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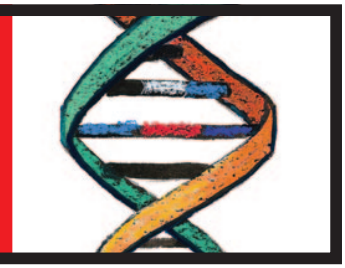
Life Sciences A Practice Focus

It Lives for 29 Years?

MedImmune/Genentech case was sparked by unpredicted patent term.



By Robin L. Teskin

A lawsuit filed April 11 in the U.S. District Court in Los Angeles has grabbed the attention of the life sciences community. The key parties are three high-profile biotech developers: MedImmune, Genentech, and Celltech. MedImmune is challenging the validity and enforceability of an important Genentech patent. Behind that patent, MedImmune charges, is an illegal, anti-competitive agreement that "profoundly and fundamentally altered the competitive landscape in the biotechnology industry."

The Genentech patent under fire, U.S. Patent No. 6,331,415, claims methods for producing monoclonal antibodies—methods that are used by many biotech companies to produce antibodies for human therapy. For reasons that will become clear, this patent is also known as the new Cabilly patent.

What is curious is that the new Cabilly patent contains the same claims as a Celltech patent, U.S. Patent No. 4,816,397—otherwise known as the Boss patent. However, where Celltech's patent would have expired in early 2006, Genentech's patent, which apparently exists because of a settlement between the two companies, will not expire until the end of 2018.

And therein lies the problem. Rather than passing into the public domain in a few short years, valuable antibody technology will stay protected until 2018. Companies practicing these patented methods face paying royalties for an additional dozen years. This fact has frustrated many biotech companies that licensed the Boss patent and naturally assumed that their royalty obligations would end in 2006.

MedImmune has taken that frustration one step further and gone to court, seeking to invalidate the new Cabilly patent.

How It Happened

The sequence of events began back in 1983, when Celltech and Genentech both filed patent applications.

On March 25 of that year, Celltech filed a patent application in the United Kingdom, naming Michael Boss and others as the inventors of fundamental antibody expression methods. Shortly thereafter, the company filed an international application under Patent Cooperation Treaty procedures, which became a U.S. application in 1984. The U.S. patent issued on March 28, 1989.

On April 8, 1983 (two weeks after Celltech's effective filing date), Genentech filed its U.S. patent application, naming Shmuel Cabilly and others as the inventors of similar antibody expression methods. Genentech's patent (known as the old Cabilly patent) also issued on March 28, 1989, as U.S. Patent No. 4,816,567.

Prior to the grant of the old Cabilly patent, Genentech had also filed a continuation application. This application was amended in March 1990, in accordance with U.S. Patent and Trademark Office rules: Genentech copied the Boss patent's antibody claims into its own application and requested that the PTO declare an interference between Celltech's patent and Genentech's application.

An interference is a legal proceeding unique to U.S. patent law, whereby the PTO resolves which party, if any, is entitled to priority of invention where the same subject matter is allegedly invented by two different parties. (In principle, the United States awards a patent to the first person to invent the subject matter in question. In other countries, the patent is awarded to the first party to file a patent application directed to the subject matter.)

On Feb. 28, 1991, the PTO Board of Appeals and Interferences declared an interference between Celltech's patent and Genentech's application. Celltech was accorded the benefit of its U.K. filing date and thereby deemed the senior party in the interference. The outcome of the proceeding therefore hinged on whether Genentech could establish a date of invention prior to the U.K. filing date. (Under U.S. patent law, the junior party has the burden of establishing by a preponderance of the evidence that it invented the subject matter prior to the senior party.)

Because of the patent laws in effect at the time that Celltech filed its pre-GATT application (that is, prior to implementation of the Uruguay Round Agreements under the General Agreement on Tariffs and Trade), Celltech was not allowed to present evidence of U.K. inventorship prior to its U.K. filing date. By contrast, because Genentech made its invention in the United States, it was permitted to submit corroborating evidence in an effort to establish that its inventors had conceived and reduced the subject matter to practice prior to Celltech's filing date.

After a lengthy (seven-plus years) and complex proceeding, a decision was rendered by the Board of Interferences. The board concluded that Genentech had not met its burden of establishing a date of conception prior to Celltech's U.K. filing date. Genentech was thus not entitled to a patent.

