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## ANTITRUST ISSUES INVOLVING THE PHARMACEUTICAL, BIOTECHNOLOGY, AND MEDICAL DEVICE INDUSTRIES

No industry has witnessed as much antitrust scrutiny over the past decade in the United States as the pharmaceutical industry. Unwarranted hostility to intellectual property rights, unrealistic expectations of low-cost access to high-value, high-cost pharmaceutical products, and the lure of treble damages have led to a dramatic and arguably unjustifiable expansion of U.S. public and private antitrust enforcement in the pharmaceutical industry.

Other enforcement authorities have taken notice and followed suit. On November 28, 2008, the European Commission issued a 400-page report summarizing its conclusions about certain practices within the pharmaceutical industry and their impact on

competition and pharmaceutical prices. Preceded by a series of dawn raids, the report's generally adverse tone was not a surprise. But what was surprising was the breadth of the Commission's focus and findings, and what may be shocking to U.S. observers was the Commission's obvious distaste for practices—such as obtaining multiple lawful patents and enforcing them through litigation—that would likely enjoy virtual immunity from antitrust liability in the United States.

This is the latest salvo in an increasingly multifaceted, multinational, multijurisdictional assault on intellectual property rights in the pharmaceutical industry. The industry and the IP community had already witnessed aggressive government activity in Thailand and South



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Africa, which threatened to eliminate any intellectual property rights covering HIV and AIDS drugs. But those eruptions from the developing world involved only a discrete set of products from a handful of manufacturers and attempted to address a high-profile health crisis.

Contrary to conventional wisdom, the current antitrust-based assault on the pharmaceutical and biotechnology industries in the United States and Europe is far more ominous. When the United States Federal Trade Commission began its most recent challenge to the pharmaceutical industry, it confined itself to discrete challenges to a limited set of pharmaceutical patent litigation settlements within the unique Hatch-Waxman framework. But then it expanded to include challenges to certain Orange Book listings, investigations and reports on Hatch-Waxman litigation, and a broad-ranging inquiry and anticipated report on authorized generics. Practices previously thought almost completely immune from challenge—product changes, regulatory petitioning, patenting, and patent lawsuits—have now become the focus of certain FTC investigations and the bread and butter of the antitrust plaintiffs' bar as well as the generic pharmaceutical industry.

As a result, many pharmaceutical companies have enlisted antitrust counsel with respect to activities that were once the exclusive province of intellectual property and FDA lawyers. With the new Administration designating a new FTC chairman with a record of hostility to the industry and pushing Hatch-Waxman-like legislation for follow-on biologics, there can be no question that antitrust enforcement in the U.S. is likely to escalate, not abate, in the foreseeable future. The same is likely to be true in Europe.

As with other aspects of antitrust and competition law practice, Jones Day has been at the forefront of these antitrust battles in both the United States and the European Union over the past 20 years. Our practitioners have defended clients successfully at virtually every stage of the developing (and increasingly hostile) antitrust landscape facing the pharmaceutical and biotechnology industries. Our representations of branded pharmaceutical companies range from defending sham litigation and *Walker Process* counterclaims in the Hatch-Waxman context to steering industry acquisitions through the merger review process to crafting, submitting, and defending settlements of patent infringement litigation.

Our work also involves related industries, such as medical and surgical devices and agricultural biotechnology. And our work often leads to highly visible roles in the public debate over these issues. We have testified before Congress on legislation that would ban certain pharmaceutical litigation settlements, spoken in FTC hearings on Hatch-Waxman issues and broader intellectual property and antitrust issues in the biotechnology industry, written about these issues in leading publications, and spoken before numerous private organizations (the American Bar Association, the Biotechnology Industry Organization, the Intellectual Property Owners Association, and many others) about the antitrust issues affecting the pharmaceutical and biotechnology industries.

## WORLDWIDE EXPERIENCE, REPUTATION, AND RESOURCES

Jones Day offers corporate clients sophisticated and cost-effective global representation in all aspects of antitrust matters related to intellectual property, from preventative counseling to the litigation of full-blown disputes. Issues at the interface between antitrust and intellectual property law frequently require multidisciplinary efforts and experience. Accordingly, we regularly build seamless teams of antitrust, intellectual property, appellate, and other professionals across practices and offices to effectively and efficiently serve our clients' needs, whether regional, national, or international. There are neither institutional barriers nor disincentives to doing so at Jones Day. To the contrary, Jones Day lawyers in different practices and offices routinely work together as effortlessly and effectively as if they were in adjoining offices.

Jones Day's global reach permits us to provide integrated solutions directed at avoiding both excessive caution and unnecessary disputes, even in developing jurisdictions around the world. We have antitrust lawyers in 23 cities in 12 countries and intellectual property lawyers in 27 cities in 10 countries.

