

Legal Alert:

Valley Drug Co. v. Geneva Pharmaceuticals, Inc.

December 5, 2003

A recent 11th Circuit case, Valley Drug Co. v. Geneva Pharmaceuticals, Inc., sheds light on the complex intersection of patent and antitrust law in the context of a settlement agreement between a name brand pharmaceutical manufacturer and two allegedly infringing generic manufacturers that were seeking FDA approval of a drug patented by the name brand manufacturer.¹ The plaintiffs in this case claimed that the settlement agreements constituted a horizontal contract in restraint of trade in violation of Section 1 of the Sherman Act.² The district court agreed, granting the plaintiffs' motion for partial summary judgment on the basis that the agreements were *per se* anticompetitive. On appeal, the 11th Circuit reversed. It held that such settlement agreements must be analyzed to determine whether the agreements exceed the patentee's right to exclude others from making, using, or selling the patented subject matter. If the agreements are within the scope of the exclusionary right, antitrust law is not implicated. However, if the court determines that certain provisions of the settlement agreement exceed the scope of patent protection, traditional antitrust analysis can then be applied to these provisions, including where appropriate a *per se* or a rule of reason analysis.

While the ruling in this case is straightforward, the factual background is complex. The infringement claims by the name brand manufacturer, Abbott Laboratories, arose in the context of applications for approval of pharmaceutical products by the two generic manufacturers, Geneva Pharmaceutical and Zenith Goldline Pharmaceuticals, to the Food and Drug Administration.

The FDA must approve new drugs before they are marketed or sold in the United States. To obtain approval from the FDA, the applicant must file either a new drug application ("NDA") or an abbreviated new drug application ("ANDA"). The NDA requires exhaustive safety and efficacy studies of the new drug. However, once a pioneer drug maker has received approval

¹ Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294 (11th Cir. 2003).

² 15 U.S.C. § 1.

under a NDA, subsequent generic applicants are permitted to file an ANDA, a much less onerous application that allows the applicant to piggyback on the safety and efficacy studies filed for the pioneer drug.³ The ANDA was created under the Hatch-Waxman Act with the goal of removing impediments to the approval of generic drugs.⁴ The Hatch-Waxman Act also changed the definition of patent infringement so that conducting safety and efficacy studies for FDA approval would not constitute infringement.

In seeking approval of a NDA, the pioneer drug maker is required to submit patent information to the FDA, which is then published in the “Orange Book” along with other information about the drug. An ANDA applicant relying on the safety and efficacy studies of a pioneer drug must make one of the following certifications with respect to any patent claiming the listed drug: (I) that no patent information for the brand name (NDA) drug has been submitted to the FDA (a Paragraph I certification); (II) that such patent has expired and no longer covers the approved drug (a Paragraph II certification); (III) that the patent will expire on a specific date and generic entry will occur after that date (a Paragraph III certification); or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA applicant seeks approval (a Paragraph IV certification).⁵ If certification is made under Paragraph IV, the applicant must notify the patent holder. If the patent holder brings suit for infringement within forty-five days of this notice, FDA approval of the ANDA is automatically delayed thirty months. If the court finds that the patent is invalid or not infringed, the thirty-month delay terminates; if the court finds the patent valid and infringed, the approval date is set on or after the patent’s expiration date.

In the event that a listed drug is subject to more than one Paragraph IV certification, the approval of subsequent ANDAs is delayed until 180 days after the earlier of: (1) the first commercial marketing of the drug under the previous application or (2) the date a court hearing an infringement action brought against the previous filer holds the patent invalid or not infringed. This 180-day exclusivity period is an incentive and reward for the first generic manufacturer who successfully challenges a weak or narrow drug patent.⁶

³ 21 U.S.C. § 355(j).

⁴ The Hatch-Waxman Act is commonly used to refer to the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁵ 21 USCA § 355(j)(2)(A)(vii)(I)-(IV).

⁶ Note that the recent “Medicare Prescription Drug, Improvement, and Modernization Act of 2003” bill, soon to be signed into law by President Bush, dramatically changes the scheme described herein under the current law for the 180-day exclusivity period; this bill also contains additional changes to Hatch-Waxman. A description of the changes contained in this bill is beyond the scope of this Legal Alert.

