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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 *In re 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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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.

Hospital mergers present a good example of the differences between the FTC and state AGs in the breadth of their jurisdictions. In a hospital merger, the state AG may be counseling various state agencies involved in the transaction: the CON authority, and perhaps even the hospital itself. The state AG may also examine any charitable issues to determine if the terms of the proposed merger are appropriate in light of the mission of any charitable organization involved. And of course, the state AG can also address the competition issues. In contrast, the Commission would focus just on the competition issues, but we dive deeply into those issues.

My personal role at the state AG offices and at the Commission differs tremendously. I was both a prosecutor and a manager in state AGs' offices. I was either going into court, or helping other attorneys who were going into court. I participated in negotiations on various matters, sometimes at a big table with one or more companies and many other states dealing with multi-state matters. Here, my role as a Commissioner is different. I am not the person who goes into court. Instead I am one of the four or five Commissioners who set the policy for the agency. We vote on everything, we decide everything, and that ranges from the complaints that get filed, settlements that we enter into, policy reports, initiatives, and the like.

***CHRONICLE*:** Do you see yourself more of a law enforcement official, policy maker, or where along that spectrum do you fall?

***BRILL*:** As a Commissioner, I do both. I am a law enforcement official and a policy maker. Of course, law enforcement contains a policy element. I think that was also true when I was a State Assistant Attorney General. Filing a case, presenting a case, settling a case, that all sets policy with respect to a particular defendant and, over a course of several cases, potentially with respect to the industry involved. We certainly want industry to examine our cases in order to adhere to their parameters where applicable. Of course, at the FTC we also work on policy initiatives that cover a broad swath of the economy. Our privacy report and our competition guidelines for Accountable Care Organizations are two recent examples of this.

***CHRONICLE*:** As you know, the readers of the *Chronicle* are interested in health care and pharmaceuticals in particular. As Commissioner, what are your top priorities in those areas?

***BRILL*:** On the competition side, one of my top priorities and one of the agency's top priorities is to restrict "pay-for-delay" agreements between branded and generic drug companies. The FTC is taking a two-pronged approach to restricting pay-for-delay agreements. First, we're working with members of Congress on legislation, and second, of course, we continue our law enforcement work in the area. That's our two-pronged approach. I am fully supportive of it, and it's one of the Commission's top priorities. I personally think it's important because lower cost generic drugs need to get to market as quickly as possible. That was the Congressional mandate underlying Hatch-Waxman, and I'm concerned that some activities in the pharmaceutical industry over the past ten years have subverted that Congressional mandate. And pay-for-delay has not just subverted a Congressional mandate - it has cost consumers billions in an era of escalating healthcare costs. The FTC has estimated that pay-for-delay costs consumers $3.5 billion per year or $35 billion over ten years. That's a lot of money.

Another top priority is to ensure that competition is maintained to the fullest extent possible in response to structural changes in healthcare markets, in particular in response to

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*:** So just to follow up on that, we understand that in *LabCorp* you wanted the FTC to appeal that decision. What was your reasoning behind that? Were you hoping that a decision on appeal would provide further guidance to the industry?

***BRILL*:** My starting point in *LabCorp* was the likelihood of significant harm to consumers in Southern California as a result of the merger. Additionally, I thought that there were some important principles of merger law that an appellate court should look at. I thought that the district court opinion did not adequately explain to the Commission—and to the consumers we represent—why preliminary relief was not appropriate. Given the importance of Section 7 cases, and the issues they raise for an entire industry and practitioners, it would have been helpful for the Ninth Circuit to tell us whether the district court correctly applied merger law to that transaction. When you think about escalating health care costs, the merger of two entities performing critical functions—in *LabCorp* it was testing services—ought to be closely examined in order to ensure that the merger is not going to create anticompetitive effects. Sometimes, that close examination includes an appeal from a district court decision.

***CHRONICLE*:** Can you talk a little bit about coordination with State AG offices in hospital merger cases, like the *Phoebe Putney* case in Georgia and the *Promedica* case in which that State AG also joined? Or, how was coordination with state AGs in the FTC's other cases?

***BRILL*:** Sure. We work as closely as we can with state AGs in any cases in which they are interested where we are able to have a good,

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 coordination and cooperation with the state AGs in *Promedica*, in *Phoebe Putney*, and in *Lundbeck* and other cases was pretty much the same. We were co-plaintiffs and partners.

***CHRONICLE*:** Given that health care competition issues, such as provider mergers, as we've talked about before, often impact local markets, how important is it for the FTC to get the AG on board or have their involvement in a case?

***BRILL*:** I personally think it is very important to have the state AG participate where possible because they know the local markets. We at the FTC learn a lot about the local markets during the course of our investigations, but the state AG knows these markets intimately. I think this is helpful to us, and ultimately to consumers.

***CHRONICLE*:** Another interesting case that came up this year was the *Grifols/Talecris* settlement. In particular in that case, you agreed with the complaint and ultimately with the settlement, but you said it was a "close call" in terms of whether the remedy went far enough. Could you elaborate on whether you had an alternative remedy in mind, a better solution, or were in favor of challenging the entire deal?

***BRILL*:** Just to be clear, the real issue from my perspective in saying *Grifols/Talecris* was a "close call" was whether we should challenge the merger rather than accept the remedy to which the Commission agreed. There are times when it is just not possible to negotiate effective relief. Or the relief we might want would so gut the deal that the parties can't agree to it. As you said, I ultimately did vote to accept the consent decree. My concern was that, even though the consent brought a new player to the market, there are still lingering issues in that particular market given the history of past coordination, and the number of players left in it. So I'm very interested to see what happens going forward with the new entrant. I remain hopeful that the consent preserved competition.

***CHRONICLE*:** Let's shift gears a little bit and talk about the FTC's activities in consumer protection as it relates to the health care and pharmaceuticals industries. In 2009, the FTC issued final Guides Concerning the Use of Endorsements and Testimonials, which, among other things, eliminated the safe harbor allowing advertisers to describe unusual results so long as they used a "results not typical" disclaimer. Watchers of late-night television may still see this ad from time to time. And most of the FTC's enforcement activities in this area have involved exaggerated claims of weight loss. Does the FTC intend to continue pursuing these types of actions? Do you expect an expansion beyond the weight loss arena?

***BRILL*:** The Endorsements and Testimonials Guides laid down some important general principles regarding how we would apply Section 5 unfair and deceptive practices to endorsements and testimonials. The one you articulated—the "results not typical" disclaimer—is one of them, and it is true that it is heavily relied on in the weight loss area. This is a very important health care issue. Weight loss and obesity are areas to which we pay pretty close attention, and we will continue to use the new guides in our weight loss cases going forward. But I don't think the "results not typical" principle will be the only tool we use in the weight loss area. By the way, I hope that you are seeing less of that disclaimer on late-night television. I believe that to be the case.

To your second question, the Endorsements and Testimonials Guides do not apply only to

weight loss. There have been other cases in which we have looked at endorsements and testimonials where the guides have been relevant. For instance, the issue whether endorsers are paid endorsers has been raised in both the weight loss area and also in the technology space. In the latter, people have pronounced certain apps to be "fabulous" or other software to be "wonderful" in, for example, the iTunes store. It turned out these reviews were paid for, but not disclosed as such, triggering the guides. So overall, the Endorsements and Testimonials Guides have a pretty broad reach.

***CHRONICLE*:** The FTC recently settled a case with Reebok, which was one of the largest ever consumer protection settlements by the federal government in the advertising context. That settlement involved Reebok's advertising with respect to "toning shoes" or toning apparel and exaggerated claims about the products. What initially caused the FTC to focus on or take action against Reebok? To what extent does this action serve as a message to other advertisers in the health care industry?

