Antitrust Issues That Arise in ANDA Disputes

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The structure of the pharmaceutical industry almost invariably leads to antitrust issues. Patent protection is strong. The patentee, prior to generic entry, usually has a monopoly over the particular pharmaceutical dosage, but often not as to a therapeutic category. The patent-based monopoly can lead to large profits—sometimes more than a billion dollars per year for blockbuster drugs. When a generic product is introduced to the market, the substitution for the patentee product is rapid, often above 90% in the first six months, and virtually guaranteed, given healthcare and insurance policies.

Thus, antitrust issues that follow abbreviated new drug application (ANDA) disputes arise in two main ways: (1) accusations that settlements between the patentee and the generic allow the brand to extend its patent based monopoly; and (2) accusations that the patentee engaged in some form of anticompetitive behavior to keep the generic out of the market, such as sham patent litigation or patent litigation based on a fraudulently acquired patent.

I. LEGAL THEORIES IN PRIVATE ANDA ANTITRUST CASES

ANDA antitrust cases usually arise under two kinds of statutory claims. The first and most common claim asserts monopolization offenses under federal law—Section 2 of the Sherman Antitrust Act. Second, ANDA antitrust cases—typically brought by “indirect purchasers”—may also assert state-law causes of action and will generally do so when federal law does not afford them a right to recovery.

A. Monopolization (Sherman Act Section 2) Offenses

Section 2 of the Sherman Act makes it unlawful for a firm to “monopolize.” Monopolization has two elements: “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”

In the ANDA context, three kinds of monopolization claims have appeared most often: (1) sham litigation claims charging that the patentee asserted one or more patents against an ANDA holder without a reasonable basis; (2) Walker Process claims arising from alleged fraud on the U.S. Patent and Trademark office in obtaining a patent; and (3) product switching claims asserting that the brand company timed its switch from one generation of a product to another in order to preclude generic competition.

1. Sham Litigation

The issue in sham litigation cases is whether the ANDA litigation’s effect on competition was lawful or unlawful. The first part of the inquiry is whether the brand drug company has monopoly power. (As noted above, this inquiry is an element of every monopoliza-

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Monopoly Power

A firm has monopoly power if it can raise prices substantially above the competitive level for a significant period of time. In theory, this power can be established by direct evidence. In practice, a firm has monopoly power is evaluated by a two-step process of defining a relevant product market and then looking at whether the firm has a dominant share of that market, among other factors.

In ANDA antitrust cases, the relevant product market dispute often centers on what products are in the market. The legal test for a relevant market involves whether the products are reasonable substitutes for each other in the buyer’s point of view. In pharmaceutical markets, this analysis is complicated because the “buyer” is not a single person. Rather, the prescriber, the pharmacist, the insurance carrier and the patient all take a role in “buying” a drug. The defendants will argue for a broader market definition so that it does not have a dominant share. Typically, this broad market definition will include an entire therapeutic class or at least several different classes of drugs within the therapeutic class. As an example, the brand could argue that the relevant market includes all drugs that treat cholesterol or depression. By contrast, the plaintiff will argue that the relevant product market is just the particular active ingredient molecule used in the reference drug, or even just the reference drug itself. This narrower market will allow for an easier showing of dominant share.

b. The PRE Test For Sham Litigation

Like all litigation, a brand company’s patent infringement lawsuit in response to a Paragraph IV certification constitutes protected petitioning activity under the First Amendment. Sham litigation is not, however, immune from antitrust liability as petitioning activity. As noted above, sham litigation has two required elements: First, the lawsuit must be objectively baseless such that no reasonable litigator could realistically expect success on the merits. By definition, if probable cause to sue exists, then no finding of sham litigation can arise. Second, if a challenged lawsuit is objectively meritless, a court must examine the litigant’s subjective motivation. The subject element of the sham litigation test requires showing that the objectively baseless lawsuit sought to use governmental process as an anticompetitive device.

Cases trying to apply this standard in ANDA cases have run into at least three recurring practical challenges. First, the defendant will argue that a good-faith comparison of the claims to the accused device provides sufficient grounds to establish objective reasonableness to sue as a matter of law. But, this reliance on pre-litigation analysis raises the question of whether the patentee also waives attorney-client privilege by doing so.

