Legal Backgrounder

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RECENT PATENT RULING INTRUDES ON KEY ANTITRUST IMMUNITY DOCTRINE

by

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Patent rights have never been so important to the development of new pharmaceutical medicines. With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, known commonly as the Hatch-Waxman Act, Congress reworked the legal protections for pioneer drug makers. It gave generic drug manufacturers the right to rely on the testing and clinical data developed by the pioneer. It also granted generics immunity from claims of patent infringement during development of the generic copy in exchange for added protection for the pioneer's patent rights. Finally, the law provided pioneers with restoration of part of the patent term lost to FDA review and an opportunity to vindicate its patent rights for a limited period of time (thirty months) before FDA approval of the generic version. The loss of exclusivity in a pioneer's safety and efficacy data puts extraordinary emphasis on a pioneer's patent portfolio as the means for protecting the pioneer's investment in developing and proving a new drug product. Perhaps not surprisingly, it has also brought extraordinary scrutiny to bear on the pioneer's use of its patents. *See, e.g., Coalition Seeks to Curb Patent Extensions*, W. POST, Mar. 25, 2002, at A1.

It is in this context that the court in *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002), attempted to define the scope for antitrust law in policing a pioneer's invocation of the patent provisions of the Hatch-Waxman Act. The court concluded, in reasoning unnecessary to its decision, that pioneer drug manufacturers are not entitled to the legal protections from antitrust liability ordinarily associated with regulatory submissions and court filings when they submit their patents to FDA in order to invoke the patent provisions of the Hatch-Waxman Act.

The consequences of the court's conclusion are severe. The Hatch-Waxman provisions, by their express terms, delay generic entry into the marketplace, and consequently their invocation is readily subjected to accusations of anti-competitive intent and claims for damages commensurate with the high cost of drug development. The court's departure from settled doctrines of antitrust law was unwise and, as this LEGAL BACKGROUNDER undertakes to show, deserves a second look.

Antitrust Liability in a Regulatory Context: The Noerr/Pennington Doctrine. The Supreme Court has warned that our democratic traditions, and the constitutional right to petition government for redress, counsel against establishment of "a category of lawful state action that citizens are not permitted to urge." *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 379 (1991). This warning has been enforced, in the antitrust domain, through the Noerr/Pennington doctrine, which holds that solicitation of government action is generally immune from challenge under the antitrust laws. The doctrine protects both the use of anticompetitive means in seeking government action and the solicitation of government action that is itself anti-competitive. In addition, it applies to all forms of government petitions, including regulatory submissions and court filings. *See id.* at 380-82.

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The protection afforded by the doctrine is not absolute, however. Where a party's conduct in seeking government action is a "sham" — that is, where it involves "the use of the government process — as opposed to the outcome of the process — as an anticompetitive weapon" — immunity may be lost. *Professional Real Estate Investors, Inc. v. Columbia Pictures, Inc.*, 508 U.S. 49, 61 (1993).

Of course, enforcement of a patent implicates the actions of two separate government entities, namely, the issuance of the patent by the United States Patent and Trademark Office and the enforcement of the patent by the federal courts. Antitrust immunity applies to both steps. Actions taken to obtain a patent from the PTO are outside the scope of antitrust law in the absence of so-called "Walker Process" fraud before that agency. However, actions taken to enforce a patent are subject to antitrust liability only if shown to be both objectively and subjectively baseless. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). The Federal Circuit has recognized "a presumption that the assertion of a duly granted patent is made in good faith," which ensures that few infringement suits will fall outside the protective shield of Noerr/Pennington. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998).

The Hatch-Waxman Act adds one more layer of government regulation, that of FDA, to the enforcement of a pharmaceutical patent. When a pioneer drug manufacturer obtains FDA approval for a new drug product, the pioneer is required to submit information to FDA on any patent which "claims the drug" or which "claims a method of using such drug," and for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1). FDA publishes a list of the qualifying patents, along with their expiration dates, in its *Approved Drug Products With Therapeutic Equivalence Evaluations*, invariably referred to as the "Orange Book."

The Orange Book provides generic manufacturers with a list of approved new drug products for which generic drug applications might be submitted. For pioneers, the listing of patents in the Orange Book ensures that FDA will require the generic to certify in its application either that it will accept deferral of approval until expiration of the listed patent (a "paragraph III" certification) or that the listed patent is invalid or not infringed (a "paragraph IV" certification). The listing also guarantees the pioneer that it will receive notice of the generic applicant's patent certification and the opportunity to enforce the patent, if appropriate, before FDA approval of the generic. Specifically, the statute provides the pioneer with 45 days in which to evaluate the notice, and if the pioneer disputes the generic's contentions and files a suit for patent infringement within that 45-day period, FDA will defer approving the generic application for up to thirty months while the patent case is litigated. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Orange Book listing is thus a threshold requirement for triggering the Hatch-Waxman patent provisions ensuring a pioneer both notice and the opportunity to sue before the generic enters the market.

