

American Bar Association

AR SECTION OF

ANTITRUST LAW

# Chronicle

Health Care and Pharmaceuticals Committee Newsletter

### 💳 Chair's Report 💻

### Seth C. Silber, Washington, D.C.

As usual, the Health Care and Pharmaceuticals Committee remains active in presenting programs across the health care and pharmaceutical spectrum. Below is a description of some recent and future programs.

- Consistent with the Antitrust Section's enhanced focus on consumer protection issues, we recently conducted a program on marketing issues relating to dietary supplements entitled "Recent Developments in Dietary Supplement Regulation, Enforcement & Litigation." The program was organized and moderated by Committee Vice-Chair Amy Mudge, and featured Michael McGuffin (President, American Herbal Products Association), Mark Levine (Senior Attorney, National Advertising Division of the Better Business Bureau), Trent Norris (Arnold & Porter), and Katie Bond (Kelley Drye & Warren). The program was a big success, and hopefully the first of many forays into the area of consumer protection. If you missed the program, audio is available on the Antitrust Section's website the (http://www.abanet.org/antitrust/at-bb/audio/09/01-09.shtml) and extensive written presentations are available well as (http://www.abanet.org/antitrust/at-committees/at-hcic/programs.shtml). А summary of the program will also be available in the next issue of the Chronicle.
- As part of our ongoing cooperation with various law schools, we are presenting "Practicing Law In A Dynamic Environment: The Case of Biologics" in conjunction with the Boston University School of Law. This program will describe ongoing regulatory and technical changes in markets for "biopharmaceuticals" or "biologics" in the US and Europe, and discuss the problems that these dynamics raise for counsel who are asked to advise clients about the legality of particular competitive conduct. Vice-Chair Phil Nelson conceived of and organized this program. It will be moderated by Fran Miller, N. Neal Pike Scholar and Professor of Law at Boston University. Panelists will include: Elizabeth Jex (FTC), Kenneth Cohen (Goodwin Procter), Linda Horton (Hogan & Hartson), and Bruce Leicher (Senior VP and GC of Momenta Pharmaceuticals). The program will take place on the Boston University campus on February 19th starting at 12:45. To register to attend in person please email Dawn Higgins at higgins.d@ei.com; or to register to dial-in please check our Committee program page for the flyer (http://www.abanet.org/antitrust/at-committees/at-hcic/programs.shtml).
- Finally, please join us at the Spring Meeting on March 25th at 3:45 for our Committee's program entitled "Health Care Mergers and Collaborations-Is Enforcement Sufficiently Protecting Consumers." This program will be moderated by Mark Botti (Akin Gump), and feature the following panelists: Josh Soven (DOJ), Mindy Hatton (American Hospital Association), Bob Bloch (Mayer Brown), and Cory Capps (Bates White).

As you can see, our programming calendar is quite full. However, we are always looking for new ideas for future programs. Please feel free to contact me (202-973-8824 or <u>ssilber@wsgr.com</u>) if you have any ideas, or would otherwise like to get involved in our Committee's activities.

### Editors' Report

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### Christi Braun, Washington, D.C.

Using two recent Federal Trade Commission ("FTC") settlements as case studies, the opening article of this issue of the <u>Chronicle</u> provides excellent guidance for readers regarding generic drug mergers and the FTC's analyses thereof. Drawing on their knowledge and experience, authors Steve Bernstein and Jeff White review the recent Teva/Barr and Sun/Taro mergers and the FTC's settlements with the parties.

If you missed our committee's teleconference in October regarding the convergence of health care competition policy in the United States and Europe, the second article will provide the highlights. Adrienne Van Winkle summarizes the panelists' presentations, as well as their moderated discussion.

The third article, which is by Economist Caterina Nelson, focuses on the recent Norvir antitrust cases. Dr. Nelson provides a detailed discussion of the litigation history and the questions that the litigation raises. Although the article focuses on the controversy surrounding one company's drugs, the story is one from which lessons can be learned.

Readers interested in our upcoming program on biologics at Boston University will note with interest the final article, which summarizes the panel presentations at the FTC's recent workshop on Follow-on Biologics. Valentina Rucker and Jacob Wolman capture for readers the contrasting views of the panelists on the pressing topics of the day.

The next issue of the <u>Chronicle</u> will feature an interview with Josh Soven, Chief of the Antitrust Division's Litigation I Section. In case you missed "Recent Developments in Dietary Supplement Regulation, Enforcement & Litigation" and aren't able to listen to the recording, you'll be able to read a summary of the program in the next issue, as well.

If you have ideas for articles, or would like to write an article, concerning pharmaceutical or health care antitrust topics (foreign or domestic), please contact me at <u>cibraun@ober.com</u> or (202) 326-5046, or my co-editor Tracy Weir at teweir@hhlaw.com or (202) 637-8873.

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### Generic Drug Merger Enforcement in 2008



Over the past five years, a wave of consolidation has occurred in the generic drug industry and the Federal Trade Commission ("FTC") has taken enforcement actions in a number of transactions.<sup>3</sup> In 2008, the FTC reviewed and took enforcement actions in two additional transactions involving generic drug (i) Sun Pharmaceutical companies: Industries Ltd.'s ("Sun") proposed \$454 million acquisition of Taro Pharmaceutical Industries Ltd. ("Taro"),<sup>4</sup> and (ii) Teva Pharmaceutical Industries Ltd.'s ("Teva") \$8.9 billion acquisition of Barr Pharmaceuticals Inc. ("Barr").<sup>5</sup> The FTC's actions with respect to these two transactions, along with the prior body of FTC enforcement in the generic drug industry, provide useful information for antitrust counsel regarding the antitrust issues that may arise in future generic drug mergers. In this article, we summarize the consent orders accepted by the FTC in these two recent transactions and provide additional practice pointers in connection with federal antitrust review of generic drug mergers.

#### I. Recent Generic Drug Transactions

The FTC's recent enforcement actions in Sun/Taro and Teva/Barr demonstrate its commitment to closely reviewing generic By Steven K. Bernstein, Esq.<sup>1</sup> Jeff L. White, Esq.<sup>2</sup> Weil, Gotshal & Manges LLP



drug mergers and requiring divestitures or other remedies intended to protect consumers of generic pharmaceuticals.

### A. Sun/Taro

On August 13, 2008, the FTC announced that it had accepted a consent order to resolve antitrust concerns raised by Sun's proposed \$454 million acquisition of Taro.<sup>6</sup> The consent order required Sun to divest all of its rights and assets necessary to manufacture and market three generic drugs: (i) immediate-release carbamazepine tablets, (ii) chewable carbamazepine tablets, and (iii) extendedrelease carbamazepine tablets.<sup>7</sup>

According to the FTC, carbamazepine is an anti-convulsant used primarily as an antiepileptic drug to prevent and control seizures.<sup>8</sup> In the U.S. market for generic immediate-release carbamazepine tablets, the FTC found that Taro, Teva, and Sun were the only significant suppliers, with Taro accounting for approximately half of the relevant market.9 In the market for generic chewable carbamazepine tablets, the FTC found that Teva was the leading supplier and accounted for approximately 65 percent of sales, followed by Taro and Sun.10 In the market for generic extended-release carbamazepine tablets, the FTC found that Sun and Taro were the only two companies

anticipating approval from the FDA to manufacture and market a generic version in the U.S.<sup>11</sup> To resolve its antitrust concerns in these three markets, the FTC accepted a consent order that required Sun to divest its products to Torrent Pharmaceuticals Ltd., or an alternative Commission-approved buyer.<sup>12</sup>

### B. Teva/Barr

On December 19, 2008, the FTC announced that it had accepted a consent order in connection with Teva's proposed \$8.9 billion acquisition of Barr, requiring divestitures of generic drug products in 29 markets.<sup>13</sup> According to David Wales, Acting Director of the FTC's Bureau of Competition, "Teva and Barr are direct and significant competitors for a large number of generic drugs that many Americans use on a daily basis, [and the divestitures] will ensure that the markets for these vital drugs remain competitive and consumers are not forced to pay higher prices, or even forego treatment, as a result of this deal."<sup>14</sup>

The markets in which the FTC required divestitures include generic: (1) tetracycline hydrochloride capsules, (2) chlorzoxazone tablets, (3) desmopressin acetate tablets, (4) metoclopramide hydrochloride tablets, (5) carboplatin injection, (6) tamoxifen citrate tablets, (7) metronidazole tablets,

9 A fourth supplier, Apotex, had a share of 1 percent. See id.

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<sup>&</sup>lt;sup>2</sup> Jeff L. White is an associate in the Washington, D.C. office of Weil, Gotshal & Manges LLP.

<sup>&</sup>lt;sup>3</sup> See Steven K. Bernstein & Jeff L. White, Generic Drug Merger Enforcement: A Guide for Antitrust Practitioners, ANTITRUST HEALTH CARE CHRONICLE, Oct. 2005, at 7; Steven K. Bernstein & Jeff L. White, Recent FTC Enforcement Trends in Generic Drug Mergers, ANTITRUST HEALTH CARE CHRONICLE, Mar. 2007, at 2. In addition, the authors comprehensively analyzed the FTC's enforcement of generic drug mergers over the last 15 years. Steven K. Bernstein & Jeff L. White, Federal Antitrust Review of Generic Drug Mergers: A Proposal for a More Flexible Approach, 4 NYU J. Law & BUS. 465 (2008).

<sup>&</sup>lt;sup>4</sup> Sun Pharm. Indus. Ltd., Docket No. C-4230 (consent order issued Sept. 19, 2008) [hereinafter Sun/Taro], available at http://www.ftc.gov/os/caselist/0710193/index.shtm.

<sup>&</sup>lt;sup>5</sup> Teva Pharm. Indus. Ltd. and Barr Pharm., Inc., File No. 081-0224 (proposed consent order issued Dec. 18, 2008) [hereinafter Teva/Bari], available at http://www.fic.gov/os/caselist/0810224/index.shtm.

<sup>&</sup>lt;sup>6</sup> Press Release, Fed. Trade Comm'n, FTC Challenges Sun Pharmaceuticals' Purchase of Taro Pharmaceutical Industries (Aug. 13, 2008), <u>http://www.ftc.gov/opa/2008/08/suntaro.shtm</u> [hereinafter Sun/Taro Press Release].

<sup>&</sup>lt;sup>7</sup> Sun/Taro, Decision and Order, available at http://www.ftc.gov/os/caselist/0710193/080919sunpharmdo.pdf.

<sup>8</sup> Sun/Taro, Analysis of Agreement Containing Consent Orders to Aid Public Comment, available at <a href="http://www.ftc.gov/os/caselist/0710193/080813sunpharmanal.pdf">http://www.ftc.gov/os/caselist/0710193/080813sunpharmanal.pdf</a>.

<sup>&</sup>lt;sup>10</sup> Cadista, the only other approved supplier of generic chewable carbamazepine tablets, was not supplying the product at the time of the FTC's investigation. Id.

<sup>&</sup>lt;sup>11</sup> Id.

<sup>12</sup> Id.

<sup>&</sup>lt;sup>13</sup> Press Release, Fed. Trade Comm'n, FTC Intervenes in Teva Pharmaceutical Industries' Proposed \$8.9 Billion Acquisition of Barr Pharmaceuticals (Dec. 19, 2008), <u>http://www.ftc.gov/opa/2008/12/tevabarr.shtm</u> [hereinafter Teva/Barr Press Release].

trazodone hydrochloride tablets, (8) (9) glipizide/metformin hydrochloride tablets, (10) cyclosporine liquid, (11) cyclosporine capsules, (12) flutamide capsules, (13) mirtazapine orally disintegrating tablets, (14)deferoxamine injection, (15) epoprostenol sodium (freeze-dried powder) injection ("epop"), (16) weekly fluoxetine capsules, and (17) thirteen oral contraceptive products.<sup>15</sup>

As noted, 13 of the 29 markets in which divestitures were required involved generic oral contraceptive products. In two of these markets (generic Ortho-Cyclen® and Ortho Tri-Cyclen<sup>®</sup>), the FTC found that the proposed acquisition would substantially lessen competition because Teva and Barr were two of only three active suppliers in the U.S.<sup>16</sup> In 10 of these markets (generic Ortho-Cept<sup>®</sup>, Mircette<sup>®</sup>, Triphasil<sup>®</sup>, Alesse<sup>®</sup>, OrthoNovum® 1-35, OthroNovum® 7/7/7, Loestrin<sup>®</sup> FE (1mg/.02 mg & 1.5 mg/.03 mg), Loestrin<sup>®</sup> FE (1mg/.2 mg), Loestrin<sup>®</sup> FE 24, and Ovcon<sup>®</sup> 35), Barr is an active supplier in the U.S. and Teva is developing a competing product.<sup>17</sup> The FTC concluded that the proposed acquisition would eliminate one of a limited number of firms capable of developing a competing product and well-positioned to enter the markets in a timely manner.<sup>18</sup> Finally, in one of the 13 markets (generic Ortho Tri-Cyclen<sup>®</sup> Lo 28), the FTC found that Teva and Barr were two of a limited number of firms developing this product.<sup>19</sup>

The 16 remaining markets involved products other than generic oral contraceptives. In three of these markets (generic tetracycline hydrochloride tablets, chlorzoxazone tablets, and desmopressin acetate tablets), the FTC found that Teva and Barr were the only companies manufacturing and selling products in the U.S. and that the proposed acquisition would create a monopoly in each of these markets.<sup>20</sup> In two of the 16 markets (tamoxifen citrate tablets and cyclosporine liquid), the FTC found that the proposed acquisition would substantially lessen competition by reducing the number of generic suppliers from three to two.<sup>21</sup> In nine of the 16 non-contraceptive markets (metoclopramide hydrochloride tablets, carboplatin injection, metronidazole tablets, trazodone hydrochloride tablets, cyclosporine flutamide capsules, capsules, glipizide/metformin hydrochloride tablets, deferoxamine injection, and mirtazapine orally disintegrating tablets), the FTC found that Teva and Barr were two of only four active competitors in the U.S. and that the transaction would reduce the number of competitors from four to three in each relevant market.22

In the final two markets (epop and fluoxetine weekly capsules), the FTC found that the proposed acquisition would eliminate important and significant future competition between Teva and Barr.<sup>23</sup> In the market for epop, Teva is currently the only active generic supplier in the U.S., and Barr had a generic epop product in development.<sup>24</sup> In the market for fluoxetine weekly capsules, the FTC stated that Teva and Barr both had generic products in development and that there are few firms capable of, or interested in, entering this market.<sup>25</sup>

In order to resolve its competition concerns in each of these 29 markets, the FTC required divestitures of—depending on the market— Teva's or Barr's rights and assets necessary to manufacture and market the generic products to Watson Pharmaceuticals, Inc. ("Watson") or Qualitest Pharmaceuticals Inc. ("Qualitest").<sup>26</sup>

### II. Analysis of the FTC Enforcement Actions

The FTC's past merger enforcement actions in the generic drug industry provide valuable insight into whether remedies will be required in future generic drug transactions. Antitrust counsel that know and understand the FTC's enforcement history in this area can advise generic drug clients more effectively and potentially help speed up the agency's review by knowing which arguments are likely to carry weight and The following section which are not. analyzes some of the key factors that the FTC considers when evaluating generic drug mergers and explains the potential impact of the recent FTC cases on future transactions.

### A. The Relationship Between Branded Drugs and Their Generic Equivalents

In every FTC enforcement action involving generic drug mergers since early 2003, the FTC has excluded the branded version of the drug from the relevant market consisting of its generic equivalents.<sup>27</sup> The FTC's recent trend to exclude the branded drug from the relevant market may, in part, stem from the results of its July 2002 study on the impact of generic entry on pharmaceutical prices.<sup>28</sup> In that study, the FTC found that the price of a generic drug tends to fall until at least the fifth generic competitor enters the market.<sup>29</sup> In addition, while generic entry tends to decrease the price of generic drugs in that market, it can also cause the price of the branded version of the drug to increase due to the inelastic demand among certain users of brand-name products.<sup>30</sup> Thus, ongoing generic entry can create a significant divergence in the price between the branded and generic versions of the product.

<sup>16</sup> Teva /Barr, Analysis of Agreement Containing Consent Orders to Aid Public Comment, available at <u>http://www.ftc.gov/os/caselist/0810224/081219analysis0810224.pdf</u>.

- <sup>17</sup> See id.
- <sup>18</sup> *Id.*
- <sup>19</sup> *Id.*
- <sup>20</sup> *Id*.
- 21 Id.
  22 Id.
- Id.
  Id.
  Id.
- -- IU. 24 Soo
- <sup>24</sup> See id.
- <sup>25</sup> See id.
- <sup>26</sup> Id.

<sup>27</sup> In Baxter International Inc.'s proposed acquisition of Wyeth, the FTC included the branded version in certain markets. See Baxter Int/Inc., 135 F.T.C. 49 (2003).

<sup>28</sup> See FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002) [hereinafter FTC Generic Drug Study], available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. In 1994, FTC Commissioner Deborah K. Owen stated that the question of whether or not a branded drug is in the same relevant product market as its generic counterparts may vary over time and depends on the relative price differential between the branded and generic versions. The Dow Chem. Co., Docket No. C-3533 (proposed consent agreement issued May 24, 1994), Concurring Statement of Commissioner Deborah K. Owen on Proposed Consent Agreement with Marion Merrill Dow Inc. (on file with FTC).

<sup>29</sup> FTC Generic Drug Study, *supra* note 28, at 9.

<sup>&</sup>lt;sup>15</sup> *Id.* 

In each of the generic drug merger enforcement actions since early 2003, the FTC has cited this price differential as a reason for excluding the branded version from the relevant market. For example, in analyzing Teva's proposed acquisition of IVAX in 2006, the FTC stated that "[b]ecause there are multiple generic equivalents for each of the products at issue here, the branded versions no longer significantly constrain the generics' pricing."<sup>31</sup>

Until recently, however, the FTC has not explicitly stated how many generic suppliers must be in the market before the branded drug is excluded from the relevant market because it no longer imposes a significant competitive constraint on its generic equivalents. The FTC's enforcement actions in 2008 marked the first time that the Commission has acknowledged in a consent order that the branded version is no longer considered to be a constraint on its generic counterparts once there are at least two generic suppliers in the market. For example:

- In *Sun/Taro*, the FTC stated that "[b]ecause there are at least two generic equivalents for each of the products at issue, the branded versions no longer significantly constrain the price of the generic drugs."<sup>32</sup>
- In *Teva/Barr*, the FTC stated that "[a]fter more than one generic product is introduced, competition among the generic competitors drives pricing, and the branded product's pricing largely becomes competitively irrelevant."<sup>33</sup>

The FTC's statements in these matters provide some clarity regarding its position on the relationship between branded drugs and their generic equivalents. These statements also may provide an opportunity for antitrust counsel to argue that, in markets with multiple generic competitors, an acquisition of rights in a generic version by a branded drug company would not raise significant antitrust concerns.

