

The Complexities of Litigating Generic Drug Exclusion Claims in the Antitrust Class Action Context

BY M. SEAN ROYALL AND JOSHUA LIPTON

ONE STRIKING TREND IN ANTITRUST litigation over the last decade has been an explosion in the number of cases challenging alleged exclusion of generic drugs by branded pharmaceutical manufacturers. Quite often today, when a branded pharmaceutical manufacturer is unsuccessful in making patent, scientific, or regulatory arguments in opposition to a prospective generic entrant, the branded manufacturer is soon faced with lawsuits brought on behalf of purported classes of direct and indirect purchasers.¹

The stakes in these cases can be enormous, as plaintiffs routinely seek as compensatory damages a large portion of the branded manufacturer's revenues over a multiyear period. Damage claims often reach into the billions of dollars, even before trebling and before accounting for inevitable duplication in claimed injuries to direct and indirect purchasers. In a number of these cases, the plaintiffs have secured settlements of hundreds of millions of dollars.²

Generic drug manufacturers do not bear the massive costs of developing pioneer drugs and conducting the clinical trials necessary for a new drug application to the FDA, which helps to explain why generic drugs typically sell for highly discounted prices. When generic drugs hit the marketplace, the result in most instances is a large shift in volume from the branded drug to the less expensive generics. If generic drugs enter the market before the branded manufacturer recoups the steep costs of developing a pioneer drug, the considerable risks and costs associated with innovating and gaining FDA approval for the branded product may result, in the end, in a net loss. Because branded manufacturers often plow the profits from blockbuster drugs into research and development for new products, a loss in profitability can lead to setbacks in new drug innovation, which is the core driver of long-term success for any branded drug-maker.

Branded manufacturers thus have strong incentives to consider potential legal actions for defending their investments in franchise drug products, provided there are good-faith bases to do so. This often takes the form of patent enforcement lawsuits against prospective generic entrants or petitions to the FDA to consider scientific and regulatory matters that bear on whether a proposed generic product should be deemed bioequivalent and approved for use. Of course, not all patent enforcement suits or regulatory petitions are successful. Successful or not, the process of resolving such matters before the FDA or through litigation takes time, and final FDA approval for generic drugs can be delayed during the pendency of regulatory or court proceedings. It is this potential for delay, arguably flowing from unsuccessful legal and regulatory activities, that gives rise to follow-on antitrust complaints.

Such governmental petitioning, however, is protected from antitrust scrutiny by the *Noerr-Pennington* doctrine, even where it is specifically motivated by a desire to exclude competition. Accordingly, the types of antitrust cases addressed here typically are built around allegations designed to fall within an exception to *Noerr-Pennington* immunity—most commonly that the branded manufacturer's patent enforcement and FDA petitioning activities were a “sham” designed to delay generic entry solely through legal process, with no expectation of success on the merits. Such antitrust cases typically are filed only after the generic drugs in question have received final FDA approval and have been launched in the marketplace.³ The standard plaintiff's contention is that, absent the defendant's alleged sham conduct, FDA approval and market entry would have occurred earlier, and lower-priced generic drugs would have been available to consumers sooner than occurred in the real world. In antitrust terms, the claim is that the defendant “perpetuated its branded drug monopoly” by engaging in baseless petitioning, and that this “exclusionary conduct” is a form of monopolization, actionable under Section 2 of the Sherman Act. Although only direct purchasers have standing to seek damages under federal antitrust law, indirect purchaser claims, usually based on state antitrust or unfair competition laws, typically mimic the direct purchaser allegations.

M. Sean Royall and Joshua Lipton, both partners in the Antitrust Practice Group of Gibson, Dunn & Crutcher LLP, have represented several branded pharmaceutical manufacturers in pharma-antitrust cases. The authors wish to thank Amanda Tessar for her valuable substantive input, and Krista Hanvey and Jonathan Whalen for their research support.

Even more than in a typical antitrust class action case, antitrust suits involving generic drug exclusion claims raise complexities of proof at virtually every stage. Issues of patent law, biotechnology, and FDA practice often intersect with sophisticated issues of economics and antitrust law, presenting significant challenges for both the litigating parties and the courts. In this article, we provide an overview of some of the difficult issues that can arise in such cases, and then address a variety of practical considerations.

