FEDERAL ANTITRUST REVIEW OF GENERIC DRUG MERGERS: A PROPOSAL FOR A MORE FLEXIBLE APPROACH

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In recent years, the generic pharmaceutical industry has experienced significant consolidation and, as a result, has seen increased antitrust enforcement activity by U.S. federal antitrust authorities. Since 1994, the U.S. Federal Trade Commission ("FTC" or "Commission") has taken enforcement actions requiring divestitures or other remedies in at least eleven generic drug mergers.[1] Of those eleven transactions, eight have occurred in the last five years, six of those in the last two years.[2]

Given the growing pressure faced by generic pharmaceutical companies to reduce costs,[3] consolidation in the industry

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1. As explained further in Part I, while both the FTC and the Antitrust Division of the U.S. Department of Justice have been delegated the authority to review certain transactions under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, the FTC typically reviews transactions involving the pharmaceutical industry based on its expertise in the area.

2. These transactions include (i) Novartis AG's acquisition of Hexal AG, including its U.S. generic pharmaceuticals business, Eon Labs, Inc., (ii) Baxter International Inc.'s acquisition of ESI Lederle Inc., a subsidiary of Wyeth, (iii) Mylan Laboratories Inc.'s acquisition of E. Merck oHG, (iv) Actavis Group hf.'s acquisition of Abrika Pharmaceuticals, Inc., (v) Hospira, Inc.'s acquisition of Mayne Pharma Limited, (vi) Watson Pharmaceuticals, Inc.'s acquisition of Andrx Corporation, (vii) Barr Pharmaceuticals, Inc.'s acquisition of PLIVA d.d., and (viii) Teva Pharmaceutical Industries Ltd.'s acquisition of IVAX Corporation.

3. *See* Andrew Dowell et al., *Mylan Is Now Big Generics Player After Deal for Unit of Merck KGaA*, WALL ST. J., May 14, 2007, at A3 ("Tight profit margins in the generics business have forced a wave of consolidation as companies attempt to cut costs and improve profits.").

can be expected to continue for the next several years.[4] Further consolidation and the likely antitrust enforcement activity that will result may have a profound impact on the ultimate shape of the generic pharmaceutical industry.

This article first provides a brief overview of the U.S. antitrust review process for mergers and acquisitions. Second, this article summarizes the Commission's merger enforcement history in the generic drug industry over the last fifteen years. Third, this article identifies the general merger enforcement principles applied by the FTC in generic drug transactions and the key issues that the agency likely will examine in future transactions in this industry. Finally, this article proposes an alternative, more flexible approach to be taken by U.S. antitrust authorities in circumstances where a prolonged regulatory review may run counter to the public interest, such as in situations where there are identifiable benefits to closing the transaction quickly and the risk or magnitude of anticompetitive harm resulting from the transaction is small.

I.
BRIEF OVERVIEW OF THE U.S. MERGER REVIEW PROCESS

Under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR Act"),[5] parties to certain mergers, acquisitions, tender offers, and other transactions must file a notification form and submit a filing fee with the U.S. Department of Justice ("DoJ") and the FTC and observe a statutory waiting period before they are permitted to consummate the transaction.[6] For most transactions, the applicable waiting period is thirty days after the required notification under the HSR Act is made.[7] During these thirty days, the reviewing agency typically analyzes the proposed transaction and makes a determination as to the extent of any antitrust concerns. If the reviewing agency has concerns about the effect the transaction may have

4. *See, e.g.*, Drew Buono, *Consolidation pace steady as big companies get bigger*, DRUG STORE NEWS, Sept. 24, 2007, at 32.

5. 15 U.S.C. § 18a (2000).

6. *See id.*

7. § 18a(b)(1)(B). In the case of a tender offer, the waiting period is fifteen days. *Id.* Parties to a proposed transaction may also request that the agencies grant early termination of the applicable waiting period, which, if granted, has the effect of permitting them to consummate the transaction sooner. § 18a(b)(2).

on competition, it may extend the waiting period by requesting the submission of additional information or documentary material relevant to the proposed transaction (often referred to as a "Second Request").[8] Where these requests for additional information are made, the waiting period in most cases is extended until thirty days after the parties comply with the requests.[9]

In circumstances where the reviewing agency believes that a transaction would violate the antitrust laws, the agencies may seek an injunction in federal court to prevent the parties from closing their deal. In practice, however, rather than litigating a transaction in court, the agencies and the merging parties often resolve antitrust concerns by entering into a settlement (often referred to as a "consent agreement" or "consent order") that requires the parties to divest certain assets to a third party or take some other remedial action. The aim of such divestitures or other remedies is to restore the competition that would have been lost as a result of the transaction. At the same time, the remedy permits the remaining parts of the transaction to go forward.

For transactions involving the pharmaceutical industry, including generic drug mergers, the FTC, rather than the DoJ, typically takes the investigatory lead given its particular expertise in the area.[10] For generic drug transactions, the FTC usually conducts a detailed investigation into the merging parties' competing or "overlapping" products, research and development pipelines, and relationships with third-party manufacturers or distributors, as well as the presence of competitors, substitutable products and/or formulations, barriers to entry, and many other factors. Where the FTC identifies significant antitrust concerns in a relevant product market, the merging parties often attempt to resolve those concerns by agreeing to

8. § 18a(e)(1)(A).

9. § 18a(e)(2). In the case of a cash tender offer, the waiting period is extended until 10 days after the acquiring company complies with the requests. *Id.*

10. To determine which agency will review a transaction, the agencies have implemented a "clearance" process. Essentially, one agency must provide "clearance" for the other agency to investigate the transaction. The principal ground for clearance is expertise in the product or products involved in the anticipated investigation. *See* ABA Section of Antitrust Law, Antitrust Law Developments 392-93 (6th ed. 2007).

divest a product line or to take other remedial action such as entering into a licensing arrangement that establishes a new competitor in the market.

II.
PAST GENERIC DRUG MERGERS AND FTC ENFORCEMENT

In the past fifteen years, at least eleven transactions involving generic drug companies have been subject to FTC enforcement actions that resulted in divestitures or other remedies. A review of this enforcement history, including how it has evolved over time and the competitive dynamics of the markets in which enforcement actions were taken, sheds light on how the antitrust review process may impact future generic drug transactions.

A. *Mylan / Merck (2007)*

On May 12, 2007, Mylan Laboratories Inc. ("Mylan") announced that it had signed a definitive agreement to acquire E. Merck oHG ("Merck Generics"), the generic drug business of Merck KGaA, for approximately $6.7 billion.[11] According to Mylan, the transaction was intended to broaden and diversify its product portfolio to include approximately 560 products and allow it to achieve approximately $250 million in synergies by the end of the third year after closing.[12]

Roughly four-and-a-half months later, on September 27, 2007, the FTC entered into a consent agreement with the parties settling charges that the proposed transaction was likely to substantially lessen competition in five generic drugs markets: (1) acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine hydrochloride tablets; (4) nicardipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets.[13]

For generic acebutolol hydrochloride, a beta blocker used to treat hypertension, the FTC found that Mylan and Merck

11. Press Release, Mylan Labs. Inc., Mylan Laboratories to Acquire Generics Business of Merck KGaA (May 12, 2007), http://investor.mylan.com/phoenix.zhtml?c=66563&p=irol-newsArticle&ID=999586&highlight.

12. *Id.*

13. Press Release, Fed. Trade Comm'n, FTC Challenges Mylan's Proposed Acquisition of Merck's Generic Subsidiary (Sept. 27, 2007), http://www.ftc.gov/opa/2007/09/mylanmerck.shtm.

Generics (which indirectly sold the product through a distribution agreement with Par Pharmaceutical Companies, Inc. ("Par")) were the only two suppliers in the U.S. of generic versions of the drug and had market shares of 59% and 41%, respectively.[14] As a result, the FTC alleged that the proposed transaction would give Mylan a monopoly in this market.[15]

In the market for generic flecainide acetate tablets, the FTC alleged that Mylan and Merck Generics (through a distribution agreement with Par) were two of five suppliers in the U.S.[16] Generic flecainide acetate is an anti-arrhythmia drug used in the treatment of certain heart conditions.[17] The FTC alleged that the proposed transaction would combine the two largest suppliers of generic flecainide acetate tablets in the U.S., increase Mylan's market share from 57% to approximately 78%, and reduce the number of suppliers in the marketplace from five to four.[18]

Generic guanfacine hydrochloride is an alpha blocker used in the treatment of hypertension and is available in 1 mg and 2 mg strengths.[19] The FTC found that Mylan was the leading U.S. supplier of generic guanfacine hydrochloride with approximately 53% market share.[20] Mylan and Merck Generics (through a distribution agreement with Par) were two of six suppliers of the drug in the U.S. The FTC noted, however, that only four competitors – Mylan, Merck Generics/Par, Watson Pharmaceuticals, Inc. ("Watson"), and Actavis Group hf. ("Actavis") – supplied a 2 mg formulation.[21] The FTC further stated that customers preferred purchasing the 1 mg and 2 mg strengths from the same supplier, and therefore the competitive significance of those companies that did not supply generic guanfacine in both formulations was limited.[22] As a re-

14. *In re* Mylan Labs. Inc. and E. Merck oHG, FTC File No. 071-0164 at 1-2 (Sept. 27, 2007) (Analysis of Agreement Containing Consent Orders to Aid Public Comment), http://www.ftc.gov/os/caselist/0710164/070921analysis 0710164.pdf [hereinafter Mylan/Merck].

