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Editor's Report

In this winter edition of the Chronicle, we are pleased to bring four articles covering a range of antitrust and consumer protection-related topics in the health care and pharmaceuticals industries.

Our lead article is a recent interview of FTC Commissioner Julie Brill conducted by editors of the Chronicle. The interview covers a broad range of issues, including recent FTC enforcement actions and Commissioner Brill's priorities in antitrust and consumer protection as they relate to the health care and pharmaceuticals industries.

In our second article, David Argue and John Gale of Economists Incorporated put under the microscope the predatory pricing analysis used in the DOJ's recent challenge to United Regional Hospital over alleged exclusionary contracts with third-party payors. The authors conclude that the Division's predation analysis in United Regional was insufficient to support a finding of antitrust injury.

In our third article, Jay Levine of Bradley Arant and Luciano Racco of Winston & Strawn analyze the FTC's recent decision in the North Carolina Board of Dental Examiners and issues relating to the state action doctrine.

In our fourth article, Seth Silber and Jonathan Lutinski of Wilson Sonsini and Rachel Taylon of Kutak Rock analyze antitrust issues that may arise from a pharmaceutical company's use of the FDA citizens petition process as a mechanism for delaying or preventing generic drug entry.

We are always interested in hearing from our committee members. If there is a topic that you would like to see covered in an article or a committee program, please contact Seth Silber (ssilber@wsgr.com) or Christi Braun (cjbraun@mintz.com). If you are interested in writing an article for the Chronicle, please contact Jeff White (jeff.white@weil.com), Gus Chiarello (gchiarello@ftc.gov), or Leigh Oliver (leigh.oliver@hoganlovells.com).

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Washington, D.C.

What's Inside

An Interview with FTC Commissioner Julie Brill

U.S. Federal Trade Commission

Julie Brill was sworn in as a Commissioner of the Federal Trade Commission in April 2010. Prior to becoming Commissioner, she had a distinguished career in public service, most recently serving as the Senior Deputy Attorney General and Chief of Consumer Protection and Antitrust for the North Carolina Department of Justice from February 2009 to April 2010. Before that, Commissioner Brill served as an Assistant Attorney General for Consumer Protection and Antitrust for the State of Vermont for more than 20 years. She also has lectured on consumer protection and antitrust issues at Columbia University's School of Law. Commissioner Brill also is an active member of the ABA. Throughout her career Commissioner Brill has published numerous articles, testified before Congress, and served on national expert panels focused on consumer protection and antitrust issues. The interview, set forth below, covers various current events and antitrust and consumer protection issues in the health care and pharmaceuticals sectors. The interview was conducted last fall by editors of the Antitrust Health Care Chronicle.

The Interview

CHRONICLE: You've had a long career in the areas of consumer protection and antitrust enforcement, having served 20 years as Assistant Attorney General for Consumer Protection and Antitrust for the State of Vermont, then a stint as Chief of Consumer Protection and Antitrust for the North Carolina Department of Justice. Now you are a Commissioner of the FTC. How does being an FTC Commissioner differ from your role as a state enforcer and what are some of the similarities?

BRILL: Let's first discuss some of the differences between the state AGs and the Federal Trade Commission. Then we can talk about the role of a Commissioner versus a state enforcer. State AGs generally have a very broad mandate, and also very broad jurisdiction in terms of both the types of industries and the types of issues they cover. They defend the state's interests and they are counsel to state agencies, requiring state AGs to defend a state agency that is sued, but also to counsel the agency on a day-to-day basis. Many state AGs prosecute criminal matters as well. In addition, most state AGs are involved in the regulation of charitable organizations and other non-profits, including examining the extent to which a charity or non-profit is following its mission. In contrast, the FTC has some limitations on the sectors we can address. For example: telcos, banks, and insurance are some of the sectors where we are limited by statute. Yet, while there are some limitations to our subject matter jurisdiction, geographically we cover the entire nation. Geographically, state AGs are more limited in scope.

mergers. It's no secret that this Commission takes a hard look at hospital mergers as well as mergers involving other health care facilities. Some of our recent activity over hospital mergers includes the ongoing ProMedica case, in which the FTC was granted a preliminary injunction earlier this year. That litigation is ongoing before the Commission. We also took a hard look at the Phoebe Putney merger. Unfortunately, we did not win at trial in that case and, so far we have not been successful. To our earlier discussion regarding state AGs, we worked closely with the relevant state AG offices in both these cases. Similarly, in the Universal Health Services matter involving psychiatric facilities throughout the country, we worked closely with several local officials. We settled that matter without going to trial by requiring divestitures in three local markets – Las Vegas, Delaware, and Puerto Rico.

We have not just focused on hospital mergers in the healthcare field. Last year, we issued a complaint in the LabCorp matter dealing with lab testing facilities in Southern California. In that matter we also lost, and there was much internal deliberation regarding how far the Commission should go with our appeal. I felt very strongly that we needed to appeal the district court's decision in that case. Sometimes our healthcare cases involve small geographic areas. The merger in LabCorp affected a large geographic area, encompassing southern California and millions of consumers. It's no secret that I care a lot about consumers.

I should add here that, although many of our healthcare cases start with drawing a circle on a map around a local market, I am comforted by the fact that industry and practitioners outside that local market are still watching us very closely, so that when they are counseling their clients about a particular deal in, hypothetically, Kansas or Nebraska, FTC scrutiny is an important consideration. In other words, I think the general deterrent effect that our work has on the healthcare industry throughout the nation is very significant.