The Buspirone Decision. *Buspirone* involved allegations that the pioneer had improperly availed itself of the Hatch-Waxman provisions by misrepresenting the scope of its patent first to obtain the patent's listing in the Orange Book and then to assert it against generic applicants. The drug product at issue was BuSpar, an anxiety medication manufactured by the Bristol-Myers Squibb Company that contains the active ingredient buspirone. While Bristol had obtained a patent on the use of buspirone itself in 1980, that patent expired in November 2001.

The disputed issue in the case involved a subsequent patent, the "'365 patent," which was obtained by Bristol on the eve of the earlier patent's expiration. The '365 patent claims the administration of a compound that is one of the metabolites produced in the body following administration of buspirone. Asserting that its new patent covered administration of buspirone on the theory that use of buspirone naturally results in the use of its metabolites, Bristol submitted the patent for listing in the Orange Book in connection with BuSpar and filed patent infringement actions against the applicants for generic versions of BuSpar, thereby triggering thirty-month stays of approval of their applications.

It is fair to say that Bristol-Myers has faced difficulties when defending its interpretation of the '365 patent. Even before the *Buspirone* decision, a federal court had found Bristol's interpretation unpersuasive

and had ordered the company to withdraw its listing of the patent in the Orange Book, an order reversed by the appellate court on the ground that there is no independent cause of action for delisting. *See Mylan Pharmaceuticals, Inc. v. Thompson*, 139 F. Supp. 2d 1 (D.D.C.), *rev'd*, 268 F.3d 1323 (Fed. Cir. 2001). The *Buspirone* court similarly disagreed with Bristol's interpretation of its patent and, in a separate opinion issued the same day as its antitrust decision, dismissed the infringement claims against the generics. *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 340 (S.D.N.Y. 2002). While the court's review of Bristol's patent is lengthy, for present purposes it is sufficient to note that the court found not only that Bristol's patent did not in fact claim the use of buspirone, but moreover that Bristol could not reasonably assert that it did. *See id.* at 359.

Having reached this conclusion, the court could readily have disposed of Bristol's motion to dismiss the antitrust claims on Noerr/Pennington grounds without making new law. As noted, the "sham" exception to that doctrine is triggered by showing that challenged litigation is objectively and subjectively baseless. The court's ruling on the infringement claims supported the former, and the plaintiffs had pleaded the latter. Bristol's motion could thus have been denied under an ordinary application of the sham exception, without regard to the overall applicability of Noerr/Pennington, a point the court acknowledged towards the end of its antitrust decision. *See* 185 F. Supp. 2d. at 375-76.

The court went further, however, by concluding that Bristol was not entitled even to invoke Noerr/Pennington because the submission of patent information to FDA was not, in the court's view, a "genuine act[ ] of petitioning the government." *Id.* at 373. According to the court, Noerr/Pennington protection was limited to petitions intended to persuade the government. Further, because the court concluded that FDA was required to list any patent submitted to it and hence had only a "ministerial" role in Orange Book listing, the court found that patent submissions serve no role in persuading government officials. *See id.* at 370-71. As for the role of patent submissions in subsequent enforcement of the patent, the court reasoned that Orange Book listing was too distinct from an infringement lawsuit to be protected since either could be accomplished without the other. The court reasoned that while Orange Book listing conferred "a number of additional and automatic benefits under the Hatch-Waxman Amendments, . . . Bristol-Myers's First Amendment right to petition the courts for an authoritative declaration of its rights, for a preliminary injunction or for any other damages it may sustain as a result of patent infringements by its competitors would not be burdened by not having listed its patent in the Orange Book." *Id.* at 373.

Analysis of the Buspirone Reasoning. The court's view of FDA's role in listing patents is subject to considerable criticism. While FDA does defer to the pioneer's description of what a patent claims, as the Agency disclaims any expertise in patent law, FDA requires certification from pioneers attesting that the submitted patent satisfies the listing criteria. *See, e.g,, Pfizer, Inc. v. FDA*, 753 F. Supp. 171 (D. Md. 1990) (affirming FDA's refusal to list patent when pioneer was unable to make the required certification). The *Buspirone* court failed even to discuss the Federal Circuit's recent suggestion that FDA's refusal to approve a generic application based on a patent listing could be reviewed under the Administrative Procedures Act, a suggestion that would seem to imply that FDA's role involves at least some decision making. *See Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002).