The Regulatory Backdrop for Branded-Generic Antitrust Litigation

Under the Food, Drug, and Cosmetic Act, the manufacturer of a new drug must secure prior regulatory approval from the FDA, and this process involves filing a New Drug Application (NDA) setting forth data concerning the safety and efficacy of the drug.⁴ In contrast to the extensive process involved in obtaining new drug approval, an applicant seeking approval of a generic drug is not required to replicate clinical trials or defend the efficacy of its product. The Hatch-Waxman Act permits a generic manufacturer to file an Abbreviated New Drug Application (ANDA), which must include data showing that the active ingredient of the generic drug is the same as that of the branded drug, that the generic drug is bioequivalent to the branded drug, and that the proposed labeling for the generic product mimics the approved labeling for the branded drug.⁵

To protect the branded manufacturer's ability to enforce its patents against proposed generic manufacturers, the Hatch-Waxman Act also provides that the FDA cannot grant final approval to a generic drug for a specified period of time if the holder of a relevant patent listed in the FDA's "Orange Book" promptly initiates a patent enforcement action against the ANDA applicant.⁶ As specified in the Act, this stay of final FDA approval extends until the earlier of (a) a district court ruling that the patent is invalid or unenforceable, or (b) thirty months from the date the branded manufacturer is notified of the ANDA.⁷ This aspect of the Hatch-Waxman Act is commonly known as the "thirty-month stay," and it typically features prominently in any antitrust suit challenging branded drug company efforts to block generics through failed patent enforcement. Although patent cases certainly can be resolved in less than thirty months, the reality is that many patent suits are not. Accordingly, in many cases, the prompt initiation of ANDA-related patent litigation by a branded-drug manufacturer results in a full thirty-month stay of final generic drug approval.

The plaintiffs in follow-on antitrust cases routinely argue that the branded manufacturer filed its patent enforcement action(s) without any hope of prevailing and solely to trigger the automatic thirty-month stay. Quite often, at some point during the pendency of the thirty-month stay, the FDA will grant conditional, or "tentative," approval to an ANDA, because final approval cannot be granted until the expiration of the stay. In a follow-on antitrust suit, the plaintiffs nor-

mally allege that the patent suit was a sham and caused actionable delay, measured by the time period between tentative FDA approval and final approval.

Where a branded drug manufacturer files a citizen petition with the FDA making scientific or regulatory arguments against generic drug approval, this can also lead to postponements in the final approval of a generic drug, although a citizen petition does not automatically stay FDA approval.⁸ The common antitrust plaintiff's argument is that the citizen petition employed objectively baseless arguments that were designed solely to complicate and delay FDA approval, without any expectation of the FDA finding merit in the positions presented by the petition. In addressing such claims, courts have shown some reluctance to delve into the underlying scientific details, in part because of judicial deference to the FDA's administrative expertise and in part because of the confidentiality and opacity of the agency's decision-making

The plaintiffs in follow-on antitrust cases routinely argue that the branded manufacturer filed its patent enforcement action(s) without any hope of prevailing and solely to trigger the automatic thirty-month stay.

process. In addition, because a citizen petition can be more akin to legislative or executive lobbying than to an adjudicatory process, such petitions are arguably entitled to even broader *Noerr-Pennington* doctrine immunity than applies to court proceedings.⁹

Although follow-on antitrust suits do not in all cases involve claims of both sham litigation and sham regulatory filings, many cases do include both elements, and we therefore consider this as the paradigm for the types of litigation addressed below.¹⁰

Revisiting Scientific and Regulatory Details in a *Noerr-Pennington* Context

Whenever an antitrust plaintiff seeks to establish liability based on allegations of sham litigation or sham regulatory filings, the *Noerr-Pennington* doctrine inevitably comes into play.¹¹ Under the sham exception to *Noerr-Pennington* immunity, petitioning conduct in the form of lawsuits and regulatory filings can be the subject of antitrust liability, but only where the plaintiff can show that the challenged petitioning was both objectively baseless and pursued with a subjective intent to harm the plaintiff through the legal process itself, as opposed to a successful outcome on the merits.¹² As applied in the types of follow-on antitrust suits addressed here, the objective prong of this test asks not whether the branded drug manufacturer should have prevailed in the underlying patent suit or regulatory petition, but rather whether the defen-

defendant's actions lacked any objective basis whatsoever.¹³ While a defendant in a follow-on antitrust case need not relitigate the full merits of the patent and regulatory issues in question,¹⁴ analysis of such sham claims often draws the litigants into scientific, patent, and regulatory complexities.

