Dominating Patents: a View from the Bridge
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Despite the obvious values of the patent systems of the world (see reference I for a review), there remain several aspects of patents that irritate not only members of the general public, but also some scientists, particularly those whose work is dependent on patented products produced by industry. One of these irritants concerns the apparent monopoly afforded by law to the patentee. Another irritant that flows from the first, and the focus of this talk, is pioneer patents that dominate a field. I will deal briefly with the monopoly aspects, then consider dominating patents and pioneer patents and the ways available for circumventing their effects.

Patents as Monopolies

In the United States, the patent statute gives the owner of the patent certain rights. Among these is the right to exclude others from making, using, or selling the invention during the term of the patent. Those who do any of these things without permission of the owner of the patent rights are either direct or indirect infringers, depending on what they did. To this extent, the patent owner does have a type of monopoly. The irritation felt by some stems from the fact that, in this country, there is a strong public policy against monopolies and monopolistic practices. This public policy resulted in the Sherman Act, which makes such practices illegal. The difficulty is that "monopoly" is used in different senses in patent law and in antitrust law; hence, its ambiguity. Because of its antitrust connotation, the word "monopoly" evokes negative reactions that are "inauspicious to a discussion of patent law" (2).

In point of fact, the patent statute, which antedates the Sherman Act by a century, was created because of Article I, Section 8, of the United States Constitution, and patent rights are not illegal monopolies in the antitrust sense of that word. Accordingly, even if a patent is obtained by fraud on the patent office, for example, by concealing some material prior printed publication ("prior art" in patent law), it is not correct to say, ipso facto, that such a patent was all along an illegal monopoly obtained in violation of the antitrust laws (3).

Furthermore, patent rights do not confer on their owner a complete monopoly. That is, while the patent owner has the right to exclude others from making, using, or selling his invention during the patent term, he himself may not have the right to practice his own invention—for example, when his patent is dominated by prior patents. I will discuss this subject further below.

Therefore, today, the federal courts, the Patent and Trademark Office (PTO), and patent attorneys all prefer to refer to "patent rights" and not to "monopoly rights," using the rationale given by Chief Judge Markey of the Court of Appeals of the Federal Circuit (CAFC) (4) and Prof. Irving Kayton (5) in several definitive treatises on the subject.

Dominant and Subservient Patents

What is a dominant patent and what are its practical effects? Let's look at the general case and then take some specific cases, mostly from real life.

Suppose, for example, a broad patent is issued in 1980, and in 1985 a different manufacturer starts selling a product or using a process that is covered by that broad patent. The manufacturer may be infringing that broad patent, even if his product or process is a newly discovered improvement over the broad-patent claims. That is, if the claims of the 1980 patent generically cover the accused product or process, there is infringement, at least in principle (more later on the elasticity of that principle). This may be even if the manufacturer obtained from the PTO one or more patents on his improvements. In this case, the broad patent dominates the improvement patent, which is referred to as the "subservient" patent. The manufacturer's patent does not give him the right to practice his own invention, merely the right to exclude others from doing so. His patent rights are subject to the patent rights of others.

Take, for instance, a specific example based on real life but embellished here to make my point. A manufacturer has devised a new way of producing human somatostatin. He uses recombinant DNA techniques to express in Escherichia coli a fusion protein that contains the desired human somatostatin polypeptide linked to an adjacent bacterial protein. Because the bacterial protein is inducible, a means is available for amplifying the gene copy number, thereby increasing the yield of the fusion protein. He then isolates the fusion protein and uses chemical techniques to cleave it, thereby isolating somatostatin in bulk. If the manufacturer patents the recombinant process for producing somatostatin, he gets a process claim because the process is novel over the prior art. The manufacturer also gets a product claim because he convinces the PTO (but not necessarily a court later) that his recombinant somatostatin is patentably distinct from the previously known somatostatin. If our manufacturer intends to make any money, he'd better compute his costs by taking into account the fact that he may need several licenses. He may need a license from Stanford for the basic recombinant DNA process (ref. 6, the Cohen-Boyer 1980 patent), from Genentech for the fusion process...
because the patent allegedly did not properly describe how to determine the affinity constants for the interaction of the antigen with the two monoclonal antibodies used in the assay.

Although MAB prevailed in the federal district court (13), this decision was overturned by the Court of Appeals for the Federal Circuit (CAFC) as being "clearly erroneous," and the Supreme Court refused to review the CAFC's decision (14). This means that the highest court in America has, in effect, said that the Hybritech patent is valid. This patent is now enshrined in the "Dominant Patent Hall of Fame."