15. *Id.* at 2.

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

sult, the FTC concluded that the acquisition was likely to lead to higher prices for this product.[23]

In the market for generic nicardipine hydrochloride, a calcium channel blocker for treating hypertension, the FTC alleged that Mylan, Merck Generics, and Teva Pharmaceutical Industries Ltd. ("Teva") were the only three suppliers active in the U.S.[24] In addition, the FTC alleged that Mylan and Merck Generics had market shares of 54% and 32%, respectively, and therefore the proposed transaction would increase Mylan's share to 86% and reduce the number of suppliers of generic nicardipine from three to two.[25]

Generic sotalol AF is a beta blocker used in the treatment of hypertension.[26] The FTC alleged that Mylan and Merck Generics were the second and third largest suppliers of generic sotalol AF in the U.S. behind Apotex Inc. ("Apotex"), and that the transaction would reduce the number of significant suppliers of the drug in the U.S. from three to two.[27] The FTC also noted that Mylan and Merck Generics were recent entrants into this market, with Mylan entering in Spring 2007 and Merck Generics entering in late 2006.[28]

To resolve the FTC's antitrust concerns, Mylan agreed to divest all of the rights and assets to Merck Generics' products in each of these five areas to Amneal Pharmaceuticals LLC.[29]

B. *Actavis / Abrika (2007)*

Actavis announced its proposed $110 million acquisition of Abrika Pharmaceuticals, Inc. ("Abrika") on November 30, 2006.[30] According to Actavis, the proposed acquisition would

23. *Id.* at 3.
24. *Id.*
25. *Id.*
26. *Id.*
27. *Id.*
28. *Id.*
29. *In re* Mylan Labs. Inc. and E. Merck oHG, FTC File No. 071-0164 at 20 (Nov. 6, 2007) (Decision and Order), http://www.ftc.gov/os/caselist/0710164/071106do0710164.pdf.
30. Press Release, Actavis Group, Actavis Acquires the Specialty Generics Company Abrika Pharmaceuticals in the US (Nov. 30, 2006), http://www.actavis.com/en/media©enter/newsroom/article.htm?location=http%3a%2f%2fcws.huginonline.com%2fA%2f134004%2fPR%2f200611%2f1090934.xml.

provide the company with a stronger position in controlled release pharmaceutical products and other high-value, technically challenging drugs.[31]

Following its review, the FTC entered into a consent agreement with the parties settling charges that the proposed transaction would lead to anticompetitive effects in the market for generic isradipine capsules.[32]

Generic isradipine is a calcium channel blocker typically used to lower blood pressure in patients, as well as treat hypertension, ischemia and depression.[33] According to the FTC, Actavis and Abrika were the only two suppliers of generic isradipine capsules in the U.S. and together accounted for 100% of the $3 million in sales in this market in 2006.[34] As a result, the FTC alleged that the proposed acquisition of Abrika by Actavis would create a monopoly for sales of generic isradipine.[35]

To settle the FTC charges, Actavis agreed to divest all of Abrika's assets and rights necessary to manufacture and market generic isradipine capsules to Cobalt Laboratories, Inc.[36]

C. *Hospira / Mayne (2007)*

On September 20, 2006, Hospira, Inc. ("Hospira") announced that it had entered into an agreement to acquire Mayne Pharma Limited ("Mayne") in a transaction valued at approximately $2 billion.[37] Hospira stated that the acquisition would create the leading generic injectable pharmaceuticals company in the world.[38] In addition, the company announced

31. *Id.*

32. *In re* Actavis Group hf. and Abrika Pharms., Inc., FTC File No. 071-0063 at 18 (May 22, 2007) (Decision and Order), http://www.ftc.gov/os/caselist/0710063/070522do0710063.pdf [hereinafter Actavis Decision and Order].

33. *In re* Actavis Group hf. and Abrika Pharms., Inc., FTC File No. 071-0063 at 1 (Apr. 16, 2007) (Analysis of Agreement Containing Consent Order to Aid Public Comment), http://www.ftc.gov/os/caselist/0710063/0710063analysis.pdf.

34. *Id.* at 2.

35. *Id.*

36. Actavis Decision and Order, *supra* note 32, at 18.

37. *See* Press Release, Hospira, Inc., Hospira Announces $2 Billion Agreement to Acquire Mayne Pharma (Sept. 20, 2006), http://www.hospira.com/NewsAndMediaCenter/pressrelease.aspx?rid=20060920.aspx.

38. *Id.*

that it expected to achieve $50 million in annual synergies as a result of the acquisition through infrastructure optimization, an improved supply chain, and administrative and other operational efficiencies.[39]

The FTC entered into a consent agreement with the merging parties settling charges that the proposed transaction would lead to anticompetitive effects in five markets for generic injectable pharmaceutical products: (1) hydromorphone hydrochloride; (2) nalbuphine hydrochloride; (3) morphine sulfate; (4) preservative-free morphine; and (5) deferoxamine mesylate.[40]

In requiring divestitures for these products, the FTC alleged that oral drugs were not close substitutes for the injectable pharmaceuticals at issue because injectables tend to be used to treat patients who have difficulty swallowing pills or that need rapid onsetting of the drug and cannot wait for it to pass through the gastrointestinal system.[41]

For hydromorphone hydrochloride, a narcotic analgesic used to treat moderate to severe pain, the FTC found that Hospira and Mayne were two of only three suppliers of a generic injectable version of the drug in the U.S.[42] Of the $39 million generic injectable market for hydromorphone hydrochloride in 2006, Hospira was the leading supplier with a 60% market share and Mayne was the second largest supplier with a 25% market share.[43]

In each of the four remaining generic injectable markets, the FTC found that Hospira was an active supplier in the U.S., there were few, if any, other current competitors, and Mayne was in the process of entering the market.[44] The FTC alleged that Mayne was one of only a limited number of firms capable of entering the relevant markets in a timely manner, and

39. *Id.*

40. Press Release, Fed. Trade Comm'n, FTC Challenges Hospira/Mayne Pharma Deal (Jan. 18, 2007), http://www.ftc.gov/opa/2007/01/hospiramayne.shtm.

41. *In re* Hospira, Inc. and Mayne Pharma Ltd., FTC File No. 071-0002 at 1 (Jan. 18, 2007) (Analysis of Proposed Consent Order to Aid Public Comment), http://www.ftc.gov/os/caselist/0710002/070118analysis0710002.pdf [hereinafter Hospira/Mayne].

42. *Id.* at 2.

43. *Id.*

44. *Id.* at 2-3.

therefore concluded that the proposed transaction would eliminate an important future competitor.[45]

To remedy its concerns in each of the five markets, the FTC required the parties to divest Mayne's rights and assets necessary to manufacture and sell the products at issue to Barr Pharmaceuticals, Inc. ("Barr").[46]

D. *Watson / Andrx (2006)*

On March 13, 2006, Watson announced that it had reached a definitive merger agreement to acquire Andrx Corporation ("Andrx") in a transaction valued at $1.9 billion.[47] According to Watson, the proposed transaction would create the third largest specialty generic pharmaceutical company in the U.S., as well as provide Watson with Andrx's patented sustained-release technologies and a deep pipeline of generic pharmaceutical products.[48]

Following its investigation, the FTC concluded that the proposed transaction would substantially lessen competition in thirteen generic drug markets, including (1) hydrocodone bitartrate/ibuprofen tablets; (2) glipizide extended-release tablets; and (3) eleven types of oral contraceptive drugs.[49]

In the market for generic hydrocodone bitartrate/ibuprofen tablets, the FTC found that there were only three active suppliers of the product in the U.S., including Watson (which marketed generic hydrocodone bitartrate/ibuprofen tablets through an arrangement with the manufacturer, Interpharm Holdings, Inc ("Interpharm")), Andrx, and Teva. According to the FTC, one additional company was in the process of obtaining FDA approval to market a generic version of this product and was expected to enter within two years.[50] To

45. *Id.* at 4.

46. *Id.*

47. *See* Press Release, Watson Pharms., Inc., Watson to Acquire Andrx for $1.9 Billion, Creating the Third Largest Specialty Pharmaceutical Company in the U.S. (Mar. 13, 2006), http://ir.watson.com/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=830357.

48. *Id.*

49. Press Release, Fed. Trade Comm'n, FTC Challenges Terms of Watson Pharmaceuticals' Acquisition of Andrx (Oct. 31, 2006), http://www.ftc.gov/opa/2006/10/watsonandryx.shtm.

