

# STEM CELLS, CLONING AND PATENTS: WHAT'S MORALITY GOT TO DO WITH IT?

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I am delighted to be with you this afternoon to wrap up this panel on “Patent and IP Issues Surrounding Stem Cell Research and Human Cloning.” Some of the things I am going to talk about have been mentioned by the other patent attorneys, but I am going to be talking about them with a little twist. For example, this Symposium asks: “Where Do We Draw the Line?” However, the question I ask, and that Dr. Jennifer McCallum<sup>1</sup> asked as well, is: “*Who* should draw the line?” This is a fundamental question in the patent arena. While Dr. McCallum and I disagree on the answer, I think we both have perspectives that are relevant in discussing both of these questions.

My remarks today are drawn largely from concepts presented in my recent article, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*.<sup>2</sup> I am going to talk about the structure of our current patent system (relative to other regimes) in regard to morally controversial biotech patents. I will also address why the issuance of such patents matters and how we came to have such patents. Lastly, I am going to talk about the efforts Congress has made, and further steps Congress should take, to address the issues such patents raise.

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1. See Jennifer McCallum, *The Reality of Restricting Patent Rights on Morally Controversial Subject Matter*, 39 NEW ENG. L. REV. 517 (2005).
2. Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003) (including an in-depth discussion and analysis of the topics highlighted in this speech).

## I. THE U.S. APPROACH: PATENT FIRST, ASK QUESTIONS LATER

Many products of biological processes (and the processes themselves) are eligible for patent protection. Inventors may obtain patents on stem cells, transgenic animals, methods of cloning mammals, and more. However, quite a few of the biotech inventions that are eligible for patent protection are morally controversial. When I talk about “morality” I am using the term in its basic sense, exemplified by the definition of morality provided by *Webster’s Dictionary*: “[T]he rightness, or wrongness of an action.”<sup>3</sup> For example, in an ABC news poll conducted a few years ago, eighty-two percent of respondents believed that cloning humans would be morally wrong—something that we should not do.<sup>4</sup>

But moral norms are not static. Societal views about what is right and what is wrong change all the time, for a variety of reasons. For one thing, as humans, we are susceptible to de-sensitization and issues that once seemed shocking can, over time, begin to seem less so. Moreover, self interest can play a role in shifting views of morality; the discovery that a controversial technology can be beneficial to us on a personal level can, in some instances, impact our view about whether it is moral.

The topic of patents on morally controversial biotech subject matter is important because quite a few such patents already exist, which is why I call ours a “patent first, and ask questions later” system. In the United States, the way things generally work is that a patent issues, and then, to the extent that a significant, or at least vocal, portion of society finds it controversial, there is an uproar and Congress is called upon to respond to the problem. Thus the patent issues first and questions regarding whether the patent should have issued are asked later.

Difficulties with the “patent first, ask questions later” approach can be seen in the areas of transgenic animal patents, medical process patents, and patents on methods of cloning humans.<sup>5</sup> These patents implicate issues such as animal suffering, human dignity, the destruction of human embryonic life, and patient access to life-saving procedures.

A recent example of a “patent first, ask questions later” situation involved a patent that issued just a few years ago to the University of Missouri and claimed a method for producing a cloned mammal, without

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3. WEBSTER’S NEW WORLD DICTIONARY AND THESAURUS 402 (MacMillan 1996).

4. See Meredith Wadman, *Politicians Accused of “Shooting from the Hip” on Human Cloning*, 386 NATURE 97 (Mar. 13, 1997).

5. Another controversial area involves mixed-human-animal chimeras and pending patent applications on such creatures. See, e.g., U.S. Patent Application No. 09/828,876 (filed Apr. 10, 2001); U.S. Patent Application No. 10/308,135 (filed Dec. 3, 2002). Patents on human embryonic stem cells are also controversial because they involve the destruction of human embryos.

limiting that claim to non-human mammals. Moreover, the patent specification stated that the invention “encompasses the living, cloned products produced by each of the methods described herein.”<sup>6</sup> After that patent was granted, the ensuing public controversy prompted Senator Sam Brownback (R-Kansas) to introduce an amendment to a Senate bill to ban human cloning patents.<sup>7</sup>

Senator Brownback’s amendment was rejected, at least in part because of the misconceptions of some senators concerning what the United States Patent and Trademark Office (USPTO) can and cannot do. In rejecting the bill, some lawmakers relied on USPTO statements declaring that the Agency would not issue patents on humans.<sup>8</sup> However, an analysis of relevant cases shows that the USPTO simply does not have the authority (outside of that imposed by the temporary Weldon Amendment)<sup>9</sup> *not* to grant patents on humans.<sup>10</sup>

