, Social and Cultural Rights is a United Nations treaty that protects people’s right to “the enjoyment of the highest attainable standard of physical and mental health.”<sup>75</sup> One hundred sixty-nine countries have ratified this treaty and protect health as a fundamental human right including almost all of the developed nations, with one important exception.<sup>76</sup> The United States signed the treaty in 1977 but has failed to ratify it.<sup>77</sup> Because the morality concerns behind biotechnology affect the

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<sup>69</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 500; Gocyk-Farber, *supra* note 61, at 1534 (describing how patent law has disfavored patents on “medical advancements” due in large part to physician dissatisfaction).

<sup>70</sup> *Patenting Medical Technology*, *supra* note 29, at 263.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 265 n.9 (citing Stewart, *Is it Ethical for Medical Men to Patent Medical Inventions?*, 29 J.A.M.A. 583, 586 (1897)).

<sup>73</sup> See *Patent First, Ask Questions Later*, *supra* note 23, at 500 (noting that “[t]he patenting of medical procedures poses substantial risks to the effective practice of medicine . . . [and the AMA] believes that it is unethical for physicians to seek, secure, or enforce patents on medical procedures.”) (citing AMA Council on Ethical and Judicial Affairs, *Ethical Issues in the Patenting of Medical Procedures*, reprinted in 53 FOOD & DRUG L.J. 341, 351 (1988)); Gocyk-Farber, *supra* note 61, at 1549.

<sup>74</sup> International Covenant on Economic, Social and Cultural Rights, art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.

<sup>75</sup> *Id.*

<sup>76</sup> *Status of Ratification*, UNITED NATIONS HUMAN RIGHTS, <http://indicators.ohchr.org> (last visited Feb. 5, 2019).

<sup>77</sup> *Id.*

global community, it is important to understand that the United States is an outlier in that it regards health as an aspirational goal rather than a fundamental human right. In a way, patent rights on medical procedures hinder that fundamental right by removing a viable treatment option, unless the treatment can be licensed.<sup>78</sup> To give away rights that limit our ability to treat diseases through a certain procedure hinders one of the core purposes of medicine.

Some patent laws recognize these moral considerations when medical procedures are involved. In 1997, the U.S. Congress adopted a statute protecting doctors from a patentee's right to exclude by prohibiting a patentee from enforcing his or her rights against a doctor.<sup>79</sup> The United States is not alone in its efforts. The European Patent Office cannot grant patents on methods of treatment or medical procedures.<sup>80</sup> Article 52(4) of the European Patent Convention prohibits the patenting of "methods for treatment."<sup>81</sup> Notably, the article does not prohibit instruments used during these methods.<sup>82</sup> Unfortunately, these mechanisms may not be sufficient to overcome the moral concerns relating to these types of patents.

Ultimately, the moral considerations may override other policy considerations, specifically that of the incentive to innovate, when dealing with medical methods. Without patents on medical methods, society runs the risk of delaying leaps in innovation that can save people's lives.<sup>83</sup> Some people may believe that doctors may simply innovate to maintain their Hippocratic Oath, which obligates them to practice their craft "for the benefit of the sick."<sup>84</sup> Even if that it is true that the medical methods business is less commercially competitive and the urgency for patent protection is not as high, denying patents on the subject matter has the grave potential of stalling vital progress.<sup>85</sup> It is a fine balance that society should grapple with.

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<sup>78</sup> Gocyk-Farber, *supra* note 61, at 1544–45.

<sup>79</sup> 35 U.S.C. § 287(c) (2000).

<sup>80</sup> Convention on the Grant of European Patents art. 52(4), Oct. 5, 1973, 13 I.L.M. 270 (as effected in 2001) [hereinafter EPC].

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> Weldon E. Havins, *Immunizing the Medical Practitioner Process Infringer: Greasing the Squeaky Wheel, Good Public Policy, or What?*, 77 U. DET. MERCY L. REV. 51, 61 (1999) ("The argument advances the view that, absent medical process patent protection, investors would lack an economic incentive to fund costly clinical research.") (citing George J. Annas, *Surrogate Embryo Transfer: The Perils of Patenting*, 14 HASTINGS CTR. REP. (June 1984), at 25–26.).

<sup>84</sup> Gocyk-Farber, *supra* note 61, at 1544 (citing TOM L. BEAUCHAMP & LEROY WALTERS, CONTEMPORARY ISSUES IN BIOETHICS 138 (1978)).

<sup>85</sup> *Id.* at 1542–43; Havins, *supra* note 83, at 61.

Similar to the incentive to innovate, morality considerations also have their downsides. If patent law, on an international level, is to include a discussion of an invention's morality, then by definition someone must make that determination. For some people, giving that power to an individual, or even a group of individuals, creates a bigger problem than the morality concerns themselves.<sup>86</sup> When fallible people start to create requirements, society risks "improvident rules (if not outright abuse of the privilege)."<sup>87</sup>

Beyond the concerns surrounding who makes the rules, affording morality too much weight may hinder the good that can come from patenting controversial biotechnology.<sup>88</sup> The logical argument does not stray far from that of the morality concerns themselves. If the society chooses not to patent morally controversial biotechnology then investments in that technology may decrease in an already high-risk industry.<sup>89</sup> With less money from investments, researchers and developers may not achieve the full promises that biotechnology can bring.<sup>90</sup> Without a doubt, the promises of biotechnology are tremendous. The technology could revolutionize areas such as "climate change, an aging society, food security, energy security[,] and infectious diseases, to name just a few."<sup>91</sup> Not only does the industry have the capabilities to solve some of the world's biggest problems, but it can do so rapidly such that by 2030 societies' use of biotechnology may parallel the use of the internet.<sup>92</sup>

Understanding how morality and biotechnology interact is only one piece of the puzzle. Before any proposal could succeed on an international level, different perspectives of incorporating morality considerations into patent law must be understood.

## II. TWO DIFFERING APPROACHES PATENT OFFICES TAKE TO PATENTING MORALLY CONTROVERSIAL TECHNOLOGIES

The international patent environment is a collection of national patent systems.<sup>93</sup> Even at regional patent offices, the members endow the regional

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<sup>86</sup> See Kevin E. Noonan, *Foreword* to DAVID KOEPSSELL, *WHO OWNS YOU?: SCIENCE, INNOVATION, AND THE GENE PATENT WARS*, at xiv (Wiley Blackwell 2015).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at xv.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> Lee, *supra* note 21.

<sup>92</sup> *Id.*

<sup>93</sup> Ben McEniery, *The Time is Nigh: A Proposal for an International Patent System*, 16 CHI.-KENT J. INTEL. PROP. 167, 168 (2016).

office with the ability to create rules and grant patents.<sup>94</sup> Minimum standards of intellectual property protection are set by the Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”).<sup>95</sup> However, the TRIPS Agreement does not require harmonization, and countries may develop distinctive rules to further specific policy objectives such as incentivizing innovation or protecting morality.<sup>96</sup>

The TRIPS Agreement does have a morality provision in Article 27 that specifically allows countries to exclude patents “which [are] necessary to protect *ordre public* or morality.”<sup>97</sup> Countries are given the choice to implement statutory language that would make morally controversial inventions unpatentable. The following subsections will explore the mechanisms used by the United States and Europe to determine the patentability of morally controversial inventions.

### A. *The United States’ Approach*

Congress regulates patent laws in the United States. Its authority to govern this area of the law comes directly from the Constitution which provides that Congress shall have the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>98</sup> Congress created the United States Patent and Trademark Office (USPTO) to exercise this power.<sup>99</sup>

The USPTO reviews a patent application on an invention, and if the patent application meets the statutory requirements then a patent will be granted.<sup>100</sup> The application process acts like a bargain. Patentees want rewards for their

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<sup>94</sup> See also MARGO A. BAGLEY, RUTH L. OKEDJI & JAY A. ERSTLING, *INTERNATIONAL PATENT LAW & POLICY* 124 (West 2013) [hereinafter *INTERNATIONAL PATENT LAW & POLICY*].

<sup>95</sup> 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*].

<sup>96</sup> Margo A. Bagley, *The New Invention Creation Activity Boundary in Patent Law*, 51 WM. & MARY L. REV. 577, 579 n.7 (2009) [hereinafter *New Invention Creation*]; Dominique Guellec, *Patents as an Incentive to Innovate*, in *THE ECONOMICS OF THE EUROPEAN PATENT SYSTEM: IP POLICY FOR INNOVATION AND COMPETITION*, 46, 55 (2007) [hereinafter *Patents as an Incentive to Innovate*]. “Encouraging innovation” is a problem that governments are constantly trying to solve. *Id.* at 55.

<sup>97</sup> TRIPS Agreement, *supra* note 95, 1869 U.N.T.S. 299 at art. 27(2).

<sup>98</sup> U.S. CONST. art. I, § 8, cl. 8.; see generally *Patent First, Ask Questions Later*, *supra* note 23, at 483 (discussing how the provision used to create the US patent system comes from “useful arts” because the term “science” did not mean what it means today).

<sup>99</sup> *About Us*, USPTO, <https://www.uspto.gov/about-us> (last visited Feb. 2, 2019).