***BRILL*:** We don't talk about the specific reasons why we focused on one particular target or matter, but I can talk about how we select cases in general. It's a matrix involving different factors. A key factor is whether we have received consumer complaints. If consumer complaints are filed with the Commission relating to a particular company or issue, we take a close look at them. We collect complaints in Consumer Sentinel, which is a centralized database for all sorts of complaints filed with a variety of public and private agencies on the state, local, federal, and international levels. The Commission, as well as law enforcement agencies nationwide, has access to the database. Undercover purchases are another important tool in our case selection matrix. We make purchases to see what happens when someone buys a given product or service. We look at the difference between what consumers are told at the time of purchase, versus what the product or service actually does. Similarly, in the advertising context, just like you watch late-night television and may see ads that say "results not typical"—hopefully fewer of them—our folks are the eyes and ears of the Commission watching advertising in all types of media to see what companies are saying about their products or services. So, we try to walk in consumers' shoes—no pun intended. After all, we are consumers too.

***CHRONICLE*:** We can imagine FTC staffers running around in Reebok toning shoes.

***BRILL*:** We did do a lot of background research in Reebok, as we do in all of our cases. Other factors that may go into case selection in the advertising context are the potential for consumer injury or safety risks. If someone is advocating a product to cure or prevent a disease, we consider those claims to be pretty important. We ask: do the claims target vulnerable populations, like the elderly or HIV-positive individuals? Is there a potential for substantial financial loss that consumers could be suffering? We have focused on particular areas, such as "hoodia" weight-loss supplements, acai-berry supplements, and cold and flu treatments. Other times, we'll focus on a particular media, such as infomercials or social media on the internet.

Part of your question relates to whether our cases send a message to the industry and, if so, what kind of message? I always hope that we send important messages to industry with our work. In *Reebok*, I think that we sent an important message to industry that was consistent with our overall advertising program: if you're going to make a claim, it needs to be substantiated.

***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 *In re 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).

issued a preliminary privacy staff report last year in which we noted that we support affirmative express consent where companies are collecting sensitive information, including health information, for the purpose of behavioral advertising. I would also note that we're not alone in this position. Industry itself shares our position and has adopted—at our urging—a self-regulatory set of principles developed by the Direct Marketing Association, the Interactive Advertising Bureau, and other advertising-related organizations. These principles say that entities should not collect prescription or medical records for behavioral advertising purposes absent the consumer's consent.[2] There's a lot of consensus around this issue.

***CHRONICLE*:** In the last two years, the FTC settled charges with Rite Aid and CVS regarding protection of medical and financial privacy of customers and employees. Rite Aid, for example, was alleged to have used open dumpsters to discard trash containing consumers' personal information. These actions were pursued jointly by the FTC and HHS. To what extent should we expect to see more cases along these lines? And do you expect future coordination among the FTC and HHS in the privacy area?

***BRILL*:** If the facts are out there, we will see more of these cases and continued coordination with HHS. The states are also very active in this area. For example, Texas, North Carolina, Connecticut, and California are all actively pursuing information disposal cases, including health information cases. We are all hoping that through these cases, as well as cases involving the inappropriate disposal of financial information, we will see changes in the way industry disposes of sensitive consumer information. And I think we have seen greater care being taken in this area. But when there's a problem, we'll step in.

Can I mention one other thing? You had asked about the use of sensitive health information in the context of behavioral advertising, and this is an incredibly important issue. But we are also concerned about the use of this kind of information for other purposes including, for instance, making decisions about consumers that would affect them in their financial lives. This is not the use of sensitive health information for behavioral advertising, but it's a very important issue nonetheless. There's a sliding scale involved in the use of sensitive health information. To the extent that we get to the end of the scale leading to employment decisions, decisions about insurance or decisions about loans being made, I think—and I believe the entire Commission thinks—that we start to get into an area that involves the Fair Credit Reporting Act. In this context, it is very important that consumers be given notice about the use of their health information, and have the right to correct it in the event it's incorrect. There are clear rules with respect to information that might be used for those purposes, and the use of sensitive health information in this context is something that we'll be very keen to make sure is handled appropriately.

***CHRONICLE*:** Now for a few general questions. In terms of your work, what do you see as the major differences between the consumer protection work of the Commission and the competition mission of the Commission?

***BRILL*:** Truthfully, from my perspective, the two are very similar: both aim to protect consumers. I think of a great deal of antitrust

[2] *See, e.g.*, Self-Regulatory Principles for Online Behavioral Advertising 17 (July 2009), at http://www.the-dma.org/government/ven-principles%2007-01-09%20FINAL.pdf.

enforcement as a subset of consumer protection work, with apologies to your antitrust readers. The difference I see is that our consumer protection work can have a more direct and immediate impact on consumers. In other words, in our consumer protection work, we are often dealing with a complaint or issue brought to us directly by consumers or by others on their behalf. For example, we might aim to stop a deceptive claim from being made that harms consumers and, where possible, get money back for the consumers who were harmed by that claim. This work has a direct and immediate effect on consumers. On the competition side, our enforcement effort is focused on ensuring that there's sufficient competition in the marketplace. This effort ultimately has an impact on consumers, but antitrust goes about it a bit more indirectly because what we are doing is trying to preserve competition in the marketplace, which leads to consumer benefit in terms of lower prices, greater innovation, and better products. So both consumer protection and antitrust protect consumers, but one feels a little more immediate than the other.

***CHRONICLE*:** Do you ever encounter issues where consumer protection considerations and antitrust considerations come into conflict? And how do you resolve such a conflict?

***BRILL*:** Yes, in fact we do. I wrote an article about this issue. There are times when consumer protection and competition work well together. There are times when they come into conflict with one another. One of the areas in which this has happened in the past is in the health care context. Sometimes we have seen a self-regulatory regime or industry trade group trying to set a standard, ostensibly for consumer protection purposes. For example, in the *South Carolina Dental* matter, the dentistry board imposed a requirement that a dentist examine every child before a dental hygienist could provide them with preventive care. The board ostensibly put this requirement in place as a consumer protection measure. Our concern was that this requirement would stifle competition with respect to preventive dental care and, in that event, consumers would be worse off because they would receive less care, or experience higher prices. The dental hygienists in that case were going to schools in low-income school districts to provide care, and that's the context in which the Dentistry Board rule was being imposed. So the Commission was concerned about the competitive effects of this rule, even though the rule was considered by some to be a consumer protection measure. There have been other cases touching on the conflict between competition and consumer protection, such as *California Dental*, which went up to the Supreme Court.

In the end, we, as a Commission, need to balance the tension between competition and consumer protection. Fortunately, because we have both competition and consumer protection in our portfolio, I think we're really well suited to the task. Of course, how you ultimately strike that balance depends on the specific facts of the case at issue.

***CHRONICLE*:** Do you have any predictions for 2012—especially with health care reform in place and the recent release of the ACO guidelines—as to where things may go from a competition perspective at the Commission?

***BRILL*:** First, I was very pleased with the reception of our final ACO guidelines as well as the guidelines that CMS issued. I don't know if I want to call it a prediction, but my hope is certainly that industry is more comfortable with the guidelines that were issued in connection with health care reform, including the final antitrust guidelines. Under these guidelines, the antitrust agencies will look at the underlying substance, the underlying structure of the

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]
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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 United Regional began its predation strategy in 1999 when it entered into bundled discount contracts with five payors, subsequently followed by contracts with three more payors.[9] Since DOJ did not allege that United Regional would have forced Kell West out of the market, its theory implies that United Regional must maintain this scheme of exclusive contracting in exchange for greater discounts for an extended period to protect its monopoly services and to keep Kell West from becoming a full-service hospital.

Among other things, DOJ accused United Regional of using these contracts to effectuate a competitively harmful strategy of below-cost predatory pricing. To test whether United Regional engaged in predatory pricing, DOJ applied a modified form of the "discount attribution" approach articulated by the district court in *Ortho* and used by the Ninth Circuit in *PeaceHealth*.[10] In general, the discount attribution approach assigns the entire amount of the discount for the bundle of services to the sales of the competitive service alone. DOJ's modification arises in how it determined which services constituted the competitive services. DOJ identified the competitive services by dividing United Regional's patients insured by payors with exclusive contracts into three groups: (1) those receiving services not available at Kell West (e.g., patients receiving cardiac surgery or obstetrics care), denoted here as "monopoly services," (2) those receiving services available at Kell West but who prefer United Regional and would not switch to Kell West,[11] denoted here as "preferred services," and (3) those receiving services available at Kell West who would switch to Kell West if the payor did not have an exclusive contract with United Regional. The third group of patients constitute what DOJ believed are the competitive sales, and it denotes these patients as "contestable." DOJ estimated that only 10% of non-Blue Cross commercially insured patients were contestable.[12] After attributing the discount on the whole bundle of services entirely to the 10% of non-Blue Cross commercial patients, DOJ concluded that United Regional's prices for the competitive services

[7] DOJ does not describe why this strategy is a credible entry deterrent or why Kell West could not finance through other means the expansion that DOJ evidently believes would be profitable.