## II. COMPARATIVE APPROACHES: ASK QUESTIONS FIRST, THEN PATENT

One of the many problems engendered by the U.S. “patent first, ask questions later” system relates to the fact that once a patent is granted, there are property rights associated with it that can be quite valuable. Holders of patents in the relevant area thus have very strong incentives to see that no change in patent eligibility standards takes place that might negate the viability of those patents. Consequently, the first issuance of a patent on morally controversial biotech subject matter changes the debate before the debate even takes place. Patents, while not always mentioned or recognized explicitly, are a very important undercurrent to virtually all of the issues that are under discussion at this conference today.

Other countries, including Japan and the European Union member countries, have statutory bars to the issuance of morally offensive patents. For example, in Article 53(a) of the European Patent Convention (EPC),<sup>11</sup>

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6. U.S. Patent No. 6,211,429 (issued Apr. 3, 2001). Since the statement was not in the claims, the patent owner does not have the right to exclude others from making cloned mammals, but the statement suggests that right is something the drafters were trying to obtain.
  7. See BNA, *Senate Refuses to Attach Ban on Clone Patents to Terrorism Bill*, 64 PAT. TRADEMARK & COPYRIGHT J. 174 (2002).
  8. See Media Advisory, U.S. Patent & Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998), at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>.
  9. The Weldon Amendment is part of the Consolidated Appropriations Bill of 2004, Pub. L. No. 108-199, 118 Stat. 3. See also discussion *infra* Part V.
  10. See Bagley, *supra* note 2, at 488-93.
  11. Convention on the Grant of European Patents, Oct. 5, 1973, Art. 53(a) (exclusion on moral grounds), available at <http://www.european-patent-office.org/legal/epc/e/>

patents can be denied on the basis of “‘ordre public’ or morality.”<sup>12</sup> But, as was noted by Ms. Morneault,<sup>13</sup> the European Patent Office (EPO) examiners have had a difficult time making those determinations. As a result, they have come up with a variety of different tests to figure out whether something is immoral: they balance competing interests, they consider whether it would be unacceptable to a substantial portion of the public, or they analyze whether it would be publicly abhorrent. Anecdotally, a fellow patent law professor who recently had the opportunity to speak with some EPO examiners quoted them as saying, “we do not know how to make these determinations about what is moral, and what is not.” That is a problem with having a very general provision on morality and not defining the term; it puts the patent examiners in the position of having to create definitions.

In addition to the “general” morality provision of Article 53(a) of the EPC, the European Union also has “specific” prohibitions on the patenting of certain morally controversial inventions via the European Union Biotechnology Directive. Pursuant to the Directive, member states cannot grant patents on, *inter alia*, processes to produce human-animal chimeras and human clones or on commercial uses of human embryos.<sup>14</sup> While giving examiners more guidance than broad general provisions, specific provisions are also problematic because technology does not stand still, and the language adopted at one point in time is unlikely to encompass all newer controversial inventions. But at least in those countries with general or specific provisions, they are attempting to ask questions first, and then patent.

### III. WHY IT MATTERS

Why does it matter whether we even have patents on these types of innovations? It matters because patents matter. The Constitution authorizes Congress 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>15</sup> This provision is a grant of authority to Congress to create a patent system and Congress chose to utilize it. The patent laws are designed to promote the progress of science

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ar53.html.

12. *Id.*

13. Monique Morneault, *Cloning Issues and the Current Patent Systems in the United States and Europe*, 39 NEW ENG. L. REV. 523 (2005).

14. See Council and European Parliament Directive 98/44/EC, 1998 O.J. (L 213) 13, ¶¶ 1-4, available at [http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l\\_213/l\\_21319980730en00130021.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf) (last visited Feb. 11, 2005).

15. U.S. CONST. art. I, § 7, cl. 8.

and useful arts by rewarding innovation with temporary exclusivity. They provide incentives to undertake research by allowing patent holders the right to exclude others from using their patented inventions for a period of years. That right can be very lucrative. In a recent year, IBM, for example, generated \$1.5 billion in licensing revenues from their patent portfolio, and other companies are trying to “beef up” and leverage their patent portfolios as well. That “right to exclude” is also granted by the federal government and is enforceable in federal court. On these morally controversial inventions then, you have a government imprimatur, which can be troubling in terms of the government incentivizing certain types of morally controversial biotech research.