CHRONICLE: I So Just to follow up, on that, we

cooperative relationship with them. In addition to Phoebe Putney and Promedica, we had the Minnesota State AG working with us closely in Ovation (or the Lundbeck case). In Androgel, we had the California State AG working with us until it got transferred. I think the level of

CHRONICLE: In 2010, the FTC reached settlements with Iovate and Nestle over food advertising claims. Many industry participants seemed to have an allergic reaction to the settlements, arguing that the FTC required too high a level of substantiation insofar as the settlements purported to require random, double-blind studies to support food claims. To what extent do these cases impact the law going forward regarding food advertising substantiation? Do you believe the reactions by industry participants were overblown? Why or why not?

BRILL: In Iovate and Nestle, in order to fence in the companies involved and set the parameters for what would happen in potential future enforcement actions involving those companies, we said that if they were to make certain types of disease or weight loss claims, then double-blind studies would be required. We didn't require random, double-blind studies for all types of future health claims that the companies were making. So, respectfully, I think some folks have overreacted to what we were requiring in those cases. As a matter of fact, the factors that we look to in analyzing how a health claim should be substantiated come from a really old case called Pfizer. It's actually nearly 40 years old.[1] The Pfizer factors are alive and well. We still use them in all of our cases. What we've said in Iovate and Nestle is that, applying the Pfizer factors, this is what we consider to be adequate substantiation for certain types of claims. To illustrate, in order to substantiate a disease-treatment claim that your product may treat cancer, scientists and experts require double-blind studies. For other types of claims, that degree of substantiation is not necessarily required. Substantiation is very fact dependent. It very much depends on the type of claims and what the scientific community would say about needing to substantiate those claims. This fits within the Pfizer factors. In Iovate and Nestle we simply sought to clarify the level of substantiation the companies were required to have if they were to make disease-treatment or other similar claims in the future. So, I believe what we have done is to help industry understand and navigate the applicable rules.

CHRONICLE: Turning to privacy, the protection of sensitive personal information has been an increasingly hot and important area. To what extent do the FTC's goals in protecting "sensitive personal information" extend into the health care industry?

BRILL: We have long been concerned about protecting sensitive personal information, including health information. We brought a case involving Eli Lilly back in 2002, which involved Lilly's failure to maintain reasonable security measures over health care information. The lack of security measures ultimately led to an email message sent by the company that revealed email addresses of subscribers to a Prozac® related newsletter. Back then, full names were often part of the email address. We were very concerned about that. And a number of states were also involved in that matter. That was a decade ago now, and our focus on protection, use, disclosure, and disposal of health data continues.

CHRONICLE: So, to what extent is the FTC concerned with behavioral advertising as it relates to the health care and pharmaceuticals industries? Should drug companies be permitted to use behavioral advertising to target consumers surfing the web? Are there other examples that may give rise to concerns?

BRILL: In the context of behavioral advertising, using health data in order to target ads would be a serious concern for us. We

[1] Pfizer Inc., 81 F.T.C. 23 (1972).

enforcement as a subset of consumer protection work, with apologies to

market, whether an ACO makes sense, and whether the ACO actually improves care. My hope is that our guidelines will aid industry in forming ACOs to the extent they make sense for the marketplace. There were clearly concerns with the initial draft ACO guidelines, to which we listened very carefully and reacted appropriately. And I think that the end product was good policy. So that's my hope for 2012, and maybe 2013 and 2014. It may take a little while for this new process to play out.

In other areas, I would like the Commission to continue our very strong program of taking appropriate enforcement actions with respect to mergers and anticompetitive practices in the entire health care arena. And I would like to see our efforts with respect to pay-for-delay continue.

Reexamining DOJ's Predation Analysis in *United Regional*

***By David A. Argue, Ph.D.*[1] *and John M. Gale, Ph.D.*[2]**
Economists Incorporated, Washington, DC

In February 2011, the U.S. Department of Justice (DOJ) published a complaint and settlement after conducting a Section 2 monopolization investigation of United Regional Hospital in Wichita Falls, Texas.[3] The 369-bed hospital was accused by DOJ of engaging in exclusionary practices with managed care plans that prevented the 41-bed, physician-owned Kell West Hospital from becoming a full-service hospital in competition with United Regional. The unusually detailed Competitive Impact Statement (CIS) issued by DOJ described various aspects of the contracts between United Regional and several small commercial payors that ostensibly harmed competition. The largest commercial payor, Blue Cross of Texas (Blue Cross) was not bound by any allegedly harmful exclusionary provisions in its contract with United Regional.

The DOJ's complaint alleged that the bundled discounts in United Regional's contracts with the non-Blue Cross plans constituted harmful predatory pricing. This conclusion relied on a novel variation of the discount attribution approach used in other managed care plan cases, *Ortho*[4] and *PeaceHealth*[5]. Ultimately, however, that variation is not compatible with DOJ's theory of competitive dynamics in the alleged United Regional market. Moreover, DOJ presented no analysis of recoupment of forgone profits or how a below-cost strategy might otherwise be profitable. These shortcomings render the predatory pricing analyses in United Regional insufficient to support the conclusion of antitrust injury.

DOJ's Theory of Competitive Harm

As articulated in the complaint and CIS, DOJ believed that United Regional harmed competition by preventing Kell West from having access to the business of the non-Blue Cross insurers.[6] United Regional allegedly denied Kell West's access to the non-Blue Cross

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[3] Complaint, U.S. and State of Texas v. United Reg. Health Care Sys., No. 07:11-CV-00030 (N.D. Tex. Feb. 25, 2011), available at http://www.justice.gov/atr/cases/f267600/267651.pdf

[4] Ortho Diagnostic Sys., Inc. v. Abbott Labs., Inc., 920 F. Supp. 455 (S.D.N.Y. 1996).

[5] Cascade Health Solutions v. PeaceHealth, 515 F.3d 883 (9th Cir. 2008).

