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# Emerging Life Sciences Companies

second edition

## Chapter 10

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### Antitrust Aspects of Patent Pooling in the Biotech Context<sup>1</sup>

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# ANTITRUST ASPECTS OF PATENT POOLING IN THE BIOTECH CONTEXT<sup>1</sup>

Perhaps the most interesting development in the area of patent pooling is the emergence of the need for pooling in the pharmaceutical/biotechnology area. Earlier forays by the antitrust agencies into pooling had generally taken place in the consumer electronics industries, where any given product might infringe dozens or hundreds of patents. In the pharmaceutical industry, by contrast, it was once fairly clear who “owned” a new chemical entity by virtue of that owner’s patent over the composition of matter.

In some respects, the rise of biotechnology has moved the pharmaceutical industry closer to the consumer electronics model. It would be a mistake, however, to try to adopt that model wholesale in trying to apply antitrust principles to biotech patent pools. Biotechnology is a misfit for the consumer electronics model in at least three respects:

1. Consumer electronics patent pools have often arisen in settings in which interoperability requirements have given rise to a formal industry standard. By contrast, in biotechnology, there is no set industry standard.
2. The relevant patents can be substitutes for some purposes and complements for others.
3. The need for certainty—and hence for pooling—can arise well in advance of the patents even being issued.

First, the key antitrust justification for forming a pool is that the patents in it are blocking or complementary rather than competing. That problem is easily resolved where there is an industry standard. Compliance with the standard is essential in order to have a marketable product at all. Any patent that would necessarily be infringed by a product compliant with the standard automatically becomes a blocking patent for any product in the field. Accordingly, in the electronics patent pools that have previously been “blessed” by the antitrust agencies, a typical governing rule of the pool has been that the only patents that would be contributed to the pool are patents that are essential to compliance with the standard.

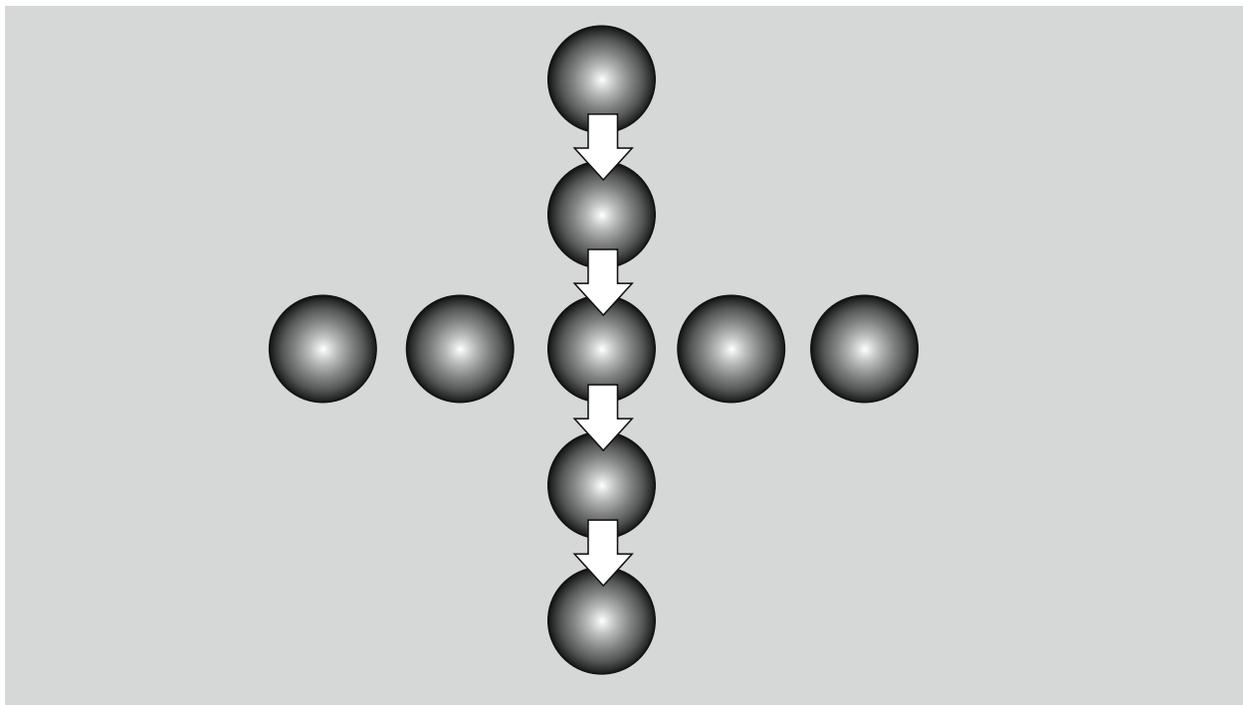
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1. A longer version of this article, titled “A Field Guide to Antitrust Issues in Standard-Setting and Patent Pooling,” was originally published in *Competition*, the journal of the Antitrust and Unfair Competition Law Section of the State Bar of California, Vol. 14, No. 2, Fall/Winter 2005. This version is reprinted with permission.