The right to exclude others from practicing is a negative right, not an affirmative right to practice; yet that right can be very powerful because it allows you to sue or negotiate for royalties when someone does practice your invention. In the words of one patent scholar, “[O]pposition to patenting cannot be viewed as irrational: [O]ffering a financial incentive such as a patent will directly or indirectly increase the activity that is of true concern to patenting opponents.”<sup>16</sup> It *does* matter whether we grant patents because of the motivation patents provide to engage in certain types of research. Another example of the power of patents relates to finances. After a decision by the Court of Appeals for the Federal Circuit that invalidated the Prozac patent,<sup>17</sup> shareholders dumped \$36 billion worth of Eli Lilly stock, which represented one-third of the company’s market capitalization. Patents matter. They are important.

#### IV. HOW IT HAPPENS

How do patents on morally controversial biotech subject matter issue? How does this “patent first” system work? There are certain statutory requirements for patentability. The invention must fall within one of the specified subject matter categories: machine, composition of matter, manufactured process; it must be useful; it must be novel and non-obvious; and it must be properly described. But those requirements do not say anything about the invention being moral. There is no statutory morality requirement in U.S. patent law. Moreover, the statute says that “[a] person *shall* be entitled to a patent unless” he or she does not meet one of the specified requirements.<sup>18</sup> So, you are entitled to a patent if the examiner cannot find a statutory basis for denying it. In *Diamond v. Chakrabarty*,<sup>19</sup> a

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16. Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1668-69 (1993).

17. See *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955 (Fed. Cir. 2001).

18. 35 U.S.C. § 102 (2004).

19. 447 U.S. 303 (1980).

seminal case on patent subject matter eligibility, the Supreme Court concluded that Congress intended patent subject-matter to “include anything under the sun that is made by man.”<sup>20</sup> It does not matter whether the invention is living or non-living, moral or immoral.

Interestingly, we previously had a morality requirement in U.S. patent law. Under the judge-made “moral utility requirement,”<sup>21</sup> an invention that was immoral would not be considered to be useful, and that reasoning was used to deny patents on gambling machines and deceptive or fraudulent devices. Over time, though, courts became uncomfortable making those kinds of *ad hoc* determinations without statutory authority. And ultimately the rule developed that if an invention had at least one useful purpose, it was eligible for patent protection.<sup>22</sup>

The Supreme Court’s *Diamond v. Charabarty* decision, however, leaves no room for reading a morality requirement into the existing patent statute. The Court noted in *Diamond* that since Congress had spoken, it was “without competence” to consider moral questions in determining the scope of patent eligible subject matter.<sup>23</sup> It concluded that determining what Congress meant by the statute is the province of the courts, nothing more. Likewise, in a later decision, the Court of Appeals for the Federal Circuit also pointed out that the interpretation of the patent statute is not a matter of discretion for the USPTO. As the court concluded, “either the subject matter falls within Section 101 or it does not, and that question does not turn on any discretion residing in examiners.”<sup>24</sup>

Even the USPTO, in answering a public question about whether DNA should be patent-eligible admitted that: “Congress creates the law and the federal judiciary interprets the law. The USPTO must administer the laws as Congress has enacted them and as the federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications. . . .”<sup>25</sup> Despite these clear pronouncements, and without statutory authority, the USPTO has also stated that it will not grant patents on humans. Unfortunately, that position statement has caused some to believe that the agency has the authority to deny such patents, when, as a statutory matter, it does not.

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20. *Id.* at 309 (quoting S. Rep. No. 1979, at 5 (1952)).

21. *See Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8568).

22. *See Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903).

23. *Diamond*, 447 U.S. at 317.

24. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991).

25. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

## V. WHO DECIDES WHERE TO DRAW THE LINE?

So who is deciding if morally controversial biotech subject matter gets patented? Patent applicants. Scientists. As noted earlier, the patent statute says that a person is entitled to a patent, unless he or she fails to meet the statutory requirements and there are no morality requirements and limitations in patent law.<sup>26</sup> Many of the arguments surrounding controversial biotech subject matter converge on fundamental questions such as “when does human life begin?” and “what does it mean to be human?” Patent applicants are no better equipped to make that determination than the average person, and yet they are the ones making these high policy decisions by virtue of the content of the applications they file with the USPTO.

For a variety of reasons detailed in my Article,<sup>27</sup> I believe that these decisions should not be made by individual patent applicants. The rate at which scientists are coming up with new technologies, and submitting them for patent protection, is far out-pacing the legal debates in this area. For example, a pending patent application claims not just cloned embryos, but later-stage cloned mammalian fetuses, cloned mammalian offspring, and progeny of the cloned offspring.<sup>28</sup> Last time I checked, humans were mammals, so this application encompasses cloned humans.

