San Diego Daily Transcript

MARCH 31, 2005

Pharmaceutical Research Tool Patents: Value Hanging in the Balance

by ***JEFFREY MCKINNEY***

Sheppard, Mullin, Richter & Hampton LLP

On April 20, the Supreme Court will hear an appeal related to the enforcement of pharmaceutical research tool patents. The court will ultimately decide whether a party can make or use inventions embraced by such patents without permission from the patent holder. Its decision will substantially affect the value of any portfolio directed to such inventions.

The pharmaceutical discovery process often invokes a wide variety of technologies. There are methods of testing (i.e., assays) that one uses to find compounds that could prove useful as drugs; there are compounds that one uses to validate a testing method; and there are biological polymers that serve as targets for testing. These technologies are the tools used by chemists, pharmacologists and biologists to find tomorrow's drugs. Patents that cover the technologies are typically referred to as pharmaceutical research tool patents.

In 1984, Congress provided a patent infringement safe harbor related to drug commercialization. The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Act") provides that, "It shall not be an act of infringement to make, use, offer to sell or sell within the United States … a patented invention … solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs or veterinary biological products [35 U.S.C. §271(e)(1)]."

The act sought, in part, to ensure that a generic drug manufacturer could perform FDA-required tests before expiration of a patent covering the subject drug. That is so the generic version of the drug could be marketed immediately upon patent expiration.

Between 1984 and 2003, the 1984 act was interpreted by courts across the United States, with federal district courts often holding drastically different views of the law. Most of the disparity related to the meaning of "uses reasonably related to the development and submission of information." For instance, does the phrase exempt any activity within a chain of activities that could ultimately result in an FDA submission? Or, does it only refer to the activities of a generic pharmaceutical company attempting to bring a lower-priced drug to market as fast as possible?

The interpretation of the 1984 act was brought to center stage in 2003, with an appeal heard by the Federal Circuit. Integra LifeSciences I, Ltd. v. Merck KgaA, 331 F.3d 860 (Fed. Cir. June 6, 2003). Integra (Nasdaq: IART) owns a series of patents related to a short peptide sequence that promotes cell adhesion. It alleged that Merck (NYSE: MRK) infringed one or more of the patents by using the sequence in a drug discovery project directed to halting tumor growth.

Jeff McKinney is special counsel in the Intellectual Property Practice Group in the San Francisco and Del Mar Heights offices of Sheppard, Mullin, Richter & Hampton LLP.

At trial, Merck asserted that its activities were exempt from infringement, since they were "reasonably related" to the development and submission of data to the FDA. (Should a drug candidate emerge from the project, Merck would eventually use it in clinical testing, and data would be obtained and submitted.)

The district court rejected Merck's assertion, however, and found that Merck's use of the sequence was an infringing activity that was not exempted by the act. Merck subsequently filed an appeal before the Federal Circuit.

In view of Merck's activities, the Federal Circuit interpreted the act narrowly. Circuit Judge Rader stated that the act does not embrace the discovery/development of new drugs simply because such compounds require regulatory approval. By implication, the act only applies where a party is attempting to commercialize a generic form of an existing medical product.

There are entire companies formed around what are arguably pharmaceutical research tools: combinatorial libraries; novel biological targets; computationally driven drug design; and, high-throughput screening assays. Typically, such companies develop a substantial patent portfolio to protect these discovery tools.

The Federal Circuit, in finding that patents can be enforced against those who use technology in a new drug discovery effort, ensured that the core patents of the previously mentioned companies have value. In other words, another party must obtain the company's permission to use its patented "tools"; permission can usually be purchased in the form of a license.

The Supreme Court, however, will shortly hear Merck's appeal, and the Federal Circuit's interpretation of the act stands squarely before it. Several entities have filed amicus briefs in support of Merck's position, including the AARP, Genentech (NYSE: DNA) and the U.S. government. It is difficult to predict how the court will interpret the act, but whatever the outcome, it will significantly affect the value of emerging technologies in the drug discovery field.