

**Remarks by**

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**Federalist Society  
Antitrust and Intellectual Property Law:  
Complementary Disciplines Promoting Innovation**

**National Press Club  
Washington, DC  
January 31, 2003**

I'd like to thank the Federalist Society for inviting me to appear on this very distinguished panel. The Federalist Society has always been an invaluable source of ideas and debate for lawyers both in and out of government. That's certainly true with this program, which addresses what I believe is one of the most important issues facing the legal and business community, the relationship between antitrust law and intellectual property law.

As an initial matter, it's important to note that, properly understood, intellectual property and antitrust law complement one another. Intellectual property law and antitrust law both seek to promote innovation and enhance consumer welfare. Properly applied, intellectual property law preserves the incentives for scientific and technological innovation, which benefits consumers through new and improved goods and services. Likewise, when properly applied, antitrust law encourages vigorous competition, which ensures that consumers have access to a wide variety of goods and services at competitive prices. As a result, when these two areas come into conflict, or when tension arises between them, it's never enough to say that antitrust law trumps intellectual property or vice versa. The goal should be to determine what's in the best interest of the consumer, both in the short term and the long term.

**A. FTC/DOJ Hearings**

As part of exploring these issues, the FTC and DOJ recently concluded an extended series of joint hearings on competition and intellectual law and policy. We held these hearings to increase our understanding of how to manage concerns at the intersection of intellectual property and antitrust. Intellectual property underlies an increasingly large part of our economy. As my colleagues well know, the number of patents issued annually by the PTO has skyrocketed, from

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<sup>1</sup> The views expressed are my own and do not necessarily reflect the views of the Federal Trade Commission or of any individual Commissioner.

around 66,000 in 1980 to more than 175,000 three years ago. These patents encompass critical advancements in biotechnology and software, as well as some novel business methods.

As intellectual property rights increase in importance, there can be some tensions between intellectual property and antitrust law. Some observers have suggested that current intellectual property law does not properly appreciate that competition, as well as intellectual property, may spur innovation. Others have argued that antitrust regulators have not yet found the right balance between the two doctrines. Through the hearings, we hoped to improve our understanding of the concerns expressed by both the IP and antitrust bars, all with a view toward understanding what policies most benefit consumers.

The hearings included 24 days of testimony on a wide variety of subjects, ranging from the Federal Circuit's jurisprudence to patent pools and cross-licensing. We heard testimony from many businesses that have an interest in intellectual property and antitrust law, including representatives from Intel, Amazon, Honeywell, and many others. We also heard from numerous scholars and practitioners, including Judge Pauline Newman of the Federal Circuit, Nobel laureate Kenneth Arrow, our moderator today, Gerald Mossinghoff, and Professor Pitofsky, under whose strong leadership as Chairman the FTC also devoted significant attention to these issues.

The hearings ended last November. Staff at both the FTC and DOJ are working very hard to evaluate the enormous amount of material submitted. We are in the process of compiling a report, which we hope to release sometime later this year.

Part of the reason for focusing on the intersection between antitrust and intellectual property is the simple fact that, with more and more of our new economy revolving around intellectual property, and more and more productive assets in the economy being intellectual property assets, an increasing percentage of FTC investigations and cases involve and are intertwined with intellectual property law. Several examples are discussed below.

## **B. Orange Book**

At the FTC, our focus to date has been on preventing anticompetitive conduct that seeks to improperly expand intellectual property rights beyond the boundaries set forth by Congress. Of course, there may well be strong pro-competitive reasons for businesses to choose to use their patents to limit distribution, so that, for example, things like exclusive dealing arrangements that are pro-competitive need to be given considerable latitude.

However, when businesses try to use their patents to suppress competition in ways not contemplated by the statutes, the antitrust laws exist to protect consumers. So, for example, antitrust principles should be applied to unilateral conduct that seeks to prevent entry from new competitors beyond the statutory time period for exclusivity. Antitrust principles should also apply to horizontal agreements that seek to limit competition beyond the statutory time limit on patents.

## 1. BuSpar

Much of the FTC's recent work has involved pharmaceuticals. In a case from early last year, generic drug manufacturers charged that Bristol-Myers had fraudulently filed a patent with the Food and Drug Administration for its branded drug BuSpar, an anti-anxiety drug. The filing caused the FDA to list the patent in question in an administrative publication known as the "Orange Book," which blocked generic drug companies from competing with BuSpar. The generic drug companies charged that Bristol-Myers had violated Section 2 of the Sherman Act. As expected, Bristol-Myers responded with a motion to dismiss that relied principally on *Noerr-Pennington* immunity.

As you know, the *Noerr-Pennington* doctrine immunizes activity that can be legitimately classified as "petitioning the government" from antitrust scrutiny. There are at least two exceptions to *Noerr*, however. *Noerr* immunity does not attach to any petitioning conduct that is deemed a "sham." *Noerr* immunity also may not attach to certain fraudulent misrepresentations. In *Walker Process*, the Supreme Court held that a patent holder may be subject to antitrust liability for attempting to enforce a patent procured through fraudulent misrepresentations to the Patent and Trademark Office ("PTO").

The FTC learned of the BuSpar case last winter. The parties alleged that, in this instance, the patent-holder was trying to abuse the patent process in contravention of both IP and antitrust principles. Given the importance of competition in the pharmaceutical industry, the Commission filed an *amicus* brief opposing the motion to dismiss. I argued the case for the Commission, and, in spring of last year, the court agreed with our position.