50. *In re* Watson Pharms., Inc. and Andrx Corp., FTC File No. 061-1039 at 2 (Oct. 31, 2006) (Analysis of Agreement Containing Consent Orders to

remedy the FTC's competitive concerns in this market, Watson agreed to terminate its marketing arrangement with Interpharm and return all rights and agreements necessary to market the generic drug back to Interpharm.[51]

For generic glipizide extended-release tablets, the FTC found that Watson was the leading supplier of the product in the U.S. with more than a 45% share.[52] Andrx was the second leading supplier with a 35% market share. Greenstone Ltd. was the only other supplier in the market.[53] After the transaction, the combined Watson/Andrx would have a market share of more than 80% and would face competition from only one other supplier.[54] The FTC required the parties to divest Andrx's rights and assets to generic glipizide to Actavis in order to address the Commission's concerns in this market.[55]

For oral contraceptives, pills taken by women to prevent ovulation and pregnancy, Andrx and Teva had an agreement under which Teva marketed oral contraceptives manufactured by Andrx.[56] The FTC alleged that in eleven markets for oral contraceptives, Watson and Andrx (through its agreement with Teva) were two of only a limited number of actual or potential competitors.[57]

In two of the eleven markets, which involved generic norgestimate/ethinyl estradiol bioequivalents of Johnson & Johnson's branded products Ortho-Cyclen and Ortho Tri-Cyclen, the FTC found that Watson, Andrx/Teva, and Barr were the only generic suppliers in the U.S. and that Watson and Andrx/Teva would have combined market shares of 28% and 56%, respectively, in the two markets.[58]

In seven of the eleven markets, which involved generic versions of Ortho-cept, Triphasil 28, Alesse, Ortho-Novum 1/

Aid Public Comment), http://www.ftc.gov/os/caselist/0610139/0610139analysis.pdf [hereinafter Watson Analysis].

51. *In re* Watson Pharms., Inc. and Andrx Corp., FTC File No. 061-1039 at 27 (Dec. 12, 2006) (Decision and Order), http://www.ftc.gov/os/caselist/0610139/061212do_public_ver0610139.pdf.

52. Watson Analysis, *supra* note 50, at 2.

53. *Id.*

54. *Id.*

55. *Id.* at 4-5.

56. *Id.* at 2-3.

57. *Id.* at 2.

58. *Id.* at 3.

35, Ortho-Novum 7/7/7, Loestrin FE (1 mg/0.020 mg), and Loestrin FE (1.5 mg/0.030 mg), the FTC found that Watson was one of only two or three generic suppliers in the U.S. and that Andrx/Teva was one of a limited number of potential competitors developing generic products to compete in the relevant markets.[59]

In the two remaining markets, which involved generic versions of Micrette tablets and generic Ovcon-35 tablets, the FTC found that Watson and Andrx/Teva were two of only a limited number of suppliers developing these products and that the proposed transaction would eliminate future competition in these two relevant markets.[60]

To remedy its concerns in each of these eleven generic oral contraceptive markets, the FTC required the parties to divest Andrx's rights and assets related to the products to Teva and to supply Teva with the products for five years so that Teva could continue selling the products until it obtained all necessary regulatory approvals to manufacture and sell the products on its own.[61]

E. *Barr / Pliva (2006)*

Barr first announced its offer and intention to acquire PLIVA d.d. ("Pliva") on June 27, 2006 in a proposed transaction valued at approximately $2.2 billion.[62] The company ultimately increased its offer to $2.5 billion.[63] According to Barr, a primary motivation for the acquisition of Pliva was to significantly lower Barr's cost structure and expand its capabilities beyond the U.S. into European and other North American

59. *Id.*

60. *Id.* at 5.

61. *Id.*

62. Press Release, Barr Pharms., Inc., Barr Announces Offer of $2.2 Billion for PLIVA d.d. (June 27, 2006), http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=876411&highlight= [hereinafter Barr June 2006 release].

63. Press Release, Barr Pharms., Inc., Barr's Amended Tender Offer for PLIVA d.d. (Sept. 11, 2006), http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=903683&highlight=Press Release; Barr Pharms., Inc., Barr Evaluating Actavis Group's Competing Bid for PLIVA d.d. (Aug. 31, 2006), http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=900886&highlight=.

markets.[64] Barr announced that it expected to achieve annual synergies of $50 million by 2008, which would grow to more than $100 million by 2009.[65]

The FTC concluded that the proposed acquisition would substantially lessen competition in three generic drug product markets: (1) generic trazodone hydrochloride; (2) generic triamterene with hydrochlorothiazide ("triamterene/HCTZ"); and (3) generic nimodipine.[66]

In the market for generic trazodone hydrochloride tablets, the FTC found that Barr and Pliva were two of five active suppliers in U.S.[67] Although the drug was available in 50 mg, 100 mg, and 150 mg formulations, the FTC noted that only three companies – two of which were Barr and Pliva – supplied the 150 mg formulation.[68] The FTC alleged that customers preferred purchasing all three formulations from a single supplier and concluded that those companies not capable of supplying all three versions were of only limited competitive significance.[69] To remedy its concerns in this market, the FTC required the divestiture of Barr's rights and assets necessary to manufacture and sell generic trazodone hydrochloride tablets to Apotex.[70]

For generic triamterene/HCTZ, the FTC found that Barr and Pliva were two of five active suppliers in the U.S.[71] The FTC concluded that the proposed transaction would reduce the number of competitors in the market from five to four and increase Barr's market share to 35%. The FTC also alleged that several of the suppliers of generic triamterene/HCTZ had a more limited competitive significance in the market than

64. Barr June 2006 release, *supra* note 62.

65. *Id.*

66. *See* Press Release, Fed. Trade Comm'n, FTC Challenges Barr's Proposed Acquisition of Pliva (Oct. 20, 2006), http://www.ftc.gov/opa/2006/10/pliva.shtm. The FTC also concluded that the proposed acquisition would substantially lessen competition in a fourth market, branded organ preservation solutions, which did not involve generic drugs.

67. *In re* Barr Pharms., Inc. and Pliva d.d., FTC File No. 061-0217 at 2 (Oct. 20, 2006) (Analysis of Proposed Consent Order to Aid Public Comment), http://www.ftc.gov/os/caselist/0610217/0610217barranalysis.pdf [hereinafter Barr/Pliva].

68. *Id.*

69. *Id.*

70. *Id.* at 4.

71. *Id.* at 2.

Barr or Pliva.[72] To address the FTC's concerns, the Commission required the parties to divest all of Barr's rights and assets necessary to manufacture and sell triamterene/HCTZ tablets to Apotex.[73]

The FTC also required divestitures in the market for generic nimodipine where Barr, through a partnership with Cardinal Health, Inc. ("Cardinal"), and Pliva, through a partnership with Banner Pharmacaps, Inc. ("Banner"), each had plans to enter the market in late 2006.[74] The FTC alleged that, at the time of the transaction, there were no firms supplying generic nimodipine and that there were no other firms that were in the process of entering the market.[75] Thus, according to the FTC, the acquisition would eliminate future competition between Barr and Pliva and result in a monopoly in the generic nimodipine market.[76] To resolve these concerns, the parties were required to either (1) return Pliva's marketing rights to Banner pursuant to a "buyer up-front"[77] agreement negotiated with Banner; or (2) return Barr's marketing rights to Cardinal in a manner that received the prior approval of the Commission.[78] The parties subsequently chose to return Pliva's marketing rights to Banner, which later entered into a marketing agreement with Heritage Pharmaceuticals Inc. and announced that it received FDA approval on January 25, 2008.[79]

F. *Teva / Ivax (2006)*

On July 25, 2005, Teva announced that it had entered into a definitive agreement to acquire IVAX in an acquisition

72. *Id.*

73. *Id.* at 4.

74. *Id.*

75. *Id.* at 2.

76. *Id.*

77. *See* discussion *infra* Parts III.F (discussion of the Commission's "buyer up-front" process).

78. *See* discussion *infra* Parts III.F.

79. *See* Drugs.com, Nimodipine, http://www.drugs.com/pro/nimodipine.html, for a description of generic nimodipine capsules manufactured by Cardinal Health for Barr Laboratories, Inc. and *Banner Pharmacaps Receives FDA Approval for Nimodipine Softgel Capsules*, MED. NEWS TODAY, Jan. 25, 2008, http://www.medicalnewstoday.com/articles/95159.php, for announcement of FDA approval.

valued at $7.4 billion.[80] Teva believed that the acquisition would combine complementary product lines and geographic presences, as well as allow it to achieve $100 million in synergies by the end of 2006 and $200 million by the end of 2007 through plant closings, product rationalization, and supply-chain efficiencies.[81]

The FTC announced on January 23, 2006 that it had accepted a consent agreement requiring divestitures in fifteen generic drug markets to settle charges that the proposed acquisition would substantially lessen competition.[82] In eleven of the fifteen markets,[83] the FTC alleged that Teva and IVAX were two of a small number of suppliers offering the drugs in the U.S.[84]

In three of the fifteen markets (the markets for generic tramadol/acetaminophen tablets, generic glipizide and metformin tablets, and generic calcitrol tablets), either Teva or IVAX had a product on the market, and the other had a competing product in development.[85] The FTC concluded that the proposed acquisition would eliminate potential competition resulting from the planned entry of one of the firms into each of the markets, thereby leading to anticompetitive effects.[86] In one of the fifteen markets (the market for generic cabergoline tablets), Teva and IVAX were both planning to enter the market and the FTC alleged that the proposed trans-

80. Press Release, Teva Pharm. Indus. Ltd., Teva to Acquire Ivax for $7.4 Billion (July 25, 2005), http://www.tevapharm.com/pr/2005/pr_536.asp.

81. Phillip Seligman, *Teva's Generic Advantage*, BUS. WK., Aug. 26, 2006, *available at* http://www.businessweek.com/investor/content/aug2006/pi20060829967054.htm.

82. Press Release, Fed. Trade Comm'n, Preserving Competition, FTC Requires Divestitures Before Allowing Teva's $7.4 Billion Acquisition of IVAX (Jan. 23, 2006), http://www.ftc.gov/opa/2006/01/tevaivax.shtm.