### B. Drug Delivery Method

The FTC's recent enforcement actions are consistent with its past tendency to define product markets narrowly based, in part, on a generic drug's form or delivery method. In *Sun/Taro*, each of the three markets in which enforcement actions were taken involved the generic anticonvulsant drug, carbamazepine.<sup>34</sup> Instead of challenging a broad market for all generic carbamazepine, the FTC found that there were narrower relevant markets for immediate-release tablets, extended-release tablets, and chewable tablets.<sup>35</sup>

In finding a separate market consisting of generic chewable carbamazepine tablets, the FTC explained that chewable tablets "come in a more convenient dosing form" than immediate-release tablets, "which makes them better-suited for pediatric, geriatric, and other patients who may have difficulty swallowing pills."<sup>36</sup> Similarly, the FTC found a separate market for generic extended-release carbamazepine tablets because they offer "the added convenience of a less frequent dosing regimen" relative to immediate-release tablets.<sup>37</sup>

Antitrust counsel advising generic drug clients should be mindful of a drug's delivery method when evaluating the antitrust implications of a proposed generic drug merger. Factors to consider in determining whether separate markets exist for different delivery methods include the relative pricing differentials between the different products, the convenience of the product relative to others, and the presence of any identifiable classes of patients that prefer or require certain delivery methods.

### C. Number of Competitors

The number of competitors active in the relevant market has traditionally been one of the most important factors in the FTC's analysis of generic drug mergers. With only a few exceptions, the FTC's generic drug enforcement actions to date have all been in markets with four or fewer pre-merger competitors. In a few limited cases, the FTC has challenged transactions in markets with five pre-merger competitors where certain "plus factors" have been present. These "plus factors" have included situations where other competitors in the markets were not fully competitive because they either did not supply all the formulations of a drug or otherwise were of limited competitive significance.<sup>38</sup> The FTC's willingness to bring challenges in certain generic drug markets with five pre-merger competitors likely stems from the above-mentioned July 2002 study on the effects of generic entry on pharmaceutical prices.<sup>39</sup>

In Teva/Barr, the FTC stated that "the proposed transaction would eliminate one of up to four competitors in each of the relevant markets."40 However, a closer review of the Commission's complaint reveals that there were actually five pre-merger suppliers in the market for generic metoclopramide hydrochloride tablets.<sup>41</sup> One of the five competitors, Actavis Group ("Actavis"), is approved only for the 10 mg strength of metoclopramide and cannot supply all formulations of the product in the U.S.<sup>42</sup> The FTC's complaint listed Actavis as a supplier of generic metoclopramide, but noted that "Teva, Barr, Mutual, and Qualitest, however, are the only suppliers of both the 5 mg and 10 mg strengths" of the product.43 The FTC's

- <sup>36</sup> *Id*.
- <sup>37</sup> Id.

<sup>43</sup> Teva/Barr, supra note 41.

<sup>&</sup>lt;sup>31</sup> Teva Pharm. Indus. Ltd. and IVAX Corp., Docket No. C-4155 (consent order issues Mar. 7, 2006) [hereinafter Teva/IVAX], Analysis of Agreement Containing Consent Orders to Aid Public Comment, available at <u>http://www.ftc.gov/os/caselist/0510214/0510214analysis.pdf</u>.

<sup>&</sup>lt;sup>32</sup> Sun/Taro, supra note 8.

<sup>&</sup>lt;sup>33</sup> Teva/Barr, supra note 16.

<sup>&</sup>lt;sup>34</sup> Sun/Taro, supra note 8.

<sup>&</sup>lt;sup>35</sup> *Id*.

<sup>&</sup>lt;sup>38</sup> See, e.g., Barr Pharm., Inc., Docket No. C-4171 (consent order issued Dec. 8, 2006), Analysis of Proposed Consent Order to Aid Public Comment, available at http://www.ftc.gov/os/caselist/0610217/0610217.shtm; Teva/IVAX, supra note 31.

<sup>&</sup>lt;sup>39</sup> See FTC Generic Drug Study, supra note 28, at 9.

<sup>&</sup>lt;sup>40</sup> Teva/Barr Press Release, *supra* note 13.

<sup>&</sup>lt;sup>41</sup> Teva/Barr, Complaint, available at <u>http://www.ftc.gov/os/caselist/0810224/081219cmp0810224.pdf</u>.

<sup>&</sup>lt;sup>42</sup> See id. See also Food & Drug Admin., Electronic Orange Book, <u>http://www.fda.gov/cder/ob/</u> (indicating that Actavis is approved for the 10 mg strength of metoclopramide only).

Analysis to Aid Public Comment did not mention Actavis at all and simply stated that "Teva and Barr are two of only four suppliers supplying all dosage forms of metoclopramide [hydrochloride]."<sup>44</sup>

The FTC's recent enforcement actions also suggest that the agency typically places more weight on the number of active generic suppliers in the market than on the market share of a particular competitor. In its analysis of *Teva/Barr*, the FTC stated that "the number of suppliers is the driving factor for prices in generic markets,"<sup>45</sup> as opposed to some other measure of competitive significance. This statement may explain why the FTC required divestitures in at least two markets where Teva or Barr accounted for only a small percentage of sales:

- In the market for deferoxamine injection, there were four pre-merger competitors in the U.S. and Teva/Barr accounted for only 16% of sales combined (of which Teva accounted for 12% and Barr accounted for only 4%).<sup>46</sup> According to the FTC, the proposed acquisition would increase the Herfindahl-Hirschman Index by only 96 points.<sup>47</sup>
- In the market for trazodone hydrochloride, there were four pre-merger competitors with Barr and Teva accounting for 71% and 4% of sales, respectively.<sup>48</sup>

Interestingly, the FTC required a divestiture in the market for trazodone hydrochloride where Teva had a 4% share, while noting the "limited success" of the fourth competitor, Watson, because it had only a 3% share.<sup>49</sup>

Antitrust counsel advising generic drug clients should be mindful of the FTC's positions regarding market participants with low

shares. Where parties to a merger have a low share, the FTC may still find that the transaction is likely to substantially lessen competition and require divestitures. However, where other competitors in the relevant market have a minor share, the FTC may discount their competitive significance and not count them as a meaningful constraint on the merging companies.

### D. Pipeline Products

Another important factor in the FTC's review of generic drug mergers is the product development pipelines of the merging parties. A close examination of these pipelines could reveal competitive issues even in situations where neither merging company has a product on the market. For example, in Sun/Taro, the FTC found that Sun and Taro were the only companies that had applied for FDA approval of generic extended-release carbamazapine tablets.50 As a result, the FTC stated that "the consolidation would result in a merger to monopoly, with the likely result that prices would be higher than they would be without the transaction and both companies had entered independently."51

Similarly, in *Teva/Barr*, the FTC required a divestiture to resolve its concerns in the market for fluoxetine weekly capsules, where Teva and Barr both had generic products in development.<sup>52</sup> The FTC noted that "[t]here are few firms that are capable of, and interested in, entering [this market]."<sup>53</sup> In addition, the FTC took enforcement actions in ten oral contraceptive markets where Barr had a product on the market and Teva was developing a competing product.<sup>54</sup> As discussed below, Teva had acquired most of these development products as the

divestiture buyer in connection with Watson's proposed acquisition of Andrx Corporation ("Andrx") in 2006.<sup>55</sup>

Antitrust counsel for generic drug clients must not overlook the development pipelines of parties to a generic drug merger. Where the merging parties are two of only a few competitors active in a market or developing a competing product, a divestiture of one of the company's development products could be required.

### E. Markets at Issue in Prior Enforcement Actions

The Teva/Barr transaction is perhaps the first generic drug merger that has involved significant overlaps in some of the same relevant markets where divestitures were required by the FTC in previous generic drug transactions. As mentioned above, Teva acquired a number of Andrx's generic oral contraceptive development products in connection with Watson's proposed acquisition of Andrx in 2006.56 In that transaction, Andrx had a marketing agreement with Teva and the two companies were jointly developing certain oral contraceptive products that would have competed with products that Watson had on the market or in development.57 To remedy the FTC's competitive concerns in those markets, Watson and Andrx agreed to divest Andrx's rights in certain of the development products to Teva.58

More than two years later, in *Teva/Barr*, the FTC found that Teva still had each of these same generic oral contraceptive products in development.<sup>59</sup> Because Barr was one of a limited number of suppliers with competing products on the market, the FTC required Teva to divest the products in development to Qualitest.<sup>60</sup> In addition, the FTC noted that

- <sup>45</sup> *Id*.
- <sup>46</sup> Teva/Barr, supra note 41.
- <sup>47</sup> *Id*.
- <sup>48</sup> *Id*.
- <sup>49</sup> Teva/Barr, supra note 16.
- <sup>50</sup> *Sun/Taro*, *supra* note 8.
- <sup>51</sup> *Id*.
- 52 Teva/Barr, supra note 16.
- <sup>53</sup> Id.
- <sup>54</sup> *Id*.

- 56 See id.
- 57 See id.
- 58 See id.
- 59 Teva/Barr, supra note 16.
- <sup>60</sup> *Id*.

<sup>44</sup> Teva/Barr, supra note 16.

<sup>&</sup>lt;sup>55</sup> See Watson Pharm., Inc. and Andrx Corp., Docket No. C-4172 (consent order issued Dec. 12, 2006) [hereinafter Watson/Andrx], Analysis of Proposed Consent Order to Aid Public Comment, available at http://www.ftc.gov/os/caselist/0610139/0610139analysis.pdf.

the divestitures of Teva's oral contraceptives products would not relieve Watson of any of its obligations to the owner of the products under the consent order issued in connection with *Watson/Andrx*.<sup>61</sup>

Nevertheless, the fact that Teva had not entered the market for any of the generic oral contraceptive products that it acquired more than two years earlier in connection with the Watson/Andrx transaction raises interesting questions about the FTC's assessment of entry in potential competition cases. In its Analysis to Aid Public Comment of the Watson/Andrx consent order, the FTC had stated that Andrx was one of a limited number of firms developing generic oral contraceptives that was well-positioned to enter the markets in a timely manner.62 According to the Horizontal Merger Guidelines, the FTC generally considers entry within two years to be timely.63 While it is unclear whether the FTC believed at the time of Watson/Andrx that Andrx would have entered within two years, the fact that divestitures were required suggests that antitrust counsel advising generic drug clients must be aware that a transaction may still be subject to an FTC challenge if their clients are among the next most-likely entrants into the relevant market, even if they are more than two years away from entering the market.

On a related note, Teva/Barr also involved four other generic drug markets that had been at issue in a prior generic drug merger: generic nicardipine hydrochloride (i) capsules, (ii) generic tramadol/ acetaminophen tablets, (iii) generic glipizide/ metformin hydrochloride tablets, and (iv) generic cabergoline tablets. In Teva's proposed acquisition of IVAX in 2006, the FTC required that Teva's or IVAX's products in these markets be divested to Barr.<sup>64</sup> A little more than two years later, Teva effectively sought to re-acquire these divested assets through its acquisition of Barr.

However, in *Teva/Barr*, the FTC required divestitures in only <u>one</u> of these four markets (generic glipizide/metformin hydrochloride tablets). The most likely explanation for the lack of an enforcement action in the other three markets is that significant changes in the competitive landscape occurred in the two years since the divestiture of those products to Barr.

Antitrust counsel may be able to point to these examples in future generic drug mergers to demonstrate that changes in the competitive landscape can occur fairly quickly in generic drug markets to alleviate competitive concerns, especially in close cases with borderline competitive issues.

### F. Overall Market Size

In generic drug transactions, the FTC has vigorously pursued divestitures without regard to the overall size of the markets affected if the agency determines that the merger is likely to result in anticompetitive effects. For example, in *Teva/IVAX*, the FTC required a divestiture in the market for generic nicardipine where the total annual U.S. sales were only \$674,000.<sup>65</sup>

Although the FTC did not provide information regarding the size of the markets at issue in either Sun/Taro or Teva/Barr, there is at least some evidence that several of the markets at issue in Teva/Barr were quite small. According to Teva's press release announcing that the FTC had accepted the proposed consent order, 16 of the divestiture products represented approximately \$60 million in annual sales (the 13 other divestiture products were pipeline products and had no sales).<sup>66</sup> This equates to an average of less than \$4 million in annual sales per product. In Europe, Teva's press release stated that the 17 divestitures required by the European Commission amounted to approximately \$6 million in the companies' annual sales.<sup>67</sup> This equates to roughly \$350,000 in annual sales per product on average in those countries.

While these sales figures provide limited indication of the size of the markets at issue in *Teva/Barr*, they serve as a useful reminder to antitrust counsel that the FTC does not accept as a defense that a company has minimal sales in the relevant market, as long as the agency believes that the transaction is likely to result in anticompetitive effects. Antitrust counsel and their clients also should be mindful that even minor product overlaps have the potential to significantly delay closing the transaction.

### G. Length of Investigation

At the outset of any deal, clients are often concerned about the expected length of the FTC's antitrust investigation and the potential for delay in closing. While predicting the length of the agency's review in generic drug mergers may at times seem like guesswork, examining the last 15 years of FTC enforcement actions in the generic drug industry provides an indication of the average length of time from deal announcement to antitrust approval where remedies are required.

Over the last 15 years, there have been approximately 11 generic drug transactions in which the FTC has taken enforcement actions. For these 11 transactions, the length of time from deal announcement to antitrust approval has ranged from four months to seven-and-a-half months.68 Surprisingly, the number of markets where divestitures are required does not appear to bear a significant relationship to the length of the agency's review. In one of the investigations lasting seven-and-a-half months--Marion Merrell Dow's proposed of Rugby-Darby acquisition Group Companies, Inc. in 1994--only one product was required to be divested.<sup>69</sup> By contrast, Hospira, Inc.'s acquisition of Mayne Pharma Limited in 2007 involved the divestiture of five products and lasted only four months.<sup>70</sup>

In 2008, the FTC's review of *Teva/Barr* lasted approximately five months, which is within the

61 *Id*.

<sup>64</sup> Teva/IVAX, supra note 31.

<sup>&</sup>lt;sup>62</sup> Watson/Andrx, supra note 55.

<sup>&</sup>lt;sup>63</sup> See FeD. TRADE COMM'N & U.S. DEPT. OF JUSTICE, HORIZONTAL MERGER GUIDELINES (1992), available at http://www.ftc.gov/bc/docs/horizmer.shtm.

<sup>&</sup>lt;sup>65</sup> *Id*.

<sup>&</sup>lt;sup>66</sup> Press Release, Teva Pharm. Indus. Ltd., U.S. Federal Trade Commission Clears Teva's Acquisition of Barr (Dec. 19, 2008), <u>http://www.tevapharm.com/pr/2008/pr\_812.asp.</u>

<sup>&</sup>lt;sup>67</sup> Press Release, Teva Pharm. Indus. Ltd., Teva and Barr Receive European Commission Approval for Acquisition (Dec. 19, 2008), <u>http://www.tevapharm.com/pr/2008/pr\_811.asp</u>.

<sup>&</sup>lt;sup>68</sup> For a detailed summary of these transactions and the approximate length of the FTC's review in each, see Bernstein & White, *Federal Antitrust Review of Generic Drug* Mergers, supra note 3, at 498.

<sup>&</sup>lt;sup>69</sup> *The Dow Chem. Co.*, 118 F.T.C. 730, 736-42 (1994).

<sup>&</sup>lt;sup>70</sup> Hospira, Inc. and Mayne Pharma Ltd., Docket No. C-4182 (consent order issued Mar. 23, 2007), Analysis of Proposed Consent Order to Aid Public Comment, http://www.ftc.gov/os/caselist/0710002/070118analysis0710002.pdf.

general range of time the agency took to review prior generic drug transactions.<sup>71</sup> Teva had signed a definitive merger agreement with Barr on July 18, 2008, and by December 19, 2008, the FTC had completed its review and accepted a proposed consent order, even though divestitures were required in 29 different product markets.<sup>72</sup>

Numerous factors can impact the length of the FTC's review of generic drug mergers, including the willingness of the parties to cooperate with the agency and provide staff with requested information in a timely manner, the number of overlaps at issue, the depth and breadth of the companies' product pipelines, the ease of finding a suitable buyer, or buyers, for the divestiture assets, and the number of divestiture buyers required. Antitrust counsel and their generic drug clients may be able to speed up the agency's review by providing up-front all relevant information about the overlapping product areas, promptly addressing the key issues identified in this article and, if necessary, beginning early the process of crafting potential remedies to address the FTC's likely antitrust concerns.

### III. Conclusion

In this article, we have summarized the FTC's enforcement activities in connection with two generic drug mergers in 2008--Sun/Taro and Teva/Barr---and we have examined several of the factors that go into the agency's analysis of generic drug mergers. In addition, we have provided tips to antitrust practitioners advising generic drug clients that may be useful in future transactions before the agency. If consolidation or additional merger activity continues in the generic drug industry, it will be interesting to see whether the FTC remains consistent with its prior enforcement actions or whether it adopts new approaches in its review of generic drug mergers.

<sup>&</sup>lt;sup>71</sup> Teva/Barr, supra note 16. We do not assess whether the FTC's review of *Sun/Taro* is consistent with the length of its prior investigations because, according to the FTC, "[t]]here is some uncertainty regarding the status of the transaction" and Taro has claimed that its agreement with Sun has been terminated. *See* Sun/Taro Press Release, *supra* note 6; *Sun/Taro, supra* note 8.

### Is There a Convergence of Health Care Competition Policy In the United States and Europe? A Comparison of Historical Policy and Ongoing Trends

### By Adrienne E. Van Winkle, Esq.\* Arnold & Porter, LLP

On October 28, 2008, the Health Care & Pharmaceuticals Committee of the ABA's Antitrust Law Section sponsored a panel discussion regarding the convergence of health care competition policy in the United States and Europe. Philip Nelson, a Principal at Economists Incorporated, moderated the panel. On the whole, the panel perceived some convergence, particularly because antitrust review is becoming more important in some European countries as they are turning to competition between private health care entities, such as hospitals, to improve health care services and lower costs. As the panel also pointed out, however, important differences remain, particularly in European countries where private markets are less important.

### Matthew Reilly

#### Assistant Director, Federal Trade Commission

Mr. Reilly began with an overview of United States hospital merger enforcement. Although the Federal Trade Commission ("FTC") continues its heightened scrutiny of proposed hospital transactions, the vast majority of merger reviews close after little investigation, and few proceed to the second request stage. Hospital mergers are unique, he explained, because they involve many different players, in a variety of industries, whose decisions are based, to a significant extent, on non-price factors such as quality of care, reputation, service, and hospital amenities.

Mr. Reilly next offered some background on United States hospital merger enforcement. The government successfully blocked several hospital mergers in the 1980s and early 1990s, but it suffered several losses from the mid 1990s through 2001 because courts chose to accept broad geographic market definitions. Between 2001 and 2008, the FTC engaged in retrospective studies of consummated mergers, allowing it to measure actual anticompetitive effects rather than hypothetical ones.<sup>1</sup> In addition, the FTC and the Department of Justice Antitrust Division ("DOJ") issued a Health Care Report<sup>2</sup> in 2004 that emphasized that, although the hospital industry has unique features, the agencies would continue to analyze these mergers under the Horizontal Merger Guidelines<sup>3</sup> and to decline special status to non-profit hospitals.

In 2008, in its first attempt at a hospital merger preliminary injunction since the late 1990s, the FTC successfully blocked the Inova-Prince William merger when the parties abandoned the transaction one month after the FTC filed suit.4 Mr. Reilly predicted that the rigorous factbased, analytical approach the FTC used in this transaction would serve as a guide for future merger reviews and that the asymmetry in the transaction and Inova's guality-of-care arguments would be issues that the agency would face again in the future.5

Mr. Reilly also addressed developments in the definition of the relevant product market for hospital services. He explained that the United States uses a cluster-market approach and defines the market as "general acute care inpatient hospital services for commercially insured patients."6 This approach, which groups services together, is used because it simplifies the antitrust analysis.