In some cases, the actions or rulings by the underlying court or agency may be dispositive of the sham issue. For example, a ruling in an underlying patent case denying a patent defendant's motion for attorney's fees or Rule 11 sanctions can effectively foreclose a subsequent claim that the patent enforcement action was so objectively baseless as to constitute a sham.¹⁵ If the branded manufacturer's patent claims survived a motion for summary judgment in the underlying case, this too can demonstrate that the patent claims, while ultimately unsuccessful, were not objectively baseless.¹⁶ On the other hand, some courts have held that there can be circumstances in which surviving summary judgment in the underlying patent case does not conclusively establish that there was an objective basis for the lawsuit.¹⁷ By the same token, even where the generic defendant achieves an early summary judgment victory in the underlying patent litigation against a branded rival, this does not mean that the branded firm's patent suit was objectively baseless.¹⁸

Assessing Causation

In any follow-on antitrust suit premised on allegations of sham petitioning, proving that the challenged petition in fact was a sham—while exceedingly difficult in most cases—is just the start. As the Supreme Court has stated, even a plaintiff who can satisfy *Noerr's* sham exception “must still prove a substantive antitrust violation.”¹⁹ One of the more difficult elements of proof in this context can be causation.

A key causation question is whether, and if so when, the FDA would have granted final approval to the generic manufacturer's ANDA absent the allegedly sham petitioning. As noted above, plaintiffs routinely argue that when the FDA grants tentative approval to an ANDA during the pendency of an ongoing patent litigation, this signals that the agency's work is done and that final approval is being withheld solely as a consequence of the Hatch-Waxman stay. Courts have accepted this interpretation of events in instances in which final FDA approval was later granted immediately upon the expiration of the thirty-month stay.²⁰

In other cases, however, the inquiry can be more complex. For example, in one recent case in which a generic manufacturer challenged alleged exclusionary conduct by a branded rival, the district court dismissed the generic's claims because it had yet to obtain FDA approval even though the Hatch-Waxman stay had long since expired. The court explained that, in the circumstances, “lack of FDA approval may be a supervening cause of [the generic manufacturer's] alleged market exclusion, thereby undermining the substantive antitrust elements of causation and antitrust injury.”²¹

It can be even more difficult to demonstrate causation where the follow-on antitrust plaintiffs claim that the defen-



Photo: SuperStock

In any follow-on antitrust suit premised on allegations of sham petitioning, proving that the challenged petition in fact was a sham—while exceedingly difficult in most cases—is just the start.

dants delayed FDA approval by filing a sham citizen petition to the FDA. In such cases, the antitrust plaintiffs must demonstrate not only that some aspect of the petition was objectively baseless, but also that the baseless aspect of the petition was the cause of any delay in FDA approval. Disaggregating antitrust injury can be difficult in any case,²² but even more so where the conduct was the subject of a multifaceted, confidential regulatory review process. Where some aspects of the petition were allegedly groundless and others were not, it can be a challenge to ascribe any delay to the allegedly “sham” component of a broader petition. Similarly, when there is evidence that other parties advocated against generic approval before the FDA or that the FDA independently considered issues beyond the scope of the challenged citizen petition, a follow-on plaintiff may have difficulty establishing that the defendant's FDA petitioning was the cause of delayed drug approval.²³ Such difficulties are amplified by the courts' reluctance to delve into the decision-making processes of expert agencies.²⁴

The causation inquiry can be complicated still further when the follow-on antitrust plaintiffs, as is often the case, claim that the branded manufacturer's underlying patent enforcement actions and FDA regulatory petitioning were both shams and both contributed to delayed FDA approval for generic counterparts to the branded drug. For instance,

one recent case dealt with a fact pattern in which the FDA granted *tentative* approval of an ANDA during the thirty-month Hatch-Waxman stay but then refrained from granting *final* approval until the branded firm's citizen petition had been fully resolved, more than a year after the Hatch-Waxman stay was lifted.²⁵ This case was ultimately decided on other grounds,²⁶ but these facts raise the potential for complex causation scenarios. If, for instance, the citizen petition was deemed not to be a sham, a court might conclude that any delay in FDA approval arguably attributable to the separate patent litigation was not actionable, to the extent that agency consideration of the lawful regulatory petition was an independent explanation for the timing of the FDA's final approval. Although this point goes more to the *Noerr-Pennington* analysis than to causation, it bears noting that lengthy consideration of a citizen petition by the FDA tends to underscore the substantive merits of the petition, making it far more difficult to characterize the petition as a sham.