[8] CIS, *supra* note 6, at 12.

[9] CIS, *supra* note 6, at 3.

[10] CIS, *supra* note 6, at 14; Ortho Diagnostic Sys., Inc. v. Abbott Labs., Inc., 920 F. Supp. 455, 467 (S.D.N.Y. 1996); Cascade Health Solutions v. PeaceHealth, 515 F.3d 883 (9th Cir. 2008).

[11] CIS, *supra* note 6, at 16. "[M]any patients are likely to choose care at United Regional even for services that competing providers offer."

[12] CIS, *supra* note 6, at 15-16. This estimate is based on usage patterns of Blue Cross and Medicare patients. One concern with using Medicare patients is that they are not representative of commercially insured patients. Medicare patients are likely to be systematically older and with no demand for obstetrics or pediatrics services.

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 in *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 which the defendant is accused of preventing entry of a competitor rather than inducing a competitor's exit. The logic of the example is easy to discern. Suppose that one firm produces both shampoo and conditioner and a second firm wants to enter the shampoo market. The incumbent hair-products monopolist offers the two-product bundle at a discount below the products' combined stand-alone prices. The discount attribution approach weighs the entire bundled discount against the stand-alone price of the shampoo, the product area in which entry is threatened. The discount is attributed entirely to the shampoo because the discount is designed to affect competition in the shampoo market. The discount has no effect on the monopoly conditioner market. Moreover, since consumers must purchase conditioner from the monopolist in any event, there would be no reason to discount its prices.

In *United Regional*, United Regional's alleged attempt to thwart Kell West's entry into the monopoly services market is analogous to the hair products monopolist's attempts to prevent entry into the shampoo market, though there are some important differences. In the *Ortho* example, the discount is intended to affect competition in the market for the competitive product (shampoo), leaving the monopoly product (conditioner) untouched. United Regional, however, has no service line that is a secure monopoly, free from threatened entry. Rather, United Regional's monopoly services markets are threatened by Kell West's expansion. Protecting against that threat, according to DOJ, was the basis for United Regional's bundled discount. The impact of the bundled discount (and the related exclusivity) was felt directly by the contestable patients who would otherwise have chosen Kell West, but the discount's ultimate aim was to thwart Kell West's service line expansion. Thus, DOJ's contestable patients were not the target of the

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

[14] *Ortho*, 920 F. Supp. at 455, 467.

[15] *Cascade Health Solutions*, 515 F.3d at 896-97.

alleged anticompetitive conduct but rather the means to accomplish it.

Once the markets ultimately affected by the alleged anticompetitive conduct are identified, it becomes clear how to attribute the bundled discount. In the hair products example, the entire discount is attributed to shampoo because that is the market with the competitive impact. In *United Regional*, DOJ theorized that the bundled discount prevented the entry of Kell West into monopoly services and thus prevented its expansion into a full-service hospital. Were Kell West to become a full-service hospital, all of the business that it could not otherwise attract (i.e., users of the monopoly services and the preferred services)[16] would become competitive. The effect of the alleged anticompetitive conduct thus was not on the 10% of patients DOJ denoted as contestable, but on all of the other patients. Rather, in DOJ's theory, the bundled discount affected United Regional's competition for all patients, and it should be attributed to all of them. As DOJ stated, "the entire discount should be attributed [ ] to the patients that United Regional would actually be at risk of losing," and it risks losing all patients to an expanded Kell West.[17] Whether United Regional would actually lose all of those patients depends on many factors like the relative efficiency of the two hospitals, but that does not change the analysis of attributing the bundled discount.

Another way to view this concept is to consider how large a discount United Regional would be willing to offer to non-Blue Cross commercial payors in exchange for exclusivity. Once again, the *Ortho* example of shampoo and conditioner shows how this line of reasoning leads to the proper discount attribution. In that example, the hair-products monopolist would be willing to offer a discount up to the present value of the incremental profit gained by maintaining market power in shampoo sales. The amount of this profit is unaffected by the conditioner market, which is not threatened by entry. Logically, the entire discount should be attributed to shampoo with none being attributed to the monopoly conditioner product. In *United Regional*, if United Regional were attempting to protect its monopoly services (and those patients who prefer United Regional) from Kell West's entry, as DOJ's theory stated, then United Regional should be willing to offer payors a discount up to the present value of the profits that United Regional derives from those payors' use of the monopoly and preferred services. By this reasoning, the discount United Regional offered payors for exclusivity is tied to and defined by the combined monopoly and preferred services markets rather than by the contestable patients, and it should be attributed to the combined monopoly and preferred services rather than only to the contestable 10%. Since Kell West's transformation into a full-service hospital also means that United Regional would risk losing the contestable patients as well, United Regional would be willing to offer a discount up to the amount of profits received from those patients also. Again, in that manner, the discount should be attributed to all patients.

[16] Although the CIS does not explain why some patients supposedly prefer United Regional for services available at Kell West, it is reasonable to assume that product differentiation is the reason. United Regional attracts patients that could go to Kell West because it is an established, large, full-service hospital whereas Kell West is a newer, smaller, limited-service hospital. DOJ's theory depends on Kell West becoming a binding competitive constraint on United Regional when it expands into a full-service alternative by adding the monopoly services. Product differentiation is the only explanation for these patients choosing United Regional over Kell West that is consistent with DOJ's theory.

[17] CIS, *supra* note 6, at 15.

Before concluding this discussion, it is helpful to consider bundled discounting in the context of a capacity constraint, especially since the CIS references an article about capacity constraints in its discussion of DOJ's version of contestable patients.[18] With a capacity constraint at Kell West, the contestable sales might more reasonably be considered to be less than the full volume of competitive sales. The standard discount attribution approach assumes that the rival supplier can take all of the sales of the competitive product from the bundled discounter if the products were unbundled. If the rival has limited capacity, however, then only a portion of the competitive sales could switch. In essence, the bundled discounter could price the competitive product on a stand-alone basis above the competitive level and risk losing sales only up to the rival's capacity level. While that reasoning may provide a justification for attributing the bundled discount entirely to the competitive product, DOJ does not make the argument in *United Regional* that Kell West's capacity is constrained. Quite the contrary, DOJ's arguments imply that Kell West could rapidly expand to rival United Regional.

In sum, it is apparent that the bundled discount in *United Regional* should be attributed to the monopoly and preferred services or, more appropriately, to all services. It is an empirical matter whether the fully allocated discount results in below-cost prices, but the implications of attributing the increased discount offered for exclusivity to a much larger portion of United Regional's patients than just the 10% is obvious: the likelihood of United Regional's discounted prices being below cost is much smaller or even non-existent.

[18] CIS, *supra* note 6, at 15 (referencing Mark S. Popofsky, *Section 2, Safe Harbors, and the Rule of Reason*, 15 GEO. MASON L. REV. 1265, 1294 (2008)).