Mr. Reilly next focused on competitive harm. The U.S. agencies undertake a traditional unilateral effects analysis to evaluate likely post-merger changes in price, but also effects of non-price consider the competition, such as amenities, services, and increased bargaining strength against health plans. The "story" of competitive harm is important, particularly when asking a court to enjoin the merger of two non-profit hospitals. In the future, he suggested, the agencies would link hospital competition to the health plan rate: competition matters, even between non profits, because it helps maintain low plan rates for employers and employees.

Mr. Reilly ended by emphasizing that improved quality of care is the most important factor when analyzing a proposed merger. Quality of care may improve if the acquired hospital obtains the acquiring hospital invests significant sums of money in the acquired hospital specifically to improve the quality of care. If both of these procompetitive efficiencies are present, verifiable, and merger-specific, Mr. Reilly believes it would be difficult for an agency to argue the merger is anticompetitive.

#### Toby Singer Partner, Jones Day

Ms. Singer provided an overview, from a private-sector perspective, of three topics: health insurance company mergers, hospital collusion cases, and exclusionary practices by hospitals.

The DOJ has been more active in health plan mergers than hospital mergers. It has reached three consent decrees, alleging a different product market in each of the

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See Evanston Northwestern Healthcare Corp., 2007 WL 2286196 (F.T.C. Aug. 6, 2007) (using post-consummation evidence of significant price increases and few efficiency gains to successfully challenge a merger and order conduct remedies).

<sup>&</sup>lt;sup>2</sup> See FED. TRADE COMM'N & DEPT. OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), available at http://www.flc.gov/reports/healthcare/040723healthcarerpt.pdf.

<sup>&</sup>lt;sup>3</sup> See Fed. Trade Comm'n & Dept. of Justice, Horizontal Merger GuideLines (1997), available at http://www.ftc.gov/bc/docs/horizmer.shtm.

See Fed. Trade Comm'n v. Inova Health Sys. Found., No. 08-CV-460 (E.D. Va. filed May 12, 2008). In re Inova Health Sys. Found., No. 9326 (F.T.C. June 17, 2008) (order dismissing compl.) available at <a href="http://www.ftc.gov/os/adjpro/d9326/080617orderdismisscmpt.pdf">http://www.ftc.gov/os/adjpro/d9326/080617orderdismisscmpt.pdf</a>.

<sup>&</sup>lt;sup>5</sup> Inova, No. 08-CV-460 (Memo. in Support of Mot. for a Scheduling Order and an Expedited Status Conference at Part II.A.).

<sup>&</sup>lt;sup>6</sup> The relevant product market does not include outpatient services because patients have more options in those instances, or tertiary services because patients will travel farther for those services than acute care.

complaints.<sup>7</sup> Ms. Singer observed that the DOJ examines each transaction on its specific facts and considers the market in which it is occurring. In each decree, the alleged affected markets were local geographic markets.

In the area of hospital collusion, the United States has both private and government enforcement; the government enforcement, however, rests almost entirely with the DOJ.<sup>8</sup> Ms. Singer discussed the significant cases, which all resulted in consent decrees. In 1983, the DOJ brought suit on a boycott theory against several North Dakota hospitals for collectively agreeing not to contract with Indian Health Service.<sup>9</sup> Then, in 1992, the DOJ filed an action against several Des Moines, Iowa, hospitals for agreeing not to compete by limiting advertising.<sup>10</sup> Third, the DOJ filed suit in 1994 against several Utah hospitals for exchanging information about nurse wages.<sup>11</sup> More recently, in 2007, the DOJ brought suit against several Arizona hospitals that engaged in collective purchasing of temporary nurse services.<sup>12</sup>

In the area of private enforcement, Ms. Singer considers most significant five current class actions against hospitals,<sup>13</sup> all alleging agreements to suppress the compensation of registered nurses. These cases are in the early stages of litigation,<sup>14</sup> but they have received a fair amount of press coverage and could result in jury verdicts of millions of dollars for registered nurses. The plaintiffs also are supported by a nurses union, which may lead its members in filing additional suits.

Last, Ms. Singer discussed exclusionary practices by hospitals. She explained that it is difficult to tell if exclusionary conduct

allegations are meritorious or just disgruntled competitor complaints. As a result, the government is more cautious in this area, and almost all exclusionary conduct cases are private litigation. Ms. Singer discussed three important exclusionary conduct cases.

Most recently, in *PeaceHealth*,<sup>15</sup> the plaintiff alleged that its larger competitor hospital excluded it from health plan networks by bundling services. The trial resulted in a jury verdict for the plaintiffs, but the Ninth Circuit reversed and the case ultimately settled.<sup>16</sup>

In *Heartland Surgical Specialty Hospital*,<sup>17</sup> which also ultimately settled, a specialty hospital alleged that the defendant hospitals and health plans conspired to exclude it from their health plan networks. A key issue in the case was whether it is legitimate to exclude a competitor from a network because that competitor would be "cream skimming" (i.e., taking all the profitable patients and leaving indigent patients and others for full-service hospitals to treat). Ms. Singer believes the alleged conduct would be acceptable if done unilaterally, but questions the legality of similar collusive conduct.

Finally, in *Little Rock Cardiology Clinic*,<sup>18</sup> the plaintiff-doctors, investors in a heart hospital that competes with the defendant hospital, alleged a product market that was a mixture of hospital and physician services. The court called the product market "incoherent" and dismissed the complaint. Ms. Singer suggested the plaintiffs would have had more success with a clearer product market definition, such as cardiac hospital services.

Ms. Singer concluded by stating that private actions are likely to increase in the future.

### Sean Ennis Senior Economist, OECD

Mr. Ennis provided an international perspective on competition law enforcement in the health care sector. He believes there is a relatively high level of competition enforcement outside the United States, although it is not well recognized. At least 23 countries outside the United States have engaged in litigation or advocacy in the health care sector.<sup>19</sup>

Mr. Ennis cautioned that it is difficult to make generalizations because each European Union ("EU") member establishes its own competition policy, but many countries are starting to promote market forces in health care delivery. For example, many countries are introducing diagnosisrelated group ("DRG") pricing for hospital services and allowing patients to decide where they want to receive services. Mr. Ennis thinks that these two measures alone can create a big impact on hospitals' demand encourage quality and improvements.

Mr. Ennis next discussed several countries as examples of changes in the marketplace. In the United Kingdom ("UK"), there are at least four reasons for increased competition. First, only 13 percent of health care expenditures are paid for by the private-insurance market. Second, the state created rules that increase patient choices for general practitioners, increase patient choices of locations for elective surgeries, and implement practicebased commissioning. Third, lengthy lead times for public construction have led to the private construction of hospitals. Finally, hospitals are competing for state funds because they are now paid on the basis of performance.

- 9 United States v. N.D. Hosp. Ass'n, 640 F.Supp. 1028 (D.N.D. 1986).
- <sup>10</sup> United States v. Hosp. Ass'n of Greater Des Moines, Inc., 1993 WL 113410 (S.D. Iowa Mar. 5, 1993).
- <sup>11</sup> United States v. Utah Soc'y for Healthcare Human Res. Admin., 1994 WL 729931 (D. Utah Sept. 14, 1994).
- <sup>12</sup> United States v. Ariz. Hosp. & Healthcare Ass'n, No. CV07-1030-PHX (D. Ariz. filed May 22, 2007).
- <sup>13</sup> See Fleischman v. Albany Medical Center, 2008 WL 2945993 (N.D.N.Y July 28, 2008) (granting in part plaintiffs' motion for class certification); Cason-Merenda v. Detroit Medical Center, 2008 WL 880286 (E.D. Mich. Mar. 31, 2008) (denying defendant's motion to dismiss); Clarke v. Baptist Memorial Healthcare Corp., No. 06-02377 (W.D. Tenn. filed June 20, 2006); Maderazo v. Vanguard Health Sys., No. 06-CA-535-OG (W.D. Tex. filed June 20, 2006); Reed v. Advocate Health Care, No. 06-C-3337 (N.D. III. filed June 20, 2006).
- <sup>14</sup> One class action is partially certified, and the remaining four are still in discovery and class certification phases.
- <sup>15</sup> Cascade Health Solutions v. PeaceHealth, 515 F.3d 883 (9th Cir. 2008).
- <sup>16</sup> Cascade Health Solutions v. PeaceHealth, 542 F.3d 668 (9th Cir. 2008) (vacating, as moot, order certifying question to the Supreme Court of Oregon due to parties' settlement).
- <sup>17</sup> Heartland Surgical Specialty Hosp., LLC v. Midwest Div., Inc., 527 F. Supp. 2d 1257 (D. Kan. 2007).
- <sup>18</sup> Little Rock Cardiology Clinic v. Baptist Health, 573 F. Supp. 2d 1125 (E.D. Ark. 2008), appeal filed, No. 08-3158 (8th Cir. Sept. 15, 2008).

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<sup>&</sup>lt;sup>7</sup> See United States v. UnitedHealth Group, Inc., 2008 WL 4493605 (D.D.C. Sept. 24, 2008) (defining the relevant product market as Medicare Advantage Plans); United States v. UnitedHealth Group, Inc., No. 1:05CV02436 (D.D.C. filed Dec. 20, 2005) (defining the relevant product market as the sale of commercial health insurance to small groups); United States v. Aetna, Inc., 1999 WL 1419046 (N.D. Tex. Dec. 7, 1999) (defining the relevant product market as HMO and HMO-based point-of-service plans).

<sup>&</sup>lt;sup>8</sup> The FTC Act, 15 U.S.C. 44, limits the FTC's jurisdiction in a conduct investigation to an entity "organized to carry on business for its own profit or that of its members." The majority of hospitals in the United States are non-profit corporations and, therefore, the FTC does not have jurisdiction to challenge their conduct.

In the Netherlands, where fees have traditionally been negotiated centrally, the market is moving out of government control with the goal of increasing the efficiency of services. The government is increasingly allowing the prices charged for services to be set by the market, and insurers may contract with different providers. While state involvement in the operations of health care delivery is decreasing, the competition authority has become more active, as evidenced by merger investigations that have reached the second stage.<sup>20</sup>

Germany also exhibits changes in the marketplace. German hospitals now operate under a dual-funding system, in which the state finances capital costs and sickness funds finance operational costs. Second, in 2004, the state introduced the DRG payment mechanism. Third, patients may move from one hospital to another, although there are fee negotiation rules, and the government determines the hospital fees.

In concluding, Mr. Ennis cited the following reasons for the historic lack of competition enforcement in Europe: (1) competition laws are relatively new; (2) hospital services were previously considered public and not covered by competition law; and (3) the centralized system of financing resulted in little private competition. He predicted that, given recent changes, more jurisdictions will have health care competition enforcement, particularly over hospital mergers.

#### Simon Pritchard

#### Senior Director of Mergers, Office of Fair Trading (UK)

Mr. Pritchard focused on the diagnostics of current UK private hospital mergers. He first gave three examples of recent prominent cases. In 2000, the Competition Commission blocked the *BUPA/Community Health*<sup>21</sup> merger at Phase II because the merged firm would have had a 40% share of the private medical services market. More recently, in the 2008 *GHG/Nuffield Hospitals*<sup>22</sup> merger, the merging parties self-assessed and

voluntarily divested two hospitals in areas in which there were competitive overlaps. Also in 2008, the Office of Fair Trading ("OFT") cleared the *Spire Healthcare/Classic Hospitals*<sup>23</sup> merger after it concluded that no market overlaps raised issues.

Mr. Pritchard observed several differences between the OFT product market definition approach and the FTC bundle of services approach for hospital mergers, although he acknowledged they are similar. First, unlike the FTC, the OFT would take into consideration outpatient and tertiary services if the facts warranted it. Second, the OFT considers the private patient units of National Health Service public hospitals to be part of the market. Lastly, the OFT considers the distinction between services paid for by a provider and services for which customers pay directly. For example, for that reason, the OFT found the cosmetic surgery product market in *Spire* to be wider than just the merging hospitals.<sup>24</sup>

As for geographic market definition, Mr. Pritchard observed that a recurring feature of UK merger analysis is to decline a binary market view. Thus, it considers the degree of competition at both the national and local levels.

Mr. Pritchard briefly addressed concentration measures. The OFT uses all available data it can acquire to analyze concentration measures. There is also no particular safe harbor rule for concentration measures, as the OFT focuses instead on the competition between the parties.

Mr. Pritchard concluded by stating that the OFT uses an efficiencies approach similar to the United States', and, although efficiencies have not had an impact in hospital merger cases yet, the foundations for the analysis are present, if needed.

#### Marc Besen Partner, Clifford Chance (Germany)

Mr. Besen discussed two areas of EU hospital merger enforcement: the European Commission's approach and case law in EU member states.

Despite the importance of the health care sector to the EU economy, Mr. Besen said the Commission does not normally review hospital mergers because the EU's required turnover<sup>25</sup> thresholds are much higher than the turnovers involved in many hospital mergers. In Fresenius,<sup>26</sup> one of the few examples of the Commission's approach to hospital mergers, the Commission identified more than six relevant product markets. It also defined five regional geographic markets by starting with a small radius of thirty kilometers and adjusting for patient flow, distance to the hospital, and zip code. Because the merger did not raise horizontal or vertical competitive constraint concerns, there was no necessity for the Commission to consider efficiencies.

Mr. Besen next summarized the state of merger review in Germany. Since 2005, Germany has reviewed more than 50 hospital mergers, and surveys predict more will occur. One reason for the high level of scrutiny is that threshold turnover levels are comparatively low, so merger review is easily triggered. Another reason is that Germany does not distinguish between public and private hospitals, and, for a public hospital, turnover includes all activity of the public entity (the state).

Mr. Besen provided two examples of German merger review. First, the Federal Cartel Office stopped the *Rhön-Klinikum*<sup>27</sup> merger in essence because the merged entity would have had a 65% market share, and there is a presumption of dominance with only a 33% market share. In contrast, in the *University Hospita*<sup>P8</sup> merger, on facts almost identical to the *Rhön-Klinikum* merger, the authorities cleared the merger because of an overriding public interest in establishing an exclusive research region.

The Netherlands are similar to Germany, explained Mr. Besen, because turnover thresholds are also low, which leads to a lot of oversight. For example, the *Ziekenhuis Hilversum*<sup>29</sup> merger was cleared after the parties offered remedies that created

- <sup>27</sup> Rhön-Klinikum AG/Bad Neustadt, Case No. B 10 123/04 (F.C.O. 10 Mar. 2005), available at www.bundeskartellamt.de.
- 28 Univ. Hosp. of Greifswald/Wolgast Dist. Hosp., Case No. B 3 1002/06 (F.C.O. 13 Dec. 2006), available at www.bundeskartellamt.de.

<sup>&</sup>lt;sup>20</sup> See, e.g., Ziekenhuis Hilversum/Ziekenhuis Gooi-Noord, Case No. 3987 (N.C.A. 8 June 2005); Ziekenhuis Walcheren/Oosterscheldeziekenhuizen, Case No. 5196 (N.C.A. 18 Nov. 2005).

<sup>&</sup>lt;sup>21</sup> BUPA/Community Hospitals, No. 51/00 (C.C. Dec. 7, 2000), available at http://www.competition-commission.org.uk/rep\_pub/reports/2000/449bupa.htm.

<sup>&</sup>lt;sup>22</sup> General Healthcare Group/Nuffield Hospitals, No. ME/3468/08 (O.F.T. 16 May 2008).

<sup>&</sup>lt;sup>23</sup> Spire Healthcare Ltd./Classic Hospitals Group Ltd., No. ME/3610/08 (O.F.T. 1 July 2008).

<sup>&</sup>lt;sup>24</sup> See id.

<sup>&</sup>lt;sup>25</sup> Under European merger control law, the term "turnover" means the amounts derived by the undertakings concerned in the preceding financial year from the sale of products and the provision of services within the undertakings' ordinary activities after deduction of sales rebates and of value added tax and other taxes directly related to turnover.

<sup>26</sup> Fresenius/Helios, M.4010 (E.C. 8 Dec. 2005), available at <u>http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en.eu/rapid/pressReleasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesAction.do?reference=IP/05/1553&format=HTML&aged=0&language=en/leasesA</u>

<sup>&</sup>lt;sup>29</sup> Ziekenhuis Hilversum/Ziekenhuis Gooi-Noord, Case No. 3897/156 (N.C.A. 8 June 2005), available at www.nmanet.nl

sufficient competition. Currently, in the *Ziekenhuis Walcheren*<sup>30</sup> merger, the authorities are conducting a second stage review after first notifying the parties that the efficiencies were not sufficient to justify the high market share.

France is the only other EU member with notable activity, observed Mr. Besen. In 2006, French authorities cleared the *AADJNON*<sup>®1</sup> merger despite combined market shares of up to 60%. Mr. Besen offered two explanations for this result: (1) there is strong public regulation of the reimbursement system in the health care sector; and (2) hospital doctors are self-employed freelancers, creating strong competition between the hospitals.

The takeaway, according to Mr. Besen, is that hospital mergers are increasingly subject to review in the EU, but certain national peculiarities must be considered. In addition, the relatively narrow product and geographic market definitions lead to large market shares in small markets. Last, he warned that regulators must remember that hospitals are competitors and cooperation creates a risk of collusion.

#### Moderated Discussion

For the moderated discussion, Mr. Nelson first asked if the FTC will continue to define the product market for hospital mergers as the acute-care inpatient market, rather than focus on medical specialties. Mr. Reilly responded that if other factors, such as medical specialties, affect the analysis, then the US agencies will take those into consideration.

Mr. Nelson next questioned the panel on how the EU clusters differ from the US clusters. One panelist suggested that the EU has not excluded outpatients because that factor was not determinative in recent cases, but he believes the EU would consider the outpatient distinction if it became relevant. Mr. Besen added that, from a practical standpoint, having 27 different enforcement systems creates different product market definitions and strong political issues that influence the decisions of enforcement authorities.

Mr. Nelson inquired whether the FTC uses the "small but significant nontransitory price increase" ("SNIP") test for hospital mergers, which Mr. Reilly confirmed. Ms. Singer cautioned that the SNIP test for hospitals may be too limiting because only certain customers are price sensitive. Mr. Pritchard said the OFT uses the same hypothetical monopolist test, but with a few differences. For example, the OFT is also happy to consider price discrimination.

Mr. Nelson turned to the empirical testing of geographic markets, and asked Mr. Reilly to elaborate on the types of data used to determine the geographic market. The FTC, he responded, uses inflow and outflow data (i.e., the Elzinga-Hogarty test) because courts have historically considered it, and because health plans look at the same factors when they determine who should be included in their networks. The FTC also considers testimony and documents from health plans and parties, econometric work based on published literature, and driving time.

Ms. Singer was pleased to hear the FTC is not just looking at inflow and outflow data. She cautioned, however, that anecdotal evidence should be taken with a grain of salt—as the courts have done—because it is more difficult to evaluate and because the parties, who lack the FTC's subpoena power, do not have equal access to anecdotal evidence and are, therefore, not in a position to explain why it could be misleading.

Providing the contrasting UK perspective, Mr. Pritchard noted that the OFT also factors in patient zip codes in defining the geographic market. The OFT starts with a 30 minute driving time, which can be a poor proxy due to population and demographics, and then includes zip codes in the analysis to prevent distortion. Mr. Besen added that the cutoff time in Germany is approximately a 20 or 30 minute drive.