83. These eleven markets included the manufacture and sale in the U.S. of generic (1) amoxicillin clavulanate potassium; (2) long-acting cefaclor tablets; (3) pergolide mesylate tablets; (4) estazolam tablets; (5) leuprolide acetate injection kits; (6) nabumetone tablets; (7) amoxicillin; (8) propoxyphene hydrochloride capsules; (9) nicardipine hydrochloride; (10) flutamide capsules; and (11) clozapine tablets. *Id.*

84. *In re* Teva Pharm. Indus. Ltd. and Ivax Corp., File No. 051-0214 at 2 (Jan. 23, 2006) (Analysis of Agreement Containing Consent Orders to Aid Public Comment), http://www.ftc.gov/os/caselist/0510214/0510214analysis.pdf [hereinafter Teva/Ivax].

85. *Id.* at 4.

86. *Id.*

action would result in the elimination of potential competition by eliminating or delaying entry from one of the two companies.[87] In each of these four markets where potential competition was at issue, the FTC found that few other firms, if any, were capable of entering in a timely manner.[88]

G. *Novartis / Eon Labs (2005)*

On February 21, 2005, Novartis AG ("Novartis") announced that it had, through its generic pharmaceuticals division, Sandoz, entered into a definitive agreement to acquire Hexal AG, including Hexal's U.S. generic pharmaceutical business, Eon Labs, Inc. ("Eon Labs").[89] The transaction was valued at $8.3 billion.[90] Novartis had projected that annual cost savings of $200 million could be achieved within three years of closing, $100 million of which could be realized within the first eighteen months after closing.[91] At the time, the proposed acquisition of Hexal AG and Eon Labs (itself valued at $1.72 billion)[92] would create the largest generic pharmaceutical company in the world.[93]

The FTC reviewed the proposed transaction and concluded that it would substantially lessen competition in three markets: (1) generic desipramine hydrochloride, (2) generic orphenadrine citrate, and (3) generic rifampin.[94] In each of these markets, the FTC found that Novartis (through Sandoz) and Eon Labs were two of only three suppliers of generic versions of the drugs in the U.S., and together would have combined market shares exceeding 70%.[95]

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87. *Id.* at 5.

88. *Id.*

89. Press Release, Novartis AG, Novartis to Acquire Hexal AG and Eon Labs, Creating the World Leader (Feb. 21, 2005), http://cws.huginonline.com/N/134323/PR/200502/981486_5.html.

90. *Id.*

91. *Id.*

92. Press Release, Fed. Trade Comm'n, Protecting Competition, the Federal Trade Commission Approves Novartis AG's Acquisition of Eon Labs (July 19, 2005), http://www.ftc.gov/opa/2005/07/novartis.shtm.

93. *See id.*

94. *Id.*

95. *In re* Novartis AG, 140 F.T.C. 480, 536 (2005) (Analysis of Proposed Consent Order to Aid Public Comment) [hereinafter Novartis/Eon Labs].

In the market for generic desipramine hydrochloride, a tricyclic antidepressant, the FTC found that Novartis and Eon Labs were the only firms that supplied all six formulations of the drug in the U.S., and that the only other generic supplier, Watson, supplied only three formulations.[96] The FTC alleged that after the acquisition, Novartis would be the only firm capable of supplying the full line of generic desipramine hydrochloride and would account for more than 95% of sales in the relevant market.[97]

In the market for generic orphenadrine citrate, a muscle relaxant, the FTC found that Novartis, Eon Labs, and Impax Laboratories, Inc. (through its generic marketing division, Global Pharmaceuticals) were the only generic suppliers in the U.S.[98] The FTC alleged that the proposed acquisition would result in a duopoly with Novartis accounting for more than 70% of sales in the relevant market.[99]

Finally, in the market for generic rifampin, a drug used in the treatment of tuberculosis, the FTC found that Novartis, Eon Labs, and Versapham, Inc. were the only generic suppliers in the U.S.[100] Accordingly, the FTC alleged that the proposed acquisition of Eon Labs would result in a duopoly and give Novartis a 70% share in the relevant market.[101]

To remedy its concerns in these markets, the FTC required Novartis to divest (i) Sandoz's rights and assets necessary to manufacture and market generic orphenadrine citrate and rifampin, and (ii) Eon Labs' rights and assets necessary to manufacture and market generic desipramine hydrochloride, to Amide Pharmaceutical, Inc.[102]

H. *Baxter / Wyeth (2002)*

On June 10, 2002, Baxter International Inc. ("Baxter") announced that it had entered into a definitive agreement to acquire the generic injectable drug business of ESI Lederle Inc.,

96. *Id.*
97. *Id.*
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*
102. *Id.*

a subsidiary of Wyeth, for approximately $305 million.[103] The proposed acquisition would enable Baxter to vertically integrate with ESI Lederle's manufacturing assets relating to generic injectables.[104] At the time, Baxter possessed no manufacturing capabilities of its own and contracted with third-party manufacturers in order to obtain a supply of injectable drugs that it could market and sell.[105]

On December 20, 2002, the FTC announced that the proposed acquisition would substantially lessen competition in markets relating to five injectable drugs, including: (1) generic propofol, (2) generic pancuronium, (3) generic vecuronium, (4) generic metoclopramide, and (5) new injectable iron replacement therapies.[106]

In the market for generic propofol, the FTC alleged that Baxter supplied the only generic injectable version available in the U.S. (through a supply agreement with GensiaSicor) and that Wyeth was one of the two best-positioned firms to enter the market in a timely manner.[107] In the market for generic pancuronium, the FTC alleged that Baxter (through its supply agreement with GensiaSicor) accounted for more than 50% of sales in the U.S. and that the acquisition of Wyeth's generic injectables business would reduce the number of competitors from three to two.[108]

In the market for generic vecuronium, the FTC alleged that Baxter (through a supply agreement with GensiaSicor) and Wyeth previously had been the two leading suppliers in a highly concentrated U.S. market, and that although Wyeth did not at the time sell a generic injectable version, it had plans to re-enter the market.[109]

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103. Press Release, Baxter Int'l Inc., Baxter to Significantly Expand Its Injectable Drug Portfolio and Manufacturing Capability With Acquisition of ESI Lederle (June 10, 2002), http://www.baxter.com/about_baxter/news_room/news_releases/2002/06-10-02esilederle.html.

104. *Id.*

105. *Id.*

106. Press Release, Fed. Trade Comm'n, FTC Requires Divestitures in Connection with Baxter's Purchase of Wyeth's Generic Injectable Drug Business (Dec. 20, 2002), http://www.ftc.gov/opa/2002/12/baxter_wyeth.shtm.

107. *In re* Baxter Int'l Inc., 135 F.T.C. 49, 97 (2003) (Analysis of Agreement Containing Consent Orders to Aid Public Comment) [hereinafter Baxter/Wyeth].

108. *Id.* at 99.

109. *Id.* at 101.

In the market for generic metoclopramide, the FTC alleged that Baxter (through a supply agreement with GensiaSicor) and Wyeth together accounted for more than half of the sales in the U.S. and that the proposed acquisition would reduce the number of competitors from four to three.[110]

Finally, for new injectable iron replacement therapies, Baxter promoted Ferrlecit, a branded injectable iron gluconate product in the U.S., under a co-promotion agreement with Watson.[111] The only other supplier of new injectable iron replacement therapies in the U.S. was American Regent, which marketed Venofer, an injectable iron sucrose product.[112] The FTC alleged that entry into the relevant market was difficult primarily due to the limited availability of raw materials necessary to develop the products.[113] The FTC further alleged that Wyeth was the best-positioned company to develop new injectable iron replacement therapies and enter the market.[114]

To resolve its concerns, the FTC required the merging parties to: (1) to divest Wyeth's rights and assets related to its development of generic propofol to Faulding Pharmaceutical Company; (2) terminate Baxter's relationship with GensiaSicor as it related to generic pancuronium, vecuronium, and metoclopramide, as well as divest all of Baxter's assets relating to those products to GensiaSicor; and (3) terminate Baxter's co-marketing agreement for Ferrlecit.[115]

I. *Hoechst AG / Marion Merrill Dow (1995)*

On May 4, 1995, Hoechst AG ("Hoechst") agreed to acquire Marion Merrill Dow ("MMD") in a $7.1 billion transaction that, at the time, created the second-largest pharmaceutical company in the world.[116] In June 1995, Hoechst reached an agreement with the FTC allowing it to close the transaction, provided that it entered into a "hold separate agreement" and

110. *Id.* at 102.
111. *Id.* at 103.
112. *Id.*
113. *Id.*
114. *Id.*
115. *Id.* at 70-80 (Decision and Order).
116. Milt Freudenheim, A $7.1 Billion Hoechst Deal for Dow Unit, N.Y. TIMES, May 5, 1995, at D1.

not take control of or influence MMD's operations or businesses until after the Commission conducted its antitrust review.[117] According to the FTC, Hoechst agreed to "a broad settlement that would restore competition in each drug category that could be harmed by the acquisition by requiring Hoechst to divest certain pharmaceutical businesses and to abide by other provisions that may be necessary."[118] The settlement provided that, at the end of the FTC staff's investigation, the Commission would then determine whether any enforcement action was necessary. If action was necessary, the FTC could choose to accept the existing settlement or a modified agreement.[119]

Following the staff's investigation, the FTC announced on September 18, 1995, that it had accepted a consent order requiring divestitures of pharmaceutical products in four markets to settle concerns that Hoechst's proposed acquisition of MMD would substantially lessen competition.[120] Only one of those markets – oral forms of mesalamine for treating ulcerative colitis and Crohn's Disease – involved a generic drug.[121] According to the FTC, MMD marketed the branded drug Pentasa, one of two oral forms of mesalamine that were available in the U.S.[122] The FTC alleged that Hoechst was one of only a few firms developing a generic version of oral mesalamine, and therefore the proposed acquisition would eliminate a significant potential competitor in the market.[123] To resolve its concerns in this market, the FTC required the parties to divest either the rights to Pentasa or the generic formulation in development to a Commission-approved buyer.[124]

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117. Press Release, Fed. Trade Comm'n, FTC Will Allow Hoechst To Acquire Marion Merrell Dow But Require That MMD Be Held Separate Pending Investigation And Possible Antitrust Settlement (June 27, 1995), http://www.ftc.gov/opa/1995/06/hoechmmd.shtm.