Parenthetically, I might point out that the only issue decided in the MAB case was patent validity, not infringement. The case was remanded to the lower court to consider the infringement issue. MAB, having already spent a reported $1.2 million in legal fees, decided to settle with Hybritech out of court. Rumor has it that MAB has taken a license from Hybritech at an up-front fee of $1 million plus a 15% royalty (instead of the usual 5%). Two other major players, namely, DuPont and American Dade, have already decided not to challenge Hybritech and have taken out licenses.

Hybritech, flushed with success and recognizing that the highest appellate court in patent matters, namely, the CAFC, is currently very pro-patent, then went after Abbott in another federal district court (15). A subsidiary of Eli Lilly, Hybritech claimed that Abbott's sandwich assay kits that involve monoclonal antibodies were infringing (remember, making, using, or selling are acts of infringement) Hybritech's patent. Involved were 13 of Abbott's best selling kits. Hybritech asked not only for damages and a permanent injunction, but also for a preliminary injunction that would have prevented Abbott from selling any of the accused kits even before the infringement trial. Preliminary injunctions are not easily obtained. They require a finding that: (a) the plaintiff will likely prevail in the infringement trial on the merits; (b) the plaintiff will be irreversibly harmed if the injunction is not issued; (c) the threatened harm to the plaintiff outweighs the harm that the injunction may inflict on the defendant; and (d) the injunction will serve the public interest. On June 12, 1987, the court, having weighed all of these elements, granted Hybritech a limited preliminary injunction that enjoined Abbott from making, using, or selling the accused 13 sandwich assay kits pending trial of the infringement issue. However, for public policy—i.e., humanitarian—reasons, the court excepted from the injunction the carcinoembryonic antigen, prostatic acid phosphatase, and α-fetoprotein kits, so that patients who were being monitored as of the date of the injunction could continue to be monitored with these kits. Also excepted were Abbott's Auszyme and Auria hepatitis B surface antigen assay kits, until such time as Hybritech or its licensees could demonstrate to the court that they are capable of making and selling such a test kit. As is customary in preliminary injunctions, the plaintiff (Hybritech) was required to put up a bond ($20 million in the present case) to pay the defendant's (Abbott's) damages in the event that Abbott ultimately prevails in the infringement suit. The preliminary injunction was stayed, pending Abbott's appeal to the CAFC, with the result that Abbott could continue business as usual and Hybritech did not have to put up the bond. As of this writing, the CAFC has not yet decided the case.

If Hybritech wins the infringement action, its patent will be among the most dominant patents in the biotechnology arena. With a bit of hyperbole, Albert P. Halluin, vice
President and chief patent counsel of Cetus, said that, "historians may view... Hybritech/Lilly as now having the opportunity of becoming the next Polaroid or Xerox in the field of diagnostics" (16).

Other companies are marketing test kits that may infringe Hybritech's claims, including Syncon and Ventrex, who each have a two-site monoclonal antibody sandwich assay for HCG (choriogonadotropin), and Centocor, which has an ovarian cancer blood test based on the same type of assay. These companies appear to be potential targets for an infringement action, unless they knuckle under and take a license.

Pioneer Patents

The last subject to be developed is the concept of the pioneer patent, and the practical benefits that flow to the owner of such a patent.

If one can demonstrate that one's invention is clearly ground-breaking, and has opened up an entire new subfield of biotechnology, then one can make a forceful argument for broad claims. One can argue that anything less than broad claims would not give the patentee his just reward, and would only teach the competition how to avoid narrowly issued claims.

Having very broad generic claims permits one to take full advantage of a judge-made doctrine known as the "doctrine of equivalents" (17). This doctrine allows a patent owner to hold as an infringement a product or process that does not correspond to the literal terms of the patent claims, but performs substantially the same function in substantially the same way to achieve the same result. This doctrine was created to prevent persons from practicing fraud on patents, i.e., by making minor changes in a product or process and maintaining that this is a new invention.

A frequently cited corollary of this doctrine is that "the range of equivalents depends on and varies with the degree of invention" (18). The courts, traditionally, have classified issued patents into four or five categories, and have interpreted the scope of their claims differently, depending on this classification:

(a) Pioneer patents—broadest scope and range of equivalents;
(b) Marked improvements—substantial scope;
(c) Narrow improvements—limited or no range of equivalents; and
(d) Paper patents—narrowest scope.

The Supreme Court offered this definition of a pioneer patent (18):

...[a pioneer patent] is commonly understood to denote a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to make a distinct step in the progress of the art, as distinguished from what is merely an improvement or perfection of what has gone before. Most conspicuous examples of such patents are the one to Howe for the sewing machine, to Morse for the electrical telegraph, and to Bell for the telephone.