A follow-on antitrust plaintiff must demonstrate not only that the generic manufacturer would have received FDA approval earlier absent the defendant's challenged conduct, but also that the allegedly excluded generic manufacturer was "ready to be a competitor."²⁷ Particularly where the products involved are complex and difficult to manufacture in commercial quantities, this element can present yet another significant evidentiary hurdle. For example, in one recent case in which the antitrust plaintiff claimed that a branded-generic patent settlement delayed entry and unreasonably harmed competition, the defendants prevailed at trial on the issue of causation because the plaintiff was unable to establish that the generic manufacturer was capable of manufacturing its product in commercial quantities.²⁸

Scrutinizing Monopoly Power Assertions

There is a significant gulf in pharma-antitrust cases between the approaches typically advocated by plaintiffs and defendants regarding proof of the relevant market and monopoly power. Plaintiffs frequently assert that a substantial difference between pre-entry branded drug prices and the post-entry generic prices constitutes direct proof that the branded manufacturer possessed monopoly power obviating the need either to define relevant markets or to assess the existence of market power through indirect proof.²⁹ Defendants, in contrast, typically argue that a gap between branded and generic prices would exist even in the absence of market power and therefore cannot be the basis for any adverse inference. Defendants therefore argue that, as in most other antitrust cases, the existence of market power can only be assessed through the conventional exercise of defining relevant markets and assessing competitive market conditions.

For example, in *In re Remeron Direct Purchaser Antitrust Litigation*, the antitrust plaintiffs argued that "because Organon's brand name price was much greater than the subsequent generic price for mirtazapine, Organon necessarily had

monopoly power prior to generic entry."³⁰ The court, however, rejected this argument, explaining that the plaintiffs had "provide[d] no evidence of excessive price-cost margins or restricted output but merely rel[ied] on the fact that later generic manufacturers could enter the market more cheaply than Remeron's price in order to establish monopoly power."³¹ The court emphasized that the branded manufacturer bore "initial fixed costs (including research, development, and the cost of being the first to gain FDA drug approval)" that were "significantly higher than those of generic manufacturers."³² Accordingly, the court concluded that, to establish market power, "there must be more proof than just a showing that a brand name drug costs more than a generic equivalent."³³

Once the court moves to a traditional analysis of market definition—involving an assessment of the interchangeability of use and cross-elasticity of demand among potential substitute products³⁴—pharma-antitrust cases present additional challenges. In contrast to most industries and products, where competitive efforts are focused on direct purchasers and/or end users of the product, competition in pharmaceutical markets often is focused on other actors in the chain of distribution.

Plaintiffs in pharma-antitrust cases frequently argue that the relevant market should be limited to a branded product and its generic equivalents because those are the only products that are interchangeable once a physician has prescribed a particular drug.³⁵ Yet this approach often overlooks substantial competition among different drugs at multiple levels of distribution before a prescription is written. For example, drug manufacturers frequently engage in intense competition to be listed on formularies of preferred or recommended drugs that are compiled by managed care organizations (MCOs) or pharmacy benefits managers (PBMs).³⁶ As part of this competition, manufacturers often pay substantial discounts and rebates to MCOs and PBMs to secure favorable placement on formularies.³⁷ Accordingly, if the relevant market analysis were focused solely on the level of product interchangeability *after* a prescription is written, a substantial amount of competition—including price competition through rebates and discounts—would be omitted from the analysis. At a minimum, the possibility of competition, discounts, and pass-through rebates at different levels of competition should be taken account in any relevant market analysis.

Out-of-Pocket Losses, Damages, and Classwide Proof of Impact

Assessing whether, and to what extent, antitrust plaintiffs and absent class members suffered out-of-pocket losses in pharma-antitrust cases also is a complex exercise. This exercise frequently involves far more than simply multiplying the price differential between branded and generic drugs by the volume purchased in the pre-entry period. When one models the but-for world that actually might have prevailed

in the absence of the alleged exclusionary conduct, a range of complexities is revealed.

For example, wholesalers that purchase directly from branded manufacturers are frequently bypassed, in whole or in part, by generic manufacturers, which often sell directly to pharmacies and other downstream customers.³⁸ For this reason, a drug wholesaler's purchases of the branded drug in the actual world may not translate one-to-one to the volume of the generic drug it would have purchased in the but-for world, because some or all of those sales would have been made directly by generic manufacturers to downstream purchasers. Accordingly, to calculate damages to a drug wholesaler, it is necessary to model not only the price it would have paid in the but-for world, but also the volume of branded and generic products it would have purchased, including any drop in volumes created by generic bypass.³⁹

