SLIDE 1

Patenting Human Organisms: Biotechnology, Morality, and the Constitution

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Talk about ethical and legal issues related to patents on human organisms. Most recently, these issues have come up in the context of debates over human cloning.

SLIDE 2: TERMINOLOGY

Because terminology matters a lot here, let me make clear what I mean by human organism. I mean human embryos or fetuses capable of developing into a human being as well as of course human beings themselves. Also, I should be clear that I will be focusing on product patents, not patents on processes for producing human organisms. The controversy has really swirled around product patents.

Before I get into the patent issues, I just want to provide some quick background on human cloning.

SLIDE 3: BACKGROUND ON HUMAN CLONING

No published case thus far of a cloned human embryo being created, but researchers are pursuing this issue.

Researchers are pursuing cloning for two distinct reasons. A small minority, usually considered to be a fringe group, is pursing the idea of cloning for the purposes of producing cloned children. A larger, more serious group is pursuing so called "therapeutic" cloning, also known as research cloning. The purpose of this process is not to create a cloned child. Rather, the aim is to create an early-stage embryo, or blastocyst, from which human embryonic stem cells can be extracted. Embryonic stem cells, which have the potential to develop into all of the various cells in the human body, have the potential to treat a variety of degenerative diseases. Studying these cells also provides insight into human embryology.

Thus far, human embryonic stem cell lines have been developed from so-called "leftover" embryos taken from fertility clinics. The problem is that cells derived from these cell lines are likely to create immune rejection problems when transplanted into an unrelated adult. By contrast, embryonic stem cell lines created through cloning the afflicted individual's own cells won't, at least in theory, precipitate immune rejection problems.

Both reproductive cloning and therapeutic/research cloning have been the subject of much controversy. On several occasions, the House of Representatives has passed bills banning all human cloning, reproductive or research-related.

SLIDE 4: CONTROVERSIAL BIOTECHNOLOGICAL RESEARCH: THE PATENT ANGLE

So what does all of this ethical controversy have to do with patents? Well, interestingly enough, one of the latest moves in the ethical controversy was a bill introduced by Senator Brownback to ban patents on human embryos. What's particularly interesting about Senator Brownback's bill is that it is typical of what happens virtually every time we have controversial biotechnological research.

Virtually every time, the issue of banning patents on such research comes in. Those who are opposed to the research itself often attack patents as another mechanism of getting at the research itself. Another reason patents are often at the leading edge of these controversies is that patents, and now patent applications, reveal what researchers may be reluctant to otherwise reveal. And because, as we all know, patents often claim more than the applicant has actually done, this can sometimes include fairly speculative plans.

SLIDE 5: HISTORY OF PATENTS AND MORALITY

It's interesting to take a brief look at the history of this pattern, where the patent system gets enmeshed in debates about the morality of the underlying research. Back in the late 1970s, when genetic engineering technologies were first introduced, and some argued in favor of a moratorium or ban on such research, the question of banning patents immediately arose as well. If you remember the famous Diamond v. Chakrabarty decision that allowed patents on recombinant bacteria, part of the opinion dealt with the argument that patents on such bacteria should not be granted because genetic engineering was a dangerous area of research.

In Chakrabarty, the Supreme Court determined that these moral issues should be addressed through regulatory mechanisms outside the patent system. According to the Supreme Court, Congress intended to allow patents on "anything under the Sun made by man."

Eventually the controversy over genetic engineering in the context of life forms like bacteria subsided. But in the late 1980s, when many groups became agitated over the genetic engineering of higher life forms, perhaps most famously the so-called Harvard oncomouse, the issue of patenting arose again. Despite the controversy, the PTO began issuing patents on higher life forms. Nonetheless, it felt compelled to issue a public statement, known as the Quigg memo, that said it would *not* issue patents on humans. The PTO indicated that such patents would conflict with the Constitution, presumably the Thirteenth Amendment. At the time, the PTO didn't clarify exactly what it meant by the term "human." But, over time it has become clear that the PTO is using the term to encompass not only human beings

that are actually born but also human embryos. In other words, what I have called “human organisms.”

Okay. Fast forward to 1998. Jeremy Rifkin, the biotechnology activist, files a patent application on a chimeric –that is, human and non-human – collection of cells. He does this explicitly for the purposes of protesting where biotechnology is headed. The Patent Office issues a press statement of a sort saying that it thinks that this application conflicts with the so-called moral utility requirement of the patent statute.