<sup>100</sup> See generally 35 U.S.C. § 101 (2012).

innovation—the patent protection.<sup>101</sup> The USPTO gives the reward in exchange for certain disclosures including the enablement of the invention.<sup>102</sup> The application must enable those skilled in the art to make and use the invention without undue experimentation.<sup>103</sup> Enablement allows the USPTO to facilitate information dissemination. The patentee adds to the collective knowledge of society and for that they receive patent protection.<sup>104</sup>

### 1. *The Utility Requirement*

In order for a patent to be granted on an invention, the examiner at the USPTO must find that the patent meets the standards set forth in § 101, including that the invention is “new and useful.”<sup>105</sup> However, the statutory requirement of utility, which is now an easily satisfied condition, was a tool that courts would use to evaluate an invention’s morality.<sup>106</sup> A patent applicant did not need to prove an invention’s moral utility, but the patent could be invalidated in litigation by arguing that an invention lacked moral utility.<sup>107</sup>

Moral utility is a judicially created doctrine that heightened the standard of an invention’s usefulness.<sup>108</sup> The standard originated from Justice Story’s jury instructions during an 1817 case, *Lowell v. Lewis*: “[a]ll that the law requires is that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society.” The word “useful,” therefore, was “incorporated into the act in contradistinction to mischievous or immoral.”<sup>109</sup> Courts used the doctrine to reject several controversial inventions.<sup>110</sup>

The scope of the moral utility doctrine whittled away as defining societies shifting views on morality became more difficult.<sup>111</sup> Eventually, the courts

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<sup>101</sup> *Stem Cells, Cloning and Patents*, *supra* note 27, at 504–05 (describing how patent rights are “designed to promote the progress of science and useful arts by rewarding innovation with temporary exclusivity”).

<sup>102</sup> 35 U.S.C. § 112(a) (2012).

<sup>103</sup> *See id.*; Gene Quinn, *Patent Drafting: Understanding the Enablement Requirement*, IP WATCH DOG (Oct. 28, 2017), <https://www.ipwatchdog.com/2017/10/28/patentability-drafting-enablement-requirement/id=89721/> (discussing enablement and undue experimentation).

<sup>104</sup> Dan L Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VIRGINIA L. REV. 1575, 1576 (2003).

<sup>105</sup> 35 U.S.C. § 101.

<sup>106</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 489.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568).

<sup>110</sup> *See generally Patent First, Ask Questions Later*, *supra* note 23, at 489 (discussing how the court rejected inventions relating to “gambling machines and fraudulent articles”).

<sup>111</sup> *Id.*

determined that Congress, and not the judiciary or the USPTO, should impose any desired moral utility requirements.<sup>112</sup>

Even today, the moral utility doctrine remains dormant. Litigants who are fighting for a patent's validity could attempt to resurrect the argument. Even if the argument was successful, which is unlikely given the court's current reading of § 101, the most recent adaptation of the moral utility requirement, that "an invention have at least one moral, legal purpose," would be easily satisfied by many biotech inventions that can improve health and cure diseases.<sup>113</sup>

Beyond litigants, the USPTO could attempt to revive the moral utility doctrine as a component of its test for utility. In 1998, an application filed on a human-animal chimera, a scientifically created animal with part human DNA and part animal DNA, provoked the USPTO into threatening to revive the moral utility doctrine.<sup>114</sup> The patent office issued a media advisory insinuating that an invention on a human-animal chimera would fail to meet the moral utility doctrine.<sup>115</sup> The USPTO walked back its statement, admitting in its own examination guidelines that it cannot reject a patent application based on morality concerns and that "when the statutory patentability requirements are met, there is no basis to deny patent applications . . . ."<sup>116</sup> Any future attempts by the USPTO to reject patent applications on moral grounds would likely be overturned by the courts given the Federal Circuit's clear language in *Juicy Whip v. Orange Bang* that there is "no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public."<sup>117</sup> The decision wiped out the moral utility doctrine unless and "[u]ntil such time as Congress" amends the utility requirements.<sup>118</sup>

Without a change to patent law by Congress, the moral utility doctrine will likely remain sidelined. The utility requirement is not the sole § 101 prerequisite

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<sup>112</sup> See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999); *Patent First, Ask Questions Later*, *supra* note 23, at 489.

<sup>113</sup> See *Juicy Whip*, 185 F.3d at 1367; *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903) (finding that the true inquiry is to "establish[] not merely that the device has been used for pernicious purposes, but that it is incapable of serving any beneficial end?").

<sup>114</sup> See U.S. Patent Application No. 10,308,135 (filed Dec. 3, 2002); *Patent First, Ask Questions Later*, *supra* note 23, at 490.

<sup>115</sup> Media Advisory, U.S. Patent & Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998), available at <https://www.uspto.gov/about-us/news-updates/facts-patenting-life-forms-having-relationship-humans>.

<sup>116</sup> Examination Guidelines for the Utility Requirement, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

<sup>117</sup> *Juicy Whip*, 185 F.3d at 1366–68.

<sup>118</sup> *Juicy Whip*, 185 F.3d at 1367; *Patent First, Ask Questions Later*, *supra* note 23, at 492–93.

that has been used to argue against patenting morally controversial technology. Section 101 details the subject matter eligible for patent protection and is the other basis used for arguing that morally controversial biotech should not be patent eligible under United States patent law.<sup>119</sup>

## 2. Patent Eligible Subject Matter

For an inventor to get a patent on an invention, it must fall within one of the categories articulated in § 101 of the Patent Act.<sup>120</sup> Section 101 allows for a patent on “any new and useful process, machine, manufacture, or composition of matter.”<sup>121</sup> According to the Supreme Court, these four categories are broad and inclusive, and were intended by Congress to include “anything under the sun made by man.”<sup>122</sup> The Supreme Court has created three non-textual exclusions to § 101: laws of nature, physical phenomena/products of nature, and abstract ideas.<sup>123</sup>

In *Diamond v. Chakrabarty*, the Court addressed the question of whether a living bacterium was patent eligible subject matter or an unpatentable product of nature.<sup>124</sup> Chakrabarty was a microbiologist who had engineered a bacteria with the ability to break down multiple components of oil, something no naturally occurring bacterium could do.<sup>125</sup> First, the court laid out the limits to subject matter eligibility under § 101.<sup>126</sup> The analysis considered these limits against Congress’ statutory intent to “include anything under the sun that is made by man” as eligible subject matter.<sup>127</sup> Ultimately, the bacteria qualified as eligible subject matter because Chakrabarty’s discovery was “not nature’s handiwork, but his own.”<sup>128</sup>

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<sup>119</sup> See 35 U.S.C. § 101.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (noting that the terms “manufacture” and “composition of matter” are expansive terms); see also *Patent First, Ask Questions Later*, *supra* note 23, at 484 (2003) (“[A]n inventor need not specify which category her invention is properly classified in as long as it can be encompassed within one of the four.”).

<sup>123</sup> *Chakrabarty*, 447 U.S. at 309.

<sup>124</sup> *Id.* at 303.

<sup>125</sup> *Id.* at 305.

<sup>126</sup> *Id.* at 309. Examples of these limits would include the law of gravity,  $E=mc^2$ , or a natural element like oxygen.

<sup>127</sup> *Id.*

<sup>128</sup> *Id.* at 310.

Although the Court decided the bacteria was not a natural phenomenon, it still faced grave concerns about patenting a living organism.<sup>129</sup> The Court found it was “without competence” to tackle these concerns and that these issues of morality are best left to the political branches.<sup>130</sup> The arguments provided some value though as “they remind us that, at times, human ingenuity seems unable to control the forces it creates.”<sup>131</sup>

The *Chakrabarty* decision has had profound effects on U.S. patent law. Importantly, the decision to allow a patent on the bacteria opened the door to the biotech industry in the United States.<sup>132</sup> After the decision, the broad availability of the patent protection to biotech subject matter helped the industry grow at a large scale and with incredible efficiency.<sup>133</sup>

The USPTO provided a further boost to biotechnology-based innovation when it granted the “world’s first” patent claiming a higher-level life form on the transgenic Harvard oncomouse.<sup>134</sup> The invention involved using human DNA to modify a mouse, making it more susceptible to developing cancer.<sup>135</sup> The patent claims notably excluded any reference to humans, likely to avoid moral and legal concerns.<sup>136</sup>

The oncomouse patent elevated two key issues: should patents be granted for higher-order animals and how will the moral repercussions be addressed?<sup>137</sup> While the USPTO granted the patent on the oncomouse without challenge, patent protection was not extended to the oncomouse in all jurisdictions.<sup>138</sup> During patent examination in Canada, the examiner rejected the inventor’s

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<sup>129</sup> *Id.* at 316.

<sup>130</sup> *Id.* at 317.

<sup>131</sup> *Chakrabarty*, 447 U.S. at 316; see also Maureen L. Condit & Samuel B. Condit, *The Appropriate Limits of Science in the Formation of Public Policy*, 17 NOTRE DAME J.L. ETHICS & PUB. POL’Y 157, 167-168 (2003) (“At their cores, scientists are motivated by curiosity . . . . There are no necessary limits to scientific curiosity—not even the limits of decency . . .”).