At the indirect purchaser level, there are additional issues raised by extraordinarily complex chains of distribution and payment, which may include not only several stages of intermediaries, but also factors affecting price, such as bypass rebates and pharmacy benefits managers who may or may not pass through the rebates or discounts they obtain from suppliers. Even when the branded product is priced substantially higher than its generic equivalent at the supplier level, this complex chain of distribution and payment can create situations in which one end user pays a higher price for the generic than another similarly situated end user paid for the branded product. In other cases, some end users may be permitted by their insurance plans to pay the same flat co-pay for both branded and generic drugs. In these circumstances, it can be difficult for the plaintiffs to demonstrate through classwide proof that all purchasers of the branded product in the pre-entry period would have been better off in a but-for world in which generic drugs were available, as is required for class certification.⁴⁰

Practical Considerations

In light of (a) the business needs of branded pharmaceutical manufacturers, which provide strong incentives to seek all lawful means to protect patent rights and marketplace positioning, (b) the uncertain outcomes of patent enforcement lawsuits and efforts to petition the FDA, and (c) a legal environment that provides a strong incentive for plaintiffs' counsel to pursue class actions whenever a branded manufacturer fails in such efforts, branded pharmaceutical manufacturers should prepare as early as possible for the possibility that they will become defendants in cases of this nature. Although no two cases are the same, frequently recurring issues provide some guideposts to help branded pharmaceutical manufacturers prepare for a potential lawsuit of this nature.

First, before filing a patent enforcement lawsuit against a generic ANDA filer, a branded pharmaceutical manufacturer should consider obtaining an opinion letter from outside patent counsel evaluating the patent and potential non-infringement and invalidity arguments. The plaintiffs in a fol-

low-on sham litigation case must demonstrate that the underlying patent lawsuit was objectively baseless and that it was subjectively brought not to obtain relief on the merits, but to use the judicial process as a weapon without regard to success on the merits. Accordingly, an opinion letter from outside patent counsel can be useful for the defense of a follow-on antitrust suit in some circumstances. Of course, decisions about whether to obtain such a pre-suit opinion and whether later to produce such privileged communications must be made with great care, considering the particular circumstances of the case and the potential for a broader waiver of the attorney-client privilege.

Second, while litigating an ANDA-related patent enforcement suit, it is important to recognize that the suit could become the subject of a follow-on antitrust action. Patent counsel should proceed with an awareness that strategic decisions in the underlying patent lawsuit—such as a decision to present (or not present) a particular witness or argument—may later be construed by antitrust plaintiffs to support a claim that the lawsuit was a sham. Similarly, patent counsel should be mindful of the potential for their internal work product and privileged client communications to be turned over to the plaintiffs' counsel and/or the court in a follow-on antitrust case, either as a result of a waiver of privilege (producing an opinion letter from outside counsel, as discussed above, may result in a limited or broader waiver of privilege depending on the circumstances) or as the consequence of a plaintiff's motion to pierce the privilege (such motions, while rarely granted, are commonly pursued by antitrust plaintiffs alleging sham petitioning). The very possibility of privileged communications becoming key evidence in a follow-on antitrust suit should serve as a sobering reminder to patent and regulatory counsel to avoid placing in writing anything that could later be misinterpreted to the detriment of their client.

Third, patent litigation counsel should be aware that non-privileged documents created in the course of litigation may be discoverable in a follow-on antitrust case, even if they are not discoverable in the underlying patent case. Specifically, the parties in a patent case frequently agree that communications with testifying experts, draft expert reports, and other such documents are not discoverable in the patent case. Such materials, however, may become discoverable in a follow-on antitrust case. In this regard, patent counsel should be vigilant to avoid any communications with expert witnesses that could be misconstrued in a manner that might undermine the expert's views and opinions.

Fourth, patent litigation counsel should be cognizant of litigating the underlying patent suit in a manner that cannot later be characterized as an attempt to delay the suit's resolution for the purpose of extending the length of the Hatch-Waxman stay. For example, patent counsel should serve discovery promptly and, where possible, avoid any unilateral motions for extensions of the case schedule. Antitrust plaintiffs may argue, after the fact, that conduct they characterize

as “delay tactics” reinforces their argument that the focus of the litigation was on something other than legitimate enforcement of patent rights and adjudication on the merits. Similar considerations should lead regulatory counsel to proceed efficiently in any dealings with FDA staff in the context of agency review of a citizen petition.