Second, the question of whether defeating a defendant’s motion for summary judgment is enough to establish objective reasonableness of suit as a matter of law remains an undecided one in the context of ANDA antitrust cases.

Third, no clear authority exists on who decides the question of whether filing the lawsuit was objectively baseless: the court or the jury. The antitrust defendant (and patent plaintiff) will argue that the court should decide the question as a matter of law, because determining whether the litigant could reasonably have anticipated the possibility of prevailing does not require resolving any disputed facts. Indeed, courts may resolve questions of probable cause without reliance on a jury for fact finding. By contrast, the antitrust plaintiffs will argue that the objective baselessness standard is akin to a negligence standard, which is a question routinely resolved by juries rather than judges. Indeed, juries can determine in professional malpractice cases whether attorney conduct was objectively reasonable.

c. Sham Citizen Petitions

A Citizen Petition is often filed by a brand drug maker, arguing to the FDA that additional testing or requirements should be imposed on a generic entrant before approval of an ANDA. The FDA must evaluate the Citizen Petition and determine if the substantive arguments have merit; this evaluation can result in a delay in approval of the generic entrant, even if the FDA does not agree with any of the arguments.

Antitrust plaintiffs thus can view brand Citizen Petitions as another form of anticompetitive act designed to delay generic entry. Generally a Citizen Petition is viewed as another form of government petitioning and thus treated the same as litigation under the PRE test. The concern over sham Citizen Petitions by brand companies led to legislation in 2007 and subsequently to FDA guidance on Citizen Petitions.

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5 PRE, 508 U.S. at 60-61; In re Tricor Antitrust Litig., 432 F. Supp. 2d at 424-25.
6 See Pf-Pharma Inc. v. Andrew Jergens Co., 360 F.3d 1295, 1302 (Fed. Cir. 2004) (rejecting defense argument that chemical analysis of product was required in pre-filing investigation).
7 See Tricor, 432 F. Supp. 2d at 426 (summary judgment not sufficient to establish objective reasonableness as a matter of law); Teva Pharms. USA, Inc. v. Abbott Laboratories, Inc. 580 F. Supp. 2d 345, 365-366 (D. Del. 2008) (sham litigation claim permitted as to claims that went past summary judgment but were dropped before trial).
9 FDC Act § 505(g). The final FDA guidance interpreting this legislation was issued in June 2011 and is available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079353.pdf.
2. Walker Process Claims

Under Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., the maintenance and enforcement of a patent obtained “by knowingly and willfully misrepresenting facts to the Patent Office” may be the basis of monopolization claims under Section 2 of the Sherman Act. In the ANDA context, a plaintiff would invoke Walker Process where the defendant engaged in “intentional fraud” to obtain a patent, and then used that patent against an ANDA filer. Because a brand drug maker and another ANDA filer challenges a patent that is pertinent to a patent listed in the Orange Book, the ANDA filer would have a valid monopolization claim if the patentee’s conduct is found to be monopolizing.13

3. Product Switching Claims

Another kind of antitrust claim that has arisen in connection with ANDA litigation involves product switching. In these cases, the ANDA applicant alleges that the brand drug maker switched formulations in a manner timed to preclude generic entry. For example, the brand drug maker will argue that the brand drug maker engaged in monopolizing conduct intended to exclude competition, without justification.14 By contrast, the brand drug maker will argue that the product changes are commercial decisions regarding improvements that courts should not meddle in under the antitrust laws. The Federal Circuit has not addressed this kind of claim in a published, precedential decision. Both sides can point to helpful precedent from leading antitrust cases: some where courts have refused to review a defendant’s conduct in product line changes and others where the courts have treated such conduct as monopolizing.14