The panel briefly discussed the role of anticompetitive effects in merger analysis. Mr. Nelson asked whether there is a serious chance that in future cases the FTC will look first at anticompetitive effects and then back into the product market and geographic market definitions. Mr. Reilly did not think that would happen because the government bears the burden of proving product and geographic markets, but he believes anticompetitive effects support those definitions and give the judge a view of the bigger picture. Ms. Singer added that the FTC in *Evanston* rejected the idea of skipping the product market definition in favor of an anticompetitive effects analysis.32

Mr. Pritchard, who previously alluded to the OFT's use of anticompetitive effects to back into in market definitions, discussed some differences from the US approach. Although

the OFT is not required to define the product market, unlike US agencies, the product market analysis remains helpful. For example, in a recent radio merger, the OFT skipped over the market definitions and used evidence based on survey work by advertisers to illustrate the anticompetitive effects of the merger. It then backed into the product market definition, just to show that the result was the same.

Last, the panel compared and contrasted the role of efficiencies. Mr. Nelson inquired whether there are efficiencies or economic forces that are unique to the EU. Mr. Ennis replied that the economic forces are similar, but compared the current state of European hospitals to the US hospitals of the 1980s. The efficiency arguments are stronger in Europe than in the US because European hospital mergers are likely to generate more efficiencies. On the US side, Mr. Reilly reemphasized that the FTC weighs heavily efficiencies related to cash investments in the merged hospital, particularly for nonprofit hospitals. Although the UK rejected efficiency arguments in 2000, Mr. Pritchard told the panel the OFT considered efficiency arguments in a recent radio merger, and suggested it would do the same for hospitals.

### Conclusion

The panel concluded that there is some convergence in health care competition policy in the United States and Europe, particularly because European countries are introducing more market-based health care However, some differences systems. remain both because European health care markets are structured somewhat differently and because the antitrust analysis that is employed differs somewhat. For example, with respect to antitrust analysis, the Europeans appear to be somewhat more willing to rely on anticompetitive effects evidence to determine if there is a competitive issue, although this evidence is of interest to both United States and European authorities.

In addition, the panel predicted that litigation and/or advocacy in the health care sector will probably increase in both places. The United States is likely to see an increase in private litigation, particularly in hospital collusion cases, and European countries are likely to review increasing numbers of hospital mergers.

<sup>32</sup> See Evanston, supra note 1.

<sup>&</sup>lt;sup>30</sup> Ziekenhuis Walcheren/Oosterscheldeziekenhuizen, Case No. 5196/47 (N.C.A. 18 Nov. 2005), available at www.nmanet.nl.

<sup>31</sup> AADJNON/Compagnie Generale de Sante, Case No. ECOC 0600080Y (F.C.A 21 June 2006), available at www.finances.gouv.fr.

### Results of Abbott's December 2003 Norvir Price Increase

In December 2003, Abbott Laboratories ("Abbott") raised the price of Norvir (ritonavir), a protease inhibitor ("PI") used in the treatment of AIDS, by 400 percent.<sup>3</sup> The Norvir price increase led to a furor among AIDS advocates, a call to boycott Abbott products, and a number of antitrust and other legal actions that are the subject of this article. The issues raised by this price increase are particularly interesting, as they sit at the intersection of patent law, antitrust law, and the Bayh-Dole Act.<sup>4</sup> This article will first describe the Bayh-Dole Act and the history of Norvir, next explain the legal consequences of Abbott's price increase, and conclude with a discussion of the economics of "monopoly leveraging" as applied to Abbott's actions.

#### The Bayh-Dole Act and the History of Norvir

In 1980, Congress passed the Bayh-Dole Act, which allows contractors, such as pharmaceutical companies, to elect to obtain rights for federally-funded inventions (i.e., patents) in order "to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . [and] to promote the

### By Caterina K. Nelson, Ph.D.<sup>1</sup> CRA International<sup>2</sup>

commercialization and public availability of inventions made in the United States by United States industry and labor . . . . "<sup>5</sup> The Act also retains rights for the government, including what are referred to as "march-in rights," under which the government can force a contractor to grant licenses for government-funded products.<sup>6</sup>

In 1988, Abbott received a \$3.5 million grant from the National Institutes of Health ("NIH") that partially funded its development of Norvir,<sup>7</sup> and a number of Abbott's patents related to ritonavir note that "[t]he Government has certain rights in this invention."8 The FDA approved Norvir in 1996<sup>9</sup> and Abbott initially marketed it as a stand-alone PI at a dosage of 1200 mg per day, but Norvir was associated with "frequently occurring adverse side effects" at this dosage.10 Subsequently, Abbott discovered that Norvir acts as a "booster" for other PIs-both increasing the efficacy of other PIs, thus reducing the required dosage (and the PI's side effects), and slowing the rate at which the virus developed resistance to the effects of other PIs)11-which is how Norvir was subsequently used (at a reduced

dosage of 100 to 200 mg per day).<sup>12</sup> As a result, the average price for a daily dose of Norvir fell from 20.52 in 1996 to 1.71 in 2003.<sup>13</sup>

Abbott received approval for Kaletra, which combines ritonavir and lopinavir, a PI not marketed as a stand-alone drug, in September 2000.14 The FDA approved Reyataz, a PI from Bristol-Myers Squibb boosted with a single 100 mg capsule of Norvir, in June 2003,<sup>15</sup> and Lexiva, a PI from GlaxoSmithKline ("GSK") that required two 100 mg capsules of Norvir for boosting, in October 2003.<sup>16</sup> By December 2003, both had reportedly made "inroads on Kaletra's market share."<sup>17</sup> According to "[p]reviously undisclosed documents and e-mails reviewed by The Wall Street Journal," Abbott executives considered three alternative approaches to countering Kaletra's falling sales, all of which focused on making Norvir less attractive: (1) removing (the palatable) Norvir tablets from the U.S. market while continuing to sell the vile-tasting Norvir solution, (2) removing Norvir from the U.S. market entirely, and (3) substantially raising the price of Norvir.<sup>18</sup> As noted above, Abbott

<sup>1</sup> Caterina Nelson is a Principal of CRA International. The author is indebted to Philip Nelson, Principal, Economist Inc. for his suggestions regarding analyses in this article.

<sup>&</sup>lt;sup>2</sup> While CRA International had a tangential role in the Norvir litigation, the author did not, and this article is based solely on public sources.

<sup>&</sup>lt;sup>3</sup> Vanessa Fuhrmans, Cost of a Longtime HIV Drug Jumps 400%, WALL ST. J., Dec. 19, 2003, at B1.

<sup>4 35</sup> U.S.C. §§ 200-212 (2006).

<sup>&</sup>lt;sup>5</sup> 35 U.S.C. § 200.

<sup>6 35</sup> U.S.C. § 203(a).

<sup>&</sup>lt;sup>7</sup> John Carreyrou, New Regimen: Inside Abbott's Tactics to Protect AIDS Drug—Older Pill's Price Hike Helps Sales of Flagship, WALL ST. J., Jan. 3, 2007, at A1. According to this article, there is some dispute about the importance of this grant to the development of Norvir. The article states that John Erickson, a "former Abbott scientist who did much of the research work on Norvir," "testified that it was unlikely that Abbott would have funded Norvir's early development" without the grant; however, Abbott said it spent "\$300 million on clinical trials of Norvir." Id.

<sup>&</sup>lt;sup>8</sup> See, e.g., U.S. Patent Nos. 5,541,206 (issued July 30, 1997), 5,635,523 (issued June 3, 1997), 5,648,497 (issued July 15, 1997), 5,674,882 (issued Oct. 7, 1997), 5,846,987 (issued Dec. 8, 1998), and 5,886,036 (issued Mar. 23, 1999).

<sup>&</sup>lt;sup>9</sup> The FDA approved the New Drug Application for Norvir, which Abbott filed on Dec. 21, 1995, under accelerated approval regulations on March 1, 1996. See Accelerated ApprovaLs UNDER 21 C.F.R. 314 SUBPART H (DRUGS) & 21 C.F.R. 601 SUBPART E (BIOLOGICS), <u>http://www.fda.gov/cder/rdmt/accappr.htm</u>.

<sup>&</sup>lt;sup>10</sup> ESSENTIAL INVENTIONS, INC., PETITION TO USE AUTHORITY UNDER BAYH-DOLE ACT TO PROMOTE ACCESS TO RITONAVIR 4, (Jan. 29, 2004), available at <u>http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf</u> [hereinafter Bayh-Dole Petition].

<sup>&</sup>lt;sup>11</sup> Meijer, Inc. v. Abbott Labs., 544 F. Supp. 2d 995, 998 (N.D. Cal. 2008).

<sup>&</sup>lt;sup>12</sup> Bayh-Dole Petition, *supra* note 10, at 4. When Norvir is used as a booster, the patient takes both Norvir and the other PI; Kaletra is the only drug that incorporates ritonavir and a PI.

<sup>&</sup>lt;sup>13</sup> Meijer, 544 F. Supp. at 998; Abbott Cites Total Cocktail Cost in Defending HIV Drug Price Hike, DRUG INDUS. DAILY, Feb. 10, 2004 [hereinafter DID Feb. 2004].

<sup>&</sup>lt;sup>14</sup> For information regarding Kaletra, *see* Food and Drug Admin., Drugs@FDA, <u>http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm</u>, and Electronic Orange Book Query, <u>http://www.fda.gov/cder/ob/docs/queryai.htm</u>.

<sup>&</sup>lt;sup>15</sup> For information regarding Reyataz, see Food and Drug Admin., Drugs@FDA, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

<sup>&</sup>lt;sup>16</sup> For information regarding Lexiva, *see* Food and Drug Admin., Drugs@FDA, <u>http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm</u>.

<sup>&</sup>lt;sup>17</sup> Fuhrmans, *supra* note 3.

<sup>&</sup>lt;sup>18</sup> Carreyrou, *supra* note 7. The article notes that according to an Abbott spokeswoman, the executives who wrote these documents were not decision makers and "were just brainstorming and quickly discarded some of the options" discussed. *Id.* The article also notes that "in a court brief filed in the California case last year opposing a plaintiffs" motion to unseal the documents, Abbott said they 'were prepared by and for some of the most senior officers at the company as part of an enormously important strategic discussion about Norvir." *Id.* 

apparently chose the third option and raised the U.S. wholesale price of Norvir from \$54 per month to \$265 per month,<sup>19</sup> while not raising the wholesale price of Kaletra.<sup>20</sup> As a result of this price increase, the cost per year for a patient taking Reyataz boosted with Norvir increased by \$2,504 (to \$11,187) and the cost per year for a patient taking a drug, such as Lexiva, that required twice-daily boosting with Norvir increased by \$5,000, while the cost per year for a patient taking Kaletra remained "about \$7,000" per year.<sup>21</sup>

Responses to the Norvir price increase included a "march-in petition" under the Bayh-Dole Act, requests for a Federal Trade Commission ("FTC") investigation, investigations by a number of state attorneys general, and lawsuits filed in both state and federal courts. The next section will discuss these responses, focusing on the suits filed in federal courts in Illinois and California.

#### Bayh-Dole March-In Petition

On January 29, 2004, Essential Inventions, a private non-profit corporation, petitioned the Secretary of the Department of Health and Human Services ("HHS") to "exercise Bayh-Dole March-In rights and grant an open license to use six patents related to the manufacture of ritonavir."<sup>22</sup> Essential Inventions made two claims in the petition: (1) "Norvir [was] not being made available to the public under reasonable terms," as "[u]nder section 203, 'reasonable terms'

includes a reasonable price;"<sup>23</sup> and (2) "[a]ction [was] needed to protect the public's health needs."<sup>24</sup> According to the petition, "[b]y dramatically increasing the cost of Norvir [used] to boost non-Abbott protease inhibitor regimes, while not increasing the price of Kaletra, Abbott clearly seeks to shift market share to Kaletra, even when Kaletra is not the best treatment for patients."<sup>25</sup>

NIH held a public hearing on May 25, 2004 and "received written comments from a variety of groups and individuals representing universities, the AIDS community, pharmaceutical interests, drafters of the Act, and other interested Bayh-Dole parties."26 NIH denied the petition on July 29, 2004, stating: "After carefully considering all the information provided and otherwise made available, the NIH does not believe the initiation of a march-in proceeding is warranted."27 NIH discussed concerns regarding the cost of drugs, stating that "because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices."28 NIH concluded: "The NIH believes that the issue of drug pricing is one that would be more appropriately addressed by Congress, as it considers these matters in a larger context. The NIH also maintains that the FTC is the appropriate agency to address the question of whether Abbott has engaged in anti-competitive behavior."<sup>29</sup>

### Other Investigations

The Norvir price increase also led to requests that the FTC investigate Abbott's actions and a number of antitrust investigations by state attorneys general. Essential Inventions was the leader of a group of U.S. activists that filed a complaint with the FTC regarding Abbott's price increase on January 29, 2004,30 and three U.S. Senators wrote then-FTC Chairman Muris "respectfully request[ing] that the Commission respond to [Essential Invention's] complaint and take any enforcement action it determines to be appropriate" in May 2004.<sup>31</sup> According to an article published in August 2004, the FTC notified Abbott that it did not plan to investigate the company's actions.32 Abbott reportedly received subpoenas from the attorneys general of Illinois and New York on February 6, 2004,<sup>33</sup> and the attorney general of California reported that he was investigating the Norvir price increase in a June 2004 press release.34

<u>Abbott's Response to These Investigations</u> and Their Aftermath

In discussing the Illinois and New York investigations, an Abbott spokeswoman reportedly noted that "[e]ven at the increased price, the drug is still the least expensive protease inhibitor (PI) on the market" and that the "company froze the price of Norvir

- <sup>21</sup> Carreyrou, *supra* note 7.
- <sup>22</sup> Bayh-Dole Petition, *supra* note 10, at 2.
- 23 Id. at 9.
- <sup>24</sup> *Id.* at 11.
- <sup>25</sup> *Id.* at 10-11.
- <sup>26</sup> OFFICE OF THE DIRECTOR, NAT'L INST. OF HEALTH, IN THE CASE OF NORVIR® MANUFACTURED BY ABBOTT LABORATORIES, INC. 3 (July 29, 2004) [hereinafter Norvir March-in], available at http://www.ott.nih.gov/policy/March-in-norvir.pdf.
- <sup>27</sup> Id., at 4. While Essential Inventions announced its intention to appeal the NIH decision to the Secretary of HHS, an HHS spokesperson was quoted as saying: "The [Bayh-Dole] law does not have any appeal right in it. It's an authority granted within the NIH." HHS Won't Consider Appeal of NIH Decision on Norvir Patent, DRUG INDUS. DAILY, Aug. 6, 2004 [hereinafter DID Aug. 2004].
- <sup>28</sup> Norvir March-in, *supra* note 26, at 5-6. According to an article published in October 2004, Representatives Henry Waxman and Sherrod Brown sent a letter to the Government Accountability Office requesting an investigation into such decisions by NIH, claiming that "NIH did not consider whether Abbott Laboratories' Norvir (ritonavir) [was] sold at reasonable terms." Waxman/Brown call for NIH investigation, PHARMA MARKETLETTER, Oct. 4, 2004.

- <sup>30</sup> Not-for-Profit Company Requests Federal Trade Commission Investigation into Abbott's Price Increase of AIDS Drug, KAISER DAILY HIV/AIDS REPORT, Jan. 30, 2004. According to the Wall Street Journal, eight Democratic Senators had requested that someone from the FTC testify at the May 2004 NIH hearing. See Leila Abboud, Abbott's Pricing on AIDS Drug Prompts Call for an Early Generic, WALL ST. J., May 13, 2004, at D7.
- <sup>31</sup> Letter from Charles E. Schumer, John McCain, and Ernest F. Hollings, U.S. Senators, to Timothy J. Muris, Chairman, FTC (May 19, 2004), available at http://schumer.senate.gov/SchumerWebsite/pressroom/Letters/SchMcCHoll%20to%20FTC%205.19.04.pdf.

<sup>34</sup> Press Release, California Office of the Attorney General, Attorney General Lockyer Sends Refund Checks to California Consumers of Anti-Cancer Drug Taxol (June 1, 2004), available at <a href="http://www.ossh.com/firearms/caag.state.ca.us/newsalerts/2004/04-059.htm">http://www.ossh.com/firearms/caag.state.ca.us/newsalerts/2004/04-059.htm</a>. The disposition of these investigations is not clear, although an article published on December 27, 2007, stated: "Illinois Attorney General Lisa Madigan has been investigating whether the price hike violates the state's consumer fraud law." See Michael Sean Comerford, Profits and Prescriptions: Drug-Pricing Strategies Questioned, CHICAGO DAILY HERALD, Dec. 27, 2007, at B1.

<sup>&</sup>lt;sup>19</sup> Fuhrmans, *supra* note 3.

<sup>&</sup>lt;sup>20</sup> Abbott Sued for Anti-trust over Norvir Price Increase by AIDS Healthcare Foundation, PR NEwswire, Feb. 11, 2004 [hereinafter PRNewswire 2004].

<sup>&</sup>lt;sup>29</sup> Norvir March-in, *supra* note 26, at 6.

<sup>&</sup>lt;sup>32</sup> DID Aug. 2004, *supra* note 27.

<sup>&</sup>lt;sup>33</sup> Sacha Baggili, Abbott Subpoenaed Over HIV Drug Pricing, WORLD MKTS. ANALYSIS, Feb. 9, 2004.

for public players, such as Medicaid as well as AIDS drug assistance programs."<sup>35</sup> Both of these statements were subsequently challenged.

The Director of FDA's Division of Drug Market, Advertising, and Communications ("DDMAC") sent a warning letter to Abbott on June 10, 2004, in which he stated that a cost chart on www.norvir.com was "false or misleading in violation of section 502(a) of the Federal Food, Drug, and Cosmetic Act because it claims that Norvir has the lowest daily cost of all antiretroviral drugs and minimizes the risks of Norvir."36 In addition, the AIDS Healthcare Foundation filed a false advertising suit against Abbott in Los Angeles Superior Court on March 17, 2004 alleging that, contrary to its assertions, Abbott had not frozen the price of Norvir for Medi-Cal patients and reimbursed the program.37

#### Antitrust Suits Filed in 2004 and Settled or Dismissed

On February 12, 2004, the AIDS Healthcare Foundation announced it had filed an antitrust lawsuit against Abbott in the District Court for the Central District of California, Western Division.<sup>38</sup> In July 2004, this suit and the false advertising suit mentioned above settled, with Abbott agreeing to "contribute to treatment programs run by the AIDS Healthcare Foundation in the United States and in Africa serving [an estimated] 10,000 patients."<sup>39</sup> Aetna filed an antitrust action on behalf of itself and others similarly situated on May 25, 2004, but dropped the suit two days later.<sup>40</sup> In addition, a suit asserting Abbott violated Illinois consumer fraud laws with respect to its price increase was filed in an Illinois state court on May 20, 2004; the court dismissed this on November 12, 2004.<sup>41</sup>

### Other Indirect Purchaser Suits Filed in U.S. District Courts

Different plaintiffs filed indirect purchaser suits in the Northern District of California and in the Northern District of Illinois. The different fates of these suits reflect differences between the Seventh and Ninth Circuits' interpretations of *Eastman Kodak Co. v. Image Technical Services, Inc.*,<sup>42</sup> and their views about monopoly leveraging.