[6] Competitive Impact Statement, U.S. and State of Texas v. United Reg. Health Care Sys., No. 7:11-CV-00030 (N.D. Tex. Feb. 25, 2011), available at http://www.justice.gov/atr/cases/f267600/267653.pdf [hereinafter "CIS"].

commercial plans by entering into contracts with those plans that excluded Kell West from their networks in exchange for increased discounts from United Regional. The discounts covered all services purchased from United Regional, not just those services that were also available at Kell West. Had these insurers included Kell West in their networks, DOJ argued, the profits Kell West would have earned from its subscribers would have enabled Kell West to expand the services it offers to include those for which United Regional is the sole community provider ("monopoly services").[7] Kell West ostensibly would have added "more beds and additional services, such as additional intensive-care capabilities, cardiology services, and obstetrics services."[8] DOJ alleged that

supplied to the contestable patients were well below its costs, so United Regional must have engaged in competitively harmful predatory pricing.[13]

Faulty Logic of DOJ's 10% Solution

A closer examination of the allegations in United Regional shows that DOJ failed to incorporate some important aspects of the competitive dynamics of its own theory. As a consequence, it reaches a mistaken conclusion about the discount attribution. The core of the alleged harm in DOJ's theory of United Regional is not that the 10% of non-Blue Cross patients could not use Kell West. Those patients are simply the mechanism by which harm is allegedly inflicted. The alleged harm is that Kell West is prevented from expanding into a full-service competitor of United Regional. By not incorporating this concept properly into its discount attribution analysis, DOJ mistakenly focused on the 10% of patients it believed to be contestable.

To better understand the implications of DOJ's theory in United Regional, it is helpful to consider a stylized example of discount attribution. The district court in Ortho used an example of bundled discounting of shampoo and conditioner to illustrate the concept of discount attribution.[14] This example was also cited by the Ninth Circuit in PeaceHealth to explain its decision about discount attribution.[15] In the Ortho example, a conditioner monopolist who also produces shampoo attempts to eliminate a shampoo rival by using below-cost bundled discounts. That example can be altered slightly without changing its substance to align it more closely to the United Regional allegations in

[13] CIS, supra note 6, at 16.

[14] Ortho,

is not an economically rational pricing strategy and therefore should be rejected as a possible explanation of United Regional's actions.

Payors' Incentives and Abilities to Affect Market Structure

An additional issue in United Regional is the implication of DOJ's assertion that if Kell West attracted just 10% of the non-Blue Cross commercial patients, it could expand into a full-service hospital. While DOJ argued that the non-Blue Cross health plans were more profitable to the hospitals than Blue Cross, 10% of non-Blue Cross patients represented only 2.5% of United Regional's entire commercial patient population.[26]

In principle, United Regional could overcome this economic incentive with a large enough

Keeping the Dentists Away – The FTC's *In re North Carolina Board of Dental Examiners* Decision

By Jay L. Levine[1]

"[r] emoves stains, accretions or deposits from the human teeth"; (2) "[t]akes or makes an impression of the human teeth, gums or jaws"; or (3) "[p]erforms or engages in any of the clinical practices included in the curricula of recognized dental schools or colleges."[5] The Board took the position that teeth whitening services fall within these provisions of the Act and thus constituted the unlicensed practice of dentistry.

Almost from the first appearance of non-dentists offering teeth whitening services, the Board began receiving complaints from dentists. Many of the complaints mentioned the low prices charged by non-dentists for teeth whitening. Only two complaints claimed that consumers had been harmed by a non-dentist's teeth whitening services.

From 2006, the Board sent at least 47 letters to non-dentist teeth whitening service providers, manufacturers of teeth whitening products, and distributors of whitening products.[6] These letters effectively ordered the non-dentists to cease and desist in providing teeth whitening services on the grounds that the non-dentists were engaging in the unauthorized practice of dentistry. Manufacturers and distributors of teeth whitening products were warned not to assist non-dentists in illegally practicing dentistry. In addition, the Board sent letters to mall operators who leased space to non-dentists warning that the non-dentists were violating North Carolina law and asking the operators not to lease space to these businesses.[7] Finally, recognizing that many of the non-dentists were operating out of salons and spas, the Board corresponded with the North Carolina Board of Cosmetic Art Examiners asking them to warn their licensees that teeth whitening constituted the practice of dentistry and that only a dentist could offer these services.[8]

Presuming that the Board's letters carried the force of law, non-dentists stopped offering teeth whitening services, manufacturers and distributors of teeth whitening products exited or did not enter the North Carolina market, mall operators cancelled existing leases and refused to lease space to non-dentists offering teeth whitening services, and the Board of Cosmetic Art Examiners posted the Dental Board's warning on its website. The FTC filed an administrative complaint against the Board on June 17, 2010, on the grounds that the Board's actions constituted an anticompetitive conspiracy in violation of Section 5 of the Federal Trade Commission Act.[9]

State Action Doctrine

The Board moved to dismiss the entire administrative case on the ground that its conduct was exempt from antitrust scrutiny by virtue of the state action doctrine. The Board further asserted the state action doctrine as an affirmative defense, and FTC staff moved to dismiss the affirmative defense. The Board also asserted that whatever anticompetitive effect was caused by its conduct, such conduct was justified because the Board was merely upholding the Dental Practices Act.

Active State Supervision is Required

In 1943, the Supreme Court held that activities of the state are exempt from antitrust liability

[5] See N.C. GEN. STAT. § 90-29(b).

[6] Comm'n Op. at 4; Initial Decision, Findings of Fact ¶¶ 208-18.

[7] Comm'n Op. at 5; Initial Decision, Findings of Fact ¶¶ 97, 288-93.