<sup>132</sup> See Dominique Guellec, *Patent Design*, THE ECONOMICS OF THE EUROPEAN PATENT SYSTEM: IP POLICY FOR INNOVATION AND COMPETITION, 114, 123 (2007) [hereinafter *Patent Design*]; Sarah Elizabeth Hagan, *DNA Real Estate: The Myriad Genetics Case and the Implications of Granting Patent Eligibility to Complimentary DNA*, 35 N. ILL. U.L. REV. 205, 210 (2014).

<sup>133</sup> *Patent Design*, *supra* note 132, at 123.

<sup>134</sup> U.S. Patent No. 4,736,866 (filed Apr. 12, 1988); see Keith Schneider, *Harvard Gets Mouse Patent, A World First*, N.Y. TIMES, Apr. 13, 1988; but see *Bioethics and Patent Law: The Case of the Oncomouse*, WIPO MAG. (June 2006), [http://www.wipo.int/wipo\\_magazine/en/2006/03/article\\_0006.html](http://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html) (the Supreme Court of Canada rejected the patent claim to the mouse body but allowed the claim “on the process for obtaining the oncomouse”).

<sup>135</sup> Hagan, *supra* note 132, at 212.

<sup>136</sup> *Bioethics and Patent Law: The Case of the Oncomouse*, *supra* note 134.

<sup>137</sup> *Id.*

<sup>138</sup> See INT’L PAT. L. AND POL’Y, *supra* note 94, at 233.

claims over the product as being “outside the scope of the definition of ‘invention . . .’ of the *Patent Act*” but allowed the claims covering the process of producing the oncomouse.<sup>139</sup> The applicants appealed the decision and the case made its way up to the Supreme Court of Canada.<sup>140</sup>

The subject matter eligibility requirement outlined in Canada’s Patent Act is nearly a carbon copy of § 101. It defines an invention as “any new and useful art, process, machine, manufacture or composition of matter . . .”<sup>141</sup> Instead of adopting the Supreme Court’s decision in *Chakrabarty*, the Canadian Supreme Court deviated from the logic that the broad scope of the statute included “anything under the sun that is made by man.”<sup>142</sup> In fact, the Court found Parliament’s intention to be clearly defined by the definition of invention as including certain subject matter, but also, “to exclude other subject matter as being outside the confines of the Act.”<sup>143</sup>

The Court ultimately concluded that the oncomouse could not be categorized as a “machine” or as a “composition of matter.”<sup>144</sup> If a patent were to be granted on a higher-life form, it would require “the clear and unequivocal direction of Parliament.”<sup>145</sup> Ultimately, both the Supreme Court of the United States and the Canadian Court have reached the conclusion that a deviation from their verdicts regarding the eligible subject matter would require an act by the legislature. But, the two courts reached antithetic conclusions about what qualifies under the national patent laws. The Canadian decision serves as a decisive alternative the United States Court could have considered.

The United States Supreme Court stood firm in its convictions that § 101 created a broad definition of eligible subject matter. In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International*, the court reemphasized that “anything under the sun that is made by man” is eligible subject matter when it upheld the patent eligibility of plants—a higher life form.<sup>146</sup>

Finally, the question of whether the human genome could be patented made its way to the Supreme Court in *Association for Molecular Pathology v. Myriad*

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<sup>139</sup> *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 (Can.).

<sup>140</sup> *Id.*

<sup>141</sup> Patent Act, R.S.C., c P-4 §2 (1985) (Can.).

<sup>142</sup> *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 (Can.).

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 134 (2001).

*Genetics, Inc.*<sup>147</sup> The Court looked at claims on the BRCA1 and BRCA2 genes, which if mutated could lead to a substantially increased chance of developing breast cancer.<sup>148</sup> The patents were littered with moral implications that the court could have addressed, but following its decision in *Chakrabarty*, the Court left the morality concerns out and simply focused on the judicially created exceptions to uphold the patent on the cDNA.<sup>149</sup>

Between the lack of a moral utility doctrine and the court's broad interpretations of patentable subject matter, moral considerations go virtually unregulated under United States patent law.<sup>150</sup> Even under the new patent statute, the America Invents Act (AIA), the only substantive limitation involves the patenting of humans and excludes patents from issuing "on a claim directed to or encompassing a human organism."<sup>151</sup> While the U.S.' approach is a weak attempt to consider a patent's moral implications, Europe's approach takes a far more sympathetic pursuit.

### *B. Europe's Approach*

Europe approaches patenting morally controversial biotechnology in a strikingly different way than the United States. In order to understand how morality considerations affect a patentee's application in a European country, you must first understand how to obtain a patent in a European country. This Comment will discuss two routes an inventor can take to obtain a patent in a European country.

First, almost all European countries have their own individual Patent Office.<sup>152</sup> The national patents provide for rights within the country the application was filed but not across Europe as a whole.<sup>153</sup> Alternatively, a patent applicant can choose to file their application at the regional patent office.<sup>154</sup>

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<sup>147</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 583 (2013).

<sup>148</sup> *Id.* at 583. At a very basic level, a mutation is a change in the genetic sequence. Even a small change in one nucleotide can have a drastic effect on the individual cell or the entire body, *id.*, but mutations are actually extremely common in human cells, and most mutations are harmless.

<sup>149</sup> *Id.* at 595–96.

<sup>150</sup> See also Hagan, *supra* note 132, at 220; *Patent First, Ask Questions Later*, *supra* note 23, at 490 (2003).

<sup>151</sup> Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284 (2011) [hereinafter *America Invents Act*].

<sup>152</sup> Geertrui Van Overwalle, *Bend or Break? The Patent System in Crisis: Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches*, 1 U.C. IRVINE L. REV. 435, 440 (2011).

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

The European Patent Office (EPO) is a regional office that can grant patents to European countries.<sup>155</sup> The members of the EU united with other states including “Albania, Croatia, the former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland, and Turkey” to form the European Patent Organisation in the hopes of creating a uniform patent system for Europe.<sup>156</sup> The Organisation was established by the Convention on the Grant of European Patents (EPC).<sup>157</sup> The EPC stipulates the requirements for obtaining a patent from the EPO.<sup>158</sup> The EPO carries out the Organisation’s mission to facilitate international cooperation and grants patents in alignment with the EPC by using one review process to validate a patent for all member states.<sup>159</sup>

A single patent application grants a patentee the opportunity to procure patent protection in any, or all, of the contracting members of the EPC.<sup>160</sup> During the patent procurement process, a patentee must designate countries in which they desire to obtain patent protection.<sup>161</sup> Each designation will require a payment to the EPO.<sup>162</sup> Once a patent is granted and the decision is published by the EPO, the patentee will receive a “‘bundle’ of individual national patents,” which must be validated in each state to ensure that the patent is enforceable.<sup>163</sup>

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<sup>155</sup> See, e.g., European Patent Office, *The European Patent Office*, <https://www.epo.org/index.html>. The EPO represents the European Patent Organisation. Niels Stevnsborg & Bruno van Pottelsberghe, *Patenting Procedures and Filing Strategies at the EPO*, ECON. OF THE EUR. PAT. SYS.: IP POL’Y FOR INNOVATION AND COMPETITION 155, 155 (2007).

<sup>156</sup> See generally *Legal Foundations*, EUR. PAT. OFF., <https://www.epo.org/about-us/foundation.html> (last visited Oct. 25, 2018). There are currently thirty-eight member states, two extension states with agreements still in force, and four validation agreements with non-member states that are in force. The current member states are: Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Former Yugoslav Republic of Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, and Turkey. The extension states are Bosnia and Herzegovina and Montenegro. The validation states are: Morocco, Republic of Moldova, Tunisia, and Cambodia. *Id.*

<sup>157</sup> EPC, *supra* note 80; *Patent First, Ask Questions Later*, *supra* note 23, at 518. Although much of patent law is national, the EPO is an example of a regional patent office. *Patent First, Ask Questions Later*, *supra* note 23, at 517.

<sup>158</sup> *The Patenting Process*, EUR. PAT. OFF., <https://www.epo.org/learning-events/materials/inventors-handbook/protection/patents.html> (last visited Feb. 3, 2018).

<sup>159</sup> See generally *Legal Foundations*, *supra* note 156; STEVNSBORG & POTTELSBERGHE, *supra* note 155, at 155-56.

<sup>160</sup> Stevnsborg & Pottelsberghe, *supra* note 155, at 156.

<sup>161</sup> *The Patenting Process*, *supra* note 158.

<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

After validation, each designated member state treats the patent as a national patent.<sup>164</sup>

Morality comes into play at the EPO through the subject matter requirements of the EPC as described in Article 52 and Article 53.<sup>165</sup> Article 52 broadly delineates the grant of a patent “for any invention[] which [is] susceptible of industrial application, which are new and which involve an inventive step.”<sup>166</sup> Later provisions of the EPC limit the breadth of Article 52.<sup>167</sup> Unlike the United States, the EPC contains a statutory morality bar, in Article 53, that prohibits the granting of a patent on “[i]nventions the publication or exploitation of which would be contrary to *ordre public* or morality.”<sup>168</sup> If a patent claim contravenes the morality provision then the claim can be rejected.<sup>169</sup>

If a patent has already been granted, a third party can still oppose the patent based on Article 53.<sup>170</sup> The concerned party can bring an opposition to the EPO “if they believe that [the patent] should not have been granted.”<sup>171</sup> Article 53 gives standing to anyone, at any time, within nine months from the time the patent issues, to oppose the grant of a patent, and hands to the public the power to help shape the law surrounding biotechnology.<sup>172</sup> People have the individual choice of bringing an opposition against a patent on the grounds of morality. The opposition proceedings illustrate the EPO’s sensitivity to public concerns. Granting this power to the public means that legislatures and scientists are not the sole morality check on innovation.<sup>173</sup> Rather, policy matters.<sup>174</sup> Public opinion matters.