Plaintiffs John Doe 1 and John Doe 2 filed a first amended class action complaint against Abbott in the Northern District of California on June 10, 2004, and Abbott filed a motion to dismiss the complaint, which the court denied on October 21, 2004.<sup>43</sup> According to Abbott, it had "a complete defense to every count in Plaintiffs' amended complaint because Defendant owns patents on Norvir and its use as a booster."<sup>44</sup>

According to Judge Claudia Wilken, while plaintiffs conceded that Abbott has a legitimate monopoly in the booster market (defined as Norvir), they contended that "Defendant's actions constitute illegal anticompetitive activity in the boosted market, which [they] define[d] as the market for PIs that are prescribed together with Norvir as a booster."<sup>45</sup> Judge Wilken explained that "[i]n *Image Technical Services, Inc. v. Eastman Kodak Co.*, the court noted that 'a monopolist who acquires a dominant position in one market through patents and copyrights may violate § 2 if the monopolist exploits that

dominant position to enhance a monopoly in another market,"46 and that Plaintiffs in this case were asserting a "monopoly leveraging theory."47 Abbott also claimed that Plaintiffs lacked standing to sue because they did not suffer an injury caused by loss of competition in the boosted market. The court noted that "Plaintiffs rely on Blue Shield of Virginia v. *McCready*," arguing that they have been forced into a Hobson's choice between "paying more for competing boosted regimens versus paying less for Defendant's Kaletra while accepting the drug's harmful side effects" and that this is "intertwined with the injury that Defendant sought to inflict on its competitors and on the boosted market."48 Shortly after this ruling, the Service Employees International Union Health and Welfare Fund ("SEIU") filed a complaint "nearly identical" to the John Does' amended complaint, and Judge Wilken denied Abbott's motion to dismiss this complaint on March 2, 2005.49

Also in March 2005, Gary Schor filed suit against Abbott in the Northern District of Illinois, Western Division, alleging, in Count 1 of the complaint, that Abbott "violated § 2 of the Sherman Act by abusing its monopoly power in the U.S. market for Norvir, its patented product, to unfairly injure competition in the market for PIs boosted by Norvir."50 Abbott argued that the complaint should be dismissed "because its patents for Norvir, which cover its use as a stand-alone drug and as a booster when combined with other PIs, preclude antitrust liability."<sup>51</sup> In his response to the motion to dismiss, Plaintiff argued that Abbott was "collaterally estopped from raising its arguments in favor of its

- <sup>35</sup> DID Feb. 2004, *supra* note 13. A May 2004 article noted a similar claim regarding Norvir's relative cost made by Dr. Leiden, the president of Abbott's pharmaceutical products group. *See* Abboud, *supra* note 30.
- <sup>36</sup> Letter from Thomas W. Abrams, Director, DDMAC, to Mile D. White, Chairman and CEO, Abbott Laboratories (June 10, 2004), *available at* <u>http://www.fda.gov/cder/warn/2004/macmis12335.pdf</u>.
- <sup>37</sup> AIDS Drug Suit, CITY NEWS SERV., Mar. 18, 2004.
- <sup>38</sup> PRNewswire 2004, *supra* note 20.
- <sup>39</sup> Abbott Settles AIDS Drug-Price Lawsuits, REUTERS, July 19, 2004.
- <sup>40</sup> Aetna Drops Lawsuit over Abbott's 400% Price Increase of Antiretroviral Norvir, KAISER DAILY HIV/AIDS REP., May 28, 2004. This article noted that, according to an article in the Hartford Courant, "some sources familiar with the case said that Abbott is an Aetna health plan customer and 'certain high-ranking Aetna officials weren't aware that the suit had been filed." *Id.* (citing Diane Levick, *Aetna Dropping Lawsuit*, HARTFORD COURANT, May 28, 2004, E2).
- <sup>41</sup> See Prescription Access Litigation, Current Lawsuits, <u>http://www.prescriptionaccess.org/lawsuitssettlements/current\_lawsuits?id=0022</u>.
- <sup>42</sup> 504 U.S. 451 (1992).

- 44 Id. at \*5-6.
- 45 *Id.* at \*7.
- <sup>46</sup> *Id.* at \*8 (quoting *Image Technical Servs., Inc. v. Eastman Kodak Co.,* 125 F.3d 1195, 1216 (9th Cir. 1997)).
- 47 *Id.* at \*8.
- <sup>48</sup> *Id.* at \*11-12.
- <sup>49</sup> SEIU Health & Welfare Fund v. Abbott Labs., No. C 04-4203 CW, 2005 U.S. Dist. LEXIS 46123, at \*2-4 (N.D. Cal. March 2, 2005).
- <sup>50</sup> Gary Schor v. Abbott Labs., 378 F. Supp. 2d 850, 855 (N.D. III. 2005).

<sup>51</sup> *Id*.

<sup>43</sup> John Doe 1 & John Doe 2 v. Abbott Labs., No. C 07-5985 CW, 2004 U.S. Dist. LEXIS 29129, at \*4 and \*2 (N.D. Cal. October 21, 2004).

motion to dismiss" by the decisions of Judge Wilken in the John Doe and SEIU cases.<sup>52</sup> In his opinion, dated July 12, 2005, Judge Robert W. Gettleman stated that collateral estoppel did not apply in this case because, among other reasons, the plaintiffs in the California case relied on a monopoly leveraging argument that was applied by the Ninth Circuit to a patentee in *Image Technical*, and Ninth Circuit case law was not binding on an Illinois court.<sup>53</sup>

Regarding the complaint's allegation that Abbott violated the Sherman Act, Judge Gettleman noted: "There is sparse case law regarding if or how the monopoly leveraging theory applied to conduct by a patentee, and what little case law there is does not concern a price increase by a patent holder."<sup>54</sup> He also noted: "Applying the refusal to deal case law to the instant case [as both parties suggested], however, is no easy task. There is no Supreme Court precedent, and a split exists between the Ninth and Federal Circuits regarding whether the monopoly leveraging theory may be applied to patent holders."55 Finally, he stated: "The court is not persuaded by plaintiff's arguments in the instant case, or by the Ninth Circuit's reasoning in Kodak II, that a patentee's right to exclude others, including by raising prices, is limited to the primary market only, particularly when, as here, it is not disputed that the use of the patented invention in [the] second market is within the scope of the patent claims"56 and dismissed the complaint. Mr. Schor appealed the dismissal to the Seventh Circuit.

By the time Schor's appeal was heard, the two indirect purchaser cases in the Northern District of California had been consolidated, Abbott had filed a motion for summary judgment, the plaintiffs had filed a Rule 54(f) motion "to deny as premature or continue" Abbott's motion, and Judge Wilken had denied as premature defendant's motion for summary judgment.57 According to the court's opinion, the plaintiffs were entitled to discovery in a number of areas, including: (1) on Abbott's market share during the period in question;<sup>58</sup> (2) as to whether Abbott had engaged in anticompetitive conduct in the boosted market;<sup>59</sup> (3) as to whether Abbott's patents were valid and enforceable, and what the scope and application of these patents to the boosted market were; and (4) as to whether the price increase "was a pretext for anti-competitive conduct in the boosted market."60 Abbott argued that the plaintiffs' pretext argument was irrelevant under In re Independent Services Organizations Antitrust Litigation, "in which the Federal Circuit ruled that exercising legitimate patent rights can never support anti-trust liability."61 Judge Wilken noted that plaintiffs' claims arose under the Sherman Act, not under federal patent law, so Ninth Circuit precedent applied.<sup>62</sup> Judge Wilken also disagreed with Abbott concerning the relevance of the district court's decision granting Abbott's motion to dismiss in Schor, as that court had expressly not followed Image Technical, which was binding on a court in the Ninth Circuit.63 On April 7, 2006, the court heard arguments on Abbott's renewed motion for summary judgment, but the matter was not decided until after the May 1, 2006 hearing in the Seventh Circuit appeal of Schor v. Abbott Laboratories.

The Seventh Circuit affirmed dismissal in *Schor* and firmly rejected the theory of monopoly leveraging.<sup>64</sup> According to Judge Easterbrook's opinion,

[t]he problem with 'monopoly leveraging' as an antitrust theory is that the practice cannot increase a monopolist's profits. Abbott has (we must assume) a monopoly, but a monopolist can take its monopoly profit just once. It can collect a monopoly profit for ritonavir and allow a competitive market to continue in other products. Or, by reducing the price of ritonavir, it can induce customers to buy more from it. But it can't do both.<sup>65</sup>

Judge Easterbrook's opinion further stated: "The monopolist's profit-maximizing strategy is not to take over the market in related products (ritonavir and other protease inhibitors are complements, not substitutes, given the bad side effects when ritonavir is used alone) but to promote competition among the other producers. The less the complements cost, the more the monopolist can charge for its own product. . . . There's no reason to think that Abbott would be better off if it took over the market in protease inhibitors and tried to charge a monopoly price for substances that complement ritonavir. And if a manufacturer cannot make itself better off by injuring consumers through lower output and higher prices, there is no role for antitrust law to play."66 The opinion also discussed Image *Technical*, stating: "[W]e must acknowledge that one court of appeals has adopted just such an undisciplined monopoly-leveraging position. . . . [W]e think it better to join the Federal Circuit in saying that Image *Technical* just got it wrong."67 The Seventh Circuit also considered whether Abbott's pricing of Kaletra was in some sense predatory and concluded it was not for the

- 58 Id. at \*7.
- 59 *Id.* at \*8.
- 60 *Id.* at \*9-11.
- 61 *Id.* at \*10.
- 62 *Id. at* \*10.
- 63 *Id.* at \*10.

66 *Id.* at 608.

<sup>52</sup> *Id.* at 853.

<sup>&</sup>lt;sup>53</sup> *Id.* at 854. Judge Gettleman also noted: "Because the denial of the motions to dismiss for lack of standing were not final orders and thus not appealable, they do not have collateral estoppel effect on defendant's arguments in support of its motion to dismiss in the instant case." *Id.* at 855.

<sup>54</sup> *Id.* at 856.

<sup>&</sup>lt;sup>55</sup> *Id.* at 857.

<sup>&</sup>lt;sup>56</sup> *Id.* at 860.

<sup>&</sup>lt;sup>57</sup> Abbott Labs. Norvir Anti-Trust Litig., No. C 04-1511 CW (Consolidated Case), No. C 04-4203 CW, 2005 U.S. Dist. LEXIS 24238, at \*2-4 (N.D. Cal. September 12, 2005). The two cases were consolidated on May 2, 2005, Abbott's motion was filed on June 1, 2005, the plaintiffs' motion was filed on June 27, 2005, and the court's opinion was filed September 12, 2005. See id. at \*2-4.

<sup>44</sup> Schor v. Abbott Labs., 457 F.3d 608, 611-12 (7th Cir. 2006). The Supreme Court denied certiorari in 2007. Schor v. Abbott Labs., No. 06-577, 75 U.S.L.W. 3435 (2007).

<sup>65</sup> Schor, 457 F.3d at 611-12.

<sup>&</sup>lt;sup>67</sup> Id. at 613-614. In fact, the Federal Circuit did not criticize the Ninth Circuit's application of a theory of monopoly leveraging, but rather the Ninth Circuit's having "adopted a rebuttable presumption that the exercise of the statutory right to exclude provides a valid business justification for consumer harm." Independent Serv. Orgs. Antitrust Litig., 203 F. 3d 1322, 1327 (Fed. Cir. 2000).

following reasons: (1) "[e]ven if the ritonavir component of KALETRA were deemed to cost the same (per milligram) as ritonavir sold as NORVIR, the imputed price of KALETRA's lopinavir component would be above the average variable cost of its manufacture" and (2) there was no possibility of recoupment since the other PIs were still profitable.<sup>68</sup>

In addition, the Seventh Circuit rejected Schor's claim that issue preclusion blocked Abbott from offering any legal defense, noting that (1) the California decisions were not final; and (2) even if they were, they would not be preclusive in Illinois, as a difference in the governing law is one of the circumstances in which issue preclusion may be inappropriate.<sup>69</sup> The Seventh Circuit concluded that *Image Technical*, as applied in the California cases, "misunderstood the Sherman Act."<sup>70</sup>

Meanwhile, back in California, Judge Wilken denied Abbott's renewed motion for summary judgment on July 6, 2006,<sup>71</sup> finding that there were disputed issues of material fact with respect to plaintiffs' direct proof of monopoly power,<sup>72</sup> with respect to plaintiffs' demonstration that Abbott had a monopoly through use of circumstantial evidence,<sup>73</sup> with respect to plaintiffs' showing of anticompetitive conduct,<sup>74</sup> and with respect to

plaintiffs' proof of antitrust injury.75 Judge Wilken also considered Abbott's asserted antitrust immunity based on its patents, ruling that there were disputed issues of material fact as to whether the patents did, indeed, cover the boosted market,76 as to whether Abbott had "impliedly license[d] patients to use Norvir as a booster,"77 and as to whether the '157 patent "was anticipated and/or obvious."78 In June 2007, Judge Wilken certified the class in the consolidated indirect purchaser suits with two subclasses: one for individuals, with Doe 1 as the class representative, and one for institutions, with SEIU as the class representative.<sup>79</sup> Abbott raised two points about class membership for Does 1 and 2, namely that both of them paid flat co-payments for drugs, rather than a percentage of Norvir's price, and that Doe 2 was taking 1200 mg of Norvir a day, which was substantially more than would be used as a boosting dose.<sup>80</sup> The judge found that the fact that they paid a fixed co-payment was not grounds for exclusion from the class, but Doe 2 was excluded from the class due to his dosage level.81

Abbott moved again for summary judgment on all claims against it in 2008. The plaintiffs opposed this motion and cross-moved "for summary adjudication that Abbott's patents do not provide a defense to antitrust liability."82 Judge Wilken denied Abbott's summary judgment with respect to the plaintiffs' § 2 claims, but granted Abbott's motion with respect to plaintiffs' claim of unjust enrichment, stating: "[B]ecause Plaintiffs' unjust enrichment claim appears to be premised wholly on Abbott's alleged violation of federal antitrust law, Illinois Brick bars them from obtaining restitution based on those claims."83 In addition, Judge Wilken found that "the claims on which Abbott relies for its patent immunity defense are anticipated by the '882 patent and are invalid."84

### Other Suits in Judge Wilken's Court

A number of pharmacies and wholesalers filed antitrust suits against Abbott in fall 2007,<sup>85</sup> and Abbott filed "an omnibus motion to dismiss based on the Ninth Circuit's recent decision in *Cascade*" that "addresses the issue of when bundled discounts can be considered anticompetitive conduct in violation of the Sherman Act."<sup>86</sup> Judge Wilken denied Abbott's motion to dismiss. In her opinion, Judge Wilken first questioned whether *Cascade Health Solutions v. PeaceHealth*,<sup>87</sup> should be applied to these cases, noting that "it is far from clear that Abbott's sale of Kaletra represents a bundled

- <sup>72</sup> According to the opinion, Abbott claimed that the plaintiffs had to show that Abbott had reduced output to produce super-competitive prices in order to supply direct proof of monopoly power. However, Judge Wilken found that "[i]t can also be shown by 'injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power." *Id.* at 806 (references omitted).
- <sup>73</sup> For example, the plaintiffs' expert calculated Abbott's share of the boosted market to be 73%, whereas Abbott stated its share was 47% as of November 2005. One difference is that plaintiffs' expert counted both Norvir and Kaletra sales in his calculation of market share. See id. at 806.
- <sup>74</sup> For example, Judge Wilken noted according to the plaintiffs' expert, "although the 400 percent price increase did not raise Kaletra's market share, it raised its market share substantially above what it would have been absent the price increase," while the defendant "offers evidence that its competitors are thriving." *See id.* at 807.
- <sup>75</sup> Judge Wilken noted that the "[d]efendant argues that Plaintiffs fail to show an anti-trust injury because paying a high price for a patented drug is not an anti-trust injury," while the plaintiffs' expert finds "that Defendant's price increase harms HIV patients by creating another barrier to entry that hinders the introduction of new PIs from Defendant's competitors," which provides evidence of anti-trust injury. See id.

<sup>76</sup> *Id*. at 810.

77 *Id*.

<sup>78</sup> *Id*. at 811-13.

<sup>80</sup> *Id.* at \*8-9.

<sup>86</sup> Meijer, Inc. & Meijer Distribution, Inc., v. Abbott Labs., 544 F. Supp. 2d 995, 1000 (N.D. Cal. 2008).

<sup>87</sup> 515 F.3d 883 (9th Cir. 2008).

<sup>68</sup> Schor, 457 F.3d at 611. The opinion also states: "And if, as Schor seems to contend, KALETRA is not as beneficial for consumers as the combination of NORVIR and a protease inhibitor other than lopinavir, then it is easy to understand why KALETRA is sold at a discount: there's no antitrust rule against reducing the price of products that consumers desire less than competitive goods." *Id.* While there may be no rule against Abbott's reducing the price of Kaletra, that is not exactly what it did. It reduced the relative price of Kaletra by increasing the cost of using competitive PIs.

<sup>69</sup> Id. at 615.

<sup>70</sup> Id. at 618-20.

<sup>&</sup>lt;sup>71</sup> Abbott Labs. Norvir Anti-Trust Litig., 442 F. Supp. 2d 800, 802 (N.D. Cal. 2006).

<sup>&</sup>lt;sup>79</sup> Abbott Labs. Norvir Anti-Trust Litig., No. C 04-1511 CW (Consolidated Case), No. C 04-4203 CW, 2007 U.S. Dist. LEXIS 44459, \*21-22 (N.D. Cal. June 11, 2007).

<sup>81</sup> Id. at \*11-13

<sup>&</sup>lt;sup>82</sup> Abbott Labs. Norvir Anti-Trust Litig., 562 F. Supp. 2d 1080, 1081-82 (N.D. Cal. 2008).

<sup>&</sup>lt;sup>83</sup> *Id.* at 1090.

<sup>&</sup>lt;sup>84</sup> *Id.* at 1089.