Apparently, the PTO changed its mind somewhat by the time it ultimately rejected the Rifkin application. At that point, according to Rifkin at least, the PTO apparently said that the patent application failed because Congress did not intend the patent system to encompass humans.

SLIDE 6: THE CURRENT CONTROVERSY: HUMAN CLONE PATENTS

Most recently, in the context of human cloning, concerns have arisen over patents on either methods for producing human clones or patents on human clone products. As I mentioned, Senator Brownback has introduced a bill proposing to forbid such patents. In addition, the President's Council of Bioethics, which was set up by President Bush after the controversy over federal funding of human embryonic stem cell research, held a hearing just last month to look into such patents. I was asked to speak there about whether the patent system should allow these patents. What I am going to say from here on out basically represents what I told the Council members.

Before I get into that, let me just clarify where things stand. Thus far, we have not seen any patents that could cover human organism products. The PTO has been extremely careful in that context. We have seen patents on processes that produce cloned embryos, and the claims on these processes do encompass all mammals, including presumably humans. Activist groups opposed to cloning have jumped in and suggested that these patents cover products as well. But that's simply not true.

That allows me to make a small editorial point. Unfortunately, in these cases, the emotional stakes gets very high, and this can affect even arguments made about such ordinarily unemotional issues as patents. Incendiary claims are not useful.

SLIDE 7: THE PTO'S REASONS FOR DISALLOWING PRODUCT PATENTS ON HUMAN ORGANISMS

All right. Back to the PTO's reasons for disallowing product patents on human organisms.

The PTO representative who spoke at the Council of Bioethics meeting last month gave all three reasons that the PTO has previously given.

First, she put forward the argument that Congress did not intend the patent system to cover humans.

Second, she gave the moral utility argument.

And finally, she gave the Constitutional argument.

By the way, before I address each of these arguments, let me make a general point. Some people have criticized the PTO for making policy in this area even though the PTO has not been given substantive rule-making authority by Congress. I think that criticism is misplaced.

Although the PTO does not have substantive rulemaking authority, it does have plenary authority to adjudicate patent applications. In that context, the PTO should, in fact must, make both legal/policy determinations and factual determinations.

Of course, under the Supreme Court's most recent Chevron-related jurisprudence, in particular the Mead case, the Federal Circuit probably does not have to defer to the PTO's legal/policy determinations. But that doesn't mean the PTO doesn't have the authority to make such determinations. In fact, the PTO can't avoid making such determinations.

Now let's look at each of the PTO arguments in turn.

SLIDE 8: THE STATUTE AND CONGRESSIONAL INTENT

First of all, I don't think the PTO can claim that Congress did not intend to cover humans. The patent statute's subject matter provision talks about processes, machines, manufactures, and compositions of matter. Under a plain meaning, or textualist, approach to statutory interpretation, the statute probably covers humans. A human is certainly a composition of matter.

Now I happen to think the plain meaning approach does not tend to work very well in patent law. (That's a question for another day.)

But even under an approach that some scholars have called "dynamic statutory interpretation," which looks at legislative history and the overall purpose of the statute, it's hard to say that Congress didn't intend to cover humans. There's no evidence that Congress thought about the issue at all.

SLIDE 9: MORAL UTILITY

What about the moral utility argument?

I am skeptical of this argument. The patent statute itself contains no suggestion that Congress intended the statute to operate as a mechanism for mediating ethical concerns about the research avenues that scientists pursue.

Now there has historically existed within the American patent law a judge-made, or common law, doctrine known as moral utility. A few court decisions from the 19th and early 20th centuries invoked the doctrine to reject patents on (inter alia) gambling machines.

But more recent decisions by the Court of Appeals for the Federal Circuit, like the felicitously titled Juicy Whip v. Orange Bang case, tend to emphasize the narrowness of the doctrine. Notably, the Supreme Court decision in *Diamond v. Chakrabarty* made no mention of this doctrine.

SLIDE 10

Of course, Congress could decide to put a moral utility doctrine explicitly into the statute. And if Congress were worried about patent examiners not having the competence to judge moral utility, it could set up some sort of advisory board to the Patent Office that guided the PTO on ethical questions.

Alternatively, Congress might specifically say that patents on human organism products (or processes, for that matter) are contrary to public morality and therefore shall not be granted.

