FTC review of generic drug mergers — Four recent consents provide significant guidance on mode of analysis and divestiture requirements

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Abstract This paper details the Federal Trade Commission's (FTC) analysis in four recent generic drug merger consents: Watson/Andrx, Barr/Pliva, Teva/Ivax, and Novartis/Eon. It discusses the FTC's basis for requiring divestitures in each of these mergers. The factual analysis is followed by some general guidance on the mode of analysis for FTC review of generic drug mergers. Based on this guidance, companies entering into such transactions can better anticipate under what circumstances the Commission will require divestitures.

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INTRODUCTION

Pharmaceutical mergers and acquisitions — like acquisitions in all other industries — are subject to antitrust review under the Hart–Scott–Rodino Act of 1976 by either the Department of Justice (DOJ) or the Federal Trade Commission (FTC). Pharmaceutical transactions have traditionally been reviewed by the FTC based on its experience in analysing competition in pharmaceutical markets.

Over the last decade, the FTC has reviewed dozens of transactions involving the pharmaceutical industry. Until recently, however, the vast majority of these transactions related to the branded industry and biotech deals. These include landmark transactions — such as Pfizer/Pharmacia, Glaxo Wellcome/SmithKline Beecham, and Pfizer/Warner Lambert — many of which presented competitive problems under the Clayton Act, and thereby required divestitures or licensing of products to remedy the alleged anticompetitive effects.[1]

Over the last two years — culminating with the FTC's consent regarding Watson's acquisition of Andrx last October — the FTC has reviewed four significant transactions involving generic drug companies. In contrast, in the decade preceding the agency's review of these four deals, the FTC only sought relief in two transactions affecting generic drug markets.[2]

The increased scrutiny of generic drug deals by the Commission is likely due to two

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factors. First, increased acquisition activity in this market, as generic firms see the benefits arising from the economies obtained via consolidation. Secondly, with consolidation comes greater concentration in the affected markets. In general, as reflected by recent antitrust enforcement activity by both the FTC and DOJ, antitrust scrutiny most often arises in deals where the number of competitors for a certain product drops to four or less.[3]

The four recent generic drug transactions are:

- Watson's acquisition of Andrx (FTC consent 31st October, 2006),
- Barr's acquisition of Pliva (FTC consent 20th October, 2006),
- Teva's acquisition Ivax (FTC consent 23rd January, 2006), and
- Novartis's acquisition of Eon Labs (FTC consent 19th July, 2006).

In all four instances, the FTC obtained divestitures of multiple generic products to remedy certain alleged anticompetitive effects.

The FTC documentation accompanying these consents — in particular, the agency's 'analysis to aid public comment' statement — provide insights regarding the FTC's approach to generic drug mergers.[4] Based on these consents, it is now possible to better predict when the agency will investigate a generic drug transaction and, more importantly, require divestitures.

This paper will first detail the FTC analysis in each of the four recent generic drug consents. It discusses the FTC's basis for requiring divestiture for some of the products. A complete list of the divested products and details on the number of competitors present in those markets is provided in Table 1. The factual analysis is followed by some general guidance on how the FTC evaluates product market in generic drug deals, how the FTC approaches both 'actual' and 'future' generic competition cases, and the duration of FTC review of these transactions.

RECENT GENERIC DRUG MERGERS

Watson/Andrx

Watson announced its intention to acquire Andrx for US$1.9bn on 13th March, 2006. The FTC's review of the transaction lasted more than five months, ultimately requiring (via consent order on 31st October, 2006) the divestiture of 13 products to remedy the alleged anticompetitive harm.[6]

In several of the markets where divestiture was required, the FTC found that Watson and Andrx were among a limited number of suppliers on the market for specific generic drug products. The FTC determined that 'evidence shows that the price of a generic pharmaceutical product at issue decreases with the entry of each additional competitor'.[7] Concerning Watson/Andrx, the FTC concluded that where the transaction would eliminate 'one of at most four competitors', anticompetitive effects were 'likely to result from a decrease in the number of independent competitors in the markets at issue'. While noting that eliminating the fourth competitor could diminish competition, the FTC obtained relief in Watson/Andrx in only one market with four competitors.[8]

In many of the remaining markets where Watson competed actively and Andrx was not yet on the market, the FTC focused on the likely competitive impact of Andrx's entry. The FTC found again that in these markets there were a limited number of competitors (generally three, including Watson), and that Andrx was likely to enter those markets in a timely manner.[9] The Commission determined that divestiture was required because anticompetitive effects were likely in these markets through the elimination of Andrx's 'future competition'. Andrx's entry, the FTC concluded, 'likely would result in lower prices'.[10]