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<sup>164</sup> See EPC, *supra* note 80, arts. 1–3.

<sup>165</sup> *Id.* arts. 52–53.

<sup>166</sup> See *id.* art. 52.

<sup>167</sup> Jasmine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT’L L. REV. 223, 232 (2002).

<sup>168</sup> EPC, *supra* note 80, art. 53. The morality Article also excludes “plant or animal varieties or essentially biological processes for the production of plants or animals” and “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body.” *Id.*

<sup>169</sup> *Id.* art. 99.

<sup>170</sup> *Id.*

<sup>171</sup> *The Patenting Process*, *supra* note 158.

<sup>172</sup> EPC, *supra* note 80, at art. 99; see Chambers, *supra* note 167, at 233.

<sup>173</sup> See Chambers, *supra* note 167, at 233 (discussing how “[i]n contrast, this type of standing is not available to U.S. citizens following the decision in Animal Legal Defense Fund”).

<sup>174</sup> See SHOBITA PARTHASARATHY, WIEBE E. BIJKER, W. BERNARD CARLSON & TREVOR PINCH, BUILDING GENETIC MEDICINE: BREAST CANCER, TECHNOLOGY, AND THE COMPARATIVE POLITICS OF HEALTH CARE 180 (Wiebe E. Bijker, W. Bernard Carlson & Trevor Pinch eds., 2007) (“... the European Patent Office has an opposition mechanism . . . . The mechanism and potential grounds for opposition suggest that public health and policy concerns are important to determinations of patentability.”).

The globalization of biotechnology means that many companies have a desire to file for a patent in multiple countries.<sup>175</sup> For this reason, many of the same inventions have been examined by both the USPTO and the EPO. One example of this was the patent on the *Chakrabarty* bacteria, the granting of which was reviewed by the Supreme Court of the United States, but not challenged in Europe.<sup>176</sup>

Another example is the Harvard oncomouse. The EPO examined the transgenic oncomouse patent in its first attempt at struggling with the morality clause.<sup>177</sup> In its first go-round, the EPO rejected the patent claiming the oncomouse.<sup>178</sup> On review, the Technical Board of Appeals noted that the oncomouse case was “precisely . . . this kind” of invention that invokes Article 53(a) considerations because of the manipulation of the genetic material of mammals.<sup>179</sup> The Board remanded the case for further consideration under Article 53(a).<sup>180</sup>

The Examining Division set out to reconsider the patent in light of the Article 53(a) objections. The EPO used a balancing test to examine the morality exception.<sup>181</sup> Ultimately, human disease, environmental concerns, and animal cruelty took the front seat in terms of state interests.<sup>182</sup> Harvard created the oncomouse to easily develop cancer with the hopes of furthering cancer research.<sup>183</sup> The potential to further this research caused the first interest in human disease to fall on the side of patentability.<sup>184</sup> With the mice remaining in the control of the laboratories using them for research, the likelihood of mass genetic dissemination proved low, and thus, the environmental concerns were not significant enough to deny patentability.<sup>185</sup> Although the EPO recognized that the mice would suffer from the inflicted cancer, the quantity of mice forced to suffer was lower due to the genetic change.<sup>186</sup> The decreased number of

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<sup>175</sup> See Murphy, *supra* note 19, at 47.

<sup>176</sup> PHILIP W. GRUBB, PATENTS IN CHEMISTRY AND BIOTECHNOLOGY 152 (Oxford University Press 1986).

<sup>177</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 519.

<sup>178</sup> T19/90, Harvard/Onco-mouse, [1990] E.P.O.R. 501 (Technical Board of Appeal 3.3.2 Oct. 3, 1990).

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Bioethics and Patent Law: The Case of the Oncomouse*, *supra* note 134. See *Patent First, Ask Questions Later*, *supra* note 23, at 520 (citing *Harvard/Onco-mouse*, 1990 E.P.O.R. 501, 527) (“the question of morality has to be examined and possible detrimental effects and risks have to be weighed and balanced against the merits and advantages aimed at.”).

<sup>182</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 520.

<sup>183</sup> *Bioethics and Patent Law: The Case of the Oncomouse*, *supra* note 134.

<sup>184</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 520.

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

suffering mice weakened the animal cruelty factor to such an extent that it was insufficient to counter-balance the potentially substantial medical benefits.<sup>187</sup> The EPO inevitably allowed the oncomouse patent to be granted finding that the invention “can generally be regarded as beneficial to mankind.”<sup>188</sup>

The granting of the oncomouse patent did not end the morality discussion, but it did give the EPO a mechanism to approach morality claims under Article 53(a).<sup>189</sup> Unfortunately, the EPO did not strictly keep to the test.<sup>190</sup> The court turned to another test, the “unacceptability test,” in *Greenpeace v. Plant Genetic Systems*.<sup>191</sup> Again, the test did not last, as the court administered a third test, this time it was the “public abhorrence test” in *Howard Florey/Relaxin v. Fraktion der Grünen im Europäischen Parlament*.<sup>192</sup>

The *Howard Florey/Relaxin* issue revolved around a patent on a sequence of DNA, coding for the hormone Relaxin, isolated from a pregnant woman through recombinant techniques.<sup>193</sup> The EPO considered a variety of arguments to the patent including the morality bar.<sup>194</sup> The difficulty of this argument rested on patentability being an inquiry of law not ethics, which was “beyond the proper remit of European patent tribunals.”<sup>195</sup> Turning to the “overwhelming consensus” of the state’s party to the EPC, the nature of the patent did not rise to the level of “abhorrent.”<sup>196</sup> The standard of abhorrence severely decreased the burden to overcome a morality challenge for an inventor seeking a patent.<sup>197</sup> Beyond creating a new test, the EPO rejected the balancing test used when examining the Harvard oncomouse.<sup>198</sup>

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<sup>187</sup> *Id.*; see *Bioethics and Patent Law: The Case of the Oncomouse*, *supra* note 130.

<sup>188</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 520–21.

<sup>189</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 521. Another transgenic mouse application was contested at the EPO in the Upjohn case, but the Upjohn mouse was created to lose its hair for the purposes of solving baldness. The balancing mechanism was used and the patent was denied because the invention “was contrary to morality and therefore not patentable.” *Bioethics and Patent Law: The Case of the Oncomouse*, *supra* note 134.

<sup>190</sup> See *Patent First, Ask Questions Later*, *supra* note 23, at 522.

<sup>191</sup> *Id.* at 522–23 (citing T356/93, *Greenpeace v. Plant Genetic Sys.*, [1995] E.P.O.R. 357, 373, (Tech. Bd. App. 1995)) (describing the unacceptability test as “[tying] patentability to the ‘public acceptability’ of the general categories of patentable subject matter”).

<sup>192</sup> *Id.* at 523–24 (citing T0272/95 *Howard Florey/Relaxin*, Application No. 83307553.4, [1995] E.P.O.R. 541).

<sup>193</sup> Justine Pila, *Intellectual Property Rights and Detached Human Body Parts*, 40 J. OF MEDICAL ETHICS 27, 28 (2014).

<sup>194</sup> T0272/95 *Howard Florey/Relaxin*, Application No. 83307553.4, [1995] E.P.O.R. 541.

<sup>195</sup> *Howard Florey/Relaxin*, [1995] E.P.O.R. 541; Pila, *supra* note 189, at 28 (discussing the fourth ground for rejecting the argument that the patent is immoral and thus not eligible for patentability).

<sup>196</sup> *Howard Florey/Relaxin*, [1995] E.P.O.R. 541.

<sup>197</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 524.

<sup>198</sup> Pila, *supra* note 193, at 28.

After establishing three different tests, each consecutive test lowering the effectiveness of the morality bar, the EPO faced a new element to consider in granting a patent. The EPO incorporated the European Union's Biotechnology Directive (Biotech Directive) to use as guidance when considering patent protection over biotech.<sup>199</sup> The EPO is an independent office that is not a part of the EU; however, all EU countries are members of the EPO.<sup>200</sup> Because the EPO is not a part of the EU, it did not have to incorporate the Biotech Directive, which "subtl[y] attempt[ed] to steer the granting policy of the EPO in the field of biotechnology indirectly."<sup>201</sup> However, the EU member states were able to encourage the EPO members to incorporate the Biotech Directive into the EPC's implementing regulations.<sup>202</sup>

The goal of the Biotech Directive was to harmonize patent law and incentivize research into biotechnology so Europe could compete within industry.<sup>203</sup> However, because directives must be individually implemented by each country, the Biotech Directive gave members of the European Union a deadline to implement the directive into their national laws.<sup>204</sup> Not all countries agreed with the directive and some choose not to implement it into their national laws.<sup>205</sup> Another goal of the Biotech Directive is to ensure an ethical component is considered when patent protection is sought.<sup>206</sup> To incentivize research, the Biotech Directive specifically allows for certain biotech inventions to be

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<sup>199</sup> EUROPEAN PATENT OFFICE, *supra* note 18 (however, the Biotech Directive was incorporated in 1999); Overwalle, *supra* note 152, at 441.