But if Congress were going to say this, it seems to me that it would have to be very clear about exactly why patents per se, as opposed to human cloning generally, are a bad idea. If Congress thinks that human cloning generally is a bad idea, it should ban human cloning directly.

SLIDE 11: Concerns about "Commodification"

Now one might argue that although the patent statute should not encompass generalized ethical concerns about the directions that scientific research may be taking, it might take into account more specific concerns about what might be called the commodification of such research. Precisely what commodification means has been the subject of much debate in the academic literature, and I will not get into that debate here.

But to give an example, we may be comfortable with, or even endorse, therapeutic cloning but nonetheless oppose giving property-like rights on the human embryo product. Alternatively, we might even be comfortable with reproductive cloning but oppose property-like rights on the human beings produced by such cloning. On this view, perhaps Congress could somehow use moral utility to address the commodification question in particular.

When patents fall short of claiming full human beings, however, it is not clear why the commodification worry should focus on patents. Indeed, whether patents are allowed or disallowed will affect commodification levels indirectly at best.[1] The patent grant confers on its holder the right to exclude others from "making, using, offering for sale, or selling the

[1] A decision to disallow patents might be justified on the grounds that particular types of research should be freely available to all scientists. Because patents do confer a right to exclude others from practicing the patented invention, broad patents on basic research can impede follow-on research and hence scientific progress. *See generally* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L. J. 813 (2001). This utilitarian/economic argument for disallowing patenting is, however, not specific to human organisms but encompasses basic research generally.

invention."[2] It does *not* confer any affirmative right of use upon the patentee.

Consequently, even if we were to allow patents on a particular invention, we could prohibit selling or otherwise "trafficking" in the invention. Under our current law, for example, individuals are not allowed to sell or otherwise traffic in human organs. There is every reason to believe, however, that individuals could still seek patents on such organs (if they could meet the other requirements of the patent statute, such as novelty and nonobviousness). Conversely, the decision to ban patents on particular inventions would not eliminate commodification. Absent other federal or state laws, individuals could still sell and buy human organisms as tangible property.

It's also worth mentioning that a Congressional decision to import any sort of morality requirement into the patent statute might exceed Congress' authority under the Copyright and Patent clause of the Constitution. The Copyright and Patent Clause states that intellectual property rights are to be granted for "limited times" in order "to promote the promote the Progress of Science and useful Arts." U.S. CONST., art. I, sec. 8, cl. 8.

A number of noted scholars have argued that Congress can enact legislation under the auspices of this clause only if it could be plausibly argued that the legislation in fact promotes the progress of science and the useful arts. *See, e.g.*, Robert Patrick Merges & Glenn Harlan Reynolds, *The Proper Scope of the Copyright and Patent Power*, 37 HARV. J. ON LEGIS. 45 (2000). The

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[2] 35 U.S.C. Section 154.

Supreme Court will consider this position in the context of a copyright case it has accepted for argument challenging the constitutionality of the Sonny Bono Copyright Term Extension Act. *See* Eldred v. Aschroft, 122 S.Ct. 1062 (2002) (memorandum granting certiorari)

SLIDE 12: PATENT ON FULL HUMAN BEINGS

Now in one context, patents on human organisms could raise patent-specific ethical concerns. If product patents were granted on full human beings, these patents would give the patent owner the power to interfere quite significantly with the autonomy of such beings. Under the patent law, the patentee's power to exclude "others" from "using" the patented invention would presumably encompass the power to restrict the patented being from "using" him/herself.

As a consequence, the patentee might have the authority to forbid the patented being from seeking employment or perhaps any type of association.

Because the patent statute also allows the patent owner to prohibit "others" from making the patented invention, the patentee would perhaps also have control over the patented being's reproduction. Needless to say, such severe limitations of autonomy would represent a serious ethical concern

SLIDE 13: THE ROLE OF THE CONSTITUTION

Ethical concerns about the patenting of human beings could be addressed, however, through the Constitution, specifically the 13th and 14th Amendments.

The 13th amendment bars not only slavery but also involuntary servitude. A good case can be made that a product patent would impose an involuntary servitude.

Admittedly, 13th Amendment jurisprudence on involuntary servitude (like 13th Am. Jurisprudence generally) has been rather sparse and has focused on cases where there has been physical or legal compulsion to work. These have typically been cases where laborers were forced to work to pay off debts that they owed.