The court denied Bristol-Myers's immunity claim and accepted most of the Commission's reasoning on the *Noerr-Pennington* issue. In particular, the court agreed with us that Orange Book filings simply do not constitute protected "petitioning," because the government does not perform an independent review but instead acts in direct reliance on the private party's representations. The court also agreed that an Orange Book filing is not incidental to petitioning, holding that Bristol-Myers could have listed its patent in the Orange Book without bringing infringement suits or relying on its Orange Book listing.

Finally, the court agreed that, even if Orange Book filings did constitute "petitioning," Bristol-Myers would not have *Noerr-Pennington* immunity, both under the sham and *Walker Process* exceptions. The court concluded that Bristol Myers's patent filing was "objectively baseless," and that the Orange Book listing and patent prosecution processes were sufficiently analogous to warrant extension of the *Noerr* exception beyond the PTO context.

## 2. Biovail

In addition to filing *amicus* briefs, the FTC has also brought its own actions in this area. Last April, the FTC settled a complaint in a case involving pharmaceutical patents and *Noerr*.

Biovail had a brand-name drug Tiazac, which is used to treat heart disease. Biovail had filed an infringement lawsuit against a generic manufacturer, Andrx, thereby triggering a 30-month stay of FDA final approval of Andrx's generic Tiazac product. Andrx won in court, however, so the stay would have been lifted early. According to the Commission's complaint, Biovail undertook a series of anticompetitive acts to trigger a new stay and maintain its Tiazac monopoly. Biovail acquired exclusive rights to a newly issued patent from a third party and listed that patent in the Orange Book as claiming Tiazac. This action forced Andrx to re-certify to the FDA and opened the door to another Biovail lawsuit against Andrx for infringement of the new patent, and to the opening of a second 30-month stay.

The Commission's complaint alleged that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA violated Section 5 of the FTC Act and Section 7 of the Clayton Act. A consent order requires Biovail to divest the exclusive rights to their original owner, with certain exceptions, and to dismiss with prejudice any and all claims relating to enforcement of the Tiazac patents. The order also prohibits Biovail from unlawfully listing patents in the Orange Book, and requires Biovail to give the Commission prior notice of patent acquisitions that it will list in the Orange Book for Biovail's FDA-approved products.

### **3. Patent Settlements**

A related area of activity involves anticompetitive settlements of pharmaceutical patent litigation. Some settlements might limit the ability of a generic to compete beyond the limitations already imposed, such as by patent law and the Hatch-Waxman Act. In particular, some makers of brand-name and generic drugs have entered into agreements under which the generic entrant is essentially paid not to compete. In the *Abbott/Geneva* matter, for example, the parties allegedly agreed that, in exchange for money paid by the branded manufacturer, the generic manufacturer would not enter the market until their patent litigation ended; would not enter the market with any other generic version of the product; and would not relinquish the 180-day period of exclusivity given to it under Hatch-Waxman as the firm first to file an application to make a generic equivalent.

Agreements of this type may unreasonably delay the entry of generic drug competition, potentially costing consumers hundreds of millions of dollars annually. Under the Commission's consent order, Abbott and Geneva were barred from entering into agreements that prevent a generic company from bringing a non-infringing drug into the market or transferring its exclusivity rights. The companies also agreed to have any similar agreements approved by a court, with prior notice to the Commission. Finally, Geneva had to waive its right to a 180-day exclusivity period so that other generic tablets could enter the market immediately.

Such anticompetitive patent settlements, along with the conduct in the BuSpar and Biovail cases, show that there is a need for antitrust law to ensure that businesses do not improperly expand IP rights beyond what the statutes permit. Orange Book filings, patent settlements, and related conduct are all subject to the antitrust laws when patent-holders attempt to improperly

stifle generic competition, beyond the time period Congress established for a patent-holder to have exclusive rights.

### **C. Standard Setting**

A similar analysis applies to standard setting, an area that has been the subject of much interest at the FTC and elsewhere. In general, of course, standard-setting can foster innovation and benefit consumers. Common standards can allow more companies to compete and lower the costs of doing business. Nevertheless, we must be aware that, in some circumstances, standards can impede competition if they both rely on patents or other intellectual property rights, and then result in monopolization or a raising of rivals' costs. This danger is particularly great if the patent-holder intentionally fails to disclose its patent rights to the standard-setting organization.

For example, in the *Dell* matter of a few years ago, Dell allegedly breached its commitment to disclose patents to a standard-setting organization before the organization developed a standard relying on those patents. To settle the FTC charges, Dell agreed not to enforce its patent rights against computer manufacturers complying with the standard.

More recently, the FTC charged Rambus, Inc. with violating federal antitrust laws by deliberately engaging in a pattern of anticompetitive acts and practices that served to deceive an industry-wide standard-setting organization. Rambus took part in a technology association that develops and issues widely adopted technical standards for a common form of computer memory. The complaint alleges that Rambus purposefully sought to, and did, convey the materially false and misleading impression that it had no relevant intellectual property rights in the standards that the technology association was adopting. This matter is currently in litigation.

At the FTC, we welcome a continued dialogue with the private bar and with the academic community on standard-setting and on other issues. Many of these issues are novel and complex, and lack a clear-cut, universal solution. Through forums like this, we hope to improve our understanding of the intersection of competition and intellectual property, and ultimately to create the best policies to enhance consumer welfare.