Our teams, big or small, consist of acknowledged talent in each of the applicable disciplines. First, our antitrust lawyers are recognized worldwide for their ability and experience. For example, *The Best Lawyers in America* has ranked the Jones

Day Antitrust Practice No. 1 nationally. *Chambers Global* has recognized Jones Day as having one of the top competition law and antitrust practices globally and has assigned our U.S. practice its highest ranking. *Chambers Asia*, has assigned top ranking to our China practice as well. Additionally—for a number of consecutive years—*PLC Which lawyer?* has ranked the Jones Day Antitrust & Competition Law Practice among the top practices in the world. Reflective of this experience and achievement, Jones Day lawyers in recent years have been chosen to head the Justice Department's Antitrust Division and to chair the Federal Trade Commission.

Second, lawyers in our outstanding Intellectual Property Practice also are global leaders in their fields. *Chambers Global* has awarded Jones Day's Intellectual Property Practice top-tier ratings. Jones Day has also shared top honors in the Intellectual Property category in *Corporate Counsel's* survey of *Fortune* 100 companies, "Who Represents America's Biggest Companies?"

Third, our renowned appellate lawyers are equally accomplished. *The National Law Journal* consistently includes Jones Day among the firms on its "Appellate Hot List." The criteria for selection each year include at least one significant appellate win before the U.S. Supreme Court, a U.S. circuit court of appeals, or a state court of last resort in a case dealing with an important legal principle or significant damages, as well as an impressive track record overall. Our appellate lawyers have argued 18 cases before the U.S. Supreme Court in the past six Terms, as well as numerous appeals in other federal and state courts, including the Federal Circuit (which has jurisdiction over most patent-related appeals), in important and high-profile matters.

Consistent with our widespread experience in this area, we frequently speak and write in the highest-profile publications and symposia on antitrust issues involving intellectual property. We have also been asked to contribute our views to government agencies and other entities, including the United States Congress, the U.S. Antitrust Modernization Commission, the U.S. Department of Justice and Federal Trade Commission, and the Organisation for Economic Co-operation and Development and other international antitrust delegations, from Egypt to the People's Republic of China.

Given the range and depth of our legal experience, it is not surprising that companies such as Abbott Laboratories, Baxter International, Bayer AG, Boehringer Ingelheim, Celgene, Eisai, King Pharmaceuticals, and sanofi-aventis have retained our antitrust lawyers.

## **WALKER PROCESS AND SHAM LITIGATION CLAIMS**

The most frequent occasion of potential antitrust liability for the branded pharmaceutical and biotechnology industries arises from their obtaining and enforcing patents, the very lifeblood of those industries and the logical reward for innovation. Antitrust counterclaims are knee-jerk responses to patent infringement lawsuits. The explosion of private antitrust challenges in the pharmaceutical industry, however, has led to the assertion of such claims by so-called purchaser plaintiffs, who are not even party to the underlying infringement litigation. Like Hatch-Waxman itself, these purchaser plaintiffs and their follow-on claims have only increased the risks and stakes for branded pharmaceutical companies. Jones Day's litigators have been at the center of these developments over the past 10 years, representing a variety of innovator companies against both potential generic rivals and putative classes of purchasers.

An example of how easily such claims can be asserted without regard to their merit came in our successful defense of **Eisai Co., Ltd.** In Hatch-Waxman infringement litigation concerning its drug Aciphex, Eisai first lost a motion for summary judgment in its favor, then went on to win the case at trial. Even before the trial, however, numerous private antitrust class actions were filed on behalf of direct and indirect purchasers in multiple federal courts. Based solely on the *denial* of summary judgment, plaintiffs alleged that Eisai's (still uncompleted) infringement action was a baseless "sham" and hence Eisai was guilty of monopolization. We persuaded the antitrust plaintiffs to consolidate and stay the actions before the same judge hearing the patent case. When he decided the patent case in favor of Eisai, the plaintiffs agreed to dismiss the antitrust cases.

As this example shows, in cases where the branded companies prevail in the underlying infringement litigation, the

patent merits generally determine the antitrust outcome. The more challenging antitrust cases arise when patent holders lose their underlying infringement litigation. Fortunately, branded companies can still prevail on antitrust claims and counterclaims alleging *Walker Process* fraud and sham litigation. These cases require the claimant to overcome the antitrust immunity ordinarily attaching to obtaining and enforcing patents and to prove market definition, causation, antitrust injury, and antitrust standing (among other things).