Both Geneva and Zenith filed ANDAs with the FDA. Geneva filed a Paragraph IV certification and was subsequently sued for patent infringement by Abbott. When Zenith filed its ANDA, Abbott had not yet listed its patent information in the Orange Book. Zenith failed to amend its ANDA and make a Paragraph IV certification after the patent information was listed. Zenith then sued Abbott to delist the patents in the Orange Book, and Abbott counterclaimed for patent infringement.

At issue in this case are the agreements entered into by both Geneva and Zenith with Abbott relating to the patent infringement claims. In Zenith's case, both parties agreed to drop the claims, and Zenith agreed to not sell or distribute any pharmaceutical product containing the drug at issue in the patent until someone else introduced a generic version or until the Abbott patent expired. Zenith also agreed not to sell or transfer its rights under any ANDA and to not aid another person in FDA approval. In return, Abbott agreed to a payment schedule, paying Zenith three million dollars upfront, three million dollars after three months, and six million dollars every three months thereafter for approximately two years or until the agreement terminated by its own terms. In Abbott's agreement with Geneva, Geneva agreed not to sell or distribute any pharmaceutical product containing any form of the drug at issue until either Abbott's patent expired, someone else introduce a generic form of the drug, or Geneva obtained a favorable court judgment that its drug did not infringe or that the patent was invalid. This condition required a final judgment from which no further appeal could be taken, including petition for certiorari to the Supreme Court. Geneva also agreed to oppose any subsequent ANDA applicant's attempt to seek approval of its application, and to join any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva's ANDA. In return, Abbott agreed to pay Geneva 4.5 million dollars each month until either someone else brought the generic drug to market or Abbott won a favorable decision in the district court on its infringement claims.

Certain anticompetitive actions are considered *per se* illegal under the Sherman Act. For example, an agreement between competitors to allocate the market is considered so obviously anticompetitive that such agreements can be deemed a violation of the Sherman Act without more than an examination of the agreement itself and the relationships of the parties to the agreement. The district court held that the agreements between Abbott and the generic drug manufacturers were *per se* illegal under § 1 of the Sherman Act, characterizing the agreements as a geographic market allocation between horizontal competitors. However, the 11th Circuit held that the agreements should not be characterized as market allocation agreements where due consideration is given to Abbott's right to exclude.

Because a patent gives its owner a lawful exclusionary right, Abbott was within its rights in excluding others from making, using, or selling the drug at issue until the patent expires or is

held invalid. To the extent the settlement agreements were within this exclusionary right granted by patent law, there is no implication of antitrust law. The fact that the Abbott patent was held invalid after the agreements were entered into is not relevant to this analysis. The reasonableness of the agreements should be judged at the time the agreements are entered into. There were no allegations in this case that Abbott procured the patent through fraud or that Abbott knew the patent to be invalid at the time of the agreements.

In holding that such settlement agreements do not implicate antitrust law, the 11th Circuit cites the need to encourage settlements in complex patent litigations. Patent holders would be discouraged from enforcing their exclusionary right through settlement if a *per se* analysis were applied, potentially exposing the patent holder to treble damages under the Sherman Act. Furthermore, the size of the settlement does not necessarily point to anticompetitive behavior. Because in this case the alleged infringers had not yet entered the market and therefore not caused Abbott any harm, Abbott would not have a damages claim against them. This changes the dynamics of settlement. The asymmetries of risk and the large profits at stake may convince even a patent holder confident in the validity of the patent to pay a potential infringer a large settlement.

The 11th Circuit notes that some provisions of the agreements may exceed the protections provided under patent law. To the extent that some provisions of the Abbott agreements exceed the exclusionary right, the district court should apply the traditional antitrust analysis, either *per se* or rule of reason where appropriate, to determine whether these provisions violate § 1 of the Sherman Act.

The 11th Circuit's decision makes clear that despite the fact that antitrust law and patent law are at odds in their treatment of monopolies, both antitrust and patent law have the common goal of serving the public welfare. The public welfare is served by the complementary objectives of antitrust and patent law to protect competition and innovation.

Please contact John L. North (404.853.8358 or john.north@sablaw.com) or William L. Warren (404.853.8081 or bill.warren@sablaw.com) if you have any questions or if we can assist you in any way.