118. *Id.*

119. *Id.*

120. Press Release, Fed. Trade Comm'n, Hoechst Settles FTC Charges of Reducing Competition for Four Drugs in Connection With MMD Merger (Sept. 18, 1995), http://www.ftc.gov/opa/1995/09/mdh.htm.

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.*

J. *IVAX / Zenith (1995)*

On August 30, 1994, IVAX announced that it had entered into a definitive agreement to acquire Zenith Laboratories Inc. ("Zenith") for nearly $600 million in a transaction that, at the time, created the world's largest generic drug manufacturer.[125]

Following its review of the proposed transaction, the FTC raised competitive concerns in the market for generic verapamil hydrochloride. Zenith was the exclusive distributor of generic verapamil hydrochloride for G.D. Searle & Co. ("G.D. Searle"),[126] while IVAX was the only other supplier of the product in the U.S.[127] In an effort to address the FTC's antitrust concerns, Zenith terminated its exclusive distribution agreement with G.D. Searle and agreed to transfer its customers of generic verapamil to G.D. Searle or its designee.[128] Even though this "fix" presumably remedied the FTC's antitrust concerns in the market, the FTC still required a consent order to prevent the parties from re-acquiring the exclusive distribution rights from G.D. Searle and to ensure that competition would be preserved by keeping two independent competitors in the marketplace.[129] On March 27, 1995, the FTC accepted a final consent order that prohibited IVAX from acquiring the rights to market and sell generic verapamil under the exclusive distribution agreement with G.D. Searle.[130]

K. *Marion Merrell Dow / Rugby-Darby (1994)*

MMD agreed to acquire the generic pharmaceutical business of Rugby-Darby Group Companies, Inc. ("Rugby-Darby") on October 4, 1993 for approximately $285 million.[131] The FTC accepted a proposed consent decree on May 24, 1994 settling charges that the proposed acquisition would substantially

125. Milt Freudenheim, Ivax to Buy Zenith Labs for $600 Million in Stock, N.Y. TIMES, Aug. 30, 1994, at D4.

126. *In re* IVAX Corp., 119 F.T.C. 357, 358-59 (1995) (Complaint).

127. *Id.*

128. IVAX Corporation, Proposed Consent Agreement With Analysis To Aid Public Comment, 60 Fed. Reg. 1782, 1784 (Jan. 5 1995) (Analysis of Proposed Consent Order to Aid Public Comment).

129. *Id.*

130. *See In re* IVAX Corp., 119 F.T.C. at 360-64 (Decision and Order).

131. *See In re* Dow Chem. Co., 118 F.T.C. 730, 732 (1994) (Complaint). *See also* Dow Chem. Co., Annual Report (Form 10-K), at 33 (Mar. 23, 1995).

lessen competition in the market for dicyclomine hydrochloride capsules and tablets.[132]

According to the FTC, MMD manufactured and sold Bentyl, the branded version of dicyclomine hydrochloride.[133] Rugby-Darby sold the only generic equivalent of Bentyl in the U.S.[134] The FTC stated that the proposed consent order would establish a new competitor and remedy the anticompetitive effects of the proposed acquisition by requiring the parties to license certain patents and production technology necessary to manufacture dicyclomine.[135] In addition, the consent order required the parties to supply the licensee with dicyclomine for up to seven years so that the licensee could supply the market until it could obtain all necessary FDA approvals to manufacture the drug on its own.[136]

III.
General Principles Relating to Generic Drug Merger Enforcement

Analyzing the enforcement history in generic drug mergers over time reveals the many factors and considerations that the FTC evaluates when determining whether divestitures or other remedies will be required in order to proceed with a transaction. The following is a summary of the key principles that can be gleaned from the generic drug transactions where FTC enforcement action was taken.[137]

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132. *See In re* Dow Chem. Co., 1994 FTC LEXIS 86, at *20 (Proposed Decision and Order).

133. *In re* Dow Chem. Co., 118 F.T.C. 730, 731 (1994) (Complaint).

134. *Id.* at 732.

135. *Id.* at 736-38 (Decision and Order).

136. *Id.*

137. Some of these general principles are discussed in earlier works by the authors. *See generally* Steven K. Bernstein & Jeff L. White, *Generic Drug Merger Enforcement: A Guide for Antitrust Practitioners*, A.B.A. Antitrust Health Care Chronicle, Oct. 2005, at 7 (explaining general principles in connection with the FTC's enforcement of generic drug mergers); Steven K. Bernstein & Jeff L. White, *Recent FTC Enforcement Trends in Generic Drug Mergers*, A.B.A. Antitrust Health Care Chronicle, Mar. 2007, at 2 (explaining same).

A. *The Competitive Impact of Branded Drugs on Generic Equivalents*

One of the key questions raised by generic drug mergers is whether the branded version of the product should be included in the relevant product market. In every generic drug merger enforcement action since *Baxter/Wyeth* in 2002, the FTC has excluded the branded version of the drug from each of the relevant markets where it found that anticompetitive effects were likely. In these recent transactions, the FTC has explained that where there are multiple generic versions of a drug either on the market or in development, the branded version no longer significantly constrains the pricing of the generic versions.[138] At first glance, the exclusion of the branded drug from a relevant market that includes the generic version seems to be inconsistent with the FTC's earlier enforcement actions in *MMD/Rugby-Darby (1994)*, *Hoechst/MMD (1995)*, and *Baxter/Wyeth (2002)*. In each of these earlier matters, the FTC considered the branded drug to compete with the generic version of the product in certain markets where the FTC took enforcement actions.

The FTC's recent treatment of the relationship between branded drugs and generic equivalents may, at least in part, be attributable to the results of its July 2002 study on the impact of generic drug entry on pharmaceutical prices.[139] That study cited evidence that generic drug prices tend to fall until at least the fifth generic supplier enters into the market.[140] Interestingly, the FTC's report also cited evidence suggesting that the price of branded drugs may actually increase following entry by multiple generic suppliers.[141] As generic entry tends to cause price-sensitive customers to switch away from the branded version, the branded supplier may have an opportunity to increase the price of its product if it begins to face in-

138. *See, e.g.*, *In re* Mylan Labs. Inc., *supra* note 14, at 2; *In re* Actavis Group hf., *supra* note 33, at 2; *In re* Hospira Inc., *supra* note 41, at 2; *In re* Watson Pharms., *supra* note 50, at 2; *In re* Barr Pharms., Inc., *supra* note 67, at 2; *In re* Teva Pharm. Indus. Ltd, *supra* note 84, at 2; *In re* Novartis AG, *supra* note 95.

139. FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 9 (2002), http://www.ftc.gov/os/2002/07/genericdrug study.pdf.

140. *Id.*

141. *Id.*

elastic demand among those customers that do not switch and will not consider the generic alternatives.[142]

A concurring statement issued by FTC Commissioner Deborah K. Owen commenting on the consent order taken in *MMD/Rugby-Darby* in 1994 also may shed some light on the FTC's treatment of the relationship between branded drugs and their generic equivalents. In her statement, Commissioner Owen suggested that the inclusion of the branded drug in the same market as the generic version may change over time with the entry of additional generic suppliers:

> A threshold issue in analyzing this merger is whether MMD's Bentyl and Rugby's generic dicyclomine are in the same product market. On the one hand, it may seem obvious that two drugs deemed to be bioequivalent by the Food and Drug Administration, must be in the same relevant product market. On the other hand, branded drugs and their generic counterparts typically vary dramatically in price, suggesting that consumers may not view the products as equivalent or interchangeable. . .Whether a particular branded drug and any generic versions are in the same market may vary over time, and depends in part upon their relative prices at the time of the merger. In general, where the price differential between the branded product and the generic product is great, the products are more likely to be in separate markets. Conversely, where the price gap between the branded product and the generic product is relatively small (for example, where there is only one generic version available to consumers), the products are more likely to be in the same market.[143]

Although Commissioner Owen's statement in *MMD/Rugby-Darby* provides some guidance by referencing situations where there is a single generic supplier, the FTC has not provided any definitive rule as to the number of generic competitors that must be present before the branded version will no

142. *Id.* (citing Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75 (1997)).