4. Monopolization Injury

The sham litigation claimant will claim injury because the litigation delayed generic drug entry and caused it either to lose profits on generic drug sales (generic drug makers) or to pay more for the brand drug rather than a less expensive generic (generic drug purchasers). Specifically, when the patentee brings such an ANDA case, it benefits from an automatic 30-month stay on the FDA’s authority to approve the generic drug. This delay arises because the FDA often will grant “tentative approval” to a generic drug some months prior to when the 30-month stay expires, meaning that only the 30-month stay arising from litigation is keeping the generic from entering the market. Numerous courts have recognized this kind of claim as stating valid antitrust injury.15

Product switching claims may give rise to claimed injury distinct from delayed generic entry. In product switching claims, which may be coupled with delay claims, the claimant argues that the generic entered but could not effectively sell its product because the brand eliminated demand for the original product (that is the subject of the ANDA application) and replaced it with a new formulation. A purchaser plaintiff would claim injury from having to pay a higher-priced brand drug rather than a generic, due to the brand drug maker’s effectively eliminating demand for the cheaper generic product.

B. State Law Claims

Long-established federal law limits money-damages recovery to direct purchasers of goods allegedly affected by anticompetitive conduct. Thus, in ANDA antitrust cases, this means that only direct purchasers (i.e. drug wholesalers, large pharmacy chains, and some integrated providers) and, if appropriate, the generic drug makers themselves, can bring antitrust claims. Numerous states have therefore passed laws to allow indirect purchaser antitrust claims, even though federal law does not allow such claims. Plaintiffs in ANDA antitrust cases routinely rely on these state statutes to get around the federal law’s bar on indirect purchaser claims.16 Given the large numbers of indirect purchasers and the cost of prosecuting claims relative to the size of most (though not all) indirect purchaser claims, antitrust plaintiffs may seek class treatment.

II. ANDA-RELATED ACTIONS BY THE FEDERAL TRADE COMMISSION

The FTC is the primary government investigator and litigator in ANDA antitrust cases and tends to bring what it calls “pay for delay” claims. In these types of claims, the FTC alleges that the brand manufacturer pays the accused patent infringer (the generic manufacturer) to settle a patent infringement case and delay its entry into the market. The FTC argues that the brand manufacturer fears that its patent will be invalidated or not infringed, or alternatively that the settlement agreement is a per se violation of Section 1 of the Sherman Act.

10 382 U.S. 172, 176-77 (1965)
11 Dippin’Dots, Inc. v. Mosey, , 476 F.3d at 1348 (Fed. Cir. 2007).
13 Tricor, 439 F. Supp. 2d at 431.
14 See e.g., Microsoft, 253 F. 3d at 65-66; Berkery Photo, Inc., v. Eastman Kodak Co. 603 F. 2d 263, 287, n. 39.
A main tenet of the FTC theory is that in order to assess anticompetitive intent and effect, the fact finder should investigate the strength of the brand’s patent claims and the status of the underlying patent litigation. If the brand had very weak claims and had lost key arguments, such as claim construction, and then settled with a large payment to the accused infringer, the FTC believes it would show anticompetitive intent and effect.

As discussed in the cases below, the main problem with the FTC theory is that the courts generally have not agreed. Courts have repeatedly found that a patent holder may settle patent litigation or license a patent on most any terms it chooses. The key fact for the court to consider in looking at antitrust claim is whether the terms of the settlement exceed the bounds of the patent: does it cover other products or a longer period of time than the patent, thus extending the patent monopoly. Barring such an over-extension of the patent term, courts have generally found that the lawful monopoly afforded by the patent precludes the FTC’s theory.

A. FTC ‘Pay-For-Delay’ Cases

1. FTC v. Abbott Laboratories And Geneva Pharmaceuticals, Inc.17

One of the first FTC ANDA antitrust actions involved an investigation and settlement with the FTC. In FTC v. Abbott and Geneva, the FTC alleged that Abbott paid Geneva approximately $4.5 million per month to keep Geneva’s version of Abbott’s patented drug Hytrin off the market. Geneva was at the time in patent litigation over the 180-day exclusivity period for the tablet formulation of the drug. Geneva was required to waive its right to a 180-day exclusivity period for its capsule version of the drug. Geneva received FDA approval to market the capsule version of Hytrin.

