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Genetic Engineering and the Patent Office

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Higher life forms created through genetic engineering or other biological or biochemical techniques are now regarded as potentially patentable. On April 7, 1987, the United States Patent and Trademark Office announced that it "now considers non-naturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter." 1077 Off. Gaz. Pat. Office 24 (Apr. 21, 1987).

This announcement has created a highly emotional controversy with the Patent Office at its center. Among those attacking the Patent Office have been environmentalists, animal rights activists, religious fundamentalists, and farmers' organizations. See Crawford, Religious Groups Join Animal Patent Battle, 237 Science 480 (July 31, 1987).

However, the action of the Patent Office is not only in accord with recently decided cases, including one by the Supreme Court, on the subject matter potentially covered by the patent laws, but is the only possible action consistent with the scope and spirit of those laws.

The catalyst for the recent announcement was a decision of the Patent Office's Board of Patent Appeals and Interferences, *Ex parte Allen*, 2 U.S.P.Q. 2d 1425 (Bd. Pat. App. & Interferences 1987). In that case, the Board ruled that oysters which had been artificially treated to alter the number of their chromosomes (cellular elements carrying the genes, the units of heredity) were properly patentable subject matter under section 101 of the patent statute, 35 U.S.C. 101 (1982).

In *Allen*, the Board broke no new ground, but basically followed two previous cases, *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. & Interferences 1985), and the leading case in this area, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). *Hibberd* basically held, following *Chakrabarty*, that higher plants are patentable subject matter, so that the reasoning in *Chakrabarty* is the basis of this entire area.

In *Chakrabarty*, the Supreme Court was forced to decide whether section 101 includes genetically engineered microorganisms in its definition of patentable subject matter. That statute, enacted in 1952, basically follows previous patent statutes going back to 1793 in its definition of patentable subject matter: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

In *Chakrabarty*, the Supreme Court, in its interpretation of this section of the patent statute, held that a genetically engineered bacterium not found in nature was indeed a "manufacture" or a "composition of matter" as those terms are used in the statute, and therefore was patentable, assuming that the other statutory requirements for patentability had been met. *Chakrabarty*, 447 U.S. at 318. In construing section 101, the Court stated that the Congress, in enacting the 1952 patent statute, had intended statutory subject matter to "include anything under the sun that is made by man." *Id.* at 309 (quoting S. Rep. No. 1979, 82d Cong., 2d Sess. 5).

In *Chakrabarty*, the Court rejected suggestions that the existence of the Plant Patent Act of 1930, 35 U.S.C. § 161 (1982), which affords patent protection to some asexually reproduced plants, and the Plant Variety Protection Act of 1970, 7 U.S.C. § 2402(a) (1982), which affords protection for certain sexually reproduced plants but expressly excludes bacteria from its coverage, were intended to limit the scope of patentable subject matter under section 101. *Chakrabarty*, 447 U.S. at 310-14. The Court stated that, according to the legislative intent underlying those statutes, they were enacted not because the plants covered by them were not patentable subject matter under section 101, but because inventions involving plants faced other obstacles to qualifying for patent protection under the existing statutes. *Id.*

Accordingly, the Court concluded that to draw a distinction between living and nonliving matter for the purpose of section 101 was insupportable, and that as long as the bacterium developed by Chakrabarty was not naturally occurring, it was entitled to a patent as a manufacture or composition of matter. *Id.* at 309-10.

For the Court to have taken a narrow view of the patent statutes, as urged by the dissent in *Chakrabarty*, *id.* at 318 (Brennan, J., dissenting) would in fact have been inconsistent with the purpose of the patent laws. This view would have refused patentability on a particular area of subject matter unless Congress explicitly intended that such an area be covered. That such an interpretation would undermine the entire patent statute was recognized by Chief Justice Burger, writing for the majority, when he stated that "[a] rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability." *Id.* at 316. In fact, under the patent law, not only is an invention that is anticipated by prior known work unpatentable, but one that, although not precisely anticipated, would be obvious to a person with ordinary skill in that art, is also unpatentable. See 35 U.S.C. §§ 102-103 (1982). Such a restricted view of patentable subject matter would clearly have made such inventions as the telegraph, electric lamp, airplane, and transistor, all of which were considered unforeseeable at the time they were made, unpatentable. See *Chakrabarty*, 447 U.S. at 310 n.10.

This untrammelled view of patentability draws support from cases involving another part of section 101, the requirement of utility. The general rule has emerged that if an invention has any utility at all which is not solely directed toward injurious or fraudulent ends, it meets the utility requirement, and does so even if the invention in fact is most often used to serve such deleterious ends. See *Ex parte Murphy*, 200 U.S.P.Q. 801 (Bd. Pat. App. 1977). After all, such inventions as the automobile and the airplane, though highly useful, certainly have their destructive sides. In general, it is for Congress and the regulatory agencies to deal with the possibly destructive effects of new inventions, and not for the Patent Office to refuse patents on them on such grounds. For the Patent Office to refuse patents on "controversial" inventions solely because some in society objected to them or because they might be misused in the wrong hands would not only result in the shutting off of the flow of new technology, but also would result in the Patent Office arrogating to itself legislative and moral powers beyond its constitutional or statutory mandate. Even the strongest opponent of genetic engineering would not wish this. In fact, the "parade of horrors," *Chakrabarty*, 447 U.S. at 316, alluded to by the opponents of that decision, really has not come to pass as the result of genetic engineering on bacteria. Even if some unanticipated or deleterious effects do emerge as a result of similar patentable work on higher organisms, including animals, that is no reason to refuse patentability of such important inventions.

Although the Patent Office was well within the law when it made its recent announcement, it probably could have avoided a good deal of the subsequent controversy if it had been more politic. It could have, for instance, not made any announcement, or could merely have announced that the Office will not reject any application for a patent, in accordance with recent court and administrative decisions, merely because the invention set forth in that application relates to living organisms. Still, the Patent Office may have performed a useful service to the scientific and legal communities by bringing the issue to the fore, and the legal community must respond with a clear understanding of the potential, as well as the perceived risks, of this new technology.

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