143. The Dow Chemical Company et al., Proposed Consent Agreement With Analysis To Aid Public Comment, 59 Fed. Reg. 34625, 34629-30 (July 6, 1994) (Concurring Statement of Commissioner Deborah K. Owen).

longer be included in the relevant market for a generic product. Further, the FTC's earlier enforcement actions have not always been consistent in their treatment of branded drugs as they relate to their generic equivalents. For example, in *Baxter/Wyeth*, the FTC included Organon BioSciences's branded vecuronium in the market even though there were three generic versions of the drug available in the marketplace.[144] In *Barr/Pliva*, however, there were no existing generic versions of nimodipine on the market and the merging companies were the only two potential generic entrants.[145] Even though there would be only one potential generic competitor after the transaction, the FTC still concluded that the branded version would not sufficiently constrain the pricing of the generic version.[146]

Despite the differing treatment of branded drugs in the FTC's earlier enforcement actions, recent cases following the FTC's 2002 study on the effect of generic entry consistently have discounted the presence of the branded drug in the relevant market. This pattern suggests that while the FTC will conduct a fact-intensive analysis of the market at issue, in many cases it will likely continue to exclude the branded version from the relevant market, particularly where there are multiple generics on the market or in development. In certain situations, however, it is possible that the FTC may reach the opposite conclusion, particularly if a proposed transaction involves a branded supplier acquiring one of very few generic competitors.

B. *A Drug's Delivery Method*

Another key factor considered by the FTC in defining the relevant market is the delivery method of the drug. For example, in *Hospira/Mayne*, all five of the relevant generic drug product markets in which divestitures were required were limited to injectable forms of the drugs.[147] In that case, the FTC found that oral formulations were not close substitutes for injectable pharmaceuticals because injectable versions are used for patients that are unable to ingest pills or that require the

144. *See* Baxter/Wyeth, *supra* note 107, at 101.
145. *See* Barr/Pliva, *supra* note 67, at 2.
146. *Id.*
147. Hospira/Mayne, *supra* note 41, at 1.

immediate onset of action and cannot wait for an oral drug to pass through their gastrointestinal system.[148] The FTC also found markets comprised of generic injectable drugs in the earlier *Baxter/Wyeth* matter.[149]

As with other factors considered by the FTC, the importance of the drug's delivery method in a particular product area will be highly fact-dependant. Based on the FTC's enforcement activities, one key issue appears to be whether there is a group of patients for which a particular delivery method tends to be the only suitable method. Where there are patients that require a particular drug delivery method, the FTC may allege a narrow product market including only those drugs of that particular delivery type (even if two products that are administered differently contain the same active ingredient(s)). While such an approach to market definition may increase the likelihood of an FTC enforcement action where the merging parties offer the same generic drugs that utilize the same delivery method, it could have the opposite effect in other cases. For example, in situations where parties to a transaction offer the same drug in different delivery forms – such as an injectable form and an oral form – the FTC may determine that the products do not belong in the same relevant market or it may include them in a broader market encompassing all forms of the active ingredient. By doing so, it is possible that the FTC may conclude that the two forms are not meaningful competitors (especially if there are significant price differences in the products) and that the proposed transaction will not lessen competition in that particular area.

C. *The Number of Competitors in the Relevant Market*

The number of competitors in the relevant market has traditionally been an important factor in the FTC's competitive analysis.[150] With one exception, all of the FTC's generic drug merger enforcement actions prior to 2006 involved markets where there were four or fewer pre-merger competitors and the transaction left the market with three or fewer com-

148. *Id.*

149. *See* Baxter/Wyeth, *supra* note 107, at 96.

150. *See* FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, MERGER CHALLENGES DATA, FISCAL YEARS 1999-2003 2-32 (2003), http://www.ftc.gov/os/2003/12/mdp.pdf.

peting firms. The lone exception was the FTC's 2002 enforcement action in *Baxter/Wyeth* involving the market for vecuronium. In that market, Baxter and Wyeth had been the two leading suppliers of vecuronium until Wyeth discontinued selling the product in 2001.[151] At the time of the FTC's investigation in 2002, however, Wyeth had announced its intentions to resume supplying generic vecuronium.[152] The FTC required a divestiture in this market even though it acknowledged that a total of four post-merger competitors would have remained as active suppliers in the marketplace.[153]

More recent cases, however, suggest that the FTC increasingly may be willing to challenge transactions that reduce the number of generic competitors from five to four in the relevant market. This willingness may again stem from the FTC's 2002 pricing study on generic entry, which, as described above, suggests that the entry of a fifth generic supplier may contribute to a reduction in prices.[154] Nevertheless, where the FTC has taken enforcement actions in markets with five pre-merger generic competitors, it has tended to cite certain "plus factors." In other words, the FTC has not challenged any markets with five significant pre-merger generic competitors, but rather has always pointed to certain flaws in the competitive strength of one or more of the remaining competitors to the merged firm in the relevant market.

For example, in *Teva/IVAX*, the FTC found that there were five pre-merger competitors in the market for generic amoxicillin in the U.S.[155] Although four suppliers would remain after the transaction, the FTC noted that the merging companies – Teva and IVAX – were two of only three suppliers of the 200 mg and 400 mg oral suspension and the 875 mg tablet formulations of the drug.[156] The FTC concluded that competitors that could not supply all generic formulations of amoxicillin were of limited competitive significance.[157] Consequently, the FTC required the merging parties to agree to a remedy to restore competition in the generic amoxicillin mar-

151. Baxter/Wyeth, *supra* note 107, at 101.
152. *Id.*
153. *Id.*
154. FED. TRADE COMM'N, *supra* note 139, at 9.
155. Teva/Ivax, *supra* note 84, at 3.
156. *Id.*
157. *Id.*

ket that would have been eliminated through the transaction.[158]

Similarly, in *Barr/Pliva*, the FTC took enforcement actions in two markets that had five pre-merger generic suppliers.[159] In the market for generic trazodone hydrochloride, the FTC found that Barr and Pliva were two of only three suppliers of the 150 mg formulation.[160] In the market for triamterene/HCTZ, the FTC noted that Barr and Pliva were strong competitors and that the other generic suppliers were of only limited competitive significance.[161]

These recent cases suggest that the FTC will closely scrutinize markets in which a generic drug transaction reduces the number of competitors for a generic drug from five to four. Moreover, the consideration of "plus factors" in these enforcement actions also highlights the fact that determining whether a particular company supplies the same generic form of a drug in the relevant market is only a starting point in the antitrust analysis. Once such a determination is made, the FTC will analyze a wide range of competitive factors, including the formulations offered by each supplier for each overlapping generic drug, to determine the competitive significance of each competitor. The FTC also will assess the market shares of each supplier and may discount the competitive significance of those with small or *de minimis* shares in the relevant market, unless there is evidence that those suppliers have the ability and incentive to expand their sales to defeat possible anticompetitive effects. While this type of detailed analysis may lead the FTC to take enforcement action in some cases where the merging firms overlap in markets with five or more pre-merger competitors, it may also lead the agency to clear a transaction where there is an overlap market with fewer competitors, if the FTC determines that one of the merging companies is an insignificant competitor.

D. *Generic Drug Development Pipelines*

In addition to looking at the number of existing competitors in a market and their relative competitive significance, the

158. *Id.* at 1.
159. Barr/Pliva, *supra* note 67, at 2.
160. *Id.*
161. *Id.*

FTC also closely analyzes the drug development pipelines of the parties to a merger and their potential competitors.

As discussed, a number of the generic drug enforcement actions taken by the FTC have involved situations where the transaction would eliminate "potential competition" by combining an existing supplier of a product with a company that had a competing product in its development pipeline. In the generic drug merger cases before 2006, the FTC's enforcement activities only involved "potential competition" situations where one of the merging parties already had a product on the market and the other had a similar product in its development pipeline. After 2006, however, three generic drug merger enforcement actions involved markets where *neither* merging party had a product on the market, but both were potential competitors into the market.

For example, in *Teva/IVAX*, the FTC challenged the transaction with respect to the market for generic cabergoline tablets used to treat Parkinson's disease where Teva and IVAX were "two of a limited number of suppliers who are capable of entering the future market."[162] Similarly, in *Barr/Pliva*, the FTC required a divestiture in the market for generic nimodipine where the entry of both Barr and Pliva was imminent and there were no other generic suppliers in the market or developing the drug.[163] Finally, in *Watson/Andrx*, the FTC required divestitures in the markets for generic Micrette tablets and generic Ovcon-35 tablets where Watson and Andrx were "two of a limited number of suppliers capable of entering these future markets in a timely manner."[164]

These cases demonstrate that overlaps in the drug development pipelines of the parties to a proposed merger may raise antitrust concerns, even in situations where neither party has a product on the market. In analyzing these issues, the FTC considers, among other things, the timing and likelihood of the parties' entry efforts. In general, a company in the early stages of development has a lower likelihood of success in reaching the market and its potential entry may still be several years away. On the other hand, merging parties that are in the late stages of development for an overlapping product are

162. Teva/Ivax, *supra* note 84, at 5.
163. Barr/Pliva, *supra* note 67, at 2.
164. Watson Analysis, *supra* note 50, at 3.

more likely to be viewed by the FTC as important potential competitors and thus, are more likely to encounter antitrust objections than parties in the very early stages of development.

