Perspective: Patents, post-*MedImmune*

Earlier this year, the Supreme Court shook the foundations of patent licensing and technology transfer, altering the balance of power between patent holders and their licensees and creating profound implications for the life-sciences industry. In *MedImmune v. Genentech*, the high court effectively paved the way for more frequent patent challenges that could disadvantage smaller companies and organizations.

For decades prior to the *MedImmune* decision, courts typically refused to allow a company that licensed a patent to challenge its validity unless that company had violated the license and faced an imminent lawsuit for infringing the patent. In *MedImmune*, however, the Supreme Court ruled that licensees shouldn't have to risk the harsh consequences of an infringement suit in order to ask a court to invalidate a patent. (Read the court's Jan. 9 decision in PDF form here.)

Now companies that license intellectual property are much freer to challenge patents, a development that has already begun to alter the playing field for patent holders and licensees alike. That's particularly true in industries such as biotechnology, where widely licensed patents that cover drug-production technologies are commonplace. Early indications based on lower court decisions also suggest that *MedImmune* may have made it easier to challenge patents in a broad variety of circumstances, not simply those in which a company wishes to avoid paying royalties by invalidating a licensed patent.

The post-*MedImmune* environment presents an acute challenge for small biotech companies and universities. These organizations generally have limited funds to fight patent lawsuits and might therefore face stepped-up legal attacks on their patents. Some licensing strategies, however, can help minimize those risks, although none are quick fixes, and their effectiveness will vary depending on the relative bargaining power of the parties involved.

IP holders, for instance, may seek to make patent lawsuits more expensive for licensees by requiring higher royalties, or even termination of the license, in the event of a challenge. In the latter case, of course, a challenge could once again expose the plaintiff to an infringement lawsuit, effectively restoring the pre-*MedImmune* status quo.

Patent holders might also seek to reduce the economic incentive to challenge a patent by "front-loading" payments — for instance, by requiring a lump-sum payment at the time of signing in lieu of a high royalty rate on potential future sales of products covered by the license. Finally, licensing companies may erect new roadblocks, such as making mandatory arbitration of any patent challenge a requirement of the initial license agreement.

Of course, many patent holders, especially emerging companies with limited resources, may not have the bargaining clout to insist on such terms. What's more, these strategies will only work for future licenses — current licenses will remain vulnerable to challenge under *MedImmune* unless they are renegotiated.

In many respects, *MedImmune* has substantially boosted the risks faced by patent holders while creating new leverage for licensees. In this sense, it parallels other recent court rulings and new patent-office rules that also threaten to erode patent protection. While well entrenched patent holders may be able to limit those risks by altering the terms of future licenses, there remains a strong possibility that the new legal environment could limit the ability of smaller companies and universities to make full use of their intellectual property, potentially even jeopardizing the pace of biomedical innovation.