[8] Comm'n Op. at 5; Initial Decision, Findings of Fact ¶¶ 314-27.

[9] See In re N.C. Bd. of Dental Exam'rs, File No. 081-0133, Complaint (June 17, 2010), available at http://www.ftc.gov/os/adjpro/d9343/100617dentalexamcmpt.pdf

legislature. The Commission found that all three elements were missing with respect to the Board's conduct to restrict teeth whitening services provided by non-dentists. The Board argued that various North Carolina statutory provisions evidence active state supervision, including requirements that Board members submit financial disclosures, and that the Board submit an annual report and an annual audited financial report to several executive agencies. However, the Commission held that because these provisions do not require the review and approval of the "particular anticompetitive acts" at issue, they could not serve as evidence that the state actively supervised the Board's conduct. As the Commission concluded, there was no evidence that any "state actor was even aware of the Board's policy toward non-dentist teeth whitening, let alone reviewed or approved it in fulfillment of the active supervision requirement."[15]

Motive Analysis – Legal Framework

After noting that the FTC did not contend that the Board's conduct was unreasonable per se, the ALJ proceeded to cite Realcomp II Ltd. v. FTC[16] for the proposition that no bright line separates a full-blown rule of reason analysis, as opposed to a quick-look analysis, and that the inquiry should be customized to the facts of the case.[17] Nevertheless, the ALJ proceeded to engage in a full rule of reason analysis, concluding that the Board possessed market power, the Board's conduct had actual competitive effects, and then rejected the Board's pro-competitive justifications.[18]

Perhaps less willing to jettison the full-blown versus quick-look rule of reason dichotomy, the Commission found "liability under an abbreviated, or quick look, approach as well as under a full rule of reason analysis."[19] Specifically, the Commission conducted its analysis "under the three modes of analysis endorsed in Indiana Federation of Dentists"[20] i.e. (1) whether the conduct is "inherently suspect," (2) indirect evidence that concerted action is anticompetitive, and (3) direct evidence of anticompetitive conduct. It seems reasonable to conclude that both the ALJ and Commission were concerned with being reversed for carrying out an abbreviated analysis and therefore decided to cover all of their analytical bases.

Concerted Action

The second notable issue the Commission had to decide, after the state action immunity question, was whether the Board was capable of conspiring or whether it was a single entity. Relying on the Supreme Court's recent American Needle, Inc. v. NFL[21] decision along with the FTC's decision in In re Massachusetts Board of Optometry,[22] both the ALJ and the Commission determined that Board members were independent economic actors, who were actual or potential competitors of each other, and were guided by their own economic self-interest.[23] Thus they were capable of conspiring to restrain trade in the relevant market. The Massachusetts Board case, where the Commission held that members of a state

[15] Id. at 16.

[16] 635 F.3d 815 (6th Cir. 2011).

[17] Initial Decision, supra note 3, at 82-84.

[18] Id. at 84-110.

[19] Comm'n Op., supra note 3, at 2.

[20] Id. at 13.

[21] 130 S. Ct. 2201 (2010).

[22] 110 F.T.C. 549 (1988).

[23] Comm'n Op., supra note 3, at 13-18; Initial Decision, supra note 3, at 71-81.

conduct that the Board defined as practicing dentistry.

Anticompetitive Effects

Both the Commission and the ALJ found that the Board's concerted action excluded non-dentists from the relevant market and prevented entry into the market by new suppliers of teeth whitening equipment.[30] The Board's letter-writing campaign was the direct cause of many non-dentists leaving the teeth whitening market and also had the effect of limiting the sources of supply of teeth-whitening products to non-dentists as well as the supply of retail space from which non-dentists could offer their services. As a result, the ALJ found that consumers had fewer choices and the Commission pointed out that both parties' experts agreed that the effect of the Board's actions was to cause prices for teeth whitening services to rise. The Board did not dispute the finding of anticompetitive effects in its appeal to the Commission.

Procompetitive Justifications

The Board offered four pro-competitive justifications for its conduct: (1) its actions served to protect the public from a health and safety risk; (2) its actions served to promote "legal" competition for teeth whitening services;

The Commission also rejected the Board's "good faith" justification, i.e., that it did not intend to violate the antitrust laws, stating that "it was not a valid defense under the antitrust laws" and cited *Professional Engineers* and *Indiana Federation of Dentists* as well as circuit court cases in support.[37] This justification does not appear to have been presented to the ALJ.

Conclusion

The FTC's *In re North Carolina Board of Dental Examiners* decision is significant because it represents another in a growing line of cases clarifying that state agencies comprised of persons who are otherwise competitors are capable of conspiring for antitrust purposes. In addition, such state agencies must be actively supervised by the state in order to qualify for state action immunity. Professional boards and associations would be wise to take note of these trends.

[37]

Abuse of the FDA Citizen Petition
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the patent actually covers the drug product for which it is listed), once listed, the brand may sue a Paragraph IV ANDA filer for infringement, obtaining an automatic 30-month stay of final FDA approval for the generic product in the process.[7]

Generic firms have also brought antitrust challenges where brand firms introduce new patented products with minor or no substantive therapeutic improvements in the hopes of preventing substitution to lower-priced generics.[8] This is referred to in the pharmaceutical industry as a "product hopping" or "switch" strategy. Because a branded drug can only be substituted for its AB-rated generic equivalent, these changes in formulation—and the subsequent shift of the market to the new formulation—may have the effect of destroying the market for the previous formulation, thereby defeating potential generic competition.

Moreover, plaintiffs have brought antitrust challenges against branded companies in the context of last minute labeling changes, which have the effect of delaying or impeding the ability of lower-priced generics to enter the market.[9] Again, since a generic product needs to be the same as its AB-rated branded equivalent, even minor changes to labeling or the products' "use code" can have significant impact on the timing or ability of a generic firm to enter the relevant market.