## **SETTLEMENTS OF LITIGATION AND INTERFERENCES**

The tremendous adverse financial consequences of erroneous legal decisions have frequently led branded pharmaceutical companies to enter into settlement agreements resolving intellectual property litigation with potential generic challengers. The unwarranted skepticism that competition and antitrust authorities have about intellectual property rights has led them to challenge or question these settlements in many cases. There has been no greater antitrust challenge for the industry over the past 10 years than challenges from the FTC and private plaintiffs to the patentee's understandable decision to manage patent litigation risk. And there has been no greater disappointment to these antitrust plaintiffs than the losses they continue to suffer in federal courts.

From the outset, Jones Day has been at the center of the legal and policy firestorm associated with what the FTC has labeled "reverse payment settlements." Jones Day has successfully defended both **Bayer AG** and **Bayer Corporation** in more than 40 federal and state antitrust class actions based on Bayer's 1997 settlement with Barr of infringement litigation involving ciprofloxacin (an antibiotic known for, among other things, its ability to combat anthrax in bioterrorism). In 2005, Bayer won summary judgment at the district court level, successfully arguing that the alleged "reverse payment" settlement agreements (involving payments by the patent holder to the generic challengers) did not violate the Sherman Act as long as the settlement excluded no more competition than the (lawfully issued) patent itself. In October 2008, the Federal Circuit affirmed that decision.

Collaborating with our intellectual property lawyers, Jones Day's antitrust lawyers have represented a number of other pharmaceutical companies in connection with their settlements of pharmaceutical patent litigation, many of which now require antitrust notifications to the Justice Department and the Federal Trade Commission. Jones Day lawyers advise pharmaceutical companies on how to structure their settlements of pharmaceutical patent litigation to best achieve their business objectives while minimizing their antitrust exposure. We have also assisted clients in avoiding antitrust challenges to settlements of patent interferences, which we believe are likely to assume increasing importance in the biotechnology industry. Jones Day has successfully defended settlement terms before the U.S. antitrust enforcement agencies, and we have represented several clients in Europe in matters involving settlement of patent litigation.

## PRODUCT LIFECYCLE MANAGEMENT

Product lifecycle management strategies, like intellectual property settlements, have long been part of standard commercial practice in high-technology industries. But the same forces driving antitrust enforcers and private litigants to challenge settlements in the pharmaceutical industry have also led them to examine, and in some cases to challenge, these strategies. Some product lifecycle management strategies emerge as part of litigation settlements and can enable branded pharmaceutical companies and their partners to offer cheaper or improved versions of branded pharmaceutical products. Other challenges to these strategies involve the application to the pharmaceutical context of often discredited antitrust theories, such as price squeezes, technological tying, or predatory innovation. Still other challenges involve efforts by antitrust enforcers and private plaintiffs to avoid the application of permissive antitrust law in areas like competitor collaborations, patenting, and FDA petitioning.

In each of these areas, it is essential for the pharmaceutical and biotechnology industries to have a strong team of antitrust and intellectual property lawyers with both broad experience and detailed knowledge of the pharmaceutical industry. Our antitrust team's across-the-board facility with antitrust law and intimate knowledge of current enforcement initiatives and actions at the FTC and DGIV enable us

to advise clients on how to maximize the commercial value of their patents and products without making inadvertent antitrust mistakes. If and when antitrust challenges arise, we have the litigators able to prevail in federal court. For example, in *Louisiana Wholesale Drug Co. v. Sanofi-Aventis, LLC and Aventis Pharmaceuticals*, Jones Day won a jury verdict in favor of the **sanofi-aventis** defendants, defeating the claims that they had monopolized a market for leflunomide, a rheumatoid arthritis drug, by filing a "sham" citizen petition with the FDA as part of a regulatory strategy allegedly designed to delay generic competition.

## TRADITIONAL ANTITRUST CLAIMS

Because so many of the government and private antitrust challenges in the pharmaceutical industry have focused on intellectual property, some forget that the industry has also seen its share of traditional antitrust scrutiny, ranging from criminal antitrust enforcement to follow-on private actions to large class actions to distribution practices.

Here, too, Jones Day has played a significant role in making modern antitrust law and defending branded pharmaceutical manufacturers from public and private foes alike. In *In re Brand Name Prescription Drugs Antitrust Litigation*, Jones Day served as national federal and state coordinating counsel for **Sandoz** (now known as **Novartis**) in multiple actions, including one of the largest MDLs in U.S. history. Plaintiffs alleged that the branded pharmaceutical manufacturers had conspired among themselves and with wholesalers to give better prices to HMOs and other purchasers than to small retail pharmacies.

Jones Day represented a European pharmaceutical company in connection with the multinational investigations into alleged cartel conduct among vitamin producers. Our client cooperated with the DOJ and the European Commission in these investigations, was accepted into the DOJ's Amnesty Program, and became the first entity ever to be granted complete immunity from all penalties by the EC. Other European companies paid the largest criminal antitrust fines in history (a total of nearly \$1 billion in the U.S. and nearly as much in the EC, along with significant fines and prison sentences in the U.S. for several European executives).