<sup>200</sup> See INTERNATIONAL PATENT LAW & POLICY, *supra* note 94, at 124. The distinction that the EPO is not under the EU is important when the two bodies differ in their decisions. An example of a disagreement relates to Article 53(b) of the EPC which has been determined to be at conflict with both a European Commission (EC) decision involving the Biotech Directive and an EPC rule implemented in light of the EC decision. See generally Cooley Alert, *EPO May Return to Patenting Plants Obtained by an Essentially Biological Process*, COOLEY (Dec. 14, 2018), <https://www.cooley.com/news/insight/2018/2018-12-14-epo-may-return-to-patenting-plants-obtained-by-an-essentially-biological-process>.

<sup>201</sup> Overwalle, *supra* note 152, at 441.

<sup>202</sup> Implementing Regulations to the Convention on the Grant of European Patents *in* EPC, *supra* note 80, at pt. II, ch. V, r. 26–29 (Implementing Regulations inserted by decision of the Administrative Council of June 16, 1999, which entered into force on Sept. 1, 1999).

<sup>203</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 525 ("The first [goal] was to clarify and harmonize the legal protection of biotech inventions in the region to increase investment in biotechnology research."); see 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).

<sup>204</sup> Sabine Louët, *French Refuse to Implement Biotech Patent Directive*, NATURE: BIOTECHNOLOGY (Aug. 2000), [https://www.nature.com/articles/nbt0800\\_820.pdf?origin=ppub](https://www.nature.com/articles/nbt0800_820.pdf?origin=ppub).

<sup>205</sup> *Id.* France believed that if it implemented the objective it would handicap their already disadvantaged biotech industry. *Id.*

<sup>206</sup> Gitter, *supra* note 203, at 2. These moral provisions proved to be the most controversial of the Biotech Directive. *Id.* at 3.

patented, including human genes.<sup>207</sup> Intelligently, the Biotech Directive creates some bright line rules on what is unpatentable due to morality issues.<sup>208</sup> These inventions include “processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit.”<sup>209</sup> Even with a morality clause and categories of statutorily disqualified inventions, the EPO still struggles with the issue of morality through individual patents and cases.

Many years after the EPO granted the patent on the Harvard oncomouse, the Court of Justice of the European Union (CJEU), a non-EPO adjudicatory body, was asked to answer three questions concerning a German patent covering the use of human embryonic stem cells.<sup>210</sup> Article 6(1) of the Biotech Directive incorporates language from Article 27 of the TRIPS Agreement, which states that “[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality.”<sup>211</sup> The TRIPS Agreement allows for a state to determine “whether a patent violates this principle within the context of its own national conceptions of morality and order.”<sup>212</sup> One exception applies to the discretion given to a State with respect to human embryos, the industrial or commercial use of which is unpatentable.<sup>213</sup> The *Brüstle v Greenpeace* case dealt with a lack of clarity within the Article 6(2) exception which did not make the meaning of “human embryo” clear.<sup>214</sup>

The lack of clarity led Germany to define “human embryo” on a national level in the Embryo Protection Act.<sup>215</sup> A subsequent act—the Stem Cell Act—was passed, which specifically allowed for exceptions on the importation of embryonic stem cells for research purposes or “to extend medical

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<sup>207</sup> Overwalle, *supra* note 152, at 452.

<sup>208</sup> Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 (EC) [hereinafter EU Biotech Directive].

<sup>209</sup> Overwalle, *supra* note 152, at 452; see Biotech Directive, *supra* note 208.

<sup>210</sup> Sophia Williams, *Brüstle v. Greenpeace: The Court of Justice of the European Union Interprets the Term “Human Embryo” Widely, Restricting Member States’ Discretion to Pass National Legislation for Biotechnological Inventions*, 20 TUL. J. INT’L & COMP. L. 571, 572 (2012).

<sup>211</sup> EU Biotech Directive, *supra* note 208 (citing Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)) (implementing the language of TRIPS art. 27).

<sup>212</sup> Williams, *supra* note 210, at 574–75.

<sup>213</sup> EU Biotech Directive, *supra* note 208.

<sup>214</sup> Williams, *supra* note 210, at 574.

<sup>215</sup> Embryonenschutzgesetz [ESchG] [Embryo Protection Act], Dec. 13, 1990, Bundesgesetzblatt, Teil I [BGBl. I] (Ger.) [hereinafter Embryo Protection Act].

knowledge.”<sup>216</sup> The *Brüstle* case brought up the question of whether human embryonic stem cells constituted human embryos within the meaning of Article 6(2) to the Court of Justice of the European Union (CJEU).<sup>217</sup>

The court discussed the need for uniformity across the law, recognizing consequences to inventors, and noted the lack of power granted to national law by the Biotech Directive to determine the definition of “human embryo.”<sup>218</sup> Both points led the Court to the conclusion that the Biotech Directive “must be regarded . . . as designating an autonomous concept . . . which must be interpreted in a uniform manner throughout the territory of the Union.”<sup>219</sup> Declining to “broach questions of a medical or ethical nature,” the court restricted itself to a purely legal analysis.<sup>220</sup>

To determine the meaning of the term “human embryo” the court began the analysis at the preamble of the Biotech Directive discussing the goal of incentivizing investment in biotechnology and preserving human dignity.<sup>221</sup> The court took the term “human embryo” to mean “any human ovum after fertilization” or “any non-fertili[z]ed human ovum into which the cell nucleus from a mature human cell has been transplanted . . . .”<sup>222</sup> Further, the court found that although Germany’s national law creates an exception for research, the Biotech Directive covers uses of embryos in that context as well because receiving a patent directly implicates industrial and commercial use of the research.<sup>223</sup> Finally, the court found that even if a patent does not claim human embryos an application will be unpatentable if the destruction of human embryos is used in the process of creating the claimed invention.<sup>224</sup>

The CJEU in the *Brüstle*’s case did not adopt the technical analysis of the EPO established by the three pre-Biotech Directive tests.<sup>225</sup> Instead, the current inquiry at the CJEU requires an expanded analysis considering the values behind the morality bar to patentability in the hopes that the statutory bar can ultimately

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<sup>216</sup> Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen [Stem Cell Act], May 28, 2002, [BGB1. 2002] at 2277 (Ger.).

<sup>217</sup> Case C-34/10, *Brüstle v. Greenpeace*, 2011 E.C.R. I-09821 ¶ 22.

<sup>218</sup> *Id.* ¶¶ 25–26, 28.

<sup>219</sup> *Id.* ¶ 26.

<sup>220</sup> *Id.* ¶ 30.

<sup>221</sup> *Id.* ¶¶ 32, 34.

<sup>222</sup> *Id.* ¶ 38 (including also “any non-fertili[z]ed human ovum whose division and further development have been stimulated by parthenogenesis”).

<sup>223</sup> *Id.* ¶¶ 41, 53.

<sup>224</sup> *Id.* ¶ 47.

<sup>225</sup> See also Pila, *supra* note 193, at 28.

achieve its goals.<sup>226</sup> After the incorporation of the Biotech Directive to the EPO, the EPO Enlarged Board of Appeals (EBOA) dealt with the rejection of the Wisconsin Alumni Research Foundation's (WARF) application directed towards cell cultures.<sup>227</sup> The EBOA did not adopt any of the pre-Biotech Directive tests, and instead, affirmed the rejection of the patent claims because the performance of the claim was the commercial exploitation prohibited by the Biotech Directive and that performance contravenes *ordre public* by involving the destruction of human embryos.<sup>228</sup>

Ultimately, European countries protect moral concerns on some level through various mechanisms both at the EPO and through national laws. Whether a patent will be granted on a morally controversial biotechnology will unavoidably depend upon who hears the case and how that court judicially interprets the statutes.

### C. Conclusion

The United States and Europe approach morality in patent law differently. The United States does not use either utility or subject matter eligibility to involve morality with patent law. European countries adopt a more sensitive approach through their statutory patent laws.

The United States' approach allows for a less restrictive developmental approach through case law.<sup>229</sup> While the courts are free to do this, the demise of the moral utility requirement and the subsequent cases examined under the subject matter eligibility requirement suggest that morality could usefully play a bigger role than it does currently. In contrast, the EPC and the EU Biotech Directive statutorily define certain inventions as unpatentable because they are deemed immoral.<sup>230</sup> Yet, as seen in the *Brüstle* case, even the statutory application of morality can be problematic. Ultimately, with the difference in approaches between the United States and Europe, an inventor can apply for a patent in both countries, and even if the patent meets all other patentability requirements, the patent may be awarded in only one or in neither.

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<sup>226</sup> *Id.*

<sup>227</sup> Case G2/06, WARF/stem cells, [2009] E.P.O.R. 15, at ¶ 1 (Enlarged B. App. 2008).

<sup>228</sup> *Id.* ¶¶ 25–29.