Most recently, however, several antitrust challenges have been brought against branded drug companies allegedly seeking to use the FDA citizen petition process as a tactic to forestall generic entry.[10] Often filed on or near the eve of generic entry, citizen petitions can have the effect of delaying final ANDA approval while the FDA sifts through and evaluates if the petitioners' arguments have merit. While, to date, the FTC has not brought an enforcement action in this area, it has expressed concern regarding the potential for misuse of citizen petitions. According to Commissioner (now-Chairman) Jon Leibowitz, the citizen petition process is "susceptible to systemic abuse. … It is no coincidence that brand companies often file these petitions at the eleventh hour before generic entry and that the vast majority of citizen petitions are denied."[11]

[7] Federal Food, Drug, and Cosmetic Act (FDCA), §§ 505(j), 21 U.S.C. §§ 355(j).

[8] See, e.g., Abbott Labs v. Teva Pharms. USA, 432 F. Supp. 2d 408 (D. Del. 2006) (alleging that through its strategy of reformulation and relabeling, Abbott foreclosed Teva from effectively competing with its AB-rated generic version of TriCor).

[9] Novo Nordisk v. Caraco Pharm. Labs., 601 F.3d 1359 (Fed. Cir. 2010) (alleging Novo manipulated its patent use code in an effort to thwart anticipated generic entry).

[10] See LA Wholesale Drug co. v. Sanofi-Aventis, No. 07-CIV-7343, 2009 U.S. Dist. Lexis 77206 (S.D.N.Y. 2009); In re Wellbutrin XL Antitrust Litig., No. 08-2433 (E.D. Pa. 2011), 268 F.R.D. 539 (E.D. Pa. 2010), 260 F.R.D. 143 (E.D. Pa. 2009); In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677 (2d Cir. 2009); In re Flonase Antitrust Litig., (No. 08-3149 (Direct), No. 08-3301 (Indirect), No. 09-1638 (Roxane) (E.D. Pa. 2008).

[11] Jon Leibowitz, Fed. Trade Comm'n, text based on speech given to Generic Pharmaceutical Annual Policy Conference, entitled "How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission has Managed to Unite the Entire Pharmaceutical Industry," (Sept. 29, 2006), available at http://www.ftc.gov/speeches/leibowitz/060929GPHApubvers. See also J. Thomas Rosch, Fed. Trade Comm'n, Remarks before the World Generic Medicine Congress, entitled "The Antitrust/Intellectual Property Interface: Thoughts on How To Best Wade Through the Thicket in the Pharmaceutical Context," (Nov. 17, 2010), available at http://www.ftc.gov/speeches/rosch/101117roschworldspeech.pdf

Strategy to Impede or Delay Generic Entry Through the Use of the Citizen Petition Process

Congress enacted federal regulations that allow individuals to express to the FDA genuine concerns about the safety, scientific, or legal issues regarding a product any time before, or after, its market entry.[12] Under these regulations, any person or entity, including a pharmaceutical company, may file a citizen petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action. The petition must describe the precise FDA action that the petitioner requests and must include a certification that the petition "includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition."[13]

While in most circumstances citizen petitions are filed for legitimate concerns regarding the safety and effectiveness of new drug products,

will not apply to petitions submitted before September 27, 2007. To the extent that a plaintiff sued a defendant—based on a scheme to monopolize a particular market dating back several years—it is possible that petitions filed before this cut-off date may have caused delay in generic approval under the pre-FDAAA regime.

Finally, a branded firm may still be able to delay generic approval while the FDA considers whether the relevant citizen petition implicates issues of public health.[26] In the high stakes world of pharmaceuticals, even relatively short delays of a few days or a couple weeks can cost generic firms and consumers millions of dollars in lost sales and overpayment of prescription drugs, respectively. Thus, with the relatively small costs of filing a citizen petition, brands may still utilize this tactic as a strategy to extend their drugs' life cycles, particularly when coupled with other exclusionary tactics used to maintain and extend their monopolies for blockbuster drugs.

Analyzing Citizen Petition Under the Antitrust Laws

An antitrust plaintiff alleging that a branded firm is using the citizen petition process to unlawfully monopolize the market for a particular drug faces a number of challenges, including the establishment of relevant market definition, market power, and antitrust injury. One of the most significant hurdles for plaintiffs in this area, however, continues to be bypassing Noerr-Pennington immunity. The Noerr-Pennington doctrine generally immunizes efforts to petition the government from antitrust liability.[27] The doctrine is based on the premise that parties should be able to exercise their First Amendment right to petition the government without penalty. However, not all conduct is immunized under the doctrine.

While petitioning is generally protected, a party is not entitled to Noerr-Pennington immunity where the petitioning activity "ostensibly directed toward influencing governmental action [ ] is a mere sham to cover … an attempt to interfere directly with the business relationships of a competitor…." Noerr, 366 U.S. at 144. In other words, when the sole goal of petitioning is to interfere with the business of one's rival, it is not protected. To prove that the petitioning is a sham, a plaintiff must demonstrate that it is both objectively and subjectively baseless.[28]

The sham exception to Noerr-Pennington was first set forth in the Supreme Court's decision in Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49, 60 (1993). In that case, the Court explained that under the objective prong, the plaintiff must show that the petition is "objectively baseless in the sense that no reasonable [party] could

[26] See Section 505(q)(1)(B). If the FDA determines that a delay of approval of an ANDA or 505(b)(2) application is necessary to protect the public health, the FDA is required to provide to the applicant not later than 30 days after making the determination: (1) that notification that the determination has been made, (2) if applicable, any clarification or additional data that the applicant should submit to the petition docket to allow FDA to review the petition promptly, and (3) a brief summary of the specific substantive issues raised in the petition which form the basis of the determination. Id.

must fail."[29] Moreover, under the subjective prong, the Court determined that plaintiffs must show that the subjective intent of the petitioning party is to inhibit competition rather than to petition the government for redress. If the plaintiff is able to prove both prongs, the relevant petitioning activity will not be entitled to Noerr-Pennington immunity.