According to the complaint, Geneva agreed not to enter the market with any generic version of Hytrin (tablet or capsule), even if it were non-infringing, until certain triggering events. The provisions ensured that no other company’s generic version of Hytrin could obtain FDA approval and enter the market during the term of the agreement, because Geneva’s agreement not to launch its product meant the 180-day exclusivity period would not begin to run.

Under the terms of the FTC settlement obtained in May 2000, Geneva was required to waive its right to a 180-day exclusivity period for the tablet formulation such that other generic Hytrin products could immediately enter the market. Part of what the FTC found particularly troubling was that Geneva made agreements as to the capsule form even though that product was not subject to any patent litigation.18

Subsequent to the FTC settlement, private litigants brought suit over the same conduct against Abbott and Geneva. The private parties alleged that they had been damaged by their inability to buy or sell a lower-cost generic during the 16 months that the agreement was in place. Although the district court initially granted plaintiffs’ motion for partial summary judgment on a theory that the Abbott-Geneva agreement was per se illegal under § 1 of the Sherman Act, the Eleventh Circuit reversed.19 The Eleventh Circuit ruled that, when analyzing the anticompetitive effects of ANDA settlements, the district court was required to—but failed to—determine whether the alleged anticompetitive effects of the settlement are broader than the exclusionary effects of the patent.20 On remand, the district court again granted summary judgment in favor of plaintiffs on their antitrust claim, again finding the agreement per se illegal because it exceeded the scope of the patent protection.21 After the District Court rendered its decision, Abbott settled with most of the plaintiffs.22

2. FTC v. Hoechst Marion Roussel/Andrx23

In one of the first cases to be litigated, the FTC charged that Hoechst Marion Roussel (now Aventis), the maker of Cardizem CD, a widely prescribed drug for treatment of hypertension and angina, paid Andrx Corporation over $80 million to refrain during the pendency of patent litigation from bringing to market any competing generic drug, without regard to whether it was allegedly infringing. This case was settled before trial, and the Commission issued final consent orders on May 11, 2001. The orders entered against Hoechst and Andrx contain relief similar to that in the Abbott and Geneva orders.

Direct and indirect purchasers also sued Hoechst and Andrx alleging that plaintiffs were harmed because, but for the reverse exclusionary payments, Andrx would have brought its generic product to market once it received FDA approval. The district court granted partial summary judgment to plaintiffs that the Hoechst-Andrx agreement was per se illegal, and, on appeal, the Sixth Circuit agreed.24 The Sixth Circuit reasoned that the agreement prohibited Andrx from marketing competing generic drugs that were not infringing, thereby exceeding the exclusionary effect of Hoechst’s patent.25 Shortly after the Sixth Circuit’s ruling, the District Court granted final approval to an $80 million settlement for the state law private plaintiffs and the state attorneys general.26

3. FTC v. Watson Pharmaceuticals, Inc.27

In January 2009, the FTC, joined by direct purchasers, indirect purchasers, and the State of California,

18 http://www.ftc.gov/speeches/anthony/sfip000601.shtm
19 Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1304 (11th Cir. 2003).
20 Id. at 1306.
23 131 F.T.C. 924 (2001) (consent order)
24 In re Cardizem CD Antitrust Litig., 332 F.3d 896, 915 (6th Cir. 2003).
25 Id. at 908 & n.13.
26 In re Cardizem CD Antitrust Litig., 218 F.R.D. 508 (E.D. Mich. October 10, 2003), aff’d in part, dismissed in part, 391 F.3d 812 (6th Cir. 2004). The Sherman Act plaintiffs (i.e., the direct purchasers) had previously settled in 2002 with Andrx and Aventis Pharmaceuticals for $110 million.
filed suit against Watson Pharmaceuticals, Par Pharmaceutical Companies, Paddock Laboratories, and Solvay Pharmaceuticals. The complaint challenged agreements in which Solvay allegedly paid generic drug makers Watson and Par to delay generic competition to Solvay’s branded testosterone-replacement drug AndroGel.

In February 2010, the district court granted defendants’ motions to dismiss the FTC complaint. The court held that the extent of the settlement’s exclusionary effect is the only relevant issue, not the presence of reverse payments or the possible subsequent invalidity of the patent. The court found that any alleged exclusionary effects from the settlement fell within the scope of the purported patent and accordingly dismissed the FTC complaint.