But property rights that entirely disallowed an individual from making choices regarding his or her employment would, at least arguably, fall within the scope of the Amendment.

In addition, the patentee's control of the patented being's right to reproduce would implicate the protections of the 14th amendment. The 14th amendment requirement that there be "state action" would be met by the fact that the patent is a right explicitly conferred by the state.

(There might even be some sort of 1st Amendment right of association violation, although this is less clear.)

The 13th and 14th amendments provides the best justification for the PTO's current policy disallowing product patents on humans. But, as I will discuss further in a moment, it seems to me that these amendments apply only to full human beings, not to human embryos. So to the extent the PTO is saying that there is a constitutional bar to patents on human organisms generally, I think it is overstating.

SLIDE 14: CAN THE PTO MAKE CONSTITUTIONAL DETERMINATIONS

Some commentators have argued that the PTO does not have the authority to make this constitutional call. I think this argument is mistaken. Although the PTO obviously does not have ultimate authority on the constitutional question, it can take into account constitutional concerns when interpreting statutes that are at least arguably ambiguous on a particular question.

Supreme Court case law has consistently indicated that where a statute is susceptible of alternative constructions, agencies can, and probably should, interpret the statute in a manner that does not raise constitutional questions. In fact, the Court has consistently invalidated agency interpretations of statutes when such interpretations did raise constitutional questions.[3] The idea behind this canon of statutory interpretation, which might be termed the avoidance canon, is that we should not lightly presume that Congress intended to infringe on constitutional guarantees.

It is fair to say that the statute is ambiguous on the question of whether full human beings constitute patentable subject matter. Although the patent statute's statutory subject matter language is broad and does not bar the grant of product patents on human beings, it hardly compels such grants.

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[3] *See, e.g.*, Solid Waste Agency v. United States Army Corps of Eng'rs, 531 U.S. 159, 172 (2001) (rejecting agency rule that strained the limits of federal power under the Commerce clause); Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Const. Trades Council, 485 U.S. 568, 575 (1988) (rejecting agency interpretation that raised First Amendment issue); Kent v. Dulles, 357 U.S. 116, 129-30 (1958) (rejecting Secretary of State's denial of certain passports implicating the right to travel).

SLIDE 15

How Will Courts View Issue?

No doubt a PTO denial of a product patent on a human being will at some point be appealed to the court system, specifically the Court of Appeals for the Federal Circuit. It is quite likely that the Federal Circuit will also view product patents on full human beings as being in serious tension with the Constitution. The Federal Circuit, and ultimately the Supreme Court, would have two options for rejecting such product patents: like the PTO, they could do it as a matter of statutory interpretation using the avoidance canon. Alternatively, as Article III courts, they could do it by similarly declaring such product patents to be an unconstitutional application of the patent statute.

SLIDE 16: APPLICATION TO UNBORN HUMAN ORGANISMS

It is important to emphasize, however, that these constitutional arguments do not apply to patents claiming human organisms that have not been born, such as embryos or fetuses. The Supreme Court has stated that a fetus is not considered a person within the meaning of the Constitution.[4] Moreover, although the Court has not specifically addressed the constitutional status of embryos, there is no reason to believe that embryos would have a greater claim to personhood or to constitutional protection than fetuses. Consequently, under current law, there is no constitutional bar to patents with claims that are strictly limited to human embryos or fetuses. So to the extent that the PTO's current policy would deny patents on human embryos and fetuses, it should probably be scaled back.

But if Congress is concerned with protecting the interests of human embryos and fetuses, it can pass legislation protecting those interests directly. As noted earlier, this legislation could address general ethical concerns or it could address more specific concerns about commodification.

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[4] Roe v. Wade, 410 U.S. 113, 157 (1973) (stating the usage of "person" within the Constitution "has application only postnatally.") *See also* Planned Parenthood v. Casey, 505 U.S. 833, 899 (1992) (Stevens, J., concurring in part and dissenting in part) (asserting that "no Member of the Court" has questioned the proposition that a fetus is not a person for purposes of federal constitutional law).

SLIDE 17

Conclusion

The issue of patenting is, in most respects, orthogonal to ethical debates on research involving the creation or manipulation of human organisms. It would be a serious mistake to modify the patent statute in response to concerns about research that are not patent specific. In the isolated circumstance where human organism research does raise ethical concerns that specifically implicate the patent system, these ethical concerns can be addressed through the Constitution.