Recent Cases Challenging Citizen Petition Under the Antitrust Laws

In recent years, there have been several cases brought by generic firms alleging that branded firms have used the citizen petition process as a

found that Ferring's citizen petition did not rise to the level of sham petitioning.[33] Indeed, the court found that the citizen petition was "First Amendment protected activity even though delay of Barr's access to the market was foreseeable."[34]

The Second Circuit, however, reversed. The Court disagreed with the district court's apparent rationale that "plaintiffs could not plausibly show the petition to be a sham i.e., objectively and subjectively baseless."[35] In its rejection of Ferring's citizen petition, the FDA had "found that the citizen petition 'had no convincing evidence' and lacked 'any basis' for its arguments."[36] Moreover, in finding that the '398 patent was unenforceable due to inequitable conduct, the district court noted that the petition may have been a "hardball litigation tactic, motivated by a desire to keep out competition for as long as possible after the expiration of the patent." The court found these allegations to be enough for the plaintiff to plausibility demonstrate that the citizen petition was a sham. In August 2011, Plaintiffs submitted a settlement to the court in which Ferring and Aventis agreed to pay $20.25 million to the plaintiff class.

Louisiana Wholesale Drug Co. v. Sanofi-Aventis

Drug wholesaler Louisiana Wholesale filed a complaint against Aventis, alleging that Aventis unlawfully delayed generic competition to its drug Arava (leflunomide) through the filing of a sham citizen petition with the FDA. Aventis had the exclusive right to market Arava in 10mg, 20mg, and 100mg strengths until March 10, 2004. On that date, five generic manufacturers submitted ANDAs seeking permission to sell generic versions of 10mg and 20mg Arava, but not 100mg Arava.

Nearly one year later, on March 31, 2005, Aventis filed a citizen petition with the FDA. The citizen petition, filed on the eve of final generic approval for 10mg and 20mg Arava, requested that the FDA not approve any ANDA for generic leflunomide unless the ANDA (1) contained bioequivalence studies confirming that five of the generic applicants 20mg leflunomide tablets are bioequivalent to one 100 mg Arava tablet, or (2) sought approval to market the 100 mg loading dose strength of Arava. The FDA denied Aventis' citizen petition on September 13, 2005 and, on the same day, approved ANDAs for six generic manufacturers to market generic leflunomide.

In denying the citizen petition, the FDA noted that Aventis' request for relief "seem[ed] to be based on a false premise," namely that if a generic manufacturer recommended the 100 mg loading dose as part of its label it either had to produce its own 100 mg tablet, or recommend using five 20 mg tablets. Aventis "seem[ed] to ignore a third possibility" that a generic leflunomide product could simply recommend a 100 mg loading dose in the label that it did not itself manufacture. The FDA noted that it was "not uncommon" for makers of brand drugs to reference in their labels drugs made by other manufacturers. Moreover, there was nothing in the FDCA or the regulations that requires a generic applicant to seek approval for all strengths of a particular drug.

Louisiana Wholesale alleged that, as a result of Aventis' citizen petition, which was both objectively and subjectively baseless, generic

[33] PRE, supra note 28; In re DDAVP Direct Purchaser Antitrust Litig., No. 05-cv-2237, slip op. at 15 (S.D.N.Y. Nov. 2, 2006).

[34] Id.

[35] In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009).

[36] Id.

reverse the FDA's denial of its citizen petition and to enjoin Roxane Laboratories sale of generic Flonase. The court originally granted the TRO, but, on March 6, 2006, it denied GSK's motion for a preliminary injunction.

GSK moved for summary judgment in all three suits claiming that its conduct of filing citizen petitions was immune from antitrust liability under the Noerr-Pennington doctrine. On June 2, 2011, the court denied GSK's motion for summary judgment.[43]

GSK conceded on summary judgment that plaintiffs had provided enough evidence to

and container shelf life.[50] The plaintiffs submitted evidence that plume geometry is a relevant factor for ANDA applicants as well as pointed to the FDA's letter stating the same.[51] The plaintiffs also argued that GSK's proposed alternative test for shelf life was impossible and directed the court to the FDA's letter stating that its method for testing shelf life was sufficient.[52] Therefore, the court found that genuine issues of fact remained.

In Request 5, GSK requested the FDA reconsider its endorsement of the geometric mean ratio method. Here the court responded that genuine issues remained because GSK's criticisms were irrelevant to Flonase because the request was relevant for solution-based nasal sprays and Flonase is a suspension based spray.

In Request 6, GSK asked the FDA to tighten specifications for droplet size distribution (DSD) which measures the size of individual droplets in the spray and spray pattern (SP) which describes the cross-sectional shape of the spray emitted.[53] The court reasoned that genuine issues of fact remained because these methods are proprietary and therefore differ based on different equipment and manufacturers. Additionally, plaintiffs presented expert testimony stating the existing standards were sufficient to ensure public safety.