The pharmaceutical/biotechnology area typically lacks standards of the type seen in consumer electronics and telecommunications, however. The lack of standards is a function of the fact that, despite the degree to which biotechnology has moved the pharmaceutical world away from the “one-patent, one-product” model that once characterized it, the pharmaceutical industry is still far from having the kind of fragmentation of component manufacture that characterizes consumer electronics and telecommunications. Quite simply, there is no need for a standard. Each vaccine maker and each pharmaceutical manufacturer is busy conducting research in secret. Such manufacturers may need rights to certain nucleic acid sequences, proteins, or research tools, and thus may face a problem of fragmentation of ownership rights, but they do not need their products to work together with the products of other manufacturers according to a common standard. Indeed, the disclosure process inherent in the standard-setting process is antithetical to the confidentiality needs of research and development.

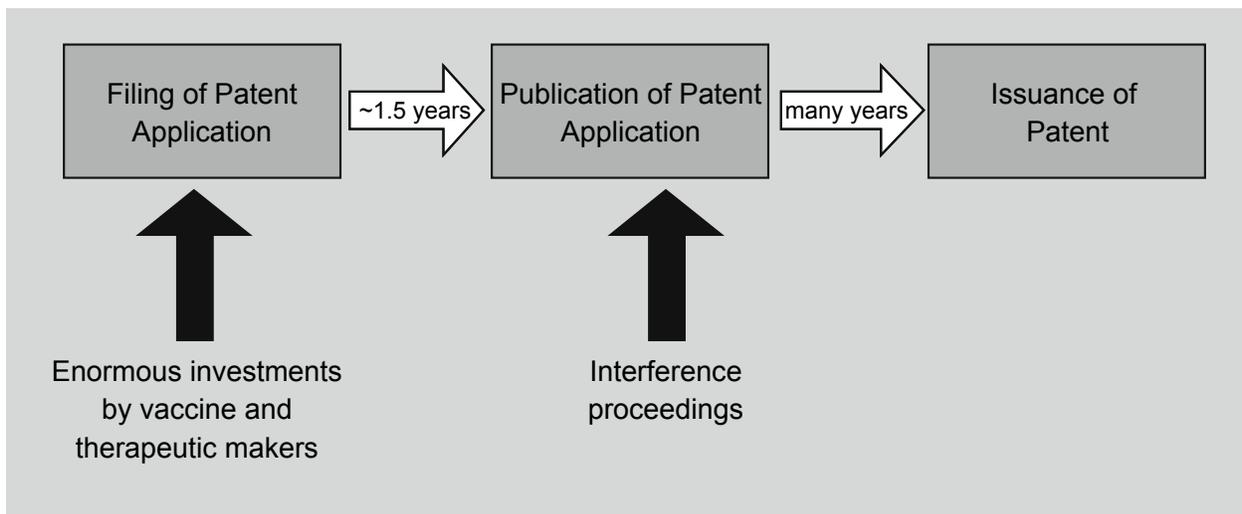
Second, the relevant patents can be substitutes for some purposes and complements for others. The Janus-like nature of complementarity and substitutability in the biotechnology area can be seen by considering the development of a vaccine to attack a new viral disease. Suppose a number of different institutions have sequenced different fragments of a new virus. They each apply for patents on the fragments they have sequenced. Will those patents, when issued, be complements or substitutes? The answer: It depends. Some vaccine makers may be working on a killed or attenuated virus vaccine that requires the entire sequence. Others may be taking approaches that attack only certain receptors and require only portions of the sequence. In this context, the “essentiality” standard causes more problems than it solves.