Investment in Predation

Setting aside the appropriateness of attributing the entire discount to the small set of so-called contestable patients, the questions remain of whether investment in a below-cost pricing strategy is economically rational and how to recoup forgone profits. Recoupment has long been a central feature of any analysis of alleged predatory pricing.[19] The reason for its pre-eminence is that no economically rational firm should be expected to invest in a strategy of below-cost pricing that offers no prospect of generating a return that will compensate for the investment. As Justice Kennedy wrote in *Brooke Group*, "[r]ecoupment is the ultimate object of an unlawful predatory pricing scheme; it is the means by which a predator profits from predation."[20]

A straightforward way to consider this issue for *United Regional* is to assess United Regional's options in choosing a pricing strategy. The first option would be to enter into exclusive contracts with the non-Blue Cross health plans in which those plans forgo a broad hospital network in exchange for a greater discount from United Regional. This, of course, is the option that United Regional chose from 1999 until its settlement with DOJ in 2011. This option can be divided into two separate possibilities that are relevant to the issue of predation. On the one hand, United Regional might offer the health plans a discount that results in United Regional's price being below cost, as DOJ alleged. Alternatively, United Regional might offer discounts to the health plans that are sufficient to compensate the plans for accepting

[19] *See, e.g.*, Brooke Group Ltd. v. Brown & Williamson Tobacco Co., 509 U.S. 222 (1993); Herbert Hovenkamp, *Discounts and Exclusion*, 2006 UTAH L. REV. 841, 844-45.

[20] *Brooke Group Ltd.*, 509 U.S. at 224.

a narrow hospital network, but nevertheless result in prices above cost. Since prices remain above cost in this latter scenario (ignoring how the discount is attributed), it cannot be the basis for allegations of predatory pricing.

A third option for United Regional would be to jettison altogether the exclusive contracts and the discounts that go with them. According to DOJ, if United Regional chose this option, Kell West's access to the non-Blue Cross patients would allow it to expand into a full-service hospital. In this no-exclusives, no-discounts scenario, United Regional would price its monopoly services at the monopoly level to maximize profits over the time period it takes Kell West to effectuate its expansion.[21] Once Kell West became a sufficient competitor to discipline United Regional's prices, United Regional would be forced to lower the prices of its formerly monopoly services to competitive levels.[22] Obviously, no basis exists in that situation for allegations of predatory pricing.

Thus, only one scenario exists in which United Regional could be engaged in the predatory strategy that DOJ alleged: pricing below costs.[23] As noted above, a logical question to ask in the context of an alleged below-cost pricing strategy is whether the strategy is economically rational, either through recoupment of lost profits or through other means. Yet despite all of the detail in the CIS, DOJ included no discussion or analysis of the economic rationality of this strategy.

It is possible that DOJ has made the same mistake as the Ninth Circuit in *PeaceHealth* and some of the Antitrust Modernization Commission members regarding recoupment. The Ninth Circuit stated that a seller of bundled products need not meet the recoupment standard as long as it makes positive profits on bundled sales.[24] In fact, any price below the single-period profit maximizing level involves an investment in the form of forgone profits that must generate an adequate financial return.[25] It is also possible that DOJ did not address this issue because it foresaw no future period in which United Regional could actually recover its investment. The perpetual discounting that is necessary in DOJ's theory to keep Kell West from entering the monopoly services market makes recoupment through a price increase impossible. DOJ does not explain how United Regional ever arrives at a point at which it can both meet the below-cost requirement of predatory pricing and still recover the forgone profits attributable to this alleged predation strategy. Absent an alternative explanation, this

[21] A complication in this scenario concerns pricing of the "preferred services." In reality, the preferred services are a set of patients who consume the same services as the contestable patients but who prefer to receive them at United Regional. United Regional cannot distinguish among those patients, so it cannot raise the price on the preferred patients alone. For this reason, United Regional would raise price in this scenario for just the monopoly services.

[22] This assumes no oligopoly interaction in a two-firm market that would yield above-competitive prices.

[23] A scenario might be conjured in which United Regional lowers its price to small plans sufficiently to entice them to sign exclusive contracts, but it still sets prices above its costs. This assumes that the health plans would be better off to accept a price that is between the single-period monopoly price and the competitive price hereafter rather than to accept the monopoly price in the first period (i.e., until Kell West expands into a to full-service hospital) followed by the competitive price thereafter. This type of above-cost limit pricing was not alleged by DOJ.

[24] Cascade Health Solutions v. PeaceHealth, 515 F.3d 883, 910 n.21 (9th Cir. 2008). *See also* Jonathan Jacobson, *Exploring the Antitrust Modernization Commission's Proposed Test for Bundled Pricing*, 21 ANTITRUST A.B.A. 23, 25-26 (Summer 2007).

[25] *See* David A. Argue, *Predatory Bundling and Recoupment in the Ninth Circuit's PeaceHealth Decision*, ANTITRUST HEALTH CARE CHRONICLE, Oct. 2007, at 5.

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] If Kell West needed so little incremental business to launch itself into full competition with United Regional, it must already have been a close competitor of United Regional. This possibility is consistent with DOJ's statement that Kell West provides a "wide range of inpatient and outpatient procedures."[27] Moreover, any other scenario would represent an extraordinary turnaround of the usual DOJ/FTC position of dismissing the competitive significance of smaller hospitals. The agencies often refuse to credit a small hospital with the potential ability to discipline a large competitor.[28]

An additional important implication of Kell West being so nearly a full competitive rival to United Regional concerns the incentives of Blue Cross. If Kell West were on the cusp of becoming a full-fledged rival of United Regional, then it should not be difficult for Blue Cross to modify its rates to Kell West to facilitate Kell West breaking United Regional's hold on the monopoly services. Regardless of Blue Cross's size, it does best by purchasing hospital services sold in a competitive market. No indication exists, however, that Blue Cross has given Kell West more favorable rates to sponsor Kell West's expansion into those services or that United Regional increased its discount to Blue Cross to prevent it from helping Kell West. Not only is there no discussion of Blue Cross's incentives vis-à-vis Kell West's expansion, but the CIS is silent about Blue Cross's demonstrated ability to resist United Regional's alleged demands for exclusivity provisions. DOJ's theory of United Regional being a "must-have" hospital implies that Blue Cross has no bargaining leverage to thwart United Regional's demands, but DOJ ignored information that is inconsistent with that theory.[29]

Similarly, the incentives of the non-Blue Cross plans must also be taken into account. Like Blue Cross, these plans have an economic incentive to foster competition among the providers from which they purchase services.[30]

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[26] CIS, *supra* note 6, at 10-11. This estimate is based on Blue Cross accounting for 75% of commercial enrollment in the area, as reported by the American Medical Association, Competition in Health Insurance: A Comprehensive Study of U.S. Markets, 2007 Update, *available at* http://www.ama-assn.org/ama1/pub/upload/mm/368/compstudy_52006.pdf.

[27] CIS, *supra* note 6, at 3.

[28] FTC v. Tenet Health Care, 186 F.3d 1045, 1052 (8th Cir. 1999); U.S. v. Mercy Health Servs., 902 F. Supp. 968, 977 (N.D. Iowa 1995).

[29] DOJ may believe that Blue Cross and United Regional are bi-lateral monopolists and thus reach an indeterminate outcome on price. If DOJ thinks that Blue Cross has market power, it should not act in a manner that harms Blue Cross's competitors, yet that is a likely outcome of the settlement. United Regional's but-for price absent the exclusive should be expected to increase. If so, the commercial plans' costs for the 90% of patients who stay at United Regional would increase, causing premiums to rise, and inducing enrollees to switch to Blue Cross, thereby strengthening Blue Cross's purchasing power.

[30] The impact of this incentive may be offset by each individual plan's incentive to free ride on the others in promoting Kell West's expansion.

In principle, United Regional could overcome this economic incentive with a large enough discount. If, however, the plans thought that Kell West could readily expand to discipline United Regional's pricing, as DOJ's theory suggests, that would increase the likelihood that they would reject United Regional's bundled-price exclusivity and instead support Kell West's expansion. If, in contrast, they doubted DOJ's estimate of Kell West's potential, the plans would be more likely to accept United Regional's offer of discounted pricing, which, of course, is what they did.