4. FTC v. Warner Chilcott Corp. and Barr Pharmaceuticals

The FTC filed a complaint against Warner Chilcott and Barr concerning an agreement allegedly to prevent entry of Barr’s generic version of Warner Chilcott’s Ovcon 35 oral contraceptive. In 2004 Warner Chilcott agreed to pay Barr $20 million in exchange for Barr’s delaying entry of its generic version of Ovcon for five years. The FTC filed for a preliminary injunction in September 2006, because it believed that Warner Chilcott was planning to launch a new chewable version of Ovcon, switch patients over to the new product, and then stop selling Ovcon. Because generic substitution would be unavailable if regular Ovcon was no longer available at the pharmacy, the FTC believed this switch strategy would have destroyed the market for generic Ovcon. Shortly after the FTC filed the request for a preliminary injunction, Warner Chilcott abandoned the provision in the 2004 agreement that prevented Barr from entering the market with its generic version, and Barr launched its generic version. In settling with the FTC, the companies agreed not to enter into any agreements not to compete.

Direct purchasers and their assignees also sued, alleging that the Warner Chilcott-Barr agreement delayed the entry of Barr’s generic version of Ovcon. After the district court granted an amended class, Warner Chilcott settled with the direct purchasers for $9 million. The district court later denied the remaining plaintiff’s summary judgment motion, and granted in part defendants’ summary judgment motion, ruling that the agreement was not per se illegal, but must instead be evaluated under the rule of reason. The court explained that it was unable to determine on summary judgment whether the proper market was Ovcon and its generic equivalent—as plaintiffs alleged—or branded and generic contraceptives—as defendants alleged. “Because the economic effects of the Agreement depend on the proper definition of the market (and the competitive effects therein), the Agreement cannot be condemned as a per se unreasonable restraint of trade.”

After the district court issued its order, Barr settled with the remaining plaintiffs for $13 million. The FTC complaint alleged that Schering-Plough Corporation, Upsher-Smith Laboratories and American Home Products Corporation entered into anticompetitive agreements in which Schering paid Upsher and American Home Products to forgo launching a competitive generic alternative to K-Dur 20, an extended-release potassium chloride supplement manufactured by Schering. According to the complaint, Schering and Upsher reached an agreement in 1997 to settle a patent infringement lawsuit, whereby Schering paid Upsher $60 million dollars and Upshur agreed not to market any generic version of K-Dur 20 until September 2001. Under the agreement, Schering received licenses to market five of Upsher’s products, but despite this fact the complaint charged Schering paid Upsher to secure its agreement to the 2001 entry date, and to ensure that no other company’s generic K-Dur 20 could obtain FDA approval and enter the market.

The case as to Schering and Upsher was tried before an FTC administrative law judge (ALJ). In an initial decision issued in June 2002, the ALJ ruled that Schering’s payments to Upsher were solely for licenses to Upsher’s products and not in exchange for agreement to the 2001 entry date. The ALJ also held that complaint counsel could not prevail absent proof that Upsher and American Home Products did not infringe Schering’s patent. In addition, the ALJ found that the relevant product market was all oral potassium supplements, and that Schering did not have monopoly power in that market. Complaint counsel appealed to the full Commission.

On December 8, 2003, the FTC reversed the ALJ’s decision. It ruled that Schering paid Upsher to delay the entry of generic competition, and not merely for the products licensed. The FTC also ruled that Schering’s agreements with both Upsher and AHP were anticompetitive because Schering’s payments resulted in greater protection from competition than the parties expected from continued litigation. In addition, the FTC considered it not necessary or desirable to adjudicate the merits of the underlying patent disputes in order to assess the competitive effects of the agreements.

Schering Plough appealed the FTC decision. In 2005, the Eleventh Circuit set aside the FTC decision, and vacated the cease and desist order. The Eleventh Circuit held that the FTC did not establish that the challenged agreements restricted competition beyond the exclusionary effects of Schering’s patent, which it believed to be the appropriate test. The FTC petitioned for a rehearing en banc and then to the Supreme Court, both of which were denied.