Jones Day has successfully defended both **Bayer AG** and **Bayer Corporation** in more than 40 federal and state anti-trust class actions based on Bayer's 1997 settlement with Barr of infringement litigation involving ciprofloxacin.

In addition, Jones Day represented **sanofi-aventis** with respect to more than 150 civil cases filed in federal and state courts around the U.S. The cases alleged that sanofi-aventis, along with the other vitamin manufacturers, engaged in a decade-long conspiracy to fix prices and allocate the markets for bulk vitamins in violation of federal and state antitrust laws. We played a significant role in a joint defense group comprising more than 15 large law firms. The federal litigation, filed on behalf of direct purchasers of bulk vitamin products, was consolidated in the U.S. District Court for the District of Columbia. While sanofi-aventis and five other manufacturers resolved class-action claims against them in November 1999, hundreds of the companies' customers opted out of the class settlement and pursued individual actions against the vitamin defendants. Sanofi-aventis resolved all of those claims prior to trial.

The state litigation, brought on behalf of indirect purchasers of vitamin products, was initially filed in more than 20 states. Jones Day, together with a small group of other law firms, crafted a multistate "coalition" in which judges overseeing litigation in the 17 states recognizing indirect purchaser causes of action agreed to coordinate the litigation under the auspices of the Superior Court for the District of Columbia. This unusual multistate arrangement facilitated a settlement of class-action claims in all 17 of the states, saving sanofi-aventis and the other settling defendants significant settlement and transaction costs. Jones Day continues to lead the joint defense group's litigation efforts in the remaining class-action and opt-out litigation. Jones Day coordinated the sanofi-aventis defense to worldwide civil litigation relating to the same price fixing, including individual and class actions in Canada, Australia, the U.K., the Netherlands, and Germany.

Jones Day also represented **sanofi-aventis** in a class action filed in the U.S. District Court for the District of Columbia on behalf of all foreign entities that purchased vitamins outside the U.S. The trial court dismissed the claims for lack of standing and subject-matter jurisdiction, but a divided panel of the Circuit Court of Appeals for the District of Columbia reversed the trial court on both grounds and reinstated the claim. In 2004, the U.S. Supreme Court reversed again, ruling that persons or entities outside the U.S. may not seek damages in U.S. courts based on anticompetitive conduct occurring entirely outside the U.S.

Additionally, Jones Day has long-standing experience in providing antitrust advice on traditional antitrust questions relating to distribution practices, such as Robinson-Patman issues, exclusive dealing, and tying and bundling.

## MERGERS, ACQUISITIONS, AND EXCLUSIVE LICENSES

Jones Day is also among the leading firms in representing companies in the merger review process before anti-trust and competition authorities throughout the world. We have represented parties to some of the largest and most challenging mergers in recent history, including AOL/Time Warner, Procter & Gamble/Gillette, XM/Sirius, and Federated/May Department Stores.

We have also steered numerous pharmaceutical, biotechnology, diagnostic, and medical device transactions successfully through multinational merger review. Success has required familiarity with quickly evolving merger policy and techniques at the relevant enforcement agencies, rapid learning and application of essential underlying facts, the construction of defenses integrating economic analysis and internal documents, and well-timed advocacy before various competition authorities.

As long-standing outside antitrust counsel for **Bayer AG**, we have represented Bayer in numerous complex merger reviews involving pharmaceuticals, diagnostics, diabetes care, and agricultural biotechnology, including the acquisition of Athenix. We have served **Baxter International** in a similar capacity on numerous reportable transactions. We have represented **Abbott Laboratories** in its acquisitions of Knoll's pharmaceutical business, Therasense Inc. (diabetes care), Kos Pharmaceuticals, Advanced Medical Optics, and Visiogen, none of which received Second Requests in the United States or extended review elsewhere. We also represented Abbott in the EU in its role as a divestee in the Boston Scientific/Guidant transaction. Recently, we represented **King Pharmaceuticals** in its acquisition of Alpharma, Inc., where we persuaded the FTC not to challenge the acquisition with respect to the long-acting opioid pipeline of both companies.

Our ability to move quickly through this process, coupled with our reputation for highly aggressive, cutting-edge merger advocacy grounded in factual and documentary evidence, is well known to government enforcers and serves our clients well. To further explore Jones Day's capabilities in this increasingly active and complex area, please contact any of the lawyers identified below.

## ADDITIONAL INFORMATION

For additional information regarding our Antitrust Issues Involving Pharmaceutical, Biotechnology, and Medical Device Industries practice, please contact your principal Firm representative or one of the lawyers listed in this publication. General email messages may be sent using our "Contact Us" form, which can be found at [www.jonesday.com](http://www.jonesday.com).

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