<sup>&</sup>lt;sup>85</sup> Abbott Labs., Annual Report (Form 10-K), at 18 (Feb. 19, 2008). Suits purporting to be class-actions were brought by Louisiana Wholesale Drug Company, Inc., Meijer, Inc., and Rochester Drug Co-Operative, Inc. Suits were also filed by Rite Aid, Inc., and Safeway, Inc.

discount."88 Abbott did not offer lopinavir as a single-ingredient drug,89 and, in fact, Abbott's expert in the indirect purchaser case "explicitly argue[d] in his rebuttal report that a bundled discount theory does not apply to Abbott's pricing structure."90 Judge Wilken then noted that Cascade itself acknowledged that, in some cases, competition may be inhibited even when the "price" charged is above the variable cost of production<sup>91</sup> and that "Abbott's sale of Kaletra . . . is a strong candidate for the exception contemplated by the Ninth Circuit," stating that "[c]ommon sense dictates that no newly developed PI could ever be sold profitably at such a price [equal to lopinavir's average variable cost], because the manufacturer would never be able to recoup its huge research and development costs."92 According to the court, application of the Cascade rule in this case would stifle competition, because even a competitor who could produce an equally effective drug for one-fifth the variable cost of lopinavir would be excluded from the market.93 As a result, the Cascade rule would "not achieve its stated goal of prohibiting pricing that results in the exclusion of equally efficient competitors" because of the "unique structural characteristics of the pharmaceutical industry, where fixed costs in the form of investment in research and development dwarf variable costs."94

Abbott also moved to dismiss allegations in the purported class-action complaints that it had illegally monopolized the "boosting market"—by initially pricing Norvir at such a low price that research to find competing boosters or ways to reduce the amount of booster needed was stifled, then reaping the benefits of its actions by raising the price of Norvir—on the grounds that its patents on Norvir entitled it to a monopoly. Judge Wilken noted that "the extent of Abbott's exclusionary rights under its patent is not clear from the face of the complaint," so dismissal of this claim would be premature.<sup>95</sup>

GSK, the manufacturer of Lexiva, also sued Abbott in November 2007, and Abbott filed an unsuccessful motion to dismiss that complaint as well. With respect to GSK's Sherman Act claims, Abbott asserted that GSK was "pleading itself out of court" by admitting in its complaint that Abbott's patent covered the booster market<sup>96</sup> and that GSK was precluded from asserting claims because it had obtained a license from Abbott allowing it to market its own protease inhibitor for use with Norvir as a booster.<sup>97</sup> Abbott also failed in its effort to have the case transferred to Illinois, with Judge Wilken stating: "As for Abbott's charge that GSK has engaged in forum shopping, it appears equally likely that Abbott is engaging in similar conduct; by litigating the case in Illinois, Abbott would be able to rely on Seventh Circuit precedent, which is more favorable to Abbott than Ninth Circuit precedent."98

On August 27, 2008, Judge Wilken certified a class of direct purchasers who purchased Norvir and/or Kaletra from December 3, 2003 through "such time as the effects of Abbott's illegal conduct have ceased."<sup>99</sup> Judge Wilkin noted that the direct purchaser class alone also alleged that "in June, 2005, after Abbott had succeeded in 'neutralizing its boosted rivals' ability to compete on price,' it began inflating the price of Kaletra" and that "[b]y

October, 2007, Abbott had raised the price of Kaletra by twenty-five percent."<sup>100</sup>

### The Indirect Purchaser Settlement and the Interlocutory Appeal

On August 13, 2008, Abbott and the indirect purchaser class entered into an unusual settlement agreement, which would take effect only if (1) Judge Wilken stayed all deadlines in the action, pending Final Approval; (2) Judge Wilkin certified three issues for interlocutory appeal, and (3) the Ninth Circuit permitted an interlocutory appeal on the merits of at least two of these issues (or, if it permitted interlocutory appeal on only one issue, Abbott chose not to exercise its right to withdraw from the agreement). The three issues to be certified were:

Whether, as a matter of law, a plaintiff can establish antitrust injury based on the payment of an increased price for a patented product in the leveraging market, where the plaintiff contends the price increase was designed to maintain or create a monopoly in the leveraged market?

Whether, as a matter of law, a plaintiff can potentially establish monopoly power-in a case where the defendant allegedly used exclusionary pricing to slow a market share decline-where some existing competitors have increased both their market share and prices since the challenged pricing decision?

Whether the Ninth Circuit's decision in *Cascade* Health *Solutions v. Peacehealth* mandates judgment

<sup>&</sup>lt;sup>88</sup> Id. at 1002.

<sup>89</sup> Id. at 1002

<sup>&</sup>lt;sup>90</sup> *Id.* at 1002.

<sup>&</sup>lt;sup>91</sup> Under Cascade, "the full amount of the discounts given by the defendant on the bundle are allocated to the competitive product or products. If the resulting price of the competitive product or products is below the defendant's incremental cost of production, the trier of fact may find that the bundled discount is exclusionary for the purpose of § 2." *Meijer*, 544 F. Supp. 2d 995, 1001 (quoting *Cascade Health Solutions*, 515 F.3d at 906 (9th Cir. 2008)).

<sup>&</sup>lt;sup>92</sup> *Meijer*, 544 F. Supp. 2d at 1003.

<sup>93</sup> Id. at 1004.

<sup>&</sup>lt;sup>94</sup> *Id.* at 1004.

<sup>95</sup> Id. at 1005

<sup>&</sup>lt;sup>96</sup> In her opinion, Judge Wilken stated: "Contrary to Abbott's characterization of these statements [in the complaint], they do not admit or necessarily imply that Abbott has a valid patent covering the entire boosted market." *Id.* at 1006.

<sup>&</sup>lt;sup>97</sup> Judge Wilken wrote: "As this Court has noted previously, a party may choose to obtain a license, even under the belief that the licensed patent is invalid or does not cover the scope claimed by the patentee, in order to avoid the possibility of litigation." *Id.* 

<sup>98</sup> Id. at 1009

<sup>99</sup> Meijer, Inc. v. Abbott Labs., No. C 07-5985 CW, 2008 U.S. Dist. LEXIS 78219, \*30 (N.D. Cal. August 27, 2008).

<sup>100 /</sup>d. at \*5-6. On a related note, Thailand issued a compulsory license for Kaletra in 2007, after which Abbott announced it would reduce the price of Kaletra by more than half. See OXFAM INT'L, INVESTING FOR LIFE: MEETING POOR PEOPLE'S NEEDS FOR ACCESS TO MEDICINES THROUGH RESPONSIBLE BUSINESS PRACTICES 13 (2007), available at http://www.oxfam.org/files/bp109-investing-for-life-0711.pdf; Abbott to Cut AIDS Drug Price Amid Patent Dispute, REUTERS HEALTH MED. NEWS, Apr. 10, 2007, available at http://www.reuters.com/article/governmentFilingsNews/idUSN1031946020070410. On the other hand, Abbott's response included "withdrawing the registration of seven new medicines in Thailand, including a heat-stable version of Kaletra (used where there is insufficient access to electricity)." See OXFAM INT'L at 20.

against a monopoly leveraging claim based on unilateral pricing conduct where there is no allegation of belowcost pricing?<sup>101</sup>

Under this agreement, Abbott is to make a non-refundable payment of \$10 million (regardless of the outcome of the appeal to the Ninth Circuit), with Abbott obligated to pay an additional \$17.5 million if plaintiffs prevail on appeal.<sup>102</sup>

On August 27, 2008, Judge Wilken issued two orders: (1) an "Order Granting Motion for Preliminary Approval of Class Action Settlement" and (2) an "Order Certifying Issues and Granting Leave to Seek Interlocutory Appeal."<sup>103</sup> On December 18, 2008, the U.S. Court of Appeals for the Ninth Circuit granted Abbott's "petition for permission to appeal pursuant to 28 U.S.C. § 1292(b)."<sup>104</sup> It appears that the Court granted Abbott's petition as to all of the orders (and related issues) for which Abbott sought appeal.<sup>105</sup>

#### Current Status of Cases

So far, Abbott has:

- prevailed in front of NIH;
- been given a "pass" by the FTC;
- been investigated by the Attorneys General of Illinois, New York, and California;
- prevailed on a motion to dismiss in Illinois state court;
- prevailed on a motion to dismiss in the District Court for the Eastern Division of the Northern District of Illinois;

 prevailed on an appeal of that decision to the Court of Appeals for the Seventh Circuit;

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- settled the antitrust and false advertising cases brought by the AIDS Healthcare Foundation in district court in California for an unknown sum;
- tentatively settled with the indirect purchaser class in the District Court for the Northern District of California (after having lost motions to dismiss and motions for summary judgment) for a minimum payment of \$10 million;
- had its interlocutory appeal to the Ninth Circuit accepted;
- lost a motion to dismiss cases brought by a now-certified class of direct purchasers and by individual direct purchasers; and
- lost motions to dismiss and to transfer the case brought by GSK to Illinois.

### Discussion

Currently, there is a split between the Seventh and Ninth Circuits regarding the theory of monopoly leveraging, with the Ninth Circuit adopting that theory in Image Technical and the Seventh Circuit rejecting it out of hand in Schor v. Abbott Laboratories.<sup>106</sup> In addition, the district court's application of Cascade is inconsistent with the Seventh Circuit's analysis regarding predatory pricing, as the district court noted that no potential competitor could price its PI at lopinavir's variable cost and still be able to recoup its research and development costs, whereas the Seventh Circuit adopted an average variable cost standard in its description of predatory pricing.

One question is whether the Seventh Circuit would have viewed Mr. Schor's complaint and the theory of monopoly leveraging differently had it had access to the documents reviewed by the Wall Street If these documents reflect Journal. alternatives being given serious consideration by Abbott decision makers, Abbott was apparently willing to forgo all U.S. profits on sales of Norvir in order to increase (or at least protect) the profits it earned on Kaletra. Clearly, the folks at Abbott believed that the profit potential of Kaletra exceeded that of Norvir, even though Kaletra was part of a market in which Abbott faced competition and Norvir was not. On the other hand, it seems clear that, had Abbott followed this strategy, NIH would have looked much more favorably on a march-in petition than it actually did, which would have defeated Abbott's purpose in withdrawing Norvir.107 Abbott also apparently believed that increasing the price of Norvir would have a similar effect on sales of Kaletra, and, if the Wall Street Journal is correct, it did lead to increased sales of Kaletra.<sup>108</sup> While Abbott may have foregone monopoly profits on sales of Norvir that would have complemented PI sales made by its competitors, it must have foreseen earning higher profits on its sales of Kaletra.

A final note: an alternative way to view the relationship between the market for boosting agents (e.g., Norvir) and the market for boosted PIs is to consider Abbott's decision regarding the level to which it should raise Norvir's price. Had Abbott not sold both Norvir and Kaletra, it would have charged the

<sup>104</sup> John Doe 1 v. Abbott Labs., No. 08-80150, December 18, 2008. In addition, "[1]he motion of 'related case plaintiffs' to appear as amici curiae and to file a 27-page brief [was] granted," as was Abbott's "motion for permission to file a brief in response to the amicus brief." *Id.* 

<sup>107</sup> Abbott's presumed inability to withdraw Norvir also removes one of the arguments commonly made regarding increasing the price of a patented products, namely that the price increase is less harmful to consumers than withdrawal of the product would have been.

<sup>&</sup>lt;sup>101</sup> SETTLEMENT AGREEMENT BETWEEN ABBOTT LABORATORIES INC., JOHN DOE 1, AND SEIU HEALTH AND WELFARE FUND 7 (Aug. 13, 2008) [hereinafter Settlement Agt.] (internal citation omitted).

<sup>&</sup>lt;sup>102</sup> Abbott would be obligated to pay one-fourth of this amount if Abbott were to be deemed the "Partially-Prevailing Party," with Abbott deemed to be such "if, without reaching a decision on the merits of any of the issues it has accepted for appeal . . . , the Ninth Circuit reverses or vacates any challenged ruling or order by the District Court and remands any matter or issue to the District Court for reconsideration or further review based upon a legal or factual standard enunciated by the Ninth Circuit that differs from any standard applied by the District Court." *Id.* at 12.

<sup>&</sup>lt;sup>103</sup> In this order, Judge Wilken noted: "Although the Court previously denied a request to certify one of these issues for interlocutory appeal, the balance of the factors is changed by the fact that the parties have resolved their other differences so that there would be no trial or second appeal following the interlocutory appeal. Moreover, the resolution of these questions on appeal would also be helpful in clarifying the issues in the related antitrust cases brought against by direct purchasers and by one of its competitors." *Abbott Labs. Norvir Anti-Trust Litig.*, No. C 04-1511 CW (order certifying issues and granting leave to seek interlocutory appeal), August 27, 2008.

<sup>&</sup>lt;sup>105</sup> The order is silent on this issue.

<sup>&</sup>lt;sup>106</sup> As noted by the Federal Circuit, there is also a split between the Ninth and Federal Circuits with respect to the circumstances that can give rise to violations of the Sherman Act by patent holders, with the Ninth Circuit's interpretation of the language in footnote 29 of the Supreme Court decision in *Eastman Kodak Co. v. Image Technical Serv., Inc.,* 504 U.S. 451 (1992), leading it to adopt a "rebuttable presumption that the exercise of the statutory right to exclude provides a valid business justification for consumer harm" and the Federal Circuit requiring proof that the patent holder obtained the patent "through knowing and willing fraud within the meaning of *Walker Process Equipment, Inc. v. Food Machinery &Chemical Corp.*" before contemplating antitrust liability. *See Independent Serv. Orgs. Antitrust Litig.,* 203 F.3d 1322, 1326-27 (Fed. Cir. 2000) (describing its view and the Ninth Circuit's view).

<sup>&</sup>lt;sup>08</sup> Abbott forecast that Kaletra sales would drop by 10 percent once Lexiva was approved, whereas Kaletra's sales increased by 10 percent over the two years following the Norvir price increase. See Carreyrou, supra note 7. According to direct purchaser class plaintiffs, Abbott also increased the price of Kaletra beginning in June 2005, increasing it by 25 percent between then and October 2007. See Meijer, Inc. v. Abbott Labs., No. C 07-5985 CW, 2008 U.S. Dist. LEXIS 78219, \*5-6 (N.D. Cal. August 27, 2008).

"monopoly price" for Norvir, which would be constrained by patients' willingness to forgo the use of Norvir as a boosting agent (i.e., switching to an unboosted PI). However, once Abbott included Kaletra in its decision regarding Norvir's price, it would likely set a price for Norvir that was above the previous "monopoly price," as some of the patients who would have otherwise chosen to use an unboosted PI would likely now switch to Kaletra. Therefore, if there were some way to

determine what the pure monopoly price would have been, a finding that the actual price charged by Abbott exceeded this would provide a method of determining interactions between the two markets.

The FTC Roundtable on Follow-on Biologics Drugs: Framework for Competition and Continued Innovation



Biologics have had a dramatic effect across many medical fields, including rheumatology, oncology, cardiology, dermatology, gastroenterology, neurology, and others. Across all medical disciplines, biologics have added major therapeutic options. Biologics are statutorily defined<sup>1</sup> and include medicines produced from living organisms by means of biological processes involving recombinant DNA technology.<sup>2</sup> Follow-on biologic ("FOB") is an informal term, referring to products intended to be sufficiently similar to an approved biologic product to permit an applicant to rely on certain existing scientific knowledge about the safety and effectiveness (or safety, purity, and potency) of the approved product. The molecules of the biologically created drugs are usually much larger and more complex than traditional pharmaceutical drugs; hence, they are also referred to as large molecule drugs, whereas traditional chemical drugs are referred to as small molecule drugs. In the arena of small molecule drugs, the Hatch-Waxman Act has set up a pathway for introduction of generic drugs.<sup>3</sup> There is now a discussion as to whether a similar pathway should be established in the large molecule arena.

On November 21, 2008, the Federal Trade Commission ("FTC") hosted an all-day roundtable titled "Follow-on Biologics Drugs: Framework for Competition and Continued Innovation." The roundtable was composed of five panels addressing various facets of the topic, including the price and market share effects of entry, the likely competitive effects of reference product regulatory exclusivity, biotechnology patent issues, the likely competitive effects of follow-on biologic regulatory incentives, and the patent resolution process.

To start the day, FTC Commissioner Pamela Jones Harbour offered welcoming remarks and stressed the importance of the FTC's involvement in any future legislation on the By Valentina V. Rucker, Esq. Jacob H. Wolman, Esq. Wilson Sonsini Goodrich & Rosati, P.C.



issue. Commissioner Harbor reminded the audience that a "principled and rigorous analysis of competitive dynamics" of the follow-on biologics market was absolutely necessary to protect consumer interests. She identified the goal of the workshop as learning more about this fastgrowing sector of the economy in order to provide meaningful advice to the policy makers.

After Commissioner Harbour finished her introductory remarks, Rachel Behrman of the Food and Drug Administration ("FDA") explained how biologics differ from the traditional chemical drugs. Generally, biologics are larger and more complex than Additionally, the chemical molecules. because biologics are derived from living cells, it is much harder to account for things such as unexpected aggregation (which can cause side effects), incorrect protein folding, amino acid modification and truncation. Also, unlike traditional chemical drugs, no legal or scientific mechanism currently exists to definitively establish that active ingredients of one biologic are identical, or at least comparable to, the active ingredients of another.

To keep the discussion consistent, the FTC moderators requested that panelists adhere to the following terminology:

- Biogeneric drugs are therapeutically equivalent, interchangeable, and substitutable at the pharmacy/point of use level with the reference product.
- **Biosimilar** drugs are comparable to the reference product. A biosimilar product could include products that are improvements to the innovator's referenced product (e.g., through dosing, effectiveness, side effect profile, etc.).
- Follow-on biologics include both biosimilar and biogeneric drug products.

#### PANEL I: Likely Market Effects of Followon Biologic Drug Competition

To start the discussion, Paul Heldman, Senior Health Policy Analyst of Potomac Research, gave an overview of biologic drug markets. He noted that the emerging follow-on biologics have less market penetration than their counterparts in the markets for small molecule (chemical) medicines. Using Omnitrope/Genotropin— the only U.S. experience with a biosimilar-as an example, Heldman demonstrated that after a year on the market FOB Omnitrop has only gained a one percent market share. Whereas the entry of a small molecule generic is usually associated with an 80 percent discount, FOB Omnitrop only provided a 30 percent discount.<sup>4</sup> Heldman opined that the reasons for the diminished discount were longer clinical development and higher marketing costs, as well as the fact that biosimilars are not substitutable at the pharmacy level.

After the market dynamics overview, participants were asked to discuss the likely price and market share effects caused by the entry of a biosimilar and a biogeneric as well as the likely competitive effects FOBs would have on reimbursement by private and public payers. Participants included: (1) Alexis Ahlstrom, MPH, Director, Avalere Health LLC; (2) Rachel E. Behrman, MD, MPH, Director, Office of Critical Path Programs, Office of the Commissioner, FDA; (3) Steven B. Brugger, MBA, Chief Operating Officer, Momenta Pharmaceuticals, Inc.; (4) Ted Buckley, PhD, Director, Economic Policy, Biotechnology Industry Organization; (5) David Golding, R.Ph, Executive Vice President for Specialty Pharmacy Services, CVS Caremark; (6) Henry C. Grabowski, PhD, Professor, Duke University; (7) John Lane, MBA, Vice President, Biologics, Hospira, Inc.; and (8) Mateja Urlep, R.Ph, MS, Head Global Marketing & Medical, Biopharmaceuticals, Sandoz International.

4 Paul Heldman, Follow-On Biologic Market: Initial Lessons and Challenges Ahead, Nov. 21, 2008, available at http://www.ftc.gov/bc/workshops/hcbio/docs/fob/pheldman.pdf.

Section 351(i) of the Public Health Service Act ("PHS Act") defines a biological product as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound . . . )."

<sup>&</sup>lt;sup>2</sup> These medications are usually one of three types: (1) substances that are (nearly) identical to the body's own key signaling proteins, e.g., "growth hormone"; (2) monoclonal antibodies, which are similar to the antibodies that the human immune system uses to fight off bacteria and viruses; and (3) receptor constructs (fusion proteins), usually based on a naturally-occurring receptor linked to the immunoglobulin frame.

<sup>&</sup>lt;sup>3</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282).

The participants continued discussing real life Omnitrope/Genotropin examples and Eprex. Panelists universally agreed that clinical studies and marketing efforts were very costly in both cases. Participants then examined the price of bringing a FOB to market and concluded that the cost of bringing a small molecule generic to market was significantly lower than the cost of introducing a FOB. Mr. Lane estimated that it would take \$30 to \$50 million to introduce a simple FOB, and the cost could approach \$75 to \$100 million for a more complex biologic, such as a virus or complex protein.