Direct purchasers also challenged the agreement as a reverse exclusionary payment under § 1 of the Sherman Act. On March 24, 2010, the district court granted Schering-Plough’s and Upsher-Smith’s motions for summary judgment. The court found Schering-Plough’s payments to settle the patent lawsuits were not per se illegal. The court explained that the reverse payment agreements were within the exclusionary scope of the patent because they permitted Upsher-Smith to market a generic version of K-Dur 20 for approximately five years before the patent expired. Plaintiffs’ appeal is currently pending before the Third Circuit.

6. FTC v. Cephalon, Inc.

The FTC and private plaintiffs filed complaints against Cephalon for engaging in an overall course of anticompetitive conduct to prevent generic competition to Provigil. The complaint alleged that Cephalon paid the generic manufacturers over $200 million dollars to abandon the patent litigation and agree to refrain from selling a generic version of Provigil until 2012. According to the complaint, the agreements not only prevented competition from the first filers but also blocked competition from other generic manufacturers because of the 180-day exclusivity held by the first filers under the Hatch-Waxman Act.

In March 2010, the district court denied the defendants’ motion to dismiss. The court declined to apply per se treatment as urged by the FTC, but found sufficient allegations that the settlement exceeded the exclusionary rights of the Cephalon patent. The FTC alleged facts suggesting that Cephalon knew that its patent was invalid and unenforceable when it brought its infringement claim, thus the alleged sham litigation exceeded the scope of the patent. The court found the patent scope could have been exceeded by settlement provisions prohibiting the marketing of future and different generic forms of Provigil than the one that allegedly infringed.

7. FTC v. Bristol-Myers Squibb Company

In this action, the FTC alleged that Bristol-Myers Squibb engaged in a pattern of anticompetitive activity over a decade in order to delay generic competition and maintain its monopoly over the anti-anxiety drug, BuSpar, and two anticancer drugs, Taxol and Platinol. The allegations as to the three drugs were similar, alleging that Bristol-Myers Squibb paid potential generic competitors to settle patent litigation to prevent introduction of generic competitors, filed false information with the FDA in order to list patents in the Orange Book, thereby automatically obtaining additional 30-month stays, and filed baseless patent infringement suits against potential generic competitors.

The case settled with a consent order that prohibited Bristol-Myers Squib from late listing patents in the Orange Book after ANDA applications have been filed, as well as a prohibition against listing any patent relating to products with the same active ingredient, or taking any action that would trigger an additional 30-month stay of a generic form of Taxol or BuSpar.

B. FTC Cases Under Other Exclusionary Conduct Theories

Not all FTC cases involve brand-generic settlements. In FTC v. Mylan the FTC charged Mylan Laboratories with restraining competition through exclusive licensing arrangements for the supply of the raw material necessary to produce the lorazepam and clorazepate tablets, thereby allowing Mylan to dramatically increase its prices. The FTC was joined in this action by 34 state attorneys general. The FTC filed this case in federal court under Section 13(b) of the FTC Act seeking injunctive and other equitable relief, including disgorgement of ill-gotten profits. Mylan ultimately settled the case, agreeing to pay $100 million for distribution to direct purchasers, injured consumers, and state agencies.

In FTC v. Biovail Corporation the FTC charged Biovail with illegally acquiring the exclusive license to a drug patent in order to prevent generic competition for its anti-hypertension drug Tiazac. The parties settled the matter and Biovail agreed to divest part of the exclusive rights of the acquired patent back to the original owner, and to refrain from taking any action that would trigger an additional 30-month stay. Andrx, the generic manufacturer, filed an antitrust action against Biovail, alleging that Biovail unlawfully delayed the approval of Andrx’s ANDA. In February 2002, Andrx and Biovail settled, agreeing that Biovail would give Andrx a non-exclusive license to its patents and Andrx would pay Biovail royalties on Andrx’s generic Tiazac product.

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35 Id. at * 68.
36 Id. at *82.
38 135 F.T.C. 444 (2003) (consent order)
40 134 F.T.C. 407 (2002) (consent order)