Conclusion

DOJ's investigation of United Regional's pricing strategies focused on several themes related to alleged anticompetitive exclusionary conduct. Central to those allegations is DOJ's assertion that United Regional used bundled discounts to implement a predatory pricing strategy. That assertion depends in turn on DOJ's novel approach of attributing the full bundled discount to United Regional's so-called "contestable" patients. Importantly, DOJ's theory that United Regional was attempting to protect is "monopoly services" from Kell West's entry, however, more logically points to a fully allocated discount, thereby undermining claims of below-cost pricing. Further, DOJ's silence on recoupment of forgone profits leaves a gap in its overall analysis of predation. The failure of United Regional's alleged below-cost predatory pricing to eliminate Kell West's threat of entry in DOJ's theory requires perpetual predation. Absent a return on the investment in lost profits, the strategy cannot be economically rational and thus cannot be accepted as the explanation for United Regional's conduct.

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

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On December 7, 2011, the Federal Trade Commission (FTC) unanimously agreed with an administrative law judge's (ALJ) holding that the North Carolina State Board of Dental Examiners (the Board) violated Section 5 of the Federal Trade Commission Act by ordering non-dentist teeth whitening service providers to stop operating in North Carolina.[3] This article analyzes notable aspects of the FTC's and ALJ's opinions including whether the Board's conduct was protected from antitrust scrutiny under the state action doctrine and the agency's motive analysis of the alleged anticompetitive conduct. The decision may give pause to professional boards and associations trying to adapt to new products and technologies.

Background

Dentists in North Carolina and around the country have been offering teeth whitening services since the early 1990s. Seeking to capitalize on this increasingly lucrative market, non-dentists began to offer these services in North Carolina around 2003. Like dentists, non-dentist providers offered single session teeth whitening to clients using similar techniques to those used by dentists (involving the application of peroxide at various concentrations to the teeth), but at a significant discount to the rates charged by dentists. It was often more convenient for consumers to obtain teeth whitening services from non-dentist providers who were located in malls, spas, and salons and typically did not require an appointment in advance of the whitening procedure, unlike dentists.

The Board consists of eight members – six dentists, one licensed dental hygienist, and one consumer. Its purpose is to regulate the practice of dentistry within North Carolina pursuant to the Dental Practices Act (the Act) in order to protect public health, safety, and welfare.[4] Among other provisions, the Act states that an individual is deemed to be practicing dentistry if the person performs any of the following: (1)

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[3] *See* In the Matter of N.C. Bd. of Dental Exam'rs, File No. 081-0133, Op. of the Comm'n (Dec. 7, 2011), *available at* http://www.ftc.gov/os/adjpro/d9343/111207ncdentalopinion.pdf [hereinafter Comm'n Op.]; In the Matter of N.C. Bd. of Dental Exam'rs, File No. 081-0133, Initial Decision by Chief Administrative Law Judge D. Michael Chappell (July 14, 2011), *available at* http://www.ftc.gov/os/adjpro/d9343/110719ncb-decision.pdf [hereinafter Initial Decision].

[4] *See* N.C. GEN. STAT. § 90-22.

"[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.

when "the state itself exercises its legislative authority in making the regulation and in prescribing the condition of its application."[10] Such immunity can be extended to non-state actors so long as the state has put into place sufficient safeguards that ensure that non-state entities are pursuing state goals as opposed to their own interests. The level of safeguard required to receive the immunity depends on the actor. A municipality can take advantage of the state action doctrine as long as it can "demonstrate that it is engaging in the challenged activity pursuant to a clearly expressed state policy."[11] Private actors must go further and prove additionally that the conduct was "actively supervised" by the State itself.[12] Accordingly, the Commission first had to decide whether the Board was subject to the active supervision requirement, and if so, whether that was proven in the instant case.

The Commission held that the Board, as a state agency consisting of financially interested members, must meet the active supervision requirement. It found that Board members had a pecuniary interest in excluding non-dentists from the market for teeth whitening services and are beholden to the very members they purport to regulate. Because active state supervision is required to ensure that the entity's decision making is guided by the interests of the state, the fact that Board members are market participants with an interest in the success of the challenged restraint mandated the Commission's conclusion that active state supervision be demonstrated.

Additionally, the state statute that provided the Board with its authority did not authorize the Board to prohibit non-dentists from engaging in teeth whitening services. Rather, under the relevant statute, the Board is simply empowered to issue and renew dentistry licenses, investigate claims of unlicensed practice of dentistry, and, if it suspects unlicensed practice, to bring an action to enjoin the unlicensed activity in state civil court or refer the matter to a district attorney for criminal prosecution.[13] As such, although technically a state agency, the Board was required to demonstrate that the state actively supervised the challenged conduct to qualify for state action immunity.

The Commission was influenced by the fact that the Board was not politically accountable to the citizenry of the state, but rather to the industry it was regulating. Without requiring active state supervision, the actions of the Board "would be subject to neither political nor market discipline to serve consumers' best interests" and there would be no "assurance that the Board's efforts to exclude non-dentists from providing teeth whitening services in North Carolina represent a sovereign policy choice to supplant competition rather than an effort to benefit the dental profession."[14]

Board's Conduct was not Actively Supervised

In the past, the Commission has considered three elements in determining whether the state actively supervised the challenged conduct: (1) development of an adequate factual record, (2) a written decision on the merits, and (3) an assessment of how the conduct is consistent with the standards established by the state

[10] Parker v. Brown, 317 U.S. 341, 352 (1943).

[11] Town of Hallie v. City of Eau Claire, 471 U.S. 34, 40 (1985).

[12] *See* Cal. Retail Liquor Dealers Ass'n v. Midcal Aluminum., 445 U.S. 97, 105 (1980).

[13] *See* N.C. GEN. STAT. § 90-40.1.

[14] *See* In the Matter of N.C. Bd. of Dental Exam'rs, File No. 081-0133, Op. of the Comm'n (Feb. 8, 2011), at 11, 13, *available at* http://ftc.gov/os/adjpro/d9343/110208commopinion.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*"– i.e. (1) whether the conduct is "inherently suspect," (2) indirect evidence that concerted action is anticompetitive, and (3) direct evidence of anticompetitive conduct.[20] 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.

optometry board were separate legal entities capable of conspiring to violate the antitrust laws, was a particularly useful analogy for the FTC.[24]

The ALJ found that Board members were required by the Dental Practice Act to be licensed and actively engaged in the practice of dentistry in order to serve on the Board. Further, the ALJ noted that during the relevant time period, a majority of the dentist Board members earned revenue from teeth whitening services. However, the ALJ rejected the FTC's argument that the anticompetitive conduct of individual Board members was attributable to the Board under an agency theory and therefore not the product of collective action. The ALJ cited various cases for the proposition that direct evidence of concerted action was not necessary and that circumstantial evidence could prove concerted action.[25] In finding concerted action, the ALJ relied on the numerous cease and desist letters issued by the Board from 2006 to 2009, a period of time in which the composition of the Board's dentist members changed. The ALJ also noted that the content of the various letters, spanning approximately three years, was very similar. The ALJ concluded that the frequency and consistency was evidence of an agreement among Board members to stifle competition in the teeth whitening service market. The Commission went further and found that discussions at Board meetings of how to stop non-dentists from providing teeth whitening services constituted "direct evidence demonstrating that the dentist members of the Board had a common plan to exclude non-dentist teeth whitening providers from the market."[26]

Market Definition

Product market definition was highly contested at trial. There are four methods for teeth whitening: (1) in-office dentist service; (2) take-home kits provided by a dentist; (3) non-dentist in-person service; and (4) over-the-counter do-it-yourself kits. The Board argued that all four methods were part of the relevant market, but the ALJ found that the relevant market consisted only of in-person service, whether offered by a dentist or non-dentist, based largely on the fact that only those methods achieved teeth whitening virtually immediately while at-home teeth whitening kits required use over a period of weeks or months to achieve the desired results.[27]

Before the Commission, however, it appears that the parties agreed that all four methods constituted the relevant product market and as a result the Commission declined to consider whether the ALJ was correct in finding a narrower relevant market.[28] Both the ALJ and Commission found that the Board had market power in the relevant market as a result of its power to exclude competition within that market.[29] This power was derived both from the Board's authority to license and regulate dentists under the Dental Practice Act, but also the perception among non-dentists that the Board could exclude them from engaging in

[24] *See* In re Mass. Bd. of Optometry, 110 F.T.C. 549, 610-11 (1988).