While the overlapping development pipelines of the merging companies can raise potential antitrust concerns, the development activities of other firms that might be potential competitors in the relevant market may help reduce the competitive concerns raised by the merger by providing additional competition that could defeat any anticompetitive effects of the transaction. It should be noted, however, that the FTC may discount new entry that only serves to replace one of the merging companies in an already highly concentrated market. In *Watson/Andrx*, for example, the FTC required divestitures in the market for hydrocodone bitartrate/ibuprofen tablets, which had three pre-merger competitors, even though a new entrant was in the process of obtaining FDA approval and was expected to enter within two years of the acquisition.[165] The FTC acknowledged the competitive impact that this potential entrant could have when it stated that "the proposed transaction would eliminate one of at most four competitors." Nevertheless, the FTC still required a divestiture in this market.[166]

The divestiture requirement in *Watson/Andrx* may have been driven by the FTC's July 2002 study on generic drug entry, which, as noted above, found that the price of a generic drug tends to fall until at least five competitors have entered the relevant market.[167] As a result, in generic drug mergers involving highly concentrated markets with four or fewer premerger competitors, the FTC may seek enforcement action unless there is evidence of multiple potential entrants into those markets.

E. *Third-Party Arrangements*

A generic drug company's relationships with third parties also can be an important factor in the FTC's analysis of a proposed transaction. In the generic drug industry, these relationships typically involve contract manufacturing or marketing and distribution agreements. The FTC has frequently required the termination of these types of agreements with third

165. *Id.* at 2.
166. *Id.* at 4.
167. FED. TRADE COMM'N, *supra* note 139, at 9.

parties (typically along with some other form of remedial relief) where it alleges that the agreements will create anticompetitive effects following a merger or acquisition. For example, in *Teva/IVAX*, the FTC raised concerns in four product markets where IVAX did not manufacture the products at issue, but instead competed with Teva for the sale of those products through a distribution agreement IVAX had with the manufacturers of those products.[168] To remedy its concerns over these arrangements, the FTC required Teva to assign the rights to IVAX's third-party distribution agreements for each of the four products to Par.[169]

In *Watson/Andrx*, the FTC's concerns in the market for hydrocodone bitartrate/ibuprofen tablets resulted from Watson's marketing arrangement with Interpharm.[170] There, Interpharm was a contract manufacturer for the product that Watson sold in competition with Andrx.[171] To remedy the FTC's concerns, the parties were required to divest Watson's rights to market the product to Interpharm.[172] In *Watson/Andrx*, the FTC also raised concerns in various markets for oral contraceptives where Andrx was the manufacturer of the products, but the products were sold to consumers by Teva through a marketing arrangement with Andrx.[173] Although it was Teva, not Andrx, that actually sold the products in competition with Watson, Andrx was required to terminate the marketing agreement and divest its oral contraceptive business to Teva in order to address the FTC's concerns.[174]

These enforcement actions make it clear that antitrust issues can arise where a party to a merger either manufactures generic products that are sold by other companies or markets products that are manufactured by another company in the same relevant market in which the other merging party com-

168. *See* Teva/Ivax, *supra* note 84, at 4-5.

169. *See id.* at 1. The four products included generic amoxicillin, generic amoxicillin/clavulanate, generic leuprolide acetate injection kits, and calcitrol injectables. *Id.*

170. *See* Watson Analysis, *supra* note 50.

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

petes.[175] Depending on the significance of the competitive concerns in those markets, the FTC may require a remedy to restore competition such as requiring the parties to terminate these third-party agreements and/or divest all rights and assets necessary for that third party to compete independently of the merged firm.

F. *Buyer Up-Front*

When the FTC requires divestitures in the pharmaceutical industry, it typically requires parties to find a buyer and enter into an agreement with that buyer for the package of assets to be sold before the consent order is accepted and the parties are permitted to close the transaction. This is referred to as the FTC's "buyer up-front" process. While the FTC in recent years has relaxed its preference for a buyer up-front in certain industries, this preference remains strong where pharmaceutical products are concerned. The most likely reason for this is that divestitures in the pharmaceutical industry typically involve divestitures of product lines rather than standalone businesses.[176] As a result, the FTC typically prefers that a buyer of the divested assets have an opportunity to examine the assets and enter into a purchase agreement that the agency can review to ensure that the package of assets to be divested identified in the consent order will include everything a buyer needs to compete effectively in the relevant market. The FTC also prefers a buyer-up-front in these cases to ensure that an acceptable purchaser for the assets exists.

The FTC has required a buyer up-front for each of the generic drug divestitures included in the last eight generic drug merger consent orders. Indeed, the only generic drug enforcement actions that did not require a buyer-up-front

175. These third-party relationships likely can take many other forms that may raise competitive issues in connection with a merger or acquisition, including, among others, licensing agreements and research and development agreements. As with other aspects of the FTC's analysis, the agency will closely scrutinize these arrangements and make a factual determination as to their potential effects.

176. *See* Fed. Trade Comm'n, Statement of the Federal Trade Commission's Bureau of Competition on Negotiating Merger Remedies, http://www.ftc.gov/bc/bestpractices/bestpractices030401.shtm (last visited Feb. 29, 2008).

were *MMD/Rugby-Darby (1994)* and *Hoechst/MMD (1995)*.[177] These two transactions, however, took place before the buyer-up-front process was widely used in FTC practice in the pharmaceutical industry.

Although recent FTC cases still make clear the agency's preference for a buyer up-front in generic drug divestitures, recent consent orders show that the FTC may allow some flexibility in crafting remedies.

One such example can be found in *Barr/Pliva* where the FTC gave the parties some choice in the particular assets and rights they were required to divest to address the FTC's concerns in the market for generic nimodipine. In that case, Barr and Pliva were each involved in a joint venture with another party to develop generic nimodipine.[178] In the consent order, the FTC listed two alternative divestiture options.[179] First, the parties could choose to divest the Pliva product to Pilva's partner, Banner, pursuant to a negotiated buyer-up-front agreement.[180] Alternatively, the parties could divest the Barr product to Barr's partner, Cardinal, provided the divestiture was accomplished in sixty days and in a manner that was approved by the Commission.[181] Thus, if the parties opted for the latter option to divest Barr's product to Cardinal, the parties would have had to negotiate a divestiture agreement with Cardinal, obtain FTC approval for that agreement, and then close on the divestiture of the product, all within a sixty-day period. The parties ultimately chose to divest the Pliva product to Banner.[182]

Similarly, in the market for organ preservation solutions (in which both Barr and Pliva supplied branded drugs), the FTC accepted a fairly non-traditional remedy by allowing a management buy-out of Pliva's branded product, Custodiol, rather than requiring a divestiture of the product to an estab-

177. A buyer up-front was not an issue in *IVAX/Zenith* because the parties resolved the FTC's concerns through a "fix-it-first" transaction and the consent order that was entered only prohibited the parties from re-acquiring the divested rights and assets.

178. Barr/Pliva, *supra* note 67.

179. *Id.*

180. *Id.*

181. *Id.*

182. *See* Barr/Pliva, *supra* note 67 and accompanying text.

lished pharmaceutical company.[183] The FTC permitted Pliva's head of marketing for organ preservation solutions to create a new entity that would market Custodiol independently of the combined Barr/Pliva.[184] Given his expertise in the relevant market, as well as evidence that venture capitalists had provided sufficient funding to capitalize the new entity, the FTC was comfortable that the new entity would be able to compete effectively and replace lost competition in the relevant market.[185] Because of the non-traditional nature of this remedy, however, the consent order also contained a "crown-jewel provision" that required the divestiture of an alternative attractive package of assets that would be attractive to a potential buyer if the management buy-out could not be completed effectively.[186] This provision required the parties, in the alternative, to divest the assets relating to Barr's organ preservation solution, ViaSpan, which held a 60% market share.[187] Although this remedy took place in a market for branded products, rather than generic products, it is possible that such an arrangement may be acceptable to the FTC in a generic drug transaction, assuming the products to be divested are sufficient to support a free-standing business.

These examples show that the FTC may permit some flexibility where circumstances warrant such an approach. Nevertheless, the long line of traditional divestitures required to remedy competition concerns in generic drug mergers suggest that flexible remedies in this industry have been the exception, rather than the rule.

G. *Length of Investigation*

The FTC's enforcement history in generic drug transactions also provides a rough indication as to the potential duration of the agency's antitrust review. Based on prior cases in the generic drug industry, particularly where a buyer up-front is required, the FTC's investigation from start to finish can be expected to last at least four months and up to seven or eight

183. *See id.*
184. *Id.*
185. *Id.*
186. *See id.*
187. *Id.*

months (and possibly even longer if significant competitive issues arise).

Table 1 provides a summary of the approximate length of the FTC's investigations in the eleven generic drug transactions where a remedy has been required. Because the date on which companies notify the FTC and DoJ of the transaction under the HSR Act is not made public unless the companies choose to disclose it themselves, the date the transaction was publicly announced has been used to approximate the date that notification was made. Typically, parties file under the HSR Act shortly after announcing that a definitive agreement has been reached. In addition, the FTC may open its own investigation once it hears of a potential transaction, whether or not the parties have filed.