Fifth, a branded pharmaceutical manufacturer should continue to evaluate the merits of a patent lawsuit as the case progresses. Antitrust plaintiffs sometimes argue that a lawsuit that is continued in bad faith becomes actionable as a sham, even if there was an objective basis for the claims at the time the lawsuit was initiated. In addition, courts have recognized that it can be difficult to evaluate the merits of a patent lawsuit within the forty-five days within which such a lawsuit must be filed to trigger the thirty-month Hatch-Waxman stay. Courts have thus acknowledged that a willingness to discontinue litigation when it becomes clear that a lawsuit has no reasonable prospect of success can weigh against a claim of sham litigation.⁴¹

Sixth, a branded manufacturer should preserve a record of its evidence supporting (a) its objective basis for any arguments made to the FDA, and (b) any factual assertions made

to the FDA in connection with a citizen petition. In addition, the branded manufacturer should consider carefully the timing of the citizen petition, as antitrust plaintiffs routinely attempt to use the timing of citizen petitions, including any perceived delay in its filing relative to the filing of the ANDA, to raise questions about the underlying merits of the filing and the motivations of the filer.

Finally, even if no ANDAs have been filed and no litigation or FDA petitioning is on the horizon, a branded manufacturer should review its customer contracts and marketing practices with counsel familiar with the nuances of pharmaceutical class action cases. For example, claims on behalf of direct purchaser classes are frequently pursued by downstream purchasers by virtue of an assignment from a direct purchaser. In such situations, anti-assignment clauses in the sales agreements with direct purchasers have been held to be a basis for dismissal of the claims brought by an assignee.⁴² In addition, a branded manufacturer should consider whether to adopt arbitration provisions in its sales contracts. Such relatively simple changes to distribution contracts can have a significant impact on high-stakes antitrust litigation. ■

¹ See e.g., *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677 (2d Cir. 2009) (challenging Orange Book listing, prosecution of patent infringement action, and filing of FDA citizen petition); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (challenging settlement agreements between branded and generic manufacturers); *In re Neurontin Antitrust Litig.*, Nos. 02-1390, 02-1830, 02-2731, 02-5583, 2009 U.S. Dist. LEXIS 77475 (D.N.J. Aug. 28, 2009) (challenging Orange Book listings and prosecution of patent infringement actions); *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2009 U.S. Dist. LEXIS 21286 (E.D. Pa. Mar. 16, 2009) (challenging prosecution of patent infringement actions and filing of FDA citizen petition); *In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 U.S. Dist. LEXIS 11756 (D.N.J. Feb. 4, 2009) (challenging settlement agreement between branded and generic manufacturers); *Meijer, Inc. v. Barr Pharms. Inc.*, 572 F. Supp. 2d 38 (D.D.C. 2008) (challenging settlement agreements between branded and generic manufacturers); *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-7343, 2008 U.S. Dist. LEXIS 81328 (S.D.N.Y. Oct. 14, 2008) (challenging filing of FDA citizen petition); *In re Wellbutrin SR Direct Purchaser Antitrust Litig.*, No. 04-5525, 2008 U.S. Dist. LEXIS 36719 (E.D. Pa. May 2, 2008) (challenging prosecution of patent infringement actions); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) (challenging settlement agreements between branded and generic manufacturers); *In re Terazosin Hydrochloride Antitrust Litig.*, No. 99-1317, 2005 U.S. Dist. LEXIS 108 (S.D. Fla. Jan. 5, 2005) (challenging settlement agreement between branded and generic manufacturers); *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349 (D. Mass. 2004) (challenging prosecution of patent infringement actions); and *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522 (D.N.J. 2004) (challenging Orange Book listing and prosecution of patent infringement actions).

² For example, settlements with classes of direct purchasers and indirect purchasers in *In re Buspirone Antitrust Litigation*, MDL No. 1413 (S.D.N.Y.), and *In re Relafen Antitrust Litigation*, No. 01-122349 (D. Mass.), totaled \$535 million and \$250 million, respectively.

³ In light of the uncertainty of the FDA drug approval process, an antitrust lawsuit is subject to dismissal for lack of ripeness if it is filed before a generic product receives final FDA approval. This is particularly the case where the antitrust plaintiff challenges an FDA citizen petition as a sham. See, e.g.,

Aventis Pharma S.A. v. Amphastar Pharms, Inc., No. 03-00887, slip op. at 22 (C.D. Cal. Feb. 17, 2009) (order granting motion to dismiss).

⁴ 21 U.S.C. § 355(b)(1).

⁵ 21 U.S.C. § 355(j)(2)(A)(ii).

