GREATER PREDICTABILITY MAY RESULT IN PATENT POOLS

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With great relief, the biotechnology industry has watched the federal courts begin to clarify the legal uncertainty surrounding the enforceable scope of seemingly broad prophetic patent claims granted by the U.S. Patent and Trademark Office for early biotechnology inventions.[2] The concerted response of the PTO to recent pronouncements from the U.S. Court of Appeals for the Federal Circuit in biotechnology cases strongly suggests that any industry fears over the stifling impact of broad pioneer patent protection on biotechnology research and development will be relatively short-lived.

Such trepidation should continue to subside and allow the biotechnology industry to begin embracing cooperative market-based technology transfer strategies similar to those relied upon in other technology sectors. A prudent consideration of any vision for future collective rights in biotechnology, however, begins with an appreciation of the specific experiences and unique demands of the industry.

For a biotechnology company, there is arguably no greater asset than a proprietary position on genetic material that serves as the platform for the development of commercially significant biological products. Besides its straightforward function as a direct template for such biologics, genetic material also has enormous potential as a basic research tool with many possible applications.

The technical leap from knowledge of a simple genetic sequence to such downstream applications, however, while perhaps grounded in accepted scientific methods, is certainly not trivial. Accordingly, certain members of the biotechnology industry have decried any possibility that the mere disclosure of a genetic sequence alone could form the basis for exclusionary patent rights against later-developed products which resulted from extensive additional scientific efforts and which determined the biological significance of that sequence.[3]

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[2] This article refers generally to biotechnology inventions to include isolated genetic molecules, such as DNA or RNA, and biologics produced through recombinant technology. For a cogent discussion of this subject matter, *see Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1207-08 n.4 (Fed. Cir. 1991), and *In re O'Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988), and references cited therein.

[3] For a scholarly discussion of possible economic consequences of patented "upstream" technology on "downstream" research and development, see Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (May 1, 1998).

Nonetheless, this possibility came to the fore recently, when the PTO announced that it would likely grant patent claims to genetic sequences, known as expressed sequence tags, or ESTs, and single nucleotide polymorphisms, or SNPs, despite minimal disclosure of their biological significance by the patent applicant.[4] n3 The patent claims receiving the preliminary approval of the PTO seemed of such broad scope that even the use of products derived from genetic material, of which only a fraction of the sequence is patented, could constitute an infringement under the patent law.

In the absence of specific guidance from the federal courts regarding the enforceable scope of such seemingly broad, prophetic patent claims, the biotechnology industry was mired in public debates over the proper scope of patent protection in this field. Irrespective of the outcome, the controversy itself has exaggerated defensive concerns, causing some biotechnology companies to adopt arguably erratic licensing strategies.[5]

In recent years, the Federal Circuit has begun to confront the issue of the proper enforceable scope of facially broad biotechnology patent claims, and it will continue to do so with increasing frequency as more biotechnology patents face litigation. In the early cases, the court reiterated the fundamental patent law requirement that the enforceable scope of the claims reasonably correspond to the enabling aspects of the disclosure provided by the patent applicants.[6]

Federal Circuit Limits Claims

Bolstered by the practical reality that many aspects of biotechnology are still fairly characterized as unpredictable, the court indicated, for example, that patent claims to a broad genus can be invalid when the disclosure sets out working examples of only a few of the species in the claimed genus.[7] The Federal Circuit predicated its rulings on the lack of information sufficient to enable one skilled in the art to practice the entire range of embodiments encompassed by the broad generic claim. As such, the validity of broad prophetic biotechnology patent claims seemed endangered.

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[4] *See* Lynn Pasahow and Andrew Kumamoto, *Human Genome Project Raises Patenting Issues*, NAT'L L.J., Oct. 20, 1997, at C31. The announcement by the PTO in February 1997 that ESTs could be patentable rekindled the controversy over gene patenting and its potential chilling effect on innovation in biotechnology. See Ed Susman, *U.S. PTO to Allow Patents on Gene Fragments called ESTs*, BIOTECHNOLOGY NEWSWATCH, March 3, 1997, at 1.

[5] *See* Mike McGee, *The Gene Chip Patent Wars*, AM. LAW., March 12, 1998, at 1 (commenting on "EST Paranoia").

[6] *See, e.g., In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

[7] *See Genentech v. Novo Nordisk*, 108 F.3d 1361, 1365 (Fed. Cir.), *cert. denied*, 522 U.S. 963 (1997).