[25] *See* Am. Tobacco Co. v. United States, 328 U.S. 781 (1946); Norfolk Monument Co. v. Woodlawn Mem. Gardens, Inc., 394 U.S. 700 (1969); Alvord-Polk v. F. Schumacher & Co., 37 F.3d 996 (3d. Cir. 1994).

[26] Comm'n Op., *supra* note 3, at 17.

[27] *See* Initial Decision, *supra* note 3, at 24-33 (ALJ's discussion of the relevant market).

[28] Comm'n Op., *supra* note 3, at 29-30.

[29] The Commission found that the Board waived any dispute over whether it possessed market power by failing to raise the issue in its opening brief. *See id.* at 30 n.19.

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; (3) it acted in "good faith"; and (4) its actions protected the public from an inferior product.[31]

Citing the Supreme Court's opinion in *National Society of Professional Engineers*,[32] the ALJ swiftly rejected the inferior product justification, stating that it amounted to a claim that competition itself was harmful.[33] Respondent did not raise this justification in its appeal before the Commission.

Both the Commission and the ALJ spent the most time rejecting the Board's public welfare justification. Both found that precedent, including the Supreme Court's decisions in *National Society of Professional Engineers* and *Indiana Federation of Dentists*,[34] required the rejection of this defense.[35] The ALJ ended its inquiry here, but the Commission rejected the justification on the additional grounds that there was no clinical evidence of public safety risk from non-dentists providing teeth whitening service. The Commission also noted that the means by which the Board sought to protect the public were not within the Board's authority.

As to the claim that the Board was promoting "legal" competition, both the ALJ and Commission quickly turned aside this justification relying on Supreme Court precedent that rejected similar assertions.[36] Both also noted that no North Carolina court has ever held that non-dentist teeth whitening violates state law.

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[30] Comm'n Op., *supra* note 3, at 29-32; Initial Decision, *supra* note 3, at 81-104 (discussion of anticompetitive effects).

[31] Comm'n Op., *supra* note 3, at 23-29, 32-33; Initial Decision, *supra* note 3, at 105-110 (discussion of pro-competitive justifications). The ALJ refused to consider an additional justification proffered by the Board—that its actions were not "unreasonable" because it was only trying to protect citizens of North Carolina from the unauthorized practice of dentistry. The ALJ found the argument to be "essentially a reiteration" of the Board's state action defense, which the Commission had already rejected, as discussed above.

[32] Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679 (1978).

[33] Initial Decision, *supra* note 3, at 108-109.

[34] FTC v. Ind. Fed'n of Dentists, 476 U.S. 447 (1986).

[35] Comm'n Op., *supra* note 3, at 33.

[36] *See* FTC v. Ind. Fed'n of Dentists, 476 U.S. 447 (1986); Fashion Originators' Guild of Am., Inc. v. FTC, 312 U.S. 457 (1941).

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.

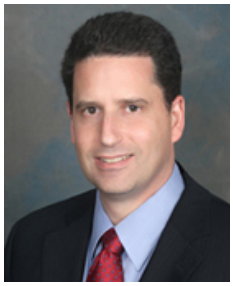
Conclusion

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] Comm'n Op., *supra* note 3, at 28; *see also* FTC v. Ind. Fed'n of Dentists, 476 U.S. 447 (1986); Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679 (1978); Va. Acad. of Clinical Psychologists v. Blue Shield of Va., 624 F.2d 476 (4th Cir. 1980); Wilk v. Am. Med. Ass'n, 719 F.2d 207 (7th Cir. 1983).

Abuse of the FDA Citizen Petition Process: Ripe for Antitrust Challenge?

By Seth C. Silber,[1] Jonathan R. Lutinski,[2] and Rachel A. Taylon[3]



Introduction

Several antitrust challenges have arisen in the context of brand name pharmaceutical companies blocking or delaying the introduction of generic pharmaceuticals through manipulation of FDA regulatory processes. Improperly impeding generic entry potentially costs American consumers billions of dollars, as it is estimated that generic drug use has saved consumers $931 billion over the last 10 years.[4] With billions of dollars at stake, generic firms have alleged, with varying success, that their branded counterparts have used a number of different strategies to keep lower-priced generics out of the market in order to prolong exclusivity for their branded drug products.

For example, generic firms have alleged that brand companies have improperly listed patents—that do not, in fact, cover the drug product that they purport to cover—in the FDA's publication commonly referred to as the "Orange Book."[5] The Orange Book is the FDA's official listing of drugs, including the patents that could be infringed upon by an ANDA applicant seeking to market a generic version of the branded product.[6] Regardless of whether an Orange Book listing is proper (i.e.,

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[4] *See* "The Generic Pharmaceutical Industry—Improving Lives For Less," The Generic Pharmaceutical Association (2011), *available at* http://www.gphaonline.org/about-gpha/about-generics/case/generics-providing-savings-americans.

[5] *See, e.g.*, In re Buspirone Patent Litig., 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) (concerning whether Bristol-Meyers-Squibb (BMS) made false filings with the FDA that caused BMS's patents to be wrongfully listed in the Orange Book in an effort to obstruct generic competition).

[6] The official name for the "Orange Book" is the "Approved Drug Products List with Therapeutic Equivalence Evaluations." It is available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

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, citizen petitions also have the serious potential to delay and/or impede competition from lower-priced generic alternatives. For example, a party could embark on a strategy of filing baseless citizen petitions with the intent and effect of using the time in which it takes the FDA to respond to the petition (i.e., the *process*, rather than the *outcome*) to delay generic entry. Additionally, citizen petitions can also be used in conjunction with other exclusionary strategies, such as product hopping, to thwart generic entry. For example, a branded firm could file a citizen petition in an effort to "buy time" to shift the market to a new formulation of the branded product, impeding generic entry on the previous formulation.

[12] 21 C.F.R. 10.30; FDCA § 505(j).

[13] FDCA § 505(q)(1)(H).

Enactment of the Food and Drug Administration Amendments Act (FDAAA)

In part to deal with the potential anticompetitive abuse of the citizen petition process, Congress passed the FDAAA, which was enacted on September 27, 2007.[14] The FDAAA adds new section 505(q) to the Federal Food, Drug, and Cosmetic Act (FDCA) and governs certain citizen petitions and petitions for stay of FDA agency action. Importantly, Section 505(q)(1)(A) provides that the FDA may not delay approval of an ANDA application because of any request to take any form of action related to the pending ANDA unless "a delay is necessary to protect the public health."[15] Moreover, the FDAAA authorizes the FDA to summarily deny any citizen petition whose primary purpose, as determined by the FDA, is to delay competition.[16]

In a report issued in June 2011, the FDA provided additional guidance on how it determines whether approval of an ANDA application may be delayed based on the filing of a citizen petition.[17] For example, if the petition cannot be summarily denied on its face, the FDA will use a "but for" test in determining whether the petition would be the cause of a delay for approval of a particular ANDA. If,

[14] Public Law 110-85 (as amended by Public Law 110-316).

[15] FDCA § 505(q)(1)(A).

[16] 21 USC 355(q)(1)(E) states, "If the Secretary determines that a petition … was submitted with the primary purpose of delaying the approval of an [ANDA] and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination…"

[17] FDA, Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug and Cosmetic Act (June 2011) [hereinafter FDA Guidance].

regardless of the petition, the ANDA *would not* be ready for final approval, then section 505(q)(1)(A) would not be implicated.[18] If, however, the ANDA *would* be ready for approval but for the petition, then the FDA will next determine if a delay of final approval is necessary to protect the public health.[19] If so, the Agency will delay the ANDA application until the public health concern is resolved. Finally, regardless of whether the FDA determines a delay is necessary to protect public health, the FDA will take final agency action on the petition within 180-days.[20]

To help assess whether the FDAAA effectively curbs abuses in the citizen petition process, Section 505(q)(3) requires the FDA to submit an annual report to Congress. That annual report provides relevant data on petitions covered by the provisions of the Act and whether these petitions have delayed approval of pending ANDA applications.[21] In its 2009 Report provided to Congress on July 29, 2010, the FDA stated that "[a]lthough FDA now has 2 years of experience implementing section 505(q), it believes it may still be too early to make a determination as to whether section 505(q) is effectively discouraging petitions submitted with the primary purpose of delaying approval of an ANDA or 505(b)(2) application."[22] The FDA 2010 report to Congress under 505(q)(3) has not yet been issued.