Finally, the court looked at the Maryland lawsuit in which GSK had filed for a TRO and preliminary injunction.[54] GSK argued that because it was granted the TRO, the lawsuit was not objectively baseless. The court rejected this assertion finding that a court's granting of a TRO does not, by itself, establish an objective basis for petitioning activity. Furthermore, the court stated that the overt denial of a preliminary injunction, and the plaintiffs' evidence of baseless in the citizen petition, raise genuine issues of fact as to whether the Maryland lawsuit was objectively baseless.[55]

The court therefore denied GSK's motion for summary judgment because genuine issues of fact remained on whether GSK's citizen petition constitute a sham and are not entitled to the Noerr-Pennington immunity. This suit is still pending.

In re Wellbutrin XL Antitrust Litigation

On January 7, 2011, purchasers of Wellbutrin XL filed a complaint against Biovail Corporation.[56] The plaintiffs sued Biovail, the producers of Wellbutrin XL (a once-a-day antidepressant) for conspiring to prevent generic

[50] Plume geometry describes the cross-sectional shape of the spray emitted from the device, measured on a plane parallel to the direction of the spray.

[51] GSK FDA Rejection Letter, *supra* note 42, at 18 ("Studies in literature have indicated that the spray angle is one aspect of product performance that determines where in the nasal cavity drug is deposited.").

[52] GSK FDA Rejection Letter, *supra* note 42, at 17 ("[FDA studies] are adequate to ensure that generic versions of the [FP] nasal spray product preserve identity, strength, quality, and purity over their shelf life.").

[53] DSD and SP provide an internal measure of the production quality of any given batch of a drug.

[54] Glaxo Grp. Ltd. v. Leavitt, No. 06-cv-649 (D. Md. Feb. 23, 2006). Responses to citizen petitions constitute final agency action and are subject to immediate review by the courts.

[55] The court denied GSK's Motion stating, "If I had any hesitation, and a man without hesitation is a dangerous man, I understand that. But if I had any hesitation whatsoever that you had any kind of likelihood of prevailing in this case, I would not hesitate. But I simply don't have it. … I just don't see any likelihood that you're going to prevail." Prelim. Inj. Hr'g 124:4-17 Mar. 6, 2006.

[56] Second Amended Consolidated Class Action Compl. and Jury Demand for End Payors, In re Wellbutrin XL Antitrust Litig., No. 2:08-cv-2433 (E.D. Pa. Jan. 7, 2011) [hereinafter "Wellbutrin Compl."].

versions of Wellbutrin XL from entering the market. Specifically, the plaintiffs allege that the defendants have: (1) filed three sham patent litigation cases, (2) filed a sham listing with the Orange Book, (3) filed a baseless FDA citizen petition, and (4) formed potentially illegal agreements with generic competitors.

In reference to the citizen petition, the plaintiffs alleged that Biovail submitted its citizen petition requesting the FDA to require ANDA applicants to perform additional studies beyond those previously submitted to prove bioequivalence. Specifically, Biovail requested that the ANDA prove bioequivalence to not only Wellbutrin XL, but also Wellbutrin IR and Wellbutrin SR. The plaintiffs complained that FDA regulations required ANDA applicants only show bioequivalence to the referenced listed drug and therefore the requests were baseless.[57] Further the plaintiffs claimed the citizen petition was a sham because "it relied on unsubstantiated theories, lacked scientific support, misapplied governing legal and regulatory standards, and was nothing more than a last-minute attempt to extend Defendants' monopoly…"[58]

In denying the citizen petition, the FDA stated that the brand manufacturers did not have "the right to be free of generic competition" once the patents had been held unenforceable, and that "Biovail [should] not be permitted to shield its market share."[59] In turn, the plaintiffs claimed that this citizen petition delayed approval of its ANDA for four months. Notably, according to a letter sent by United States Senators Debbie Stabenow (D-Mich.) and Trent Lott (R-Miss) this delay in the ANDA approval cost consumers $37 million per month.[60]

The case is currently pending in the Eastern District of Pennsylvania[61] and the court has yet to reach the question of whether Biovail's citizen petition will be given immunity under Noerr-Pennington.[62]

"Plus" Factors that Make Monopolization Claims Based on Citizen Petition Theory More Likely to Survive Motion to Dismiss or Summary Judgment

While there is a high standard to prove the sham exception to Noerr-Pennington immunity, as described above, some plaintiffs have successfully survived at the motion to dismiss and/or summary judgment stages. While there is no "formula" for a successful claim for monopolization based on the filing of baseless citizen petition, the courts have discussed certain factors that make the success of these claims more likely.

Suspect Timing

In considering whether the sham exception has been met, courts look to the timing of the filing

[57] Id. at 38.

[58] Id. at 39.

[59] FDA Letter Rejecting Biovail Citizen Petition at 16 (Dec. 14, 2006) [hereinafter "Biovail FDA Rejection Letter"], available at http://www.regulations.gov/#!documentDetail;D=FDA-2005-P-0366-0004

[60] Wellbutrin Compl., supra note 56, at 3.

[61] The indirect purchasers were recently granted class certification. See Meijer Inc. et al. v. Biovail Corp. et al., No. 2:08-cv-0243 (E.D. Pa. Aug. 11, 2011).

[62] There are two additional case filed recently which claimed a brand manufacturer filed a sham citizen petition. In re Ditropan XL Antitrust Litig., No. M:06-CV-01761-JSW (2007) was dismissed on standing grounds and the court never reached an analysis of the citizen petition. In New Mexico UFCW Union's and Emloyers' Health and Welfare Trust Fund v. Astellas Pharma U.S., Inc., Case No. 1:11-cv-11621 (D. Mass. Sept. 14, 2011), the plaintiffs claim that Astellas filed a baseless citizen petition to extend its market exclusivity of Prograf.