To this list one might add the first successful airplane and the first birth-control steroid.

If we apply this scheme to biotechnology, we quickly find a number of patents that will be seen by their owners as "pioneers": the basic recombination process for genetic engineering (6), the first expression of recombinant DNA in a eukaryotic cell (19), the basic patent for microbial polypeptide expression (7), the first two-site sandwich monoclonal antibody immunometric assay (12), the first patent for the production of interferon (20), and the patent for fused hybrid genes (21).

Claims to such pioneer patents are interpreted broadly, even more broadly than are merely dominant patents. Consequently, the doctrine of equivalents is applied to allow such claims to "catch" different equivalents, even those that did not exist at the time of application for the patent. For this reason, it is difficult to avoid pioneer patents in the commercial world. Let's consider some ways of doing so.

Of course, the most obvious way to avoid dominating patents of any type is not even to try—simply take your lumps and try for the most reasonable license possible.

One of the more useful approaches is to try to design around the dominant patent. For example, while the CACF held in Hybritech v. Monoclonal Antibodies, Inc. (14), that even fragments of a monoclonal antibody would infringe the doctrine of equivalents applied, it also held that Hybritech's claims would not cover a sandwich assay involving polyclonal antibodies. This saved Abbott's test for AME from being included in the injunction, and will also save any other sandwich assay that uses intact polyclonal antibodies or any derivative thereof.

Yet another way is to attempt to use the patent statutes to oppose the issuance of a dominating patent or to have the patent re-examined after issuance. This is accomplished by presenting to the PTO new patent and printed publication evidence of lack of novelty or on obviousness, evidence of lack of embarrassment or best-mode requirements, or evidence of fraud on the patent office, i.e., the same sorts of evidence one would use in court to have a patent declared invalid. This is a formidable task, but often accomplished.

Finally, another way to avoid being a defendant in an infringement action is to maintain that you are making and using the subject matter of a patent only for experimental, not commercial, purposes, or to supply samples for review by regulatory agencies such as the FDA. By arguing the former you are making use of a judge-made doctrine known as the "experimental use exception." This doctrine, which began in the early 19th century, has usually exempted experimental use of an invention from being construed as an infringement, as long as such use is for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" (22). Courts have consistently held, however, that if such experimental use has even a hint of a commercial purpose or goal, the exception will not apply. Thus, it is very difficult for industry or scientists allied with industry to claim the experimental use exception.

Thus, primarily scientists with no commercial ties are allowed to use the experimental use exception—or are they? Early in 1984, Johnson & Johnson/Ortho Diagnostics sent letters to two dozen researchers, some in industry, some at the National Institutes of Health (NIH), and some at universities, warning them that use of particular cell lines that produce certain monoclonal antibodies may infringe the company's patent rights to these antibodies (23). These researchers were obtaining these cell lines quite legally from the American Type Culture Collection, then using them to produce monoclonal antibodies at a cost much lower than if they had bought the same monoclonal antibodies from Ortho. Ortho's novel argument went this way: these researchers, in not purchasing their monoclonal antibodies from Ortho, were bringing economic harm to the company; therefore, the goal of the researchers in using the cell lines was commercial, and the researchers were therefore not covered by the experimental use exception. NIH's patent
counsel told the NIH scientists to ignore the warnings, and, as far as I know, Ortho has not yet sued any researcher for using the ATCC cells. But companies and their attorneys are nothing if not vigilant when it comes to lost profits, and warning letters are cheap to write. Litigation is quite possible if large sums of money are involved. Therefore, the message is to make sure of your ground if you intend to make use of the experimental use exception.

In my opinion, as litigation proceeds, many patents in biotechnology will be accorded pioneer status, and will be entitled to a broad range of equivalents. Patent attorneys are increasingly drafting broad generic claims, then using the argument of pioneer status during the prosecution of patent applications before the PTO. Patent attorneys are also increasingly using expert testimony during litigation to establish pioneer status for their client's patent or patent application so as to get courts to allow broad claims.

Like physician's office testing, dominating patents, whether pioneer or not, are an irritant that will not go away. It is up to inventive scientists to make such patents obsolete.

Note added in proof: On June 17, 1988, the CAFC found for the plaintiff in Hybritech v. Abbott Laboratories, thus keeping in place the preliminary injunction against Abbott discussed above. The lower court will now try the infringement and patent invalidity claims.

References
2. In re Kaplan, 229 USPQ 678, 681 (Fed. Cir. 1986).
17. Chisum DS. Patents, 1987; Sec. 18.04 (132–54).
18. Chisum DS. Patents, 1987; Sec. 18.04 [236–42.]