While the enactment of the FDAAA will likely curb some of the most egregious abuses of the citizen petition process (i.e., delays of 1-2 years while the brand files a series of successive and baseless citizen petitions as in *Flonase* discussed below),[23] there is still some potential for the anticompetitive use of citizen petitions to delay generic competition. For example, a carefully crafted citizen petition, drafted by a party with sophisticated regulatory counsel, may be able to successfully attempt to implicate issues relating to public health—such as "whether a proposed generic drug product is bioequivalent to the reference listed drug" or "whether an indication can be safely omitted from the labeling because that indication is protected by a patent"[24]—as a pretext to delay generic entry under 505(q).

Moreover, certain types of petitions are specifically exempted from the FDAAA. Notably, the FDAAA does not apply to petitions that "relate solely to the timing of approval of an application pursuant to the 180-day exclusivity provision at section 505(j)(5)(B)(iv) of the Act."[25] In addition, pursuant to the FDA guidance issued earlier this year, Section 505(q)

[18] FDA Guidance at 8.

[19] *Id*. In determining if public health is at issue, the agency considers "[i]f the application were approved before the Agency completed the substantive review of the issues in the petition and, after further review, the Agency concluded that the petitioner's arguments against approval were meritorious, could the presence on the market of drug products that did not meet the requirements for approval negatively affect the public health?"

[20] FDA Guidance at 3 (discussing Section 505(q)(1)(F)).

[21] FDCA § 505(q)(3).

[22] FDA Report to Congress, "Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2009," (Jul. 29, 2010) *available at* http://www.hpm.com/pdf/FDA%20FY2009%20505q%20CP%20Report.PDF.

[23] According to the FDA's reports to Congress, only two ANDAs were delayed by 505(q) petitions from September 27, 2007 through September 30, 2008 and only one ANDA was delayed by a 505(q) petition from October 1, 2008 through September 30, 2009. *Id. See also* FDA Report to Congress, "Delays in Approvals of Applications Related to Citizen Petitions and Petition for Stay of Agency Action for Fiscal Year 2008," (Apr. 28, 2009).

[24] FDA Guidance at 8.

[25] FDCA § 505(q)(4).

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 realistically expect success on the merits." However, to the extent that "an objective [party] could conclude that the [petition] is reasonably calculated to elicit a favorable outcome, the [petition] is immunized under *Noerr*, and an antitrust claim premised on the sham exception

[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.*

[27] E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961). *See also* United Mine Workers v. Pennington, 381 U.S. 657 (1965).

[28] Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993) [hereinafter PRE].

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 way to impede generic entry and maintain and extend their monopoly power. In these cases, plaintiffs allege that the branded companies pursued baseless petitioning activity for which the singular goal was to impede competition, rather than to influence the FDA to take action. These cases are discussed in more detail below.

In re DDAVP Direct Purchaser Antitrust Litigation

On February 18, 2005, direct and indirect purchasers (collectively, "Plaintiffs") of DDAVP (desmopressin acetate tablets), an antidiuretic prescription medication, filed complaints against Ferring B.V., Ferring Pharmaceuticals, Inc. (collectively "Ferring"), and Aventis Pharmaceuticals, Inc.[30] The complaints alleged that Ferring, the owner of U.S. Patent No. 5,047,398 ("'398 patent"), which claims to cover DDAVP, and Aventis, the marketer and NDA-holder for DDAVP (collectively, "Defendants"), unlawfully monopolized the market for desmopressin tablets by: (1) committing fraud or inequitable conduct on the PTO in procuring the '398 patent; (2) improperly listing the '398 patent in the Orange Book; (3) filing and prosecuting a patent infringement action against Barr Laboratories and Teva Pharmaceuticals, who had each filed ANDAs for desmopressin; and (4) filing a sham citizen petition with the FDA to further delay approval of generic desmopressin. The crux of the Plaintiffs' complaint was that lower-priced generic entry was significantly delayed as a result of Defendants' anticompetitive acts.

Ferring's citizen petition, filed on February 2, 2004 while Ferring was prosecuting its patent infringement suit against Barr, requested that the FDA require Barr to submit additional testing to demonstrate bioequivalence to DDAVP.[31] Specifically, Ferring wanted the FDA to require Barr to conduct and submit more tests—pharmacodynamic ("PD") studies measuring urine osmolarity—in order for Barr to establish the bioequivalence of Barr's desmopressin product to DDAVP. Ferring claimed that the conventional PK bioequivalence tests did not adequately address safety and efficacy of oral desmopressin therapy for nocturnal enuresis in children. On July 1, 2005, FDA rejected Ferring's citizen petition. The FDA stated that Ferring "offer[ed] no convincing evidence (i.e. data or other information) that any of [its] proposed changes were needed" and denied Ferring's petition in its entirety.[32]

In dismissing all claims by the direct and indirect purchasers of DDAVP, the district court

[29] *Id.*

[30] Complaint, Meijer, Inc. et al. v. Ferring B.V. et al., No 7:05-cv-02237 (S.D.N.Y. Feb. 18, 2005).

[31] *See* Ferring B.V. v. Barr Labs., Inc., No. 7:02-CV-9851, 2005 WL 437981, at 10 (S.D.N.Y. Feb. 7, 2005); Ferring B.V. v. Barr Labs. Inc., 437 F.3d 1181 (Fed. Cir. 2006).

[32] *See* FDA Letter Rejecting Ferring Citizen Petitions (July 1, 2005) [hereinafter "Ferring FDA Rejection Letter"] at 2.

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

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[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.*

competition to Arava was delayed from March 2005 to September 2005, or a period of at least 5 months.[37]

In denying Aventis' motion to dismiss,[38] the court found that Aventis' conduct could fall within the "sham" exception to *Noerr-Pennington* immunity. The court found persuasive the arguments of Louisiana Wholesale, specifically that Aventis as a sophisticated pharmaceutical manufacturer familiar with FDA regulations and practices could have had no reasonable belief that its citizen petition was viable. Indeed, Aventis had in the past referred to other drugs and strengths on its own generic and brand labels when Aventis itself did not manufacture either the drug or the strength indicated.

However, after a full trial on the merits, the jury unanimously sided with Aventis.[39] Additionally, Louisiana Wholesale's motion for a reversal of the verdict or new trial was denied.[40]

In re Flonase Antitrust Litigation

Flonase, previously one of the nation's top-selling drugs, is a steroid nasal spray produced by Defendant SmithKline Beecham Corporation (later known as GlaxoSmithKline or GSK) with the active ingredient fluticasone propionate. Roxane Laboratories (a generic manufacture of Flonase), and indirect and direct purchasers of Flonase all filed suit claiming that GSK filed a series of sham citizen petitions in order to delay the entrance of Roxane Laboratories' generic Flonase.[41]

In 1994, the FDA approved the NDA for GSK's Flonase nasal spray for sale within the United States. After a six-month extension, GSK's exclusive right to market Flonase in the United States ended on April 14, 2004. In the meantime, Roxane Laboratories filed an ANDA seeking approval to market an AB-rated generic version of Flonase in October of 2002.

During the period of May 2004 through June 2005, GSK made a series of petitions to the FDA regarding the FDA's approval of ANDAs for Flonase. On February 22, 2006, the FDA responded with a 24-page letter rejecting GSK's entire series of petitions stating, among other things, that "GSK is not permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved."[42] The same day the FDA issued this determination to GSK, it approved Roxane Laboratories' ANDA for Flonase. Moreover, after receiving this rejection letter, GSK filed suit in Maryland asking for a temporary restraining order ("TRO") and preliminary injunction seeking to

[37] Complaint at 7, LA Wholesale Drug Co., Inc. v. Sanofi-Aventis, No. 07-cv-7343 (S.D.N.Y. Aug. 17, 2007).