TABLE 1
APPROXIMATE LENGTH OF INVESTIGATIONS IN PRIOR GENERIC DRUG TRANSACTIONS

Transaction	Date Announced	Date Consent Order Accepted	Approximate Length of Review	Number of Products Divested
Mylan/Merck	May 12, 2007	September 27, 2007	4.5 months	5
Actavis/Abrika	November 30, 2006	April 16, 2007	4.5 months	1
Hospira/Mayne	September 20, 2006	January 18, 2007	4 months	5
Watson/Andrx	March 13, 2006	October 31, 2007	7.5 months	13
Barr/Pliva	June 27, 2006	October 20, 2006	4 months	4*
Teva/IVAX	July 25, 2005	January 23, 2006	6 months	15
Novartis/Eon Labs	February 21, 2005	July 19, 2005	5 months	3
Baxter/Wyeth	June 10, 2002	December 20, 2002	6 months	5
Hoechst/MMD	May 4, 1995	September 18, 1995	4.5 months	4**
IVAX/Zenith	August 30, 1994	March 27, 1995	7 months	1
MMD/Rugby-Darby	October 4, 1993	May 24, 1994	7.5 months	1

* Only three out of the four divested products in *Barr/Pliva* involved generic drugs.
** Only one out of the four divested products in *Hoechst/MMD* involved generic drugs.

As demonstrated in Table 1, there does not appear to be any significant correlation between the length of the FTC's review and the number of products required to be divested. Indeed, the investigation that took the least time was in *Hospira/Mayne*, where the FTC required a buyer up-front and accepted a consent order requiring divestitures of five products in approximately four months.[188] In *Teva/IVAX*, a

188. *See* Hospira/Mayne, *supra* note 41.

transaction that required the divestiture of fifteen products, the FTC required a buyer up-front and accepted a consent order in roughly six months.[189] On the other hand, the reviews of *MMD/Rugby-Darby* and *IVAX/Zenith*, each of which involved the divestiture of only one product, took approximately seven months or longer.[190]

H. *Size of Market*

The FTC's enforcement history also suggests that the size of the market is not relevant and that the agency challenges even transactions that implicate a very small amount of commerce. For example, in *Baxter/Wyeth*, the FTC required a divestiture in the U.S. market for pancuronium, which had total sales of less than $2 million.[191] The smallest market in which an enforcement action was taken, however, was in *Teva/IVAX*.[192] There, the FTC required divestitures in six markets that each had annual U.S. sales of less than $10 million.[193] One of the markets at issue in that transaction, the market for generic nicardipine hydrochloride capsules, had U.S. sales of only $674,000.[194]

Moreover, the FTC has taken enforcement actions involving small markets even though its action may have delayed the closing of a larger transaction that was otherwise competitively neutral or even pro-competitive. In *Novartis/Eon Labs*, for example, which was an $8.3 billion transaction, none of the three markets in which enforcement actions were taken had more than $15 million in sales.[195]

IV.
A Flexible Approach for Future Transactions

The eleven generic drug mergers involving FTC enforcement actions provide significant insight into the agency's enforcement practices. While creating reasonable predictability

189. Teva/Ivax, *supra* note 84.

190. *See In re* IVAX Corp., *supra* note 130 and *In re* Dow Chem. Co., *supra* note 131.

191. Baxter/Wyeth, *supra* note 107, at 99.

192. *See* Teva/Ivax, *supra* note 84.

193. *Id.* at 3-4.

194. *Id.* at 3.

195. Novartis/Eon Labs, *supra* note 95, at 535-36.

and transparency in the enforcement of the antitrust laws are often cited as important goals of the FTC,[196] there may be situations involving generic drug mergers that warrant greater flexibility by the agency in determining whether to require a remedy in a particular transaction.

The FTC generally operates under a public interest standard, and in deciding whether to bring cases, it should weigh all relevant factors in determining whether any particular enforcement action is in the public interest. Under the FTC's authority established by Congress, the FTC has the power to declare any unfair methods of competition unlawful and to file a complaint and adjudicate certain conduct so long as an administrative proceeding "would be to the interest of the public."[197]

We recommend that the FTC adopt a more flexible approach to remedies in generic drug transactions where the likelihood of anticompetitive effects is low or the magnitude of the potential effects is small, but where imposing a strict remedial requirement could delay the parties' ability to close a transaction. In applying this approach, the FTC should first assess the significance of its competitive concerns in each market. In markets where there are five or more pre-merger competitors or where there are several firms on the verge of entry, the likelihood of significant anticompetitive effects tends to be much lower than in markets that reduce the number of suppliers from three to two with no new entrants on the horizon. The FTC also should assess the amount of commerce at stake in the affected market relative to the size of the overall transaction. For example, in *Novartis/Eon Labs*, the FTC took enforcement actions in markets where the total amount of annual commerce at stake was (a) $6 million in the market for generic desipramine hydrochloride, (b) less than $10 million in the market for generic orphenadrine citrate, and (c) $14.5 million in the market for generic rifampin.[198] In contrast, the overall transaction was valued at approximately $8.3 billion and Novartis expected to achieve annual cost savings of up to $200

196. *See* FED. TRADE COMM'N, THE FTC IN 2006: COMMITTED TO CONSUMERS AND COMPETITION 2, (2006), http://www.ftc.gov/os/2006/03/ChairmanReportFinal2006.pdf.

197. 15 U.S.C. § 45(a)(1), (b) (2000).

198. *See* Novartis/Eon Labs, *supra* note 95, at 535-36.

million.[199] In those situations where the competitive risks are limited or the amount of commerce affected is small, some flexibility on remedies may be warranted.

Where flexibility on remedies may be warranted, the FTC might consider departing from its traditional stance on remedies in a number of ways:

First, the FTC should consider allowing the transaction to close without requiring the parties to find a buyer up-front. In many cases, a buyer up-front requirement can add significant time to the agency's review of a proposed transaction. In those cases where the amount of commerce at stake is small or the likelihood of competitive harm is less certain, a consent order that allows the parties to enter into a divestiture agreement with a buyer after the overall transaction closes may be in the public interest. In addition, the need for a buyer-up-front may not be necessary in situations where the divestiture is less complicated, such as where the product to be divested is produced by a third-party contract manufacturer. In such a case, the divestiture may be accomplished largely by assigning the relevant supply contract to the buyer, rather than through a more complicated process of transitioning the ongoing manufacturing operations from the seller to the buyer.

Second, the FTC should consider non-divestiture remedies to resolve its concerns in the relevant market(s). Although the FTC typically favors divestitures to remedy competitive concerns resulting from a horizontal merger,[200] a licensing remedy may be appropriate in some circumstances. For example, the FTC was willing to accept a licensing remedy in *MMD/Rugby-Darby* where the agency found that such relief would establish a new competitor capable of remedying the anticompetitive effects of the acquisition.[201] The FTC also may consider a long-term supply arrangement in order to enable a firm to enter the market as a marketer, even if not as a manufacturer, of the product. While far from a perfect rem-

199. *See supra* note 89.

200. *See* Fed. Trade Comm'n, Frequently Asked Questions About Merger Consent Order Provisions, http://www.ftc.gov/bc/mergerfaq.shtm (last visited Feb. 29, 2008).

201. *See* The Dow Chemical Company, et al., Proposed Consent Agreement With Analysis To Aid Public Comment, 59 Fed. Reg. 34625, 34630 (July 6, 1994) (Concurring Statement of Commissioner Deborah K. Owen).

edy, such a supply agreement may be an appropriate "trade-off" in limited instances.

Third, the FTC might consider a process based on the approach taken in *Hoechst/MMD*.[202] In that case, the FTC allowed the parties to consummate the transaction prior to the conclusion of the FTC's investigation, provided that the parties agreed to a settlement that prohibited Hoechst from taking control of MMD's operations or businesses until the completion of the FTC investigation and required Hoechst to commit to divest certain products if the FTC investigation found competitive problems in those areas.[203] In future transactions, the FTC could require a more narrow settlement at the early stages of the process that requires only the potential areas of competitive concern to be held separate (along with appropriate divestiture commitments) until the investigation can be completed. This solution would enable the merging parties to close the transaction and capture any benefits from doing so, but preserve the FTC's ability to obtain a suitable remedy in the event that the transaction would result in competitive harm.

In determining whether to take one of the approaches outlined above, the FTC also should be mindful of the overall level of efficiencies that the parties expect to achieve from a proposed transaction. Where the expected efficiencies in a transaction are significant, requiring a complete divestiture of the parties' assets and a buyer up-front, may delay the parties' ability to close and integrate their businesses quickly, which in turn may delay the realization of efficiencies that often drive generic drug transactions in the first place. For example, in *Mylan/Merck*, the parties expected to achieve $250 million in annual synergies by the end of the third year after closing.[204] In *Teva/IVAX*, the parties expected to achieve annual synergies of $100 million within the first year of closing and up to $200 million within the second year.[205] While the assessment and verification of efficiencies and other potential synergies often can be a time-consuming task and may not always be feasible under an approach intended to shorten the length of FTC's

202. *See supra* note 120.
203. *Id.*
204. *See supra* note 11.
205. *See supra* note 81.

investigations, in cases where the parties can convincingly demonstrate that significant benefits will flow from the transaction, an enforcement action and/or strict remedy requirement that further delays the transaction may well *not* be in the interest of the public.

V.
CONCLUSION

In this article, we have provided a detailed overview of the FTC's enforcement activities in generic drug mergers, as well as an explanation of the general principles that the FTC has applied to transactions in this industry. In addition, we have suggested some flexible approaches that the Commission might take when considering enforcement actions in markets where the likelihood of significant anticompetitive harm is low and a more traditional approach could delay the parties' ability to close an otherwise competitively neutral or pro-competitive transaction. In these situations, greater flexibility in the terms of the remedies imposed by the FTC may well be in the public interest.