<sup>229</sup> Laura C. Whitworth, *Comparison of the Implementation of Statutory Patent Eligibility Requirements Applied to Gene Patents in the European Union, the United States, and Australia*, 56 IDEA 449, 471 (2016). The patent claiming the BRCA genes was approached differently by the Australian High Court, and ultimately resulted in a different holding, which shows one issue, inconsistency, with leaving it up to judicial decisions. *Id.* at 473–74.

<sup>230</sup> *See also id.* at 473.

### III. THREE-PART PROPOSAL

Biotechnology has the potential to revolutionize the way people live their lives around the world. Yet, patent laws do not generally extend beyond the borders of a particular jurisdiction. Society finds itself in a precarious position where there is a potentially limitless industry, with profound effects on humans, and no recourse on an international level to determine if we should or should not pursue morally controversial biotechnology. It may be tempting to leave patent law “morally neutral” and up to the discretion of other agencies or areas of the law to achieve our moral goals, but that would be insufficient.<sup>231</sup> If society wants to limit the use of morally controversial biotechnology, patent laws need to be a part of that discussion.<sup>232</sup> Therefore, society must have a mechanism to utilize should we decide that the morality concerns of a particular biotechnology outweigh rewarding the innovation.

This proposal will focus on the patent component of addressing moral considerations of biotechnology. Compared to regulatory laws, patent laws are a government’s policy tool to “promote innovation, encourage the development of new technologies, and increase the fund of human knowledge.”<sup>233</sup> A patent rewards an inventor for their innovation by granting them an exclusive property right in the new technology.<sup>234</sup> The bottom line is that we have to determine if the innovation of morally controversial technology should be rewarded.

This Comment proposes a three-part plan to involve morality considerations with patent law across the international community. The first component of the plan will require an international recommendation (“Recommendation”). The next component will propose a mechanism for implementation of the recommendation on a national level, using the United States as an example. The implementation of the recommendation will result in a binding national decision on whether a patent will be granted on a morally controversial patent. The final component will take the national decision and produce it to the international market for persuasive authority.

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<sup>231</sup> See *Patenting Medical Technology*, *supra* note 29, at 318; See generally James R. Chiapetta, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 W. MITCHELL L. REV. 155, 160–61, 178 (1994) (discussing how denying patents may impede regulatory efforts by forcing inventors to protect their inventions through trade secrets and the proper venue to address moral concerns is regulatory agencies).

<sup>232</sup> See generally *Patent First, Ask Questions Later*, *supra* note 23, at 535 (discussing how denying patent protection on morally controversial technology does not stop people from practicing the technology but rather reduces the “fuel” for doing so).

<sup>233</sup> Burk & Lemley, *supra* note 104, at 1575.

<sup>234</sup> See 35 U.S.C. § 154 (2015).

### A. *International Recommendation*

Due to globalization, technological innovations affect every part of the world.<sup>235</sup> While the global effect may benefit society through improved health and increased quality of life, the moral concerns that exist with biotechnology are also not restricted by geographic limitations.<sup>236</sup> The lack of territorial restrictions combined with the incentive to innovate that patents produce means that countries will need to work together to make decisions regarding the use of morally controversial biotechnology.

This Comment proposes that an international, non-binding Recommendation be brought for consideration at the World Intellectual Property Organization (WIPO). Any country could submit the Recommendation to WIPO, but there would need to be agreement among countries for it to become a part of the agenda.<sup>237</sup> WIPO serves as the best forum for this Recommendation because it was specifically created for the purposes of facilitating cooperation.<sup>238</sup> The goal of this proposal is to give countries a mechanism through which they can agree on fundamental areas of moral concern and share national decisions.

The Recommendation would first make its way through the Standing Committee on the Laws of Patents (SCP). The SCP is a committee established by the General Assembly of WIPO to “serve as a forum to discuss issues, facilitate coordination and provide guidance concerning the progressive international development of patent law.”<sup>239</sup> At the SCP, the Recommendation would be subject to negotiations, studies, and other considerations.<sup>240</sup> Any study would likely take a substantial amount of time, but the delay would be offset by a study’s ability to facilitate cooperation with the Recommendation. Because the Recommendation will be non-binding, any information convincing various countries that making the outlined changes is in fact worth it will ultimately

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<sup>235</sup> Rhett Power, *This Is How Globalization Is Affecting Entrepreneurs*, FORBES (July 15, 2018, 7:00 AM), <https://www.forbes.com/sites/rhettpower/2018/07/15/this-is-how-globalization-is-affecting-entrepreneurs/#5de9052a1b7a>.

<sup>236</sup> Murphy, *supra* note 19, at 52.

<sup>237</sup> *General Rules of Procedure of WIPO*, WIPO, [https://www.wipo.int/policy/en/rules\\_of\\_procedure.html](https://www.wipo.int/policy/en/rules_of_procedure.html) (last visited Feb. 9, 2018) (listing Rule 5: “[t]he assembly shall adopt its agenda at the first meeting of the session”).

<sup>238</sup> *About WIPO*, WIPO, <https://www.wipo.int/about-wipo/en/> (last visited Feb. 5, 2019).

<sup>239</sup> CAROLYN DEERE BIRKBECK, *THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) A REFERENCE GUIDE 78* (Edward Elgar pub., 2016).

<sup>240</sup> Sisule F. Musungu & Graham Dutfield, *Multilateral Agreements and TRIPS-Plus World: The World Intellectual Property Organisation (WIPO)*, 3 TRIPS ISSUES PAPERS 1, 6 (2003), available at <https://quino.org/sites/default/files/resources/Multilateral-Agreements-in-TRIPS-plus-English.pdf>.

benefit the international community and increase the Recommendation's chances for success.

The Recommendation's non-binding nature does not detract from its value and does not mean that countries will refuse to comply with it. While the TRIPS Agreement has a binding venue for dispute resolution, any Recommendation in front of the SCP at WIPO would require consensus to be adopted.<sup>241</sup> That consensus, if achieved, could serve as a motivator for compliance. Each country would be amenable to implementation or they would be less likely to agree to the Recommendation.

The advantage to implementing the international recommendation in WIPO as opposed to utilizing other mechanisms of international law, like the TRIPS agreement, is that WIPO facilitates cooperation among member states, intergovernmental organizations, non-governmental organizations, and the enterprise sector.<sup>242</sup> It was specifically created for collaborative purposes such as the type of cooperation needed to face morally controversial biotechnology.<sup>243</sup> WIPO is uniquely situated to handle this recommendation.

Implementing this type of recommendation into the TRIPS agreement would result in disarray. While every member of the WTO is bound by the TRIPS Agreement, countries can choose not to comply with a WTO decision.<sup>244</sup> The TRIPS Agreement has "teeth" because violations can be punished by retaliatory sanctions.<sup>245</sup> In reality, the enforcement mechanisms of the TRIPS Agreement do not ensure compliance.<sup>246</sup> The United States in particular has been out of compliance with different TRIPS provisions for over a decade and has failed to

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<sup>241</sup> Rochelle C. Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPs and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 277 (1997); see also Catherine Saez, *WIPO Patent Law Committee Looks at Health, Quality*, INTELLECTUAL PROPERTY WATCH (June 7, 2017) (discussing how the SCP could not reach agreement on future work but decided to revert to old work programs), <http://www.ip-watch.org/2017/07/06/wipo-patent-law-committee-looks-health-quality/>.

<sup>242</sup> *Cooperation*, WIPO, <https://www.wipo.int/cooperation/en/> (last visited Feb. 5, 2019).

<sup>243</sup> *Id.*

<sup>244</sup> See Damian Paletta & Ana Swanson, *Trump Suggests Ignoring World Trade Organization in Major Policy Shift*, WASHINGTON POST (Mar. 1, 2017), [https://www.washingtonpost.com/news/wonk/wp/2017/03/01/trump-may-ignore-wto-in-major-shift-of-u-s-trade-policy/?noredirect=on&utm\\_term=.f5715d531de7](https://www.washingtonpost.com/news/wonk/wp/2017/03/01/trump-may-ignore-wto-in-major-shift-of-u-s-trade-policy/?noredirect=on&utm_term=.f5715d531de7); Daniel J. Ikenson & Robert E. Lighthizer, *Is The WTO Dispute Settlement System Fair?*, COUNCIL ON FOREIGN RELATIONS (Jan. 26, 2017), <https://www.cfr.org/article/wto-dispute-settlement-system-fair> ("WTO cannot force us to comply with its rulings").

<sup>245</sup> See Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 2 (2004).

<sup>246</sup> Elena Bourchouladze, *US Again Target of Complaints of Persistent Non-Compliance at WTO DSB*, INTELLECTUAL PROPERTY WATCH (Feb. 24, 2015), <http://www.ip-watch.org/2015/02/24/us-again-target-of-complaints-of-persistent-non-compliance-at-wto-dsb/>.

comply with a thirteen year-old decision by the WTO Dispute Settlement Body.<sup>247</sup>

The SCP will need to make final determinations regarding the areas of biotechnology that patent examiners should flag for morality considerations. One of the most objectionable parts to including morality in a decision about patents is who makes the morality determinations.<sup>248</sup> The composition of the SCP includes the WIPO member states, certain other U.N. members, and some international organizations and non-international organizations.<sup>249</sup> This composition means that the “decision maker” deciding what categories of inventions society deems concerning enough to flag is sufficiently varied. The developing nations of WIPO will have just as much say in discussions as do the major intellectual property powers, each of which gets one vote.<sup>250</sup> There will not be the problem of “unintended or intentional ignorance” because of the committee’s specific purpose of international patent development.<sup>251</sup> The committee’s ability to dig deep into the issues and coordinate studies that will explore the Recommendation’s ramifications also works to ensure that the decisions made at this level of the process are the most beneficial for the international community at large.