⁶ The ANDA must include a certification regarding the applicant's position with respect to any patents for the pioneer drug that are listed in the Orange Book. A certification stating that the patents for the pioneer drug are invalid or will not be infringed by the proposed generic manufacturer's product is known as a “Paragraph IV Certification.” Upon receipt of a Paragraph IV Certification, a patent holder must file a patent infringement lawsuit within forty-five days of receipt of the certification to trigger the automatic thirty-month stay. See 21 U.S.C. § 355(j)(5)(B)(iii). If a patent holder misses the forty-five-day deadline, it cannot bring an infringement suit immediately upon filing of the ANDA, but must wait until the generic drug is sold commercially.

⁷ 21 U.S.C. § 355(j)(5)(B)(iii).

⁸ Any person may try to affect FDA action by filing a citizen petition, which is expressly permitted by FDA regulations. 21 C.F.R. § 10.30(a). While the filing of a citizen petition does not automatically stay FDA approval of an ANDA, a delay caused by FDA review of the issues raised in a citizen petition can extend beyond the Hatch-Waxman thirty-month stay.

⁹ See, e.g., *Aventis Pharma S.A. v. Amphastar Pharms, Inc.*, Feb. 17, 2009 order, *supra* note 3, at 21 (“[T]o the extent a citizen petition urges the FDA to exercise administrative discretion, the process more closely resembles traditional or executive lobbying. In this context, courts must exercise great caution, if not abstain from interfering with the process entirely.”).

¹⁰ Cases of this nature also sometimes attack the listing of patents in the Orange Book or settlements of branded-generic patent litigation. See, e.g., *supra* note 1.

¹¹ See *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961). The Supreme Court has explained that objectively legitimate petitioning conduct, even when undertaken for the purpose of destroying competition, “is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act.” *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965).