Panelists noted that the only benefit of an abbreviated review process, when introducing a FOB, was that the company could skip Phase 2 (dose-defining) studies, but would still be responsible for Phases 1 and 3 of the clinical studies. Mr. Brugger commented that, without interchangeability, physicians would initially have to rely on costly data sets acquired by the FOB developers and physicians' personal experience, and this would blunt any market share erosion resulting from an introduction of a FOB. Ms. Ahlstrom also agreed that slow market share erosion would result because the FOB cannot be designated as interchangeable, i.e., biogeneric.

The discussion then turned to the U.S. health care market and the intricate interplay between the physician, the patient, and the third-party payer (usually an insurance company). Biologics are dose-for-dose more expensive than small molecule drugs; therefore, the marginal benefit of steering a patient toward a FOB is potentially much higher for an insurer than steering a patient/doctor from a branded small molecule drug to a generic. Dr. Buckley offered that if a FOB is significantly cheaper than the innovator's drug, even in the absence of interchangeability, the third-party payers will steer doctors towards prescribing it, making the FOB a de facto preferred drug.

Even if there were a pathway to designate FOBs as biosimilar or biogeneric, there are several factors that play a role in a brandname-to-generic drug substitution. Mr. Buckley discussed factors that affect market penetration and share erosion and concluded that interchangeability of biologics may not necessarily result in major discounts. He suggested that no one can predict what would happen if only one FOB entered the market. The biogeneric may merely shadow the innovator's drug pricing, and its introduction would not result in any significant Rather, Mr. Buckley price decrease. suggested more discounts might result from

an introduction of a FOB because it would have to price low enough to entice customers to switch. Mr. Brugger, Mr. Lane, and Ms. Urlep disagreed, stating that once the FDA designates a drug as interchangeable, it takes physicians out of the decision-making process, saves marketing costs, and forces substitution in states in which pharmacies are required to fill prescriptions with generics when available, practically guaranteeing lower prices.

Panelists then were asked about how a reimbursement scheme, such as Medicare's, affects prices. Most agreed that there are many ambiguities and potentially misaligned incentives. Mr. Heldman noted that what drives legislation is the potential for cost savings. Thus, if the lawmakers can visualize how realigning the Medicare physician payment system can achieve greater savings, then they will give that legislation higher priority.

A brief discussion of second generation drugs and what has spurred innovation followed. Panelists agreed that, even with patents protecting their intellectual property rights, innovators cannot just rest on their laurels and must continuously innovate or risk losing their foothold in the market. Over the past 20 years, the biopharmaceutical industry has been one of the most innovative sectors of the economy, even though no pathway for FOBs has been established. The question remained, however, whether there would have been more innovation had there been such a pathway. Mr. Brugger, whose company develops both branded and generic drugs, asserted that the threat of a biogeneric entrance would stimulate innovation to even a higher degree. Mr. Buckley was not convinced, however, that the threat of entry by a biosimilar would be less significant than entry by a biogeneric.

Next, panelists briefly discussed how international resources should be utilized and how data generated abroad should be treated. Ms. Behrman offered her own philosophical views on the issue, but did not feel comfortable commenting on the legal and regulatory implications. In her opinion, the FDA, as a public health agency, should not waste public resources by requiring duplicate trials unnecessarily, especially when this entails subjecting patients to studies that need not be conducted. The agency routinely looks at data generated abroad, and she stated that it should continue to do so.

Panelists concluded by addressing factors that would ultimately affect FOB entrants. Mr. Brugger stated that he would like to see a

clear path toward interchangeability because this development would allow his company to innovate in the analytical space, rather than spending resources on tests and clinical trials. Ms. Urlep, as a representative of Sandoz, underscored the importance of biologics, but indicated that Sandoz is preparing to compete in the market the way it is. Mr. Lane also saw a great opportunity for biogenerics and, in considering whether to make investments in the space, would look at the length of time granted for market exclusivity, whether there will be a patentresolution system in place, and especially whether interchangeability (full automatic substitution) is possible. All panelists agreed that final language of the legislation will, to a great extent, dictate who enters the market.

### PANEL II: Likely Competitive Effects of Reference Product Regulatory

### Exclusivity

After Linda Horton, a partner at Hogan & Hartson, gave an overview of the European experience with FOBs,<sup>5</sup> the participants were asked to discuss the pros and cons of any regulatory exclusivity period from both the innovator firms' and FOB applicants' perspectives. This panel's participants included: (1) Ms. Ahlstrom; (2) Geoffrey Allan, PhD, President and CEO, Insmed Inc.; (3) Alex M. Brill, Research Fellow, American Enterprise Institute; (4) Ms. Horton; (5) Mr. Golding; (6) Professor Grabowski; (7) Mr. Heldman; (8) Audrey Phillips, PhD, Executive Director of Biopharmaceutical Public Policy and Advocacy, Johnson & Johnson; and (9) Ms. Urlep.

The goal of the panel was to identify the purpose of a reference product data exclusivity period and to examine likely competitive effects and ways to structure the data exclusivity period. Panelists discussed issues of recoupment and innovation in relation to the time periods preventing FOB competitors from seeking regulatory approval while relying on innovator's data. Panelists also explored the pros and cons of varying the length of any regulatory exclusivity period and other ways to encourage innovation.

First, panelists were invited to comment on the data exclusivity period and its purpose. Ms. Phillips defined the data exclusivity period as the time when investment decisions are made—the data exclusivity is about protecting the data (not market exclusivity or monopoly). She stated that, on the one hand, data exclusivity "is about a period of time where the government cannot rely upon that data and, in essence, cannot tap into the investment of the innovator." On the other

hand, data exclusivity actually facilitates competition, because it allows the government, at some point in time (after the exclusivity period ends), to be able to rely upon the innovator's data and investment. Hence, currently this is a system of trade-offs, and any legislative change will disturb that status quo.

Professor Grabowski suggested that data exclusivity is a complementary feature to the patent system. The panelists then discussed how to quantify the investment and what exactly should be recouped to ensure continued investment. Ms. Phillips noted that biosimilars must prove themselves to be able to piggyback on the investment and marketing costs of the innovator. Ms. Horton pointed out that FOB companies producing biosimilars are at a great advantage because they know the goal that they are trying to achieve, even if they do not know the way to get there, and this, on its own, can yield significant savings.

Next, the panel focused on what would be the optimal way to determine the length of data exclusivity. The break-even analysis framework was suggested as helpful, as it specifically works with the relationship between data exclusivity to the break even point. It was noted, however, that the data exclusivity duration of an innovator and the break even point may occur at different periods. Professor Grabowski cited his study and discussed some new results regarding extending the model of Congressional Budget Office ("CBO") assumptions.<sup>6</sup>

Ms. Urlep added that, even one year after a biosimilar's market entry, the originator brand still has considerable market share, so in her opinion the innovator continues to recoup their investment long after a biosimilar enters the market. Mr. Allan offered that data exclusivity is a return on investment, and the cost to develop the drug in the first place should be a key consideration.

Next, panelists discussed what should be considered a part of the investment when deciding whether that investment has been recouped. Mr. Allen said that all marketing and sales expenses should be recouped. Also, a cash-flow analysis may be helpful when examining the probability of success, time, cost of capital, and an actual outlay. Ms. Phillips pointed out that a company producing a biosimilar does not have to integrate risk into their thinking because the risk has been accepted by the innovator. Mr. Brill noted the importance of the portfolio framework, as it factors in more than just the cost of succeeding—it also includes the cost of attempted sales.

The panel then addressed the driver of prices and whether there would be any significant difference between a seven-year and a ten-year data exclusivity period. Professor Grabowski suggested that one driver is the price among therapeutic alternatives. He noted that price will be driven by the interaction with payers and other competitors. Another panel member pointed out that the previous comments were based on the perspective of only the largest biologic manufacturing firms, and that a more balanced look may not support a seven-year exclusivity period.

Setting aside the topic of a data exclusivity period, the panel examined other policies that could be used to encourage research and development, such as tax credits for research investments. Panelists looked at whether such policies would be more efficient than using a recoupment model. Professor Grabowski purported that tax credits are useful in some circumstances; however, at the current moment, Congress is besieged with tax credit requests. He said that it is a welcome initiative, but involves competing with all other initiatives in the budget.

Finally, the group discussed whether the U.S. should adopt a similar structure to the European data exclusivity system. There are currently bills pending in Congress which would establish a regulatory scheme for FOBs,7 but not everyone agreed that this legislation presents the best avenue for the development of a regulatory structure. Panelists cautioned that one must tread lightly in this area so as to not disincentivize research and innovation. The European model on exclusivity should be taken into consideration, but a U.S. model must also allow for free competition after a certain point. It was generally agreed amongst panelists that a hard mathematic formula was not the way to go.

#### PANEL III: Biotechnology Patent Issues

The participants of the third panel were asked discuss the interaction between to biotechnology product patents and regulatory exclusivity periods. The panelists focused on whether there are differences between patents for biologics versus traditional chemical drug patents relating to claim drafting and Patent & Trademark Office ("PTO") allowance processes and trends regarding judicial review. Also, they discussed whether regulatory exclusivity and patent rights affect innovator firm and FOB applicant needs for business planning certainty.

The participants included: (1) Ken Dow, Assistant Patent Counsel, Johnson & Johnson; (2) Ken Goldman, MS, Vice President, Intellectual Property Strategy, Novartis

International AG; (3) Esther Kepplinger, Director, Patent Operations, Wilson Sonsini Goodrich & Rosati; (4) Jeffrey P. Kushan, Partner, Sidley Austin LLP; (5) Bruce A. Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals, Inc.; David Manspeizer, VP Intellectual (6) Property & Associate General Counsel, Wyeth; (7) Doug Norman, General Patent Counsel, Eli Lilly and Company; (8) Naomi Pearce, IP Director and Counsel, Hospira, Inc.; and (9) Rochelle Seide, Senior Counsel, Schwegman, Lundberg & Woessner.

The biotech industry implicates many types of patents. Method patents protect a specific way of producing a product such as an FOB and, thus, are not product-specific. Further, as a company approaches market introduction, it may get additional patents on production optimizing technology. Additionally, patents protecting a biologic may be multi-faceted. For example, a patent may protect not only a receptor, but also a suppressor of that receptor (called an antagonist), which treats diseases caused by over-activity of the receptor. Still other patents may protect diagnostics, research tools, and manufacturing platforms.

Patent claims in the small molecule arena can cover a precise molecule, and potentially a genus including that molecule. Some protected genera may include hundreds,

<sup>&</sup>lt;sup>6</sup> Henry G. Grabowski, David B. Ridley & Kevin A. Schulman, *Entry and Competition in Generic Biologicals*, MANAGERIAL & DECISION ECON. (2007), *available at* <u>http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=992479</u>; *see also* Henry Grabowski, *Data Exclusivity for New Biological Entities*, DUKE UNIV. DEP'T OF ECON. (June 2007) (working paper), *available at* <u>http://www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf</u>; Henry Grabowski, Iain Cockburn & Genia Long, *The Market For Follow-On Biologics: How Will It Evolve?*, 25 HEALTH AFFAIRS 1291-1301 (2006).

Access to Life-Saving Medicine Act, H.R. 1038, 110th Cong. (1st Sess. 2008) [hereinafter Waxman Bill]; Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, 110th Cong. (1st Sess. 2008) [hereinafter Inslee Bill]; Pathway for Biosimilars Act, H.R. 5629, 110th Cong. (2d Sess. 2008); Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. (1st Sess. 2008).

thousands, or even millions of compounds, providing a broad scope of protection. Such patent claims are typically not available in the biotech arena and an innovator may need multiple patents to cover a fraction of the scope available for small molecule drugs. Mr. Manspeizer stressed that patents generally do not provide certainty of protection, and biotech patents provide even less certainty than small molecule patents. Further adding to such uncertainty is the lack of clarity on the extent of allowed adjustment to the product which would result in non-infringement. For example, where a biologic is a protein, the protein is typically defined by an amino acid sequence. If a protein FOB were to copy an amino acid sequence claimed in an innovator's patent, then the innovators' patent infringement claims would be at their strongest. At the same time, Mr. Manspeizer argued, if a manufacturer of a protein FOB could change one or several amino acids from the claimed sequence and yet still is able to argue biological equivalence or biosimilar activity, then the patents that the innovator owns would be less likely to be successfully enforced against the FOB.

Ms. Pearce agreed that the patent landscape for FOBs is very complex, but offered a unique perspective as a representative of a company participating in small and large molecule markets. For small molecules, most process patents can be circumvented because the industry is mature and multiple ways of production have been developed. By comparison, in the biologics space, there may not be another commercially appropriate way to produce a product; thus, such process patents act as an additional market barrier.

Ms. Seide explained how intellectual property has changed as to the scope of claims available for innovators over the years. Biopharmaceutical patents have become narrower. Filing early is usually dictated by market pressures, and companies do not have time to test and study their biologics and, as a result, may not have a plethora of examples that would be an equivalent of a genus claim in the small molecule patent application. Thus, the companies only provide a narrow description of their discovery. In combination, this typically leads to limited scope in the claims allowed by the PTO to issue as a patent. This is further aggravated by the courts' unwillingness to go outside of the specific language of a claim, because they consider pharmaceuticals, both chemical and biologics, to be a very unpredictable technology.

The doctrine of equivalents has been severely curtailed over the last 10 years by the decisions of the Supreme Court and the Federal Circuit.<sup>8</sup> This narrowness affects the strength of a patent because it gives incentives to design around a product without any threat of infringement litigation. Thus, innovators experience a two-way pressure: on the one hand, only narrowly formulated claims will be awarded by the PTO; on the other, the innovator can only litigate infringement that exactly matches its patent claims. Later in the discussion, Ms. Kepplinger pointed out that the PTO recently put out new written description guidelines. Although these guidelines allow for 85 percent likeness to meet written description, these guidelines do not say that a similar partial description will suffice for proper enablement.9

Mr. Goldman agreed with Ms. Kepplinger and Ms. Pearce that the scope of the patents has been narrowed in the past 10 years and advocated a specific approach to biologics, one that ensures continued innovation by protecting innovator's rights. Mr. Norman further argued that if biologics innovators were forced to work in the small molecule framework, incentives for continued research and development would be eliminated. He noted that whereas a small molecule, and some simple biologics, will always look the same and, therefore, any infringement would be easy to detect, for some complex biologics, the FOB producer might change a few non-material components (e.g., amino acids in a protein) and argue that the FOB is materially different from the claimed biologic. Ms. Pearce was not convinced that minor and immaterial sequence changes would protect a FOB from an infringement risk, thus she did not find "circumvention" concerns plausible.

Several panelists then touched upon patent term adjustment. The patent term adjustment mechanism is a relatively recent process for extending patent term due to delays at the PTO. It was suggested that as the backlog at the Patent Office increases, patent term adjustment becomes increasingly important and thus should apply to both large and small molecule products. Ms. Pearce commented that, in the biopharmaceutical market, patent term adjustments are common practice, whereas they are rare in the small molecule space.<sup>10</sup>

Mr. Norman suggested that there is room for improvement. There is a limitation under the Patent Term Restoration Act, which was a part of the Hatch-Waxman Act that put a five-year cap on the amount of restoration a patent applicant can obtain. Often, a fiveyear cap on patent term restoration means that the patent holder does not get 14 years of market exclusivity. When combined with how difficult it is to move an application through the FDA, the number of new products being launched is declining rapidly from year-to-year. Further, the innovators are unable to carry out clinical trials on preventative medicine because those can take up to 10 years. Innovation is bypassed because there are not proper rewards.

Not all panel participants thought that innovators in the biologics market do not have sufficient protection. Mr. Leicher stressed that it is very important to keep economic and patent analyses together. One should avoid the tendency to consider economics and competition in a ten-year context, but then switch to 30 years in the context of patents. He offered a view different to Mr. Kushan, who argued that because many biologics' behaviors as drugs are unpredictable, one should not disassociate the scientific foundation of the discussion from the legal foundation. Mr. Leicher, on the other hand, thought that if the inventor tries to cover as much of the biology as possible, then there are much broader protections for biotech patents.

Panelists then attempted to answer how well existing patents cover the investments of biologics innovators. An appropriate balance needs to be found between competition and innovation. One panelist suggested that any discussion of competition must necessarily include the competition between innovator companies. To promote competition between the innovators there must be sufficient data exclusivity, including for new indications.

<sup>&</sup>lt;sup>8</sup> See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722 (2002) (holding that narrowing, in the face of a rejection, will cause the patent holder to lose the equivalents, except those unforeseen at the time of the narrowing amendment); see also In re Donaldson Co., 16 F.3d 1189 (Fed. Cir. 1994) (limiting the Doctrine of Equivalents).

<sup>9</sup> U. S. Patent & Trademark Office, WRITTEN DESCRIPTION TRAINING MATERIALS, Revision 1, Mar. 25, 2008, <u>http://www.uspto.gov/web/menu/written.pdf</u>. Example 11 is significant. The USPTO has changed their position as compared to 1990s.

<sup>&</sup>lt;sup>10</sup> Ms. Pearce then compared the top three selling small molecule injectable oncology drugs and the equivalent top-selling biopharmaceutical molecules. In the small molecule market, no patent has received a patent term adjustment. She noted that between four and 15 patents have received a patent term adjustment for the equivalent top-selling biopharmaceutical molecules. The period of those adjustments ranged from one year to four years.

Other panelists agreed that the public benefits most from the development of new drugs and new methods to cure diseases. Just because innovators' contributions are so important, however, does not mean that they should be allotted exclusivity forever. Instead, panelists advocated a balanced framework to account for incentives to innovate, as well as consumers' interest in dynamic markets and cheaper prices.

Mr. Goldman was convinced that although aggressive and intelligent patent prosecution provides innovators with a broad enough patent, the patent system alone is not going to satisfy the risk that innovators face of not getting the return on their investment. Therefore, Novartis believes that the biotechnology patent should not be coupled with the FOB regulatory review scheme.<sup>11</sup> He continued that data exclusivity (at least as good as currently in force in Europe) would go a long way toward providing that type of assurance and reduce that risk. Generally, Mr. Goldman would leave all decision-making to the FDA when it comes to determining which products are biosimilar or biogeneric and promoting consistent regulatory standards.

#### PANEL IV: Likely Competitive Effects of Regulatory Incentives for Generics Manufacturers

During the fourth panel, the participants examined the likely competitive effects of granting regulatory incentives to FOB manufacturers. Participants included: (1) Mr. Allan; (2) Aaron Barkoff, PhD, Partner, McDonnell Boehnen Hulbert & Berghoff LLP; (3) Marc A. Goshko, MS, Executive Director Legal Affairs, TEVA Pharmaceuticals, North America; (4) Steven B. Miller, MD, MBA, Senior Vice President and Chief Medical Officer, Express Scripts, Inc.; (5) Mr. Norman; (6) William B. Schultz, Partner, Zuckerman Spaeder LLP; and (7) Bryan Zielinski, MS, Assistant General Counsel, Intellectual Property, Pfizer.

The panel first turned to the question of whether a marketing exclusivity period is necessary to encourage entry by FOB manufacturers. Several panelists emphasized that legislators should be sure that future advances in technology and scientific knowledge can be accommodated by the legislation that Congress puts in place. Mr. Schultz noted, for example, that a generics company will face significant hurdles in efforts to persuade the FDA that a FOB is interchangeable with a reference product.