Not surprisingly, Genentech appealed that decision in the U.S. District Court in San Francisco. During the litigation, Genentech submitted new evidence in the form of a draft patent application from the files of Cabilly, the company's lead inventor, which Genentech claimed predated Celltech's U.K. filing date.

Based on this new evidence, Genentech filed a summary judgment motion requesting that it be awarded priority of invention. Celltech opposed the motion on substantive grounds, but did not challenge whether Genentech had exercised due diligence in only now locating this document. The District Court denied Genentech's motion. Nevertheless, the parties settled their dispute.

> Behind the so-called new Cabilly patent, MedImmune charges, is an illegal, anti-competitive agreement that 'profoundly and fundamentally altered the competitive landscape in the biotechnology industry.'

While the settlement agreement was filed under seal and remains confidential, this is known: Celltech conceded priority of invention, and the case was ended in Genentech's favor. The PTO subsequently revoked the Boss patent and issued the new Cabilly patent covering the same subject matter. The new Cabilly patent essentially extends patent coverage on antibody manufacture by 12 years.

A joint press release from Genentech and Celltech issued on Dec. 18, 2001, the same day as the new Cabilly patent, suggests that Celltech will not suffer from its willingness to lose the Boss patent early. Genentech agreed to compensate Celltech for all royalties that it would have accrued until the normal expiration of the Boss patent in 2006, and to grant licenses to Celltech for use of the antibody expressions processes covered by the new Cabilly patent.

What Lessons Can Be Learned

MedImmune argues that this happy ending constitutes unlawful collusion. It is too early to predict whether the case will bear out that charge. But even the facts so far remind us that patent laws can be manipulated to extend the patent term and suggest that some changes would be wise—to protect the public's interest in access to technology and to ensure a predictable patent term for all companies:

- *Interference proceedings should be expedited.* The Celltech/Genentech interference ran more than seven years. Why it took so long is unclear. However, it appears that neither party had sufficient incentive to expedite the process.

Celltech had no incentive because it was the patentee and would continue to collect royalties as long as it held the Boss patent. Genentech had no incentive because its new Cabilly application had been filed before the patent law changes required by the Uruguay Round Agreements. Consequently, Genentech knew that, if granted, the new Cabilly patent would last a full 17 years from its issue date (not 20 years from its filing date, as the law now states for new patent applications). Thus, a delay in the issue date might simply serve to extend Genentech's patent rights into more lucrative years for the biotech industry.

These facts suggest that the Board of Interferences itself should exercise every means available to expedite the interference process. And this is especially critical where a pre-GATT patent application is involved.

- *Section 146 litigants should not be permitted to submit new priority evidence in support of a pre-GATT patent application.* Under 35 U.S.C. §146, any party to an interference unhappy with the board's decision "may have remedy by civil action." But in the future, such parties should be barred from submitting new evidence to prove priority of invention. This would minimize the risk of patents being issued as a result of §146 litigation that unduly extend intellectual property protection of fundamental technology.

Granted, this is not a perfect solution: Such a rule might infrequently result in a patent being awarded to the later inventor. But over the majority of cases, such a rule would more fairly balance the interests of the public in rapid access to new technology against the interests of the inventor in fully exploiting his or her innovation.

- *In some instances, settlement agreements of interference disputes should be made public.* A key issue in the MedImmune litigation is whether Genentech and Celltech unlawfully colluded to extend the two companies' proprietary position on antibody expression. Whether the parties colluded is uncertain in part because the agreement was filed under seal. In the future, settlement agreements that result in significant patent term extensions should be made public.

Requiring parties to open such settlement agreements would potentially divulge some propriety information. But, again, the public interest weighs heavier. If such agreements were available for inspection, parties considering whether to license a patent awarded or retained as a result of an interference would be in a better position to assess the patent's validity. And, of course, requiring settlement agreements to be made public would reduce the likelihood of parties entering into unlawful arrangements.

Whether or not the deal between Genentech and Celltech was in any way improper is unclear. The courts will determine that in due course. But appropriate authorities should act to ensure for the future a predictable and reasonable patent term for pre-GATT applications.

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