Laboratories' ANDA, present any evidence that the ANDA failed to demonstrate bioequivalence, or raise any public health concerns.[64] Moreover, in the GSK FDA Rejection Letter, the FDA stated that the tests and factors it uses in determining bioequivalence were sufficient. The plaintiffs in DDAVP, made the same types of claims stating that the citizen petition lacked scientific basis and was contrary to current practices. The FDA specifically stated that the citizen petition requests made in DDAVP lacked "any basis" for its arguments.

The vast majority of companies involved in these law suits are large pharmaceutical companies which have substantial experience in complying with FDA procedures and regulations. In turn, there is an expectation that these companies have knowledge of FDA practices and procedures. Therefore, if the citizen petition requests action that the company knows is contrary to FDA practice, courts may use this as a telling factor that the petition was baseless and part of a scheme to delay generic entry.

Tone of FDA Rejection of Citizen Petition

The tone of the FDA rejection letters also appears to play a role in plaintiffs surviving a dispositive motion. When the FDA harshly criticizes the citizen petition filer, the court may use it as a relevant factor in making its decision. For example, in DDAVP, the FDA found that the citizen petition lacked "any basis" and "had no convincing evidence."

Further, in Louisiana Wholesale, the FDA noted that Aventis' requested relief "seem[ed] to be based on a false premise." Additionally in Wellbutrin, the FDA stated, that the brand manufacturers did not have "the right to be free of generic competition" once the patents had been held unenforceable, and that "Biovail [should] not be permitted to shield its market share."[65] In Flonase the FDA stated, "[t]he policies behind the Hatch-Waxman dictate that GSK should not be permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved…."[66] The court in Flonase also took into account the Maryland Court's outright rejection to GSK's request for a preliminary injunction.[67]

The FDA's response to citizen petition undoubtedly plays a major role in the determination if a petition is considered objectively baseless. Obviously if the FDA takes action based on the citizen petition, the petition will not be found to be baseless.[68] On the other hand, as is present in these cases, the fact that the FDA strongly criticized the requests may tend to show that a petition is objectively baseless and therefore not entitled to Noerr-Pennington immunity. While not expressly called out as a factor, the courts in these cases have recited and quoted extensively from the language contained in the FDA's letters

[64] Id. at 8.

[65] Biovail FDA Rejection Letter, supra note 59, at 16.

[66] GSK FDA Rejection Letter, supra note 42, at 24.

[67] The court denied GSK's Motion stating, "If I had any hesitation, and a man without hesitation is a dangerous man, I understand that. But if I had any hesitation whatsoever that you had any kind of likelihood of prevailing in this case, I would not hesitate. But I simply don't have it. … I just don't see any likelihood that you're going to prevail." Prelim. Inj. Hr'g 124:4-17 Mar. 6, 2006.

[68] Although the plaintiffs in Louisiana Wholesale successfully passed the preliminary motions stage, the defendants were able to present evidence at trial showing the FDA took action based in part on one of the citizen petition requests. This is one factor the court later pointed out in subsequently denying Plaintiffs JNOV after the jury had sided with Defendants.

rejecting the branded firms' citizen petition. Clearly, a strongly worded rejection from the FDA—chastising petition for the lack of foundation for the citizen petition filed—is likely to play a role in the fact finders' analysis of baselessness.[69]

Petition Actually Caused Delay

In all four of the cases above, the courts found it important that the FDA granted final approval of the ANDAs on the same day as it rejected the brand manufacturer's citizen petition, suggesting that the citizen petition was indeed holding up generic entry and competition. Indeed, the court in Louisiana Wholesale specifically remarked on the FDA's statement that it would not grant the generic ANDA applicants approval while it addressed the Aventis' citizen petition. Moreover, in Flonase, the FDA seemed likely to approve Roxane's generic, then reversed its thinking and issued a deficiency based on the citizen petition, and finally approved the ANDA based primarily on Roxane's original ANDA submission.

While a consideration of whether the citizen petition actually delayed generic entry may relate more to the establishment of antitrust injury—rather than the establishment of the sham exception to Noerr-Pennington immunity—it is important to note that causation is a critical component to successful monopolization challenges based on the filing of baseless citizen petitions. In other words, to the extent that other factors—such as failure to obtain bioequivalence or manufacturing issues—may have caused delay in the generic firm's ability to obtain FDA approval, defendants may have strong arguments that their citizen petition, even if baseless, had no adverse effect on competition.

Although the four factors reviewed above are certainly not all a court takes into account in its decision, facts that represent egregious examples of most or all of these factors have pushed courts to find that claims based on the filing of baseless citizen petition can, in some circumstances, survive dispositive motions and proceed towards trial.

Conclusion

The abuse of the citizen petition process is an area of flux in the world of pharmaceutical antitrust. With the enactment of the FDAAA, there is a potential that the most egregious abuses of the ANDA process are likely to be curbed as the FDA may no longer delay approval of a pending ANDA application, as a result of a citizen petition, unless "a delay is necessary to protect the public health."[70] That said, it appears that the jury is still out on whether the FDAAA will effectively eliminate the potential for anticompetitive use of citizen petitions to impede or delay generic entry. According to the FDA's most-recent report to Congress, it is "too soon to determine whether section 505(q) is discouraging petitions submitted with the primary purpose of delaying approval of an ANDA."[71] Moreover, there are key exceptions to the FDAAA, including agreements relating solely to 180-day exclusivity as well as agreements that predate September 2007, which, as discussed above, could be relevant as part of a continued conspiracy to monopolize a particular drug market.

[69] Conversely, a letter from the FDA tending to show that petitioner's argument had legitimate bases that were carefully considered by the FDA is also likely to factor into the judge's analysis, as it tends to show that the citizen petition was not objectively baseless.

[70] FDCA § 505(q)(1)(A).

[71] FDA Report to Congress, *supra* note 22.