The Recommendation should include, at a minimum, flagging medical treatment methods, cloning, genetic alterations on humans, and higher-life forms. The categories are broad because the international community should be over-inclusive in its consideration of morally controversial inventions. The purpose of the recommendation intersects with the second component in that it indicates to the patent offices where the major concerns lie.

Although the broad categories will increase the number of patent applications reviewed overall, their benefits outweigh the alternative of creating more narrow categories. The goal of reviewing moral considerations is to move the law with science. Maintaining narrow categories would leave the international community vulnerable to the same exploitation of science as it would be without a plan.

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<sup>247</sup> *Id.*

<sup>248</sup> *See also* Noonan, *supra* note 86 (“if we posit rules we need to impose a rule-giver”).

<sup>249</sup> *Standing Committee on the Law of Patents (SCP)*, WIPO, <https://www.wipo.int/policy/en/scp/> (last visited Feb. 12, 2019).

<sup>250</sup> DEERE BIRKBECK, *supra* note 239, at 78.

<sup>251</sup> Noonan, *supra* note 82.

Simply recommending what might be worth a morality consideration is not sufficient. National patent laws will need to adapt to these morality concerns by adjusting their own practices.

### *B. Implementation on a National Level*

While the WIPO Recommendation provides a good start, national laws will have to adapt to accommodate to the Recommendation and work to enforce flagging patents with questionable patent claims. Each individual patent office can approach the task through its own mechanism. This Comment proposes that patent offices, particularly the USPTO, should utilize a pre-screening method of flagging.<sup>252</sup> This pre-screening method would work similarly to the United States' current approach to screening for national security interests.<sup>253</sup>

As required by section 181, the USPTO pre-screens patent applications for potential threats to national security.<sup>254</sup> If a patent application is flagged because the Commissioner of Patents believes the disclosed invention “might . . . be detrimental to the national security,” then the application is sent to defense agencies for review.<sup>255</sup> The defense agency, upon a finding that the disclosure “would be detrimental,” notifies the Commissioner of Patents to keep the invention secret via a secrecy order.<sup>256</sup> The Commissioner then keeps the application sealed and notifies the applicant that the patent would not be published or granted for as long as the security interest remains.<sup>257</sup> The application would be stayed for a period of one year, but the secrecy order can be renewed so long as the national interest requires it.<sup>258</sup>

If a secrecy order is issued an inventor may not commercially exploit the invention.<sup>259</sup> Yet, once the secrecy order terminates, an applicant may receive a patent if the invention is patentable.<sup>260</sup> Thus, patent laws do not leave the patentee empty handed.<sup>261</sup> Section 183 allows for the patentee to receive compensation if a patent would have been granted *but for* the secrecy order.<sup>262</sup>

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<sup>252</sup> See generally *Patent First, Ask Questions Later*, *supra* note 23, at 543–44.

<sup>253</sup> 35 U.S.C.S. § 181 (2012); see *Patent First, Ask Questions Later*, *supra* note 23, at 543–44.

<sup>254</sup> 35 U.S.C.S. § 181.

<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> *Id.*

<sup>258</sup> *Id.*

<sup>259</sup> See *Farrand Optical Co. v. United States*, 317 F.2d 875, 876 (2d Cir. 1962).

<sup>260</sup> Gary L. Hausken, *The Value of a Secret: Compensation for Imposition of Secrecy Orders Under the Invention Secrecy Act*, 119 MIL. L. REV. 201, 218 (1988).

<sup>261</sup> See generally 35 U.S.C.S. § 183 (2018).

<sup>262</sup> *Id.*

This Comment proposes that the USPTO, and other patent offices around the world, ought to implement a pre-screening process where every patent application that relates to a new biotechnology is screened. Patent inspectors will utilize pre-established categories of potentially morally controversial biotechnology to flag claims for further review. Any claim that is flagged will be held back from the patent prosecution process.<sup>263</sup> The controversial claim will then be reviewed by a committee that could be separate or situated in the USPTO for a determination of whether the biotechnology claim is something that society ought to reward with a property right, or if the technology is too morally controversial.<sup>264</sup> If the committee approves of the claim, then the applicant may file for compensation. The approved claim would then be reexamined for patentability and if granted would join the rest of the claims in getting patent protection. Any claim that is determined to be too morally controversial to grant a patent on would be barred from receiving patent rights. The USPTO will share this information with other patent offices and with WIPO through the work share system described in the Recommendation.

The inspectors at the USPTO can be any examiner that works within the patent office. The purpose of the inspector is not to make morality determinations, so there is no concern of “unintended or intentional ignorance” as there is with decision makers.<sup>265</sup> The inspector is only tasked with following the guidelines of the WIPO Recommendation.

Once an inspector flags an application, the claim will be removed and held for examination.<sup>266</sup> An applicant may file a continuation-in-part to move the unflagged part of the application through the regular patent process.<sup>267</sup> Holding back only the potentially controversial claim serves two purposes. First, it prevents the process from becoming overburdened. Second, it combats the argument that this process will inhibit the incentive to innovate that patents promote.

Currently, of all of the patent applications published worldwide every year, the portion of biotechnology patents filed is relatively small. In 2015, 55,399 biotechnology patents were filed across all patent offices, making the share of biotechnology patents only 2.2% of all published patents.<sup>268</sup> Not all biotech

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<sup>263</sup> See *Patent First, Ask Questions Later*, *supra* note 23, at 543.

<sup>264</sup> *Id.*

<sup>265</sup> Noonan, *supra* note 86.

<sup>266</sup> See generally *Patent First, Ask Questions Later*, *supra* note 23, at 543.

<sup>267</sup> See also 37 C.F.R. § 1.53(b)(2) (2013).

<sup>268</sup> World Intellectual Property Organization [WIPO], *World Intellectual Property Indicators 2017: Patents*, at 64, available at [https://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_941\\_2017-chapter2.pdf](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2017-chapter2.pdf).

inventions will create concerns that qualify the patent for flagging, and the patent office's only hold back the individual claims of concerns. Additionally, every jurisdictional patent office will work together to achieve the goal of making decisions on all of the controversial claims. Because of the workshare system, each country will not need to evaluate each claim independently. The efficiency of offices working together will negate the argument that this system inhibits innovation. Non-controversial claims will quickly be released from their hold and allowed to continue through the prosecution process.

A patent is a legal protection for a product of human ingenuity.<sup>269</sup> Unfortunately, human ingenuity often takes significant time and resources, and once created the invention costs little to copy.<sup>270</sup> Patents give an inventor the right to exclude competitors so that he or she may recoup the cost of the invention.<sup>271</sup> The patent can serve as an incentive for investors and businesses, and it can also serve as an incentive for research and the progression of science.<sup>272</sup> Undisputedly, patents have an effect on economics and industries.<sup>273</sup>

Patents play a major role in companies since a company can maximize value through patents.<sup>274</sup> The patent affects a company's future strategy as the company determines if it should sell, buy, or license technology.<sup>275</sup> French economists found that "88 percent of U.S., European, and Japanese businesses . . . actually rely upon the information disclosed in patents to keep up with technology advances and direct their own [research and developments] efforts."<sup>276</sup>

A resolution for businesses afraid of being denied a patent would be to maintain the invention as a trade secret. For example, Myriad maintained the

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<sup>269</sup> MUELLER, *supra* note 14, at 8.

<sup>270</sup> *Id.* at 9. For example, it took ten years and \$12 billion dollars to synthesize the human genome, but in time it could cost \$100,000. Endy, *supra* note 51.

<sup>271</sup> MUELLER, *supra* note 14, at 9.

<sup>272</sup> See Dominique Guellec, Bruno van Pottelsberghe & Nicolas van Zeebroeck, *Patent as a Market Instrument*, in THE ECONOMICS OF THE EUROPEAN PATENT SYSTEM, 85, 106 (2007) [hereinafter *Patent as a Market Instrument*]; Robert Hart, *Should You Be Able to Patent an Organism?*, SLATE: FUTURE TENSE, [http://www.slate.com/articles/technology/future\\_tense/2017/04/the\\_synthetic\\_biology\\_community\\_is\\_divided\\_on\\_intellectual\\_property.html](http://www.slate.com/articles/technology/future_tense/2017/04/the_synthetic_biology_community_is_divided_on_intellectual_property.html) (last visited Oct. 26, 2018).

<sup>273</sup> MUELLER, *supra* note 14, at 24; see also Phelps, *supra* note 65 (discussing how it cannot be proved "that the patent system by itself" increases innovation and growth, but, "on balance and over the long term, patents are strongly correlated with increased innovation, knowledge sharing, and economic growth").

