Patenting of Industrial Biotechnology: A Gamble That Pays Off

by Kristin Timmer[1] and Jeffrey A. Wolfson[2]

We have come a long way from that one word from "The Graduate." *Plastics*, once conventionally manufactured from petroleum, is a field that has drastically expanded to include industrial biotechnology, which relies on micro-organisms rather than merely petroleum to develop biofuels, chemicals, and bioplastics. Enzymes or micro-organisms are essentially miniature biofactories that convert plant sugar, starch, or oil into biodegradable polymers used to make various products, including bottles, carpet, clothing, and cosmetics. With the new focus on renewable energy and resources, industrial biotechnology has enormous and increasing market potential. The U.S. Supreme Court's landmark decision in *Diamond v. Chakrabarty*, 44 U.S. 303 (1980), permitted the patenting of genes and living organisms and spurred innovation and the growth of industrial biotechnology in the U.S. There are concerns by some, however, that the over-proliferation of patents in industrial biotechnology may now stifle research and innovation in this exciting and emerging field.

The U.S. International Trade Commission ("ITC") Office of Industries recently issued a report that evaluated the influence of patents on the innovation of industrial biotechnology[3]. The 64-page report analyzed patents granted from January 1975 to December 2006 and focused on enzymes or micro-organisms that catalyze chemical reactions. One significant ITC finding is that companies, universities, and other players in the industrial biotechnology field hedge their expenditures on research and development by making use of the U.S. patent system as discussed below.

Numbers: The number of issued industrial biotechnology patents steadily increased from the mid-1980s, following the *Diamond* opinion, until 1999. Delays and stricter standards at the United States Patent and Trademark Office ("USPTO") then appear to have caused a decline in the absolute number of issued industrial biotechnology patents in 2000-2005. During a rapid uptick in growth in this emerging field, the filing of biotechnology applications increased by about 40 percent during that same period even as the absolute number of patents issuing in this field decreased. There was a resurgence in the number of industrial biotechnology patents granted in 2006, but unfortunately, the ITC report did not address the time period after December 2006 so no effective conclusions can be drawn as to the current trend.

Players: Universities and companies of all sizes own industrial biotechnology patents. Moreover, there is a steady stream of new participants in this emerging field. According to the ITC report, the "steady stream of new entrants is noteworthy because of the critical role that new entrants, and particularly start-up firms, have played in the development of the biotechnology industry."[4] Additionally, it appears that the top 10 industrial biotechnology patent owners each own fewer patents as compared to other industries, suggesting a greater fragmentation of industrial biotechnology patents among a larger number of companies.

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[3] USITC, *Industrial Biotechnology: Development and Adoption by the U.S. Chemical and Biofuel Industries*, USITC Publication 4039, October 2008.

[4] *Id.* at 3-7.

Player strategy: During the time period explored, *i.e.*, before the current seismic economic shifts, industrial biotechnology companies continued to increase R&D expenditures and file patent applications to build robust patent portfolios. Novozymes, a leading player in enzyme technologies, conducts a Freedom of Operation Analysis (FOA) at a preliminary stage of projects to determine whether the project may be blocked by third party patent rights.[5] In our experience, several clients use ongoing programs like this to minimize litigation risk and liability, breathing new life into the old adage that an ounce of prevention is worth a pound of cure. The FOAs are updated regularly throughout the project with any recent and relevant patent activity. Patents are then sought by Novozymes to help obtain operational freedom, to create value, and to limit competitors' activities. Indeed, Novozymes obtained an impressive 334 patents and filed an estimated 447 pending patent applications from 1997 to 2007, a pace of approximately 44 new filings and 33 patents issuing each year over a decade.[6] Thus, the ITC Report does not reflect that non-practicing entities are snapping up patent portfolios to enforce in litigation or to pursue nuisance settlements, as often happens in the business method and computer software fields. Rather, the ITC Report reflects businesses including small startups, and non-profit universities and consortia, conducting research and seeking patent protection to pursue royalties should the technology be successfully commercialized, which is typically considered an appropriate use of the patent system to create incentives for further innovation.

One publicly known industrial biotechnology case study recently involved Novozymes in an intellectual property dispute with Genencor, another leader in enzyme technologies. While Novozymes' patent application related to alpha amylase enzymes was pending before the USPTO, Novozymes' attorneys determined that Genencor's Spezyme® Ethyl alpha-amylase product infringed their pending claims. The very day Novozymes' alpha amylase application issued as a patent, Novozymes sued Genencor for patent infringement. Novozymes prevailed and was awarded enhanced damages because Genencor's continued product sales over roughly 18 months until a trial decision was issued was determined to constitute willful infringement. The parties settled and Genencor paid Novozymes a total damage award of $15.3 million.

The ITC Report, and our experience assisting Biotech/Pharma clients, shows that securing patent rights is extremely important and valuable to industrial biotechnology companies. Patents do not typically create a barrier to research and innovation in industrial biotechnology. Rather, patents usually pose the biggest problem only to companies that hastily launch products and services without conducting a careful advance review of the relevant patent landscape. Thus, it appears that patent rights are integrally involved with a winning strategy to develop and commercialize products in the exciting field of industrial biotechnology, without significantly negatively affecting the ability to commercialize products and services in the industrial biotechnology sector.

Haynes and Boone, LLP's intellectual property attorneys are well versed in all aspects of patent law, including securing domestic and foreign protection, preparing freedom to operate opinions to minimize the risks of litigation, strategic portfolio management, diligence of IP assets, IP agreements, and enforcing patents and defending against claims of patent infringement. If you have any questions regarding patent law involving biotechnology, pharmaceuticals, or any other aspect of intellectual property law, please contact one of the attorneys listed below.

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[5] Lambiris, Novozymes, "The Importance of Patents," September 3, 2008.
[6] USITC, *Industrial Biotechnology*, 2008, 4-6.