The Federal Circuit further corralled anxieties of a skittish biotechnology industry when it decided *Regents of the University of California v. Eli Lilly & Co.* last year.[8] In *Lilly*, the appellate court provided yet another legal basis for limiting the scope of biotechnology patent protection. The Federal Circuit upheld the district court's invalidation of patent claims broadly directed to vertebrate insulin-encoding cDNA when the patent applicant had disclosed the genetic sequence of only rat cDNA.

In contrast with earlier biotechnology cases focusing on the enabling aspect of the disclosure, the Federal Circuit in *Lilly* held the patent claims invalid for inadequate written description. The court concluded that the disclosure of a single species of genetic material does not provide an adequate written description necessary to support patent claims to a broad genus of genetic material.

Indeed, these pronouncements by the Federal Circuit indicate that the effective scope of patent protection for certain biotechnology inventions may be far more limited than the facial breadth of the patent claims granted by the PTO for those inventions. To alleviate this inconsistency, the PTO apparently will adopt a closer scrutiny of patent applications for biotechnology inventions -- at least with ESTs and SNPs -- in an attempt to ensure that the scope of the patent claims is supported by an adequate written description and enabling disclosure.[9]

This prospective remedy, however, still leaves numerous issued patents for which the true enforceable scope of the claims might be suspect in view of the Federal Circuit's more recent holdings. A potential consequence of this uncertainty is inaccuracy in the valuation of patent rights in the various risk assessments informing freedom-to-operate opinions, licensing arrangements and pre-litigation strategies.

As the Federal Circuit continues to refine its patent law jurisprudence regarding biotechnology inventions, however, the picture of the patent landscape in the biotechnology area will come into sharper focus. With more recognizable and reliable legal boundaries established, companies can finally turn their attention to the business of invention. Such increased patent predictability should allow the biotechnology industry to begin embracing the benefits of collective rights.

Motivation for Cooperation

With intellectual property portfolios taking shape in a maturing industry, the transactional costs of increasing technology transfer can begin to account for an alarming proportion of an individual company's research and development expenditures. In addition to the expense of potential litigation, this economic inefficiency is a strong motivation for industry members to enter into a cooperative dynamic that facilitates more

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[8] 119 F.3d 1559 (Fed. Cir. 1997).

[9] *See* James A. Coburn, *ESTs and Partial Sequences: Repercussions for the Biotech Client*, INTELLECTUAL PROP. TODAY, August 1997, at 7.

cost-effective common access to vital technology, while preserving competitive business practices sufficient to thwart antitrust implications.

One scholar has studied the establishment of private collective rights organizations, or CROs, and common property resource institutions, or CPRs, in various industries, characterizing such measures as voluntary assumptions of liability rules to maintain the overall ability of an industry to accommodate consistent innovative growth in an IP-right-dominated field.[10] n12 Companies positioned at the forefront of this new industry arena will help shape the next era of commercial development in biotechnology.

The industry advantages of a patent pool, one type of private CRO, are well-recognized across geographic and technological lines. A patent pool is one mechanism by which two or more companies practicing related technologies can assign or license their patents to establish a clearinghouse for patent rights.[11]

Aside from the decreased transactional costs realizable from a bulk technology transfer infrastructure, other distinct benefits inure to the cross-licensed patent pool members. For example, contributing members can rely upon the patent pool for the freedom to operate in the field for commercial and research endeavors and as a revenue source with the royalty income stream generated from nonmember licensees.

The international community has embraced private CROs. For example, de facto patent pooling arrangements represent standard corporate practice in Japan, where companies favor the acquisition of extensive patent portfolios as a defensive measure against litigation and other business conflicts. Patent pools have particular advantage in Japan in view of the traditionally narrower scope of protection granted in their individual patents and the consequentially greater number of patents in a given technology, when compared with the United States. These aspects, in conjunction with different cultural norms, motivate Japanese corporations to commit their respective patent portfolios to pooling arrangements to obtain less costly access to vital technology as well as an added measure of security against competitor conflicts.

Beyond the well established private CROs in the automotive, aircraft, electronics, and telecommunications industries, and the monolithic collective copyright licensing

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[10] *See generally* Robert P. Merges, *Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293 (1996).

