New Patent Legislation Sets Dangerous Precedent
And Stifles Research
(September 2, 2003)

Background

On July 23rd, the House passed by voice vote an amendment on human patenting offered by Dave Weldon (R-Fla.) as part of the Commerce-Justice-State appropriations bill (H.R. 2799).

The text of the amendment is:

> "None 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."

This provision is objectionable for the following reasons: 1) Since the language does not define "human organism" it could preclude patenting of many biotechnology inventions (see attached chart), thereby impeding the development of new and potentially life saving products; and 2) the language is unnecessary as it is current PTO policy not to issue patents on humans. Moreover, this amendment would preclude the U.S. Patent and Trademark Office (PTO) from granting patents on an organism of human species at any stage of development produced by any method, a living organism made by human cloning, and a process of human cloning.

Key Points

- **The language is vague, overly broad and would jeopardize many human-derived biotechnology inventions[1].** Among the biotech inventions that would be placed in

[1] Four categories of inventions can be claimed: "a new and useful *process, machine, manufacture* or *composition of matter*." Any new and useful improvement to any of those may also be patented. The courts and the PTO have determined that multicellular living organisms, including animals, are patentable. In general, however, courts have interpreted the patent statute to deny protection for claims directed to "products of nature." Only things that have been specifically altered in their physical makeup through human intervention, and as a result differ from the corresponding products in their natural states, may be the subject of a U.S. patent claim. For example, a bacterium discovered in the wild may not be patented as a "thing," but a purified composition containing the bacterium in a form distinct from how it is found in nature may be patented. Similarly, an animal or human produced by conventional reproduction—with no intervention by an "inventor"—would not qualify as a patentable "manufacture" because it is a product of nature. Living organisms that possess physical characteristics resulting from human intervention qualify for protection because such living organisms are no longer "products of nature."

jeopardy are stem cells and stem cell production methods, all cell and tissue therapy products and methods including methods of making replacement tissue and organs, methods for therapeutic cloning, gene patents, transgenic animals capable of making human proteins, methods for inducing production of an exogenous protein by humans (such as gene therapy), and claims involving the *in situ* or *in vivo* formation of an active ingredient. These inventions often lead to important new products.

- **The language "encompassing a human organism" creates uncertainty about the PTO's definition of a "human organism."** There is no clear indication of where something ceases to be human and becomes something else. For example, would a mouse with a human transgene be considered "encompassing" a human organism? It has been reported that the chimpanzee genome is 98 percent similar to the human genome. Would a human cell or organ transfected with chimpanzee DNA be considered as "encompassing" a human organism? Would a method of making human stem cells for therapeutic purposes be considered a claim that "encompasses" a human organism?

- **Investment and research into developing biotechnology products would halt if the amendment were enacted into law.** It takes 10 to 12 years and approximately 800 million to bring a biotechnology product into the market. Investors need assurance that their investment in this risky endeavor will eventually pay off. Without patent protection on products developed through biotechnology, investors would not invest in inventions that cannot be protected by the patent system. Treatments for tissue regeneration for burn victims, bone marrow regeneration after chemotherapy and growth hormone deficiency are some conditions for which lifesaving biotechnology therapeutics would not be available.

- **Current PTO practice prevents patenting of human beings.** Current PTO practice prohibits patents on subject matter that includes within its scope a human being. In 1987, Donald J. Quigg, assistant secretary of commerce and commissioner of patents and trademarks, issued a memo stating, "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter." Accordingly, since 1987, the PTO has rejected any claim that encompasses a human being. The statutory basis for the PTO's rejection of patents encompassing a human being is found in title 35 U.S.C. 101, which delineates patent-eligible subject matter. Moreover the PTO cites the constitutional prohibition against any party owning property right in a human being (the Thirteenth Amendment)[2] as a basis for rejecting claims to humans.

- **Revising patent laws in order to deal with ethical concerns can have serious long term implications for all industry sectors.** This amendment is tantamount to opening up the patent laws in order to carve out specific subject matter from patentability and must be considered carefully. Revision of the patent laws to exclude one subject area

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2 *Ibid.*

3 U.S. patent applications are published in unamended form 18 months after they are filed. They thus represent the applicant's original claims and do not indicate any likelihood that any original claim will be granted. No exclusive rights attach to the publication of a patent application.

from patent eligibility can lead to other types of exclusions. For example opening up the Patent Act could open the door and create a pathway to preclude patents on virtually any item or industrial product.

- **Specific exclusions from patent eligibility are inconsistent with the U.S. positions in the international arena.** The Word Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement allows countries to deny patents on plants and animals, which has been a source of U.S. concern for many years. At the international level, the United States has consistently fought to provide broad patent coverage for transgenic plants and animals and other key biotechnology sectors. Carving out technology areas, such as those identified in the Weldon Amendment, from the U.S. patent system would be inconsistent with long-standing U.S. trade and IP policy and would set a dangerous precedent internationally.

- **The PTO concern about the strength of the Quigg memo to prevent a patent on a human being is unfounded.** The PTO believes that the substance of the Quigg memo should be put into law in order to strengthen the agency's position. Their fear is that the Supreme Court cannot prevent the patenting of a human being because of the holding in *Diamond v. Chakrabarty* where the Court declared that "anything under the sun made by the hand of man" is eligible for patenting. Although published patent applications[3] indicate that some parties have filed broad claims to cloned animals and cloning methods that could be used in the context of human reproductive cloning, such claims most likely reflect the creativity of patent attorneys, who are trained to claim inventions as broadly as possible, rather than the intentions of the inventors or their sponsoring institutions. Moreover, these patents, as other overly broad patents can be challenged either in the courts, or through the PTO's re-examination procedures. Press reports suggest that some people, in a handful of countries, are attempting—or claim to be attempting—to clone human beings. These are clearly unethical scientists who are not positioned to succeed with such methods. Moreover, these parties are not generally the users of the patent system.

Contact information

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UNMODIFIED HUMAN CELL AND TISSUE PRODUCTS	MODIFIED CELL TYPES	PRODUCTS AND METHODS FOR "CLONING"
Mature oocyte Mature spermatozoon	Enucleated oocyte or spermatazoon Genetically modified oocyte or spermatozoon	Methods of nuclear transfer Methods of making a transgenic mammal Methods of culturing gametes, zygotes or embryonic tissues Methods of genetically modifying cells or tissues Genetic vectors (particularly cell type-specific vectors)
Zygote		
Blastocyst		Methods of selecting cell populations Methods of isolating cell types or cellular structures Methods of identifying genetic characteristics (e.g., karyotype, polymorphisms)
Totipotent stem cell*	Genetically modified stem cells	
Pluripotent stem cell*		
Embryo	Genetically modified embryo or embryonic tissue	Products and methods to promote or facilitate embryo implantation
Fetus		
Human (post-birth)	Genetically modified somatic cells and tissues Cultured tissue/synthetic organs	

The subject matter in the gray boxes is generally not patentable under current law.

*Cells and tissue structures as they exist in vivo cannot be patented under current law because they have not been modified by the "hand of man." However, cells or tissues that are newly isolated or have novel structural or functional properties are potentially patentable.

Human beings are generally understood not to be patentable subject matter under current law based on the U.S. Patent and Trademark Office policy not to allow any claim to an organism unless it expressly or implicitly excludes humans.