We need to look at what should be patented, and who should be making the decision. I am convinced that the authority and institutional competence in this area lies with Congress. The Constitution authorizes Congress to create a patent system in the first place. Unlike scientists or the courts, Congress is accountable to the public—it holds hearings and takes testimony on relevant topics. Of course, this is a politically sensitive subject. What is human, what is not human? It is very difficult for Congress to grapple with such questions on which society itself is deeply divided. Nevertheless, in our current system, Congressional failure to act is an action in and of itself.

There are several approaches that Congress could take in addressing patents on morally controversial biotech subject matter. Obviously, it could continue with the system that we have, *consciously* understanding that there are no limits, and that applicants are ever expanding the range of morally controversial patented biotech subject matter. Or, it could come up with a general morality provision, similar, perhaps, to EPC Article 53(a),<sup>29</sup> but I doubt that would be very helpful—the European Patent Office itself does

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26. See discussion *supra* Part IV.

27. See Bagley, *supra* note 2, at 509-16.

28. U.S. Patent Application No. 09/828,876, *supra* note 5.

29. Convention on the Grant of European Patents, *supra* note 11.

not have much success with that provision. Alternatively, it could add specific prohibitions—which it actually did with the Weldon Amendment, which I will say just a little bit more about in a moment. Or it could take an intermediate approach, which is probably the most viable option. It would be great if Congress still had an Office of Technology Assessment to advise it, a body that could actually study these issues, bringing in people on different sides of the debate, to help Congress make informed decisions about whether there should be morality-based limits and if so, what those limits should be.<sup>30</sup> Intermediate approaches, developed after study and analysis, could include having the USPTO flag patents for review and assessment by a special board. Another option would be to have a pre- or post-grant opposition period at the PTO for people to oppose patents on some morality-related basis. There are many approaches that Congress could adopt if lawmakers gain the political will to adequately address this issue.

The Weldon Amendment, while well-intentioned, is an example of Congress inadequately addressing the issue. The amendment was included as part of the 2004 Consolidated Appropriations legislation, and provided that none of the funds appropriated to the USPTO this year could be used to issue patents directed to or encompassing human organisms.<sup>31</sup>

In introducing the measure, Representative Dave Weldon (R-FL) called the provision “a clarification” of the USPTO policy against patenting humans. However, as I have already mentioned, the USPTO policy stands in direct contradiction to the United States Supreme Court interpretation of the patent statute.<sup>32</sup> The Amendment is also troubling because it gives no guidance to the USPTO on what is “human.” What percent of human cells must a body contain to qualify as “human?” What is the appropriate measure of “humanness?” A further problem with the Amendment is the fact that it does not amend the patent statute. Thus, it does not provide the basis for an examiner to reject any claims in a patent application. Moreover, it is a temporary appropriations provision—it expires yearly and must be re-enacted if it is going to continue in force.

#### CONCLUSION

In conclusion, patents on some categories of morally controversial biotech subject matter are here to stay. It is very hard for Congress to retrench and remove subject matter from patent eligibility after patents covering such subject matter have issued. I do not think there is any going

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30. While perhaps less nimble than the now defunct Office of Technology Assessment, the National Academy of Science could certainly be helpful in this approach.

31. The Consolidated Appropriations Bill of 2004, Pub. L. No. 108-199, 118 Stat. 3.

32. See discussion *supra* Part IV.



back in the area of stem cell patents or transgenic animal patents. However, the patent eligibility of other subject matter, such as humans, is still in flux, and is a topic that Congress needs to study and address—not put a bandage on with vague, facially non-substantive enactments like the Weldon Amendment.

Until Congress takes the necessary action (i.e., holds hearings, commissions reports) to figure out what is human, to decide what societal values to promote, and to delineate what types of inventions should be eligible to receive the Government's patent imprimatur, the categories of morally controversial biotech subject matter on which patents have issued will continue to grow. Such "high policy"<sup>33</sup> decisions should not be delegated to the USPTO; it would be unrealistic, impractical, and ultimately inefficient to expect examiners to resolve these issues on an ad hoc basis.

Ultimately, where we go from here is a question for Congress. Congress must clarify the limits of patent-eligible subject matter, and the extent to which moral issues should be considered in patenting decisions, or there will be no limits. Thank you.

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33. See *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

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