- ¹² Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60–61 (1993) (*PRE*).
- ¹³ The mere fact that an antitrust defendant lost a patent infringement suit does not indicate that the underlying suit was objectively baseless. See, e.g., *White v. Lee*, 227 F.3d 1214, 1232 (9th Cir. 2000). As the Supreme Court has explained, “When the antitrust defendant has lost the underlying litigation, a court must resist the understandable temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation.” *PRE*, 508 U.S. at 60 n.5 (internal quotation marks omitted). Of course, if the antitrust defendant prevailed in the underlying case, that outcome is dispositive of a follow-on claim of sham petitioning because “[a] winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.” *Id.*
- ¹⁴ Moreover, in such cases the plaintiffs typically take advantage of hindsight reasoning. Once a lawsuit has been lost, it is often easy to point to specific pieces of the puzzle that led to that result. But the plaintiffs’ burden under the sham exception is to demonstrate that the purportedly sham lawsuit was objectively baseless at the time it was filed—not that a litigant with full hindsight into the way a complex litigation matter unfolded would have known the lawsuit would turn out to be unsuccessful. See, e.g., *Hoffmann-La Roche, Inc. v. Genpharm, Inc.*, 50 F. Supp. 2d 367, 380 (D.N.J. 1999) (“[T]he question is whether a reasonable litigant could have realistically expected success on the merits at the time the suit was filed.”).
- ¹⁵ See, e.g., *Q-Pharma, Inc. v. Andrew Jergens Corp.*, No. 01-1312, 2002 U.S. Dist. LEXIS 27222, at *24–*25 (W.D. Wash. Nov. 18, 2002) (holding that because the court had previously denied a motion for Rule 11 sanctions, Q-Pharma did not act unreasonably in bringing the claims); *Johnson v. Con-Vey/Keystone, Inc.*, 856 F. Supp. 1443, 1448 (D. Or. 1994) (an earlier finding that the patent infringement lawsuit was not frivolous in connection with a motion for attorneys’ fees showed that the suit was not objectively baseless).
- ¹⁶ See, e.g., *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221 (S.D.N.Y. 2002).
- ¹⁷ See, e.g., *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 362–63 (D. Mass. 2004) (holding that issues relevant to determining motion for summary judgment on claim of sham litigation were not before the court on the summary judgment motion in the underlying case); *Calloway v. Marvel Entm’t Group*, 854 F.2d 1452, 1472 (2d Cir. 1988) (“It is . . . entirely possible that a baseless factual claim will survive a motion for summary judgment, particularly where an attorney prepares an affidavit for a client stating a material fact for which there was no basis.”).
- ¹⁸ See, e.g., *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 461–62 (D.N.J. 2003) (dismissing antitrust counterclaims because there was an objective basis for the patent suit, even though the court granted summary judgment for the generic manufacturers on the underlying patent infringement claims).
- ¹⁹ *PRE*, 508 U.S. at 61.
- ²⁰ See, e.g., *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 687, 697 (E.D. Mich. 2000).
- ²¹ *Aventis Pharma S.A. v. Amphastar Pharms, Inc.*, No. 03-00887, slip op. at 4 (C.D. Cal. May 15, 2009) (order dismissing third amended counterclaim).
- ²² See, e.g., M. Sean Royall, *Disaggregation of Antitrust Damages*, 65 ANTITRUST L.J. 311 (1997).
- ²³ See, e.g., *Aventis Pharma S.A. v. Amphastar Pharms, Inc.*, May 15, 2009 Order, *supra* note 21.
- ²⁴ See, e.g., *Mt. Hood Stages v. Greyhound Corp.*, 616 F.2d 394, 398–400 (9th Cir. 1980).
- ²⁵ See *In re Ditropan XL Antitrust Litig.*, MDL No. 1761 (N.D. Cal. 2007).
- ²⁶ The court in that case did not address the causation issue on the merits. The direct purchaser claims were dismissed because the plaintiff was not actually a direct purchaser and had not secured a valid assignment from a true direct purchaser. And the indirect purchaser claims were voluntarily dismissed.
- ²⁷ *Bourns, Inc. v. Raychem Corp.*, 331 F.3d 704, 711 (9th Cir. 2003).
- ²⁸ See *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1041 (9th Cir. 2009).
- ²⁹ See, e.g., *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (“Where evidence indicates that a firm has in fact profitably [raised prices substantially above the competitive level], the existence of monopoly power is clear.”).
- ³⁰ 367 F. Supp. 2d 675, 681 (D.N.J. 2005).
- ³¹ *Id.* at 682; see also *id.* at 681 n.10 (citing PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW, AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* 516 (2d ed. 2002) (“No matter how accurately measured, of course, a substantial excess of price over marginal cost does not necessarily bring excess returns on investment. A firm generates excess profit only if price exceeds its average total cost, including its cost of capital.”); William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 HARV. L. REV. 937, 939 (1981) (“When the deviation of price from marginal cost . . . simply reflects certain fixed costs, there is no occasion for antitrust concern.”)).
- ³² *Remeron*, 367 F. Supp. 2d at 682.
- ³³ *Id.* at 683.
- ³⁴ See, e.g., *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (“The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.”).
- ³⁵ See, e.g., *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000) (“As to ‘reasonable interchangeability,’ Plaintiffs allege that, due to FDA regulations, once a physician prescribes Cardizem CD, a consumer patient may only purchase Cardizem CD or its FDA-approved AB-rated bioequivalent. . . . Accordingly, no heart patient who entered a U.S. pharmacy with a physician’s prescription for Cardizem CD could obtain any drug other than Cardizem CD prior to [generic entry].”).
- ³⁶ See, e.g., *Merck-Medco Managed Care, Inc. v. Rite Aid Corp.*, 22 F. Supp. 2d 447, 452 (D. Md. 1998) (“PBMs can . . . lower costs through the use of ‘formularies,’ or lists of preferred or recommended drugs. Drug manufacturers competing for market share have a strong interest in seeing their products included in these formularies. The manufacturers may offer significant discounts for the privilege of being listed.”).
- ³⁷ *Id.*; see also, e.g., *J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 485 F.3d 880, 884 (6th Cir. 2007).
- ³⁸ See, e.g., *Valley Drug Co. v. Geneva Pharms., Inc.*, 350 F.3d 1181, 1191 (11th Cir. 2003).
- ³⁹ The complexity of this modeling is further increased when the generic and branded products are not only priced differently, but have different values. For example, not all branded and generic drugs have identical formulations and/or release mechanisms, which can result in different pharmacokinetic properties, even among AB-rated bioequivalent drugs. If the generic product carries a lower price but also has a lower value (such as where there is consumer concern with side effects with the generic product), assessing the existence or extent of injury from an inability to purchase the generic product must take this factor into account, along with any differences in prices and volumes.
- ⁴⁰ See, e.g., *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 332 (E.D. Mich. 2001) (excluding from the proposed class end users with third-party health care benefits that allow them to pay the same fixed price for either brand-name or generic prescription drugs).
- ⁴¹ See, e.g., *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009) (“There is insufficient evidence in this record to allow a jury to conclude that Abbott’s seventeen suits constituted ‘sham’ litigation . . . Abbott filed suit quickly in order to preserve its rights under Hatch-Waxman, but it did not persist in litigation when it became obvious that the suits were baseless.”).
- ⁴² See *In re Ditropan XL Antitrust Litig.*, No. 06-01761, MDL No. 1761 (N.D. Cal. Oct. 11, 2007) (order granting motion to dismiss direct purchaser’s second amended complaint).