More troubling is the court's crabbed reading of Noerr/Pennington as limited to attempts to "persuade" government officials. The consequence of this, as the court acknowledges, is to deny protection where the petition seeks redress to which the petitioner is statutorily entitled. 185 F. Supp. 2d at 371-72. Yet the right to petition the government surely makes no distinction between petitions for mandatory redress and those for discretionary relief; to hold otherwise is to establish precisely the "categories of state action that citizens are not permitted to urge" the Supreme Court warned against.

The proper distinction is instead whether the alleged harm to competition results from solicited government action as opposed to private conduct. *See, e.g., Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500, 502 (1988); *see generally* 1 P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 202c, at 160 (2d ed. 2000) (observing that Noerr/Pennington immunity "applies equally to all petitions for government actions when the antitrust challenge is to the consequence of the government action itself"). Strikingly, the sole legal

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authority the court cited to support its distinction among petitions was a series of cases denying Noerr/Pennington protection to tariff rates. *See* 185 F. Supp. 2d at 370-71. However, in those cases the alleged harm to competition arose from the purportedly unlawful rates charged by the private defendants; the submission to and subsequent review of those rates by government agencies did not itself cause harm. By contrast, all of the harm alleged in the Hatch-Waxman context arises from government action specified by law; namely, FDA's actions in listing the patent in the Orange Book, requiring the generic applicant to certify to the patent, and then deferring approval of the generic application for thirty months if the pioneer files suit.

Equally dubious is the court's refusal to treat Orange Book listing as antecedent to subsequent Hatch-Waxman patent litigation. Whether or not listing is essential to the filing of a patent infringement action at all, it is certainly critical to the prosecution of such an action before generic entry, since only with listing is the pioneer entitled to notice from the generic and the opportunity to pursue its infringement case for thirty months before the generic application may be approved. While the court dismissed these procedural rights as simply "additional and automatic benefits" of the Hatch-Waxman Act, distinct from litigation, the same could be said of pre-litigation infringement letters often sent prior to the filing of ordinary patent suits, which preserve a patent owner's damage claim under 35 U.S.C. § 285 and which the court acknowledged were protected under Noerr/Pennington. The court's bald assertion that loss of the Hatch-Waxman related remedies would not "burden" a pioneer's right to vindicate its patent in court belies the traditional benefits of pre-deprivation relief and contravenes Congress' judgment in enacting Hatch-Waxman that the litigation procedures set forth in the Act were an important recompense for the generics' right to infringe the patent in developing their product. *See* 35 U.S.C. § 271(e)(1).

Moreover, while the court found Bristol's patent suit to meet the "sham" standard, at least for motion to dismiss purposes, the court's reasoning implies that submission of patent information to FDA may be attacked even where subsequent infringement litigation is not thought by the court to be a sham. Missing from the court's opinion is an explanation of how that submission has significance to the antitrust laws aside from the pioneer's subsequent action in filing suit and triggering the thirty-month stay. It is telling that, even in the context of denying application of Noerr/Pennington to patent submissions, the court felt compelled to reiterate its finding that the subsequent litigation met the sham standard. *Id.* at 373 n.4. In fact, at least aside from unusual circumstances not present in the case, the only impact of Orange Book listing on generic entry is the thirty-month stay on generic approval obtained upon the filing of suit. Here too, the court has established a category of state action that pioneer drug manufacturers may seek only at their peril, concluding that provisional remedies associated with the enforcement of pioneer pharmaceutical patents, unlike all other litigation remedies, are subject to liability without Noerr/Pennington protection.

Conclusion. By denying a pioneer drug manufacturer's patent submissions to FDA the protections of Noerr/Pennington, the *Buspirone* court's decision exposes a pioneer's decision to bring Hatch-Waxman patent litigation to legal peril not faced by any other litigant. In light of the important role assigned to patent litigation by the Hatch-Waxman Act in protecting the pioneer's investment in drug development, the court's decision, at a minimum, substantially alters the balance struck by Congress in allowing generics to piggyback on the pioneer's clinical testing.

To be sure, the balancing of interests between pioneer and generic drug manufacturers is presently a matter of great controversy. But Noerr/Pennington exists, in the Supreme Court's words, because "the antitrust laws regulate business, not politics." *Omni*, 499 U.S. at 383. The *Buspirone* decision intrudes on this important distinction.

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