[11] Under the present administration, the U.S. Department of Justice has become increasingly tolerant with respect to the antitrust implications of patent pooling arrangements. *See* Andrea C. Brunetti, *Wading Into Patent Pooling*, INTELLECTUAL PROP., November 1997 (www.ipmag.com/brunetti.html). Indeed, Acting Assistant Attorney General Joel Klein publicly expressed a shift in the Antitrust Division's view by stating recently that "by promoting the dissemination of technology, cross-licensing and pooling arrangements are often pro-competitive." *See id.*

organizations of ASCAP and BMI,[12] n14 the biotechnology industry can learn from recently advocated CROs in other newly burgeoning technologies. For example, a recent agreement among nine companies and Columbia University created a patent pool directed to the MPEG-2 video standard.[13]

Similarly, the Digital Video Broadcasting Project, or DVB, a collective of more than 200 broadcasters, manufacturers, and regulatory bodies in over 30 countries worldwide, recently formed a patent pool containing the patent rights necessary to cover the implementation of DVB standards.[14] As these examples indicate, the establishment of a patent pool can be an integral component of the standard business practice in an industry, the heart of which rests with fundamental proprietary technology.

Patent Pooling Possibilities

Indeed, the interplay between historical experiences and future prospects in biotechnology makes patent pooling arrangements a ripe consideration for the industry. For the reasons stated earlier, the staking of early patent positions by commercial entities to specific fragments of this genetic information will not likely cause a dramatic shift in the continuing development of the industry. The enforceable scope of such patents should not preclude the realization of financial rewards associated with the complex research efforts of biotechnology companies to understand and to harness the biological processes involved.

At its core, biotechnology is the exploitation of nature's design, standing on the shoulders of the biological templates of DNA and RNA. For biotechnology, genetic information represents an "industry standard" analogous to those described above in the electronics and telecommunications areas. Accordingly, the landscape of increasing patent protection to this genetic material favors the voluntary entry of biotechnology industry members into patent pooling arrangements.

Indeed, the vast amount of genetic information, and its significance as a fundamental research tool even absent functional knowledge, can give rise to an almost overwhelming number of patents, the true value of which may be unascertainable without the cooperative efforts of other companies. In any event, the overall transactional costs associated with risk assessments based upon this relatively uninformed valuation of

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[12] ASCAP and BMI are the respective acronyms for the American Society of Composers, Authors and Publishers, and Broadcast Music Inc. For a cogent discussion of these CROs, *see* Merges, *supra* n.10, at 1328.

[13] *See MPEG-2 Patent Pooling Approved*, EETIMES (visited April 22, 1998) (http://pubsys.cmp.com/eet/news/97/961news/mpeg.html). Lawrence A. Horn, vice president, licensing, of MPEG LA, the administrative entity of the MPEG-2 patent pool, provided valuable insights on the dynamics of patent pooling arrangements.

[14] *See DVB Project Promotes Pooling of DVB Patents* (visited April 28, 1998) (www.dvb.org/dvb_news/dvb_pr037.html).

patent rights may alone outweigh any perceived benefit to the maintenance of an isolationist business strategy.

The establishment of a biotechnology patent pool will depend on the convergence of several factors. The first involves the determination of the patents necessary to undertake a particular research effort. Once the patent pool members set out research goals and define the technological aspects required to accomplish those goals, an independent licensing agent or patent pool administrator can assess which patents would be essential to achieve a freedom to operate in this regard. This assessment should involve the technical and legal expertise of qualified biotechnology patent attorneys.

A biotechnology patent pool can thus have a more horizontal scope relating broadly within a discipline, for example, encompassing genetic information likely associated with a particular biological function. Alternatively, a biotechnology patent pool can reflect a more vertical integration of scientific methods across various disciplines, for example, providing freedom to operate from genetic screening and lead identification to drug discovery. The determination of the appropriate scope of technology governed by the patent pool further allows the administrator to decide whether an invitation to patent pool membership should be extended to certain nonmembers owning essential patents.

During the patent pool's existence, a responsibility of the administrator will also be the strict regulation of the composition of the portfolio, which will likely change through the addition of newly issued, essential patents and the deletion of expired, nonessential, invalid or unenforceable patents. The administrator can further attend to the solicitation and engagement of nonmember licensees, the collection and distribution of royalty income, and the enforcement and termination of licenses.

The fundamental features of a patent pool include the integration of complementary technologies, the reduction of transaction costs, the clearance of blocking patent positions and the avoidance of costly infringement litigation. Its effectiveness springs principally from a consensus among the participants that individual patent rights will be made available to other members on fair, reasonable and nondiscriminatory terms. In any event, the ability to obtain a straightforward, reliable freedom to operate in an otherwise complex arena of intellectual property will be a dominant appeal of a biotechnology patent pool for prospective participants and nonmember licensees alike.

Given the dynamics of biotechnology research and development, the reliance by the industry on cooperative market-based technology transfer strategies through patent pools or other CROs may be inevitable. If so, the prospects for future success will likely depend on the swift acceptance and implementation of such collective rights programs.