

Biotech and ethics collide in patent-funding debate

On Jan. 23, President Bush signed into law appropriations omnibus bill H.R. 2673 authorizing funding for the federal government including the Patent and Trademark Office. The bill contained a controversial rider on human patenting introduced by Dave Weldon, R-Fla., that states [n]one of the funds appropriated or otherwise made available by this act may be used to issue patents on claims directed to or encompassing a human organism."

The Weldon amendment represents a strategy for restraining scientific research in a controversial field by prohibiting the issuance of patent claims to a particular technology.

Inadvertently, it may affect America's international standing in developing countries as a fierce proponent of robust intellectual property systems.

The PTO already had a 17-year-old ban on patent claims if their "broadest reasonable interpretation as a whole" encompasses a "human being." Patent officials in 1987 cited the 13th Amendment as textual support for the constitutional prohibition on property interests in human beings.

However, Weldon, a physician, pointed to a recent report wherein researchers described culturing human male and female embryonic cells for six days as an example of a study "universally condemned as unethical and unnecessary."

He insists there is a need to "draw the line where some rogue scientists fail to exercise restraint" and that the investigators should not be allowed to financially exploit science by being granted an "exclusive right to practice such ghoulish research."

Curtailing Research

Opponents of the Weldon amendment argue that a strategy for restraining scientific research by prohibiting the issuance of patent claims to a particular technology demonstrates a basic misunderstanding of the patent system.

A patent merely allows the holder to exclude others from making, using, selling or importing an invention and does not allow the holder to exercise an invention. It does not, as Weldon suggested, give the patentee the "exclusive right to practice ... ghoulish research," or anything else, for that matter.

In fact, at least nine states have criminalized the destruction of human embryos for research purposes.

Additionally, because the Food and Drug Administration, not the PTO, is the final arbiter of



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safety and efficacy of human therapeutics, its approval alone determines the size of an exploitable market for a given technology.

Thus, opponents suggest the amendment was motivated by an alternate agenda.

Groups such as the Biotechnology Industry Organization fear that the ripening of the Weldon amendment into law has unnecessarily obfuscated the standards of patentability for ground-breaking technologies relating to therapeutic cloning and gene therapy.

However, upon close examination, the scopes of the PTO ban and the Weldon ban look substantially identical.

The Legal Bottom Line

While the PTO bans patent claims directed to "human beings," the Weldon law recited "human organisms." But in the Congressional Record, Weldon strenuously asserted the amendment exactly reflects the scope of the PTO ban on the patentability of human beings "at any stage of development."

Weldon clarified that a human embryo was defined as a human organism whereas a stem cell was not.

His measure, Weldon said, would not affect any existing patents on human stem cells lines or have any bearing on stem cell research, including methods for creating human embryos.

When assessing the patentability of biotechnological subject matter, the PTO and — ultimately the courts — must consider not only the Constitution, the "everything under the sun that is made by man" standard set forth in the U.S. Supreme Court's Chakrabarty case, but also the Weldon law, at least for now.

Because the Weldon law is part of an appropriations bill for 2004, it is limited in its

impact, affecting only patents that issue this year. A similar bill would have to be passed and signed into law each following year for the ban to remain in effect.

International Trade Implications

Opponents of the law say revising patent laws to deal with moral issues through transient funding bills sets a dangerous precedent.

To this end, the Weldon law may effect the nation's credibility in vital negotiations over the scope of global intellectual property rights, as set forth in the Trade Related Aspects of Intellectual Property agreement of the World Trade Organization.

Although TRIPS Article 27(2) allows members to exclude from patentability inventions the economic exploitation of which might be considered immoral, the United States has not used this provision and generally does not use patent laws to regulate such activity.

Many in the developing world perceive the TRIPS regime lacks the flexibility that is needed with respect to the compulsory licensing of patented drugs to allow those countries to adequately address their unique public health needs.

However, the United States has taken a hard line in arguing for very limited drug import exceptions to TRIPS.

It has now been suggested that the United States' alteration of its patent laws through an appropriations bill such as the Weldon amendment represents the sort of patent circumvention the United States is keen on persuading developing countries to abandon.

The pharmaceutical community is concerned that developing countries could raise Article 27(2) as providing a mechanism for excluding pharmaceutical products from patentability, thereby obviating TRIPS' complex system of compulsory licensing on the grounds that one could find their commercialization, in view of certain public health needs, morally offensive.

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