<sup>274</sup> Joseph P. Hamilton, *Patents: How the Right to Exclude Turns Innovation Into Success*, AICHE: CHENECTED (Mar. 1, 2010), <https://www.aische.org/chenected/2010/02/patents-how-right-exclude-turns-innovation-success>.

<sup>275</sup> *Patent as a Market Instrument*, *supra* note 270, at 106.

<sup>276</sup> Phelps, *supra* note 65.

genetic testing database from its patient tests and can now hold this information as a trade secret.<sup>277</sup> Trade secrets ultimately pose a problem by inhibiting the public disclosure that the patentee gives up in order to gain the right to exclude. Patents bargain with inventors in a way that allows the invention to become public knowledge by giving the inventor the right to exclude others.<sup>278</sup> Without the incentive of the right to exclude, the benefit of public disclosure is obsolete and instead replaced with “every incentive to be secretive and guard jealously their discoveries from competitors [which] could, of course, be copied with impunity.”<sup>279</sup> If a company chooses to keep their information a secret, the public never gets access to it and innovation could be stalled.<sup>280</sup>

A decrease in financial investments could stifle innovation on important biotechnology inventions that could generate improved medicines. If less research, and by consequence, less discovery occurs in the medical field it raises the question of whether patent law really promotes the “Progress of Science.”<sup>281</sup> Investors will put less money towards research and development in areas where patent rights are uncertain or avoid the industry as a whole, which reemphasizes the importance of the certainty patent holders get in their right to exclude.<sup>282</sup> While the incentive to innovate involves a complex discussion of bargains, cost-benefits analysis, business investments, licensing, and trade secret concerns, it remains one of the major policy considerations behind the patent system across all jurisdictions.<sup>283</sup> For the biotechnology field to continue its growth, the incentive to innovate must be kept at the forefront of the discussion so that the field can reach its full potential.<sup>284</sup> That is not to say that the incentive to innovate must be the sole consideration in future biotechnology and patent discussions. In fact, the incentive to innovate must be considered against the morality issues that the biotech innovations bring to the table.

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<sup>277</sup> See Eleonore Pauwels, Op-Ed., *Our Genes, Their Secrets*, N.Y. TIMES, June 18, 2013, available at <https://www.nytimes.com/2013/06/19/opinion/our-genes-their-secrets.html>.

<sup>278</sup> See MUELLER, *supra* note 14, at 31.

<sup>279</sup> Phelps, *supra* note 65.

<sup>280</sup> See MUELLER, *supra* note 14, at 9.

<sup>281</sup> U.S. CONST. art. I, § 8, cl. 8. This result would be counterproductive to the argument used in *Myriad* that allowing patents on the BRCA1 and BRCA2 genes would inhibit this growth. Hagan, *supra* note 132, at 221.

<sup>282</sup> Molly Jamison, *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate*, 15 CHI. J. INT'L L. 688, 705 (2015).

<sup>283</sup> See also Phelps, *supra* note 65 (noting Professor Khan's summary of “the role of patents in helping U.S. startup businesses grow the economy from an agrarian backwater into the most powerful industrial economy on the face of the earth”).

<sup>284</sup> Hart, *supra* note 270.

Importantly, the structure of this proposal recognizes the importance of the incentive to innovate. Any non-flagged portion of the patent gets to proceed through prosecution. Real investment can still happen because an applicant or a business can still get patent protection and the right to exclude others. Additionally, creating an opportunity to receive compensation for held claims that are ultimately non-controversial means that companies will recoup some of the lost costs. The only money that the patentee loses is over controversial claims.

Once a claim is flagged, it would make its way to a committee established by Congress.<sup>285</sup> This Comment does not purport to recommend certain people for this committee by position, but rather state the importance and function of the committee. Ideally, the people who sit on the committee will be of the highest ethical and intellectual capacity. It would be helpful to have a small committee of people who understand the science involved in biotechnology and the industry's future. This would help determine the severity of any concerns. Examples of suitable people may include members of the National Academy of Sciences, who go through an extensive vetting before being elected as members.<sup>286</sup> Another avenue could be to revitalize the Office of Technology Assessment (OTA).<sup>287</sup> Before the OTA's demise, it provided non-partisan research to Congress and even prepared reports covering biotechnology and transgenic animals.<sup>288</sup> While the science is important, there must be educated people on the committee who can study, debate, and consider the moral concerns that the technology implicates.

While assessing the overall moral implications of patenting a new biotechnology, the committee will need to assess if the invention is either too controversial to receive the government reward of a patent right or is so beneficial that a patent's right to exclude harms society.<sup>289</sup> Congress can establish guidelines for the committee during their discussions that may include the illegal nature of practicing an invention, the lack of informed consent, or general public opinion.<sup>290</sup> Having elected representatives with the power to

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<sup>285</sup> *See generally Patent First, Ask Questions Later*, *supra* note 23, at 532–33, 543–44 (discussing how Congress “seems clearly to be the best suited to make determinations”).

<sup>286</sup> *Membership Overview*, NAT'L ACAD. OF SCI., <http://www.nasonline.org/membership/> (last visited Feb. 11, 2019).

<sup>287</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 543.

<sup>288</sup> *Id.* at 543 n. 340.

<sup>289</sup> *See Id.* at 535.

<sup>290</sup> *New Invention Creation*, *supra* note 96, at 590, 600–01.

make patent law in the United States puts Congress in the best position to hash out the final details of the committee.<sup>291</sup>

Any committee established by a country adhering to the WIPO Recommendation will be tasked with the difficult decision of determining if an inventions morality concerns bar it from receiving a patent.

### *C. Facilitating a Work Share System*

This Comment proposes that WIPO, through the Recommendation, establish a work share system for the countries of WIPO.<sup>292</sup> The purpose of the workshare system would be to give patent offices and the public as a whole, ammunition for the determination of morally controversial biotechnology.

After a patent office flags a claim to be held for consideration, the patent office can add this information into the work share system. That will allow other patent offices to know that the claim has been flagged and will be considered in the future for morality concerns. This information can help patent offices from reinventing the wheel and duplicating the assessment of individual claims.

Once a decision is rendered regarding the patentability of the claim, the work share system would disseminate the information to other patent offices and the public. Each patent office would then be able to see the decisions of other patent offices regarding why patents had been approved or barred after the morality screening process. For many patent offices, past decisions can act as persuasive authority to adopt the same result. If a country elects not to follow the decision of other patent offices, the decision would still be available to the public. Access to why a decision was made and what considerations took place could easily sway public opinion on an already controversial subject matter. With that information at the public's disposal, it gives them ammunition to affect change in their countries.

Ultimately, the Recommendation provides an international tool for patent offices to refer to when pre-screening morally controversial technology. As patent offices come to their final decisions regarding the patentability of a controversial claim, they can share that information with the international community through the work share system. This proposal allows for society to

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<sup>291</sup> *Patent First, Ask Questions Later*, *supra* note 23, at 532–33, 536–37.

<sup>292</sup> *See generally Sharing Search and Examination Work Product*, WIPO, <https://www.wipo.int/patents/en/topics/worksharing/sharing-work-products.html> (last visited Feb. 13, 2019).

have a mechanism for evaluating if morally controversial patent claims should be eligible for patent protection.

### CONCLUSION

Technology has taken people to space and provided almost every corner of the globe with access to the internet, and both of those events were world altering. It is hard to predict where the next incredible breakthrough will be, but there is a good chance that it is in the realm of biotechnology. The industry's capabilities are truly limitless, and society should promote that innovation with patent protection. Therefore, society should also be aware of some of the deeply concerning consequences that developing biotechnology can have on society. We should not continue blindly into the abyss without adequately preparing ourselves for what comes next. That preparation needs to include an international component given the ease with which technology and innovation spreads across borders.

If society ever wants to ensure its own protection from the exploitation of science it will need a mechanism to prevent governments from providing rights over the fruits of innovation so that the incentive to develop morally controversial biotechnology decreases.<sup>293</sup> The proposed Recommendation at WIPO has the ability to bring territorially limited patent laws together to protect morality. By creating categories for patent offices to flag, the international community is defining where the areas of concern lie. It is then up to the patent offices and national law to adhere to the regulation and consider the moral implications of a technology during the patent procurement process. When the patent office reaches a final decision, the conclusion should be turned over to the international community in order to encourage a level of uniformity, but also as a way of facilitating open communication.

We can improve our scientific capabilities in all areas without degrading our moral compass. Biotechnology can provide humans with the answers to what some have considered unsolvable issues, such as ending world hunger; but in doing so, we must have a way to protect ourselves from our own curiosities. We

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<sup>293</sup> See also *Patent First, Ask Questions Later*, *supra* note 23, at 546.

must do this for ourselves and for our future. By creating an international Recommendation and adhering to it on a national level, the international community can ensure that science and curiosity does not move so quickly that it outpaces the law.

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\* Notes and Comments Editor, *Emory International Law Review* Vol. 34. J.D. Candidate, Emory Law (2020). The author greatly appreciates the insights, comments, and advice of Professor Margo A. Bagley without whom this Comment would not have been possible. The author would also like to thank *Emory International Law Review*, and all those who helped to brainstorm, collaborate, proofread, and aid in the making of this Comment.