An earlier panel considered the extent to which the number of entrants in a market guarantees savings for consumers. This panel turned to the question of how to incentivize a second FOB manufacturer (as well as the third, fourth, and so on). Mr. Zielinski suggested that no incentive should be necessary, even for the first generic entrant, and the market dynamic itself should be sufficiently enticing to attract additional generic entrants. Because the innovator will have already spent all of the money and taken the business risk in developing the biologic product, any FOB manufacturer should not need an additional incentive just for "following the path" established by the innovator. Mr. Goshko indicated that an exclusivity period based on reasonable parameters should be sufficiently enticing to develop the first FOB, but not so limiting as to discourage other entrants from bringing their own products onto the market.

In 1984, the Hatch-Waxman Act essentially created a generics industry. Mr. Miller observed that the environment in 2008 is very different from that of 1984. The generics industry is now established for small molecule products as well as biologics, so, in considering incentives, it is important to look at the circumstances differently. The exclusivity period must be earned for doing more than just following on. For example, the market for Erythropoietin ("EPO") is so large that an FOB manufacturer would probably not need incentives to challenge an innovator's patents. The situation for smaller biologics markets may differ, however.

Mr. Norman cautioned that any new legislation should avoid creating a bounty on the intellectual property rights of innovators. Another panelist pointed out that none of the proposed bills adopt a 180-day exclusivity on FDA approval,12 as the Hatch-Waxman Act In some of the bills under does. consideration, the first FOB product to get approval as а biogeneric, i.e. interchangeable, (not to file, nor to challenge a patent) gets marketing exclusivity for some time, but other manufacturers may still get FDA approval and enter the market themselves.

Mr. Allan said that once there is legislation to let FOBs be developed, companies will line up. They will have to wait for patents to expire and invest between \$50 million and \$100 million in developing a product. If there are any more barriers to getting a company's return on investment, it will only be anticompetitive. For this reason, he opposes any exclusivity provisions for FOB manufacturers.

Mr. Norman added his perspective as an innovator. Eli Lilly often has to make difficult decisions about where to place its investments. The company turns down many opportunities because it cannot hope to recoup an investment in those products. In exchange for the appropriate level of certainty of market exclusivity-for the sake of argument, 14 years-the company would be willing to enter into a "fork in the road," whereby a year or two after launching a product the innovator could choose either the statutory exclusivity period or the relevant patent estate (and give up its rights to the other option). This would give the FOB industry certainty of what drugs would be available and when, allowing FOB manufacturers to make their decisions accordingly. Admittedly, one result of such a framework would be that the innovator would almost always choose the fork that gave it the longer period of protection.

The panel briefly discussed whether legislation should restrict a FOB company from selling a marketing exclusivity right to an innovator company (or to otherwise negotiate a delay of entry). Mr. Norman noted that companies will always try to exploit legislation in ways that legislators might not have considered when they crafted it, and that legislators should do their best to anticipate and prevent such exploitation. Mr. Goshko noted that Congressman Waxman's proposed bill would mitigate, if not eliminate, such settlement agreements.<sup>13</sup>

The panel then looked at how these questions have been addressed in Europe. Mr. Barkoff and Mr. Zielinski said that in Europe, not only is there no marketing exclusivity for biologics, but also there is none for traditional generic products. The U.S. is the only country in the world that offers marketing exclusivity to generic drugs manufacturers. This suggests that marketing exclusivity is not necessary. Whether it is advisable is a separate question—would we

<sup>&</sup>lt;sup>11</sup> Public Comment, Robert Pfizer, President and CEO of Novartis, *Emerging Health Care Competition And Consumer Issues – Project No. P083901*, Sept. 30, 2008, http://www.ftc.gov/os/comments/healthcarecompissues/537778-00009.pdf.

<sup>&</sup>lt;sup>12</sup> See, e.g., Inslee Bill, supra note 7; Waxman Bill, supra note 7.

have more cost savings to consumers, or more introductions of FOB products, without the exclusivity period? Another argument against an exclusivity period is that many generics companies do not even make the exclusivity period a cornerstone of their business model. They file knowing that they will not be the first filer and have a different litigation strategy.

Mr. Schultz pointed out that Europe is a very different market—it has price controls. Generic drugs are much less of a market factor there. Mr. Miller observed that Europe also has a shorter period of data exclusivity—to ask for a longer period of exclusivity, as well as a free market for pricing, in the United States seems counter to the success that Europe has had. Incentives may not be necessary in every case, but we need to look for the best way to incentivize FOB entrance in the extremely small markets.

Mr. Schultz added that, if the purpose of exclusivity is to make sure there is sufficient incentive for innovation to discover new molecules, then there is some attraction to having exclusivity vary based on the profitability of the product. When such an approach has been tried on the Hill, it has run into problems, but that may not always be true. It is very important to pay attention to the question of whether any exclusivity beyond Hatch-Waxman is necessary. Is the patent system sufficient, or are biologics so different that manufacturers need additional exclusivity?

Finally, Mr. Miller mentioned that to fail to coordinate any new legislation with an adjustment to Medicare would be a lost opportunity. If FOB products share J-Codes with reference products, there will be much better uptake.<sup>14</sup>

#### PANEL V: Patent Dispute Resolution

The final panel of the day addressed the need for, and the likely competitive effects of, different ways to structure a process to resolve patent disputes between innovator firms and FOB applicants prior to FDA approval of FOB products. Participants included: (1) Mr. Dow; (2) Mr. Goldman; (3) Mr. Leicher; (4) Ms. **Kepplinger;** (5) Mr. Kushan; (6) Mr. Manspeizer; (7) Hans Sauer, MS, PhD, Associate General Counsel, Intellectual Property, BIO; (8) Ms. Seide; (9) Mr. Schultz; and (10) Christine J. Siwik, Partner, Rakoczy Molino Mazzochi Siwik LLP.

#### Case Study

Ms. Seide started the discussion with a case study, with the aim of demonstrating a typical biologic reference product's patent portfolio. This served as the starting point for the panel's discussion of what a patent dispute resolution process should look like for biologics products.

The case study laid out four patent tiers, each of which would have different technical specifications and, potentially, different owners. Tier 1 was comprised of drug target patents, which would include claims drawn to a target receptor, the DNA encoding that receptor, and generic therapeutic treatment of cancer using agents that inhibit the receptor binding. Tier 2 was comprised of technology platform patents, which would include claims for technology to make the agents claimed in Tier 1. Tier 3 comprises sponsor company patents-the result of the innovator's additional development work. Tier 3 claims could include new therapeutic treatment targets (e.g., another form of cancer), a process claim on an improved method of making a Tier 1 product, or another extension of the work represented by the first two tiers. Finally, Tier 4 comprises biomarker patents, which include claims on biomarker assays for identifying particular types of patients. (Ms. Seide noted that Tier 4 claims may not survive scrutiny in the Federal Circuit and, potentially, the Supreme Court.)

Each of these patent tiers might be owned by a different company or university. Each patent, furthermore, is on its own timetable one might have seven years of patent term remaining by the time a biologic is approved, for example, while another has 12 years remaining.

#### Panel Discussion

The panel began with the question of whether a patent resolution pathway is needed before the expiration of a data exclusivity period. Ms. Siwik noted that the Hatch-Waxman Act has demonstrated that patent disputes should be resolved concurrently with FDA review so that the product is ready to launch as soon as it is approved. If the system is too cumbersome, however, it can delay the market launch of a generic product, which is expensive and discourages generics manufacturers from investing in the process. The contours of an appropriate regulatory scheme should be viewed through the prism of business risk, according to Mr. Sauer. The Hatch-Waxman Act's infringement safe harbor, which created an artificial act of infringement for a generics manufacturer to challenge a patent without incurring damages, was a significant factor in fostering such a successful industry. Compare that with the legislative options that have been proposed thus far.<sup>15</sup> Biologics manufacturers tolerate even less business risk than small molecule drugs, and, going forward, a patent resolution process will be vital to offset the risks.

Mr. Manspeizer emphasized that a good patent resolution process will be characterized by "certainty, fairness, and full disclosure." It is important to look at the patent resolution mechanism in the context of the overall legislative framework and account for the uncertainty that patent litigation provides by rewarding the risk with an exclusivity period.

Speaking for Novartis, Mr. Goldman disagreed because launching at risk is "the norm" in the biotech industry—not just for FOB manufacturers, but for innovators as well. Each company can take these risks into account in making decisions. The U.S. is the only country in the world that links a patent challenge of a small molecule product to marketing exclusivity, and he asserted that it is not required for biologics. Novartis does believe in a notification period of 45 to 90 days following FDA approval.

Mr. Leicher noted that, while waiting to challenge patents until the end of the approval period works for large companies, small companies cannot afford to wait to fight those battles. From a small company's perspective, certainty is important. They need a reasonable opportunity, early on, to clear out patents that should not be obstructing the release of a follow-on product. Without a process to determine whether a reference product's patents are strong, competition will be harmed. Europe is not a representative example because there biologics manufacturers have the freedom to challenge patents at any time. He noted that the same challenges would not be possible in the U.S. without a statutory mechanism.

The panel turned next to the effect the absence of a pre-approval patent process would have on the market, and whether a data exclusivity period could suffice.

<sup>15</sup> Waxman Bill, *supra* note 7.

<sup>&</sup>lt;sup>14</sup> A J-Code is the reimbursement code Medicare assigns to certain approved injectable products. For more information, see Healthcare Common Procedure Coding System ("HCPCS") Level II Coding Procedures, Aug. 15, 2008, *available at* <u>http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/LeveIIICodingProcedures.pdf</u>.

Mr. Dow said that it takes a certain amount of unavoidable business risk to launch a biologic product, but without some method of resolving patent disputes before approval, the FOB manufacturer will have to make the decision of whether to launch and risk a patent lawsuit. If they do decide to launch at risk, then the market will be distorted. It is impossible to "put the genie back in the bottle" and restore the market if the patentee wins-getting a preliminary injunction to prevent market entry will be very difficult. The argument some parties have made about the lack of price competition for biologics is not supported by the Johnson & Johnson's experience.

Mr. Kushan and Ms. Seide agreed that making investments eight to ten years before a payoff is difficult enough for FOBs—it is very important that patents be challengeable prior to approval. Ultimately, in Mr. Kushan's view, it is very simple: "we have to litigate the patents that are going to be infringed by the [FOB]."

Mr. Goldman argued that companies that are worried about not having enough money should not be eager to jump into expensive litigation 30 months earlier than necessarythey may in fact be bringing on litigation costs earlier than necessary. He also noted that under a scheme giving a sponsor 45 to 90 days notice of a generic product, the sponsor has an opportunity to file for an injunction based on a patent infringement claim. If an injunction is granted, there is no danger of market price erosion. Even if an injunction is not granted, any resulting price erosion may not be irreversible. He suggested that following the EU system of post-grant litigation may be the best way to solve the problem without linking the FOB approval process with challenging patents.

Mr. Schultz made the point that the basic trade-off under the Hatch-Waxman Act was that the brand companies got patent extensions of up to five years, and the generic companies got a streamlined system of getting their drugs to the market. The theory was that the day that patent protection expired, the generic should be ready to enter the market. Mr. Schultz explained that the idea is to challenge patents early, to make that happen. Whether or not that theory succeeded, he suggested that goal should be the same for biologics. Patent disputes should be settled before the FOB goes on the Mr. Schultz stated that data market. exclusivity is not dispositive-there is still a need to resolve patents in dispute early. Ms. Siwik noted that the Hatch-Waxman Act included a de facto patent extension, because a sponsor kept its exclusivity while generics performed their research and

development. Thus, patent litigation must begin early enough to be resolved before the innovator's data exclusivity expires.

With the assumption that a patent resolution process will be a part of the new legislative framework, the panel discussed the best timing for a FOB applicant to provide notice of its application to the sponsor company.

Mr. Kushan said that notice should be timed close enough to the potential approval to make sense-three or four years before approval, late enough that the FOB manufacturer knows what patented technology is necessary to the product, but early enough so that any patent disputes can be litigated without delaying the FOB's According to Ms. Siwik, the release. particular method of notice must be constructed anticompetitive to avoid consequences. Under some proposed bills, FOB manufacturers would be required to turn over their entire Abbreviated Biologics License Application (and other manufacturing data) to anyone who wanted it, without any assurances of confidentiality, which could pose a serious problem.

Mr. Manspeizer concurred insofar as the need for a patent dispute mechanism that starts early enough to be resolved before the data exclusivity period concludes, but late enough that the process is set. If the data exclusivity period is long enough, there is plenty of time to do that. In the example here, 14 years of data exclusivity (ten years of true exclusivity, and then four years of market exclusivity) allows for 48 months for patent dispute litigation. Mr. Manspeizer noted that 48 months should suffice to carry a dispute up through the federal appeals court, if necessary. The true issue is whether it should be a limited number of patents, or all patents that both sides want to bring to the process. There must be a mechanism for both sides (innovators and FOB manufacturers) to lay their cards on the table. Once a basic structure is in place, then the mechanism can be established.

Mr. Goldman argued that the patent system should be completely separate from the FDA approval process because there is no way for legislation to account for all of the numerous patents (with asynchronous expiration dates) that comprise a typical biologic product's IP bundle. Novartis believes that a notice provision is not necessary, and might even be harmful to competition, because it would require disclosure of confidential data at an inappropriate time. For this reason, Mr. Goldman suggested that notice is only proper after approval. Mr. Dow observed that the longer the data exclusivity period, the less of an issue the patent resolution process becomes—more patents will expire before the data exclusivity period ends.

Mr. Kushan asserted that notice should be required for the owners of any potentiallyinfringed patents. The list should be manageable once the FOB manufacturer's technology is known. It is important, however, that there be a "confidentiality bubble" around the information exchange. The information in the notice must identify what technology will be used by the FOB: process technologies, product identity, and intended use. Mr. Leicher agreed with much of these assertions, but thought that notice should go only to the sponsor, to keep the notice mechanism simple.

Mr. Sauer noted that giving notice only to the sponsor would mirror the Hatch-Waxman Act, but would not necessarily account for situations in which the innovator does not have first enforcement rights for all relevant patents. Ms. Siwik countered that, even now, generics manufacturers regularly give notice to third party patent-holders, and it is realistic to think that the same thing will happen with biologics.

Ms. Seide explained that generic companies have a very difficult time identifying process patents in the current system, and that type of patent will be important for biologics. She also expressed concern that the system not be over-simplified at the expense of thirdparty patentees.

Ms. Kepplinger suggested that if one lesson was learned, it is that a Hatch-Waxman system leads to a lot of litigation. A reduction in the amount of litigation should be one goal of a new framework for biologics—the money spent on litigation could be better spent on other things, like designing more pharmaceuticals.

The panel then turned to the question of whether the timing of FDA approval should be related to the resolution of patent litigation. Mr. Sauer observed that under Hatch-Waxman, people understand linkage (of a FOB's FDA approval and the resolution of litigation) to mean two different things-the delay of FDA approval based on pending litigation against the generic manufacturer by the sponsor (which delays generic entry by up to 30 months), and the delay of FDA approval based on the resolution of a patent dispute in the sponsor's favor (which delays generic entry until the valid patent expires). The former delay has been necessary but criticized, while the latter delay is unobjectionable. Ms. Siwik agreed that linkage based on pending litigation creates an

anticompetitive incentive for sponsors to file suit, regardless of their chance of success, because the 30-month delay in generic entry is initiated before litigation is resolved.

Mr. Kushan said that, if the question is whether the FDA should defer approval of a FOB application until the expiration of a valid infringed patent, the answer must be yes. If a FOB elects to use a patented technology, the FOB must be prepared to have its application deferred until that technology is no longer patented. In concert with early patent resolution, this allows the FOB to change its methodology to avoid patent infringement.

Mr. Dow expressed concern that without some kind of linkage, a problem sometimes occurs when a patent is termed valid and infringed: what can be done if the infringing generic product has already launched? The remedies—pulling the drug from the market or creating a compulsory license system are not acceptable. The only answer is to avoid the situation with a pre-approval patent resolution process.

The next issue the panel addressed was what to do in the event of new patents claiming the reference product: what happens if they are issued once the patent resolution has begun? Mr. Leicher suggested that there should be a statutory artificial act of infringement, so that the new patent can be integrated into the ongoing litigation. Ms. Siwik noted that this solution would sometimes result in litigation dragging on too long, as new patents get folded into litigation that has already stretched on for months or years.

Mr. Manspeizer and Mr. Leicher agreed that there should be a mechanism to incorporate new patents when (and only when) the FOB applicant is seeking approval for the same particular use for a drug. Mr. Sauer and Mr. Goldman suggested that later-issuing patents are normal litigation issues that fall under the standard business risk, and that no special allowances need be made to accommodate them. Mr. Kushan added that we cannot make any conclusions about whether latecoming patents will be narrower or broader. The first patent out of the gate might be extremely narrow, while a later patent could be significantly broader, or vice versa—so we need a bit of flexibility to allow for variability. If the litigation is over, a new suit may be necessary. Mr. Sauer concurred that, as a practical matter, innovators must simply include the chance of patent litigation in their consideration of the business risk of developing a product.

Mr. Dow argued that in order to provide an incentive to investigate subsequent indications, sponsors must be eligible for data exclusivity for secondary indications. Reliance solely on patent protection would sometimes allow FOBs to be used for a secondary indication, even if the secondary indication remained under patent protection-doctors could not be prevented from using the generic drug for the secondary indication, as long as the first indication's patent had expired.

The panel next addressed what penalties, if any, should result from a party failing to participate in a patent resolution process. Mr. Goldman cautioned that a sue-or-lose penalty (in which a party must sue for infringement of a patent or lose the right to enforce it) is an extreme penalty, and seems to detract from constitutionally-appointed patent rights. Ms. Seide concurred that taking away a property right from a patent owner is too strong a penalty-it is worth the loss of certainty until the patents in question expire to ensure that patent-owners are not disenfranchised. Mr. Kushan also expressed concern about "the abrogation of a property right," noting that to see that penalty as the only contemplated sanction is unsettling. The right way of thinking, perhaps, is to allow declaratory judgment for follow-on applicants.

Ms. Siwik and Mr. Schultz emphasized that the entire purpose of the system is certainty. If a patent holder can hold back on litigating its patents until near the end of development, or just before the FOB's launch, that certainty is lost. Mr. Manspeizer said that, if the framework is designed the right way, such that it is based on principles of certainty and full disclosure, a sue-or-lose system should work. But there must be fair play rules on both sides-if the follow-on applicant changes its process in the middle of application in order to bring in a patent that was otherwise not infringed by the old process, the owner of the relevant patent should not be forced to sue.

The panel finished the session by discussing what each participant believes to be the main goal of a patent resolution system. Mr. Dow said that the patent resolution process should resolve patent disputes during the exclusivity period, so all parties have certainty as to when the FOB product can be launched. Mr. Leicher noted that, for small manufacturers, financing is dependent on getting resolution of patent disputes before the patents expire. Ms. Kepplinger added that it is important to make sure that innovators have an incentive to innovate, whether that incentive comes from the patent system or elsewhere. Mr. Manspeizer emphasized that the most important consideration is that any legislation must be adequate to deal with the issues that will occur over the next 20 to 50 years. Mr. Sauer mentioned the importance of certainty to patients, providers, and payers-certainty ensures that people who really need these drugs will get them. Ms. Siwik concluded by assuring the rest of the panel that the generics are not "out to stick it to the brands." Without brand manufacturers, the generics industry cannot function. So from the perspective of generics, the key is to balance incentives, resolve key patent disputes early, and avoid a system that links the patent process to the approval process.



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