Furthermore, it is important to understand how limited the problems are that the “essentiality” standard solves. To see this, consider the following diagram:



The vertical circles represent complements, and the horizontal circles represent substitutes. In the rows in which there is only one circle, the patent is essential to implementation of the standard, and in the consumer electronics patent pools covered by the Department of Justice Business Review Letters,<sup>2</sup> those patents remain in the pool. In the row in which there are multiple circles, however, no single one of the patents is essential to implementing the standard, and therefore all of the patents of that type are ejected from the pool. What has been accomplished for consumers? The answer is, not much. As long as there are multiple monopolies, all required to implement the standard, the pool solves a double-marginalization problem<sup>3</sup> by setting price at the monopoly-profit-maximizing level, rather than at a higher level. It is true that ejecting the competing patents from the pool will not worsen consumer welfare because competition will prevent the excluded patents from causing a double-marginalization problem. But welfare will not be improved, either, because whether those patents are in or out, the pool will not want to set a price higher than the monopoly-profit-maximizing price. If the benefit of the “essentiality” standard is so slight, then perhaps we should not hesitate to adjust it in light of the difficulty of applying it in the biotechnology context.

Third, perhaps the most important difference that needs to be taken into account is that the need for certainty—and hence for pooling—can arise well in advance of the patents even being issued. Consider the following diagram, representing the timeline of patent filings of various parts of the sequence of a new virus:



In a serious public health crisis, it would be imperative that vaccine and therapeutics makers—potential licensees from the pool—begin their complementary work as soon as possible. That

2. Business Review Letter from Joel I. Klein to Garrard R. Beeney (June 26, 1997), available at <http://www.usdoj.gov/atr/public/busreview/1170.htm> (pool of the patents necessary to comply with the MPEG2 standard); Business Review Letter from Joel I. Klein to Garrard R. Beeney (Dec. 16, 1998), available at <http://www.usdoj.gov/atr/public/busreview/2121.htm> (Digital Versatile Disc (DVD) technology); Business Review Letter from Charles A. James to Ky P. Ewing (Nov. 12, 2002), available at <http://www.usdoj.gov/atr/public/busreview/200455.htm> (3G Patent Platform Partnership for third-generation mobile communication systems).

3. “Double marginalization” refers to the fact that when two or more complementary inputs are required to produce a product, and each input is produced by a monopolist, each monopolist will charge a monopoly price without regard to the impact of declining unit sales on the other monopolist. In this situation, if the same monopolist owned both inputs, it would lower its price, increase sales, and simultaneously increase its own profits and improve consumer welfare.

work requires substantial investment. It has been reported that the average cost of launching a successful new biotechnology prescription product exceeded \$1.2 billion in 2006.<sup>4</sup> If those costs are largely sunk by the time patents issue, the vaccine and therapeutics makers can be held up by the successful patentees. To avoid this result, the vaccine and therapeutics makers will want to know up front the license terms they will confront, whatever the patent situation may be many years in the future after the patent prosecutions and interferences are complete.

In light of this fact, consider a scenario in which none of the patents will ever be complements because all of the patent applications are identical. Suppose that one, and only one, of the applications will be successful, and that applicant will be able to claim the entire sequence and all of its fragments. The only problem is that right now, when most of the investments have to be made, we have no idea which one of the applications will be successful. In that scenario, the patent applications should be treated, for antitrust purposes, as functional complements. Vaccine and therapeutics makers will need to reach terms with all of the applicants. If the applicants bargain independently, there will be a double-marginalization problem. If they are allowed to form a pool, welfare will be improved. The argument for antitrust law to stay its hand here is thus even stronger than in *Brunswick Corp. v. Riegel Textile Corp.*,<sup>5</sup> in which Judge Posner pointed out that if the only dispute is over who owns a patent, not whether there would be a patent at all, then the outcome is a matter of indifference to the antitrust laws (as opposed to some other body of law) no matter how reprehensible the conduct that wrests ownership away from the rightful inventor. In this case, the action of forming a pool is not merely competitively neutral but is actually a benefit to consumer welfare—even though, by hypothesis, the patent applications are not complements in the traditional sense at all.

## Conclusion

Antitrust law has proven highly adaptable to new technology and new factual settings. Biotechnology companies confronting the need for patent pooling should be careful not to be imprisoned by old models, but instead should ensure that their antitrust lawyers address the actual business needs of their situations.

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4. Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu/Research/Milestones.asp>).

5. 752 F.2d 261 (7th Cir. 1984), *cert. denied*, 472 U.S. 1018 (1985).