[38] *See* LA Wholesale Drug Co., Inc. v. Sanofi-Aventis, No. 07-cv-7343(HB), 2008 WL 169362, 1 (S.D.N.Y. Jan. 18, 2008) (motion to dismiss); LA Wholesale Drug Co., Inc. v. Sanofi-Aventis, No. 07-cv-7343(HB), 2008 WL 4580016, (S.D.N.Y. Oct. 14, 2008) (summary judgment).

[39] Judgment, LA Wholesale Drug Co., Inc. v. Sanofi-Aventis, No. 07-cv-7343 (S.D.N.Y. Dec. 9, 2008).

[40] LA Wholesale Drug Co., Inc. v. Sanofi-Aventis, 2009 U.S. Dist. Lexis 77208 (S.D.N.Y. 2009).

[41] The three suits are: (1) direct purchasers of Flonase in *American Sales Co., Inc. v. SmithKline Beecham Corp.*, No. 08-cv-3149 (E.D. Pa. July 3, 2008); (2) indirect purchasers of Flonase in *IBEW-NECA Local 505 Health & Welfare Plan v. SmithKline Beecham Corp.*, No. 08-cv-3301 (E.D. Pa. July 14, 2008); and (3) a generic manufacturer of FP in *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, No. 09-cv-1638 (E.D. Pa. April 17, 2009). The suits are grouped up under *In re Flonase Antitrust Litig.* [hereinafter Flonase Litig.].

[42] FDA Letter Rejecting GSK Citizen Petitions at 24 (Feb. 22, 2006) [hereinafter "GSK FDA Rejection Letter"], *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2004-P-0152-0005.

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 fulfill the second, subjective prong necessary to demonstrate sham petition. Thus, the only issue at hand was whether GSK's conduct was "objectively baseless" in that GSK could not realistically expect its petitions to succeed. In reasoning through each of the series of six citizen petitions filed by GSK, the court found that genuine issues of material fact remained as to whether GSK's conduct was objectively baseless and therefore constituted a "sham."

In *Request 1*, GSK requested the FDA to refrain from approving ANDAs prior to issuing final guidance on nasal aerosols and nasal sprays and a statistical appendix.[44] The court responded that this request could be objectively baseless based on evidence that the FDA is not obligated to issue any guidance and ANDA applicants are not required to use the guidance. Additionally, in regard to issuing the statistical appendix, this request is often impossible as the FDA often lacks data to do so. The FDA also rejected this request, explaining that it "is desirable" to issue the final guidance before ANDA approval but "it is not always possible" to do so.[45]

In *Request 2*, GSK requested the FDA require ANDAs to include data from perennial allergic rhinitis (PAR) and perennial non-allergic rhinitis (PNAR) studies.[46] The court reasoned that genuine issues of fact remain as FDA guidance cannot require ANDA applicants to perform specific tests unless the tests are required by law. Additionally, the FDA rejected this request stating that there is no reason that drug performance would be different in PNAR or PAR patients.[47]

In *Request 3*, GSK requested the FDA to require pharmacokinetic data to be collected over the entire dosage interval of in vivo tests.[48] The court stated that this petition could be a sham by pointing both to the FDA's rejection letter stating that four consecutive samples during the dosage are sufficient and to expert evidence stating the same.[49]

In *Request 4*, GSK requested the FDA to reconsider its in vitro test for plume geometry

[43] *See* Flonase Litig., *supra* note 41.

[44] In 1999 the FDA issued a draft guidance entitled *Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action* [hereinafter *2003 Draft Guidance*]. This guidance was amended in 2003, but was never finalized.

[45] GSK FDA Rejection Letter, *supra* note 42, at 22.

[46] The FDA approved Flonase to treat the nasal symptoms of seasonal allergic rhinitis (SAR), PAR and PNAR. The *2003 Draft Guidance* provided that an ANDA could be approved to treat all three indications even if the application only included data from SAR patients.

[47] GSK FDA Rejection Letter, *supra* note 42, at 12.

[48] The FDA analyzes pharmacokinetic data generated from a single dose treatment over time. The *2003 Draft Guidance* required an applicant to take measurements at least four consecutive times during the dose interval.

[49] GSK FDA Rejection Letter, *supra* note 42, at 13-14 ("FDA believes that four consecutive sampling times using the maximum clinical dose is sufficient to detect whether two [FP] nasal spray suspension products [are bioequivalent.]").

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 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 *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.

of the citizen petition. Courts have reasoned that a NDA holder filing a citizen petition on the eve of an ANDA approval can be suspect.

For example, in *Louisiana Wholesale* discussed above, the court seemed to suggest that the timing of the petition was a factor in determining whether it was a sham. In deciding whether triable issues of fact existed with respect to the "reasonability and viability" of Aventis's citizen petition, the court held that additional discovery may clarify the circumstances surrounding Aventis' filing "one year after the generic manufacturers submitted their ANDAs for FDA approval when no new health and safety information on the loading dose or leflunomide in general and no new FDA regulations on labeling had occurred." Although it would seem that the timing would be more probative in determining the brand's subjective state of mind in filing a citizen petition (i.e., whether the petition raise legitimate safety issues or was intended as a vehicle to delay generic entry), it appears that the court considered this as part of the threshold question of whether the petition was objectively baseless.

Additionally, in *Flonase* the court noted that GSK did not file its first citizen petition until 2004, on the eve of potential generic entry and approximately two years after Roxane Laboratories had filed its ANDA application. Indeed, as the plaintiffs complained, "… just days after the expiration of the statutory exclusivity period for GSK's Flonase, and on the eve of what could have been the FDA's approval of Roxane Laboratories' ANDA, GSK filed the first in a series of objectively baseless citizen petitions…"[63]

[63] Complaint of Roxane Laboratories, Inc. at 7, Roxane Labs., Inc. v. SmithKline Beecham Corp., No. 09-cv-1638 (E.D. Pa. April 17, 2009) [hereinafter "Roxane Compl."].

Relief Requested Contrary to FDA Regulations and Practice

Another significant factor is whether the party filing the citizen petition made requests for relief with the FDA that were contrary to FDA regulations and practice. Arguments made by sophisticated parties in the face of clear and contradictory FDA regulations may provide further evidence of an objectively baseless petition.

For example, in rejecting Aventis' motion for summary judgment, the *Louisiana Wholesale* court found it significant that Aventis' citizen petition requested relief that it knew was contrary to FDA regulations and practice. First, Aventis demanded that generic manufacturers produce their own 100 mg tablets in order to succeed with their ANDAs, but Aventis knew that the FDA permitted generics to receive approval for some—but not all—dosage strengths of a branded drug, and cited nothing to contrary. Second, Aventis demanded that if the generics tried to substitute five 20 mg tablets to achieve the loading dose, they had to demonstrate bioequivalence between those tablets and the 10 mg tablet. But again, Aventis knew it was not required to establish bioequivalence between different dosage strengths of the same drug. Finally, Aventis insisted that the generics not be able to reference the 100 mg loading dose in the label, but Aventis knew that the FDA permitted manufacturers to cross-reference other drugs or other dosages because it did so in two other instances. Not only did Aventis cross-reference other drugs in manufacturing other brands and generics, but also, with respect to its own authorized generic leflunomide product, Aventis did not produce a generic 100 mg loading dose and referenced the brand tablet in the label.

In *Flonase*, the plaintiffs contended that GSK's requests did not address the adequacy of Roxane

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.

To the extent that the FDAAA does not fully reign in the anticompetitive use of citizen petitions, there are several examples of cases filed in recent years that have survived dispositive motions—bypassing *Noerr-Pennington* immunity and proceeding through discovery—based on this conduct. Synthesizing those cases, it is apparent that several of the "plus" factors described above are predictive of whether a monopolization claim based on the manipulation of the FDA regulatory process through the filing of baseless citizen petitions is likely to be viable. While only time and continued monitoring of the FDAAA will tell whether these types of abuses are likely to be eradicated in the future, it is clear that potential plaintiffs pursuing these types of claims should emphasize these "plus" factors in any prospective litigation.