Finally, both Watson and Andrx were poised to enter two markets, Mircete and Ovcon-35. The FTC alleged that Watson and Andrx

Table 1: Products required to divested in Watson/Andrx, Barr/Pliva, Teva/Ivax, and Novartis/Eon

Transaction	Products divested	Number of competitors/entrants
Watson/Andrx	Hydrocodone bitartrate/ibuprofen	3 (with one other likely entrant)
	Glipizide ER	3
	Ortho-Cyclen	3
	Ortho Tri-Cyclen	3
	Ortho-cept	2–3 with Andrx as likely entrant
	Triphasil 28	2–3 with Andrx as likely entrant
	Alesse	2–3 with Andrx as likely entrant
	Ortho-Novum 1/35	2–3 with Andrx as likely entrant
	Ortho-Novum 7/7/7	2–3 with Andrx as likely entrant
	Loestrin FE (1 mg/0.020 mg)	2–3 with Andrx as likely entrant
	Loestrin FE (1.5 mg/0.030 mg)	2–3 with Andrx as likely entrant
	Mircete	Watson and Andrx both were likely entrants
	Ovcon-35	Watson and Andrx both were likely entrants
Barr/Pliva[5]	Trazodone hydrochloride	5 (but only 3 on certain formulations)
	Triamterene/HCTZ	5
	Nimodipine	0 (Barr and Pliva only likely entrants)
Teva/Ivax	Amoxicillin clavulanate potassium	4 (but only Teva and Ivax on one formulation)
	Ceflacor LA	2
	Pergolide mesylate	2
	Estazolam mesylate	3
	Leuprolide acetate	3
	Nabumetone	3
	Amoxicillin	5 (but only 3 on certain formulations)
	Propoxyphene hydrochloride	4
	Nicardipine hydrochloride	4
	Flutamide	4
	Clozapine	3 (plus Teva entering market)
	Tramadol/acetaminophen	3 (plus Teva as likely entrant)
	Glipizide/metformin hydrochloride	2 (with Ivax as likely entrant)
	Calcitrol	2 (with Ivax as likely entrant)
	Cabergoline	0 (with Teva and Ivax likely entrants)
Novartis/Eon	Desipramine hydrochloride	3 (but only N and E on all formulations)
	Orphenadrine citrate ER	3
	Rifampin oral	3

were two of a limited number of suppliers capable of entering these markets, and thus, the merger could lead to competitive harm through the elimination of one of two credible, future suppliers.[11]

Barr/Pliva

In July 2006, Barr filed a tender offer—valued at approximately US$2.5bn — to acquire Pliva. The FTC's review, which lasted approximately three and a half months, required the divestiture of three generic products (and one branded product).[12]

The FTC required divestiture because it was concerned about the reduction of actual and future competition. For two product overlaps, the FTC was concerned about the reduction of actual competition. In the first market, Barr and Pliva were among five suppliers of generic trazodone hydrochloride. Only three of those suppliers (including Barr and Pliva), however, sold a full line of dosages of the drug, in particular a 150 mg formulation. Through its investigation, the FTC found that many customers prefer to purchase all formulations (including the 150 mg dose) from one supplier, and thus discounted the competitive significance of two of the other suppliers.[13] In the second market, for the product triameterene/HCTZ,

again Barr and Pliva were among five suppliers. The FTC stated that 'there is evidence that several of these suppliers may have a more limited competitive significance' than Barr and Pliva, and on that basis, the agency alleged that the transaction likely would result in harm in this market.[14]

The FTC also was concerned about future competition. The Commission alleged that both Barr and Pliva were the only firms likely to enter the market for generic nimodipine, and that there were no current generic suppliers. Thus, by removing one of two likely entrants, the acquisition would eliminate 'future competition' and result in a 'monopoly' for generic nimodipine.[15]

Teva/Ivax

Teva proposed buying Ivax in July 2005 for approximately US$7.4bn. This merger created the world's largest generic firm, and thus, inevitably presented some competition issues. The FTC's review of this transaction ended approximately six months later with a consent that required the divestiture of 15 products.[16]

In a couple instances (Ceflacor LA and pergolide mesylate), Teva and Ivax were the only generic suppliers on the market; the obvious competitive concerns thereby led to a divestiture requirement.[17] In several other instances there were either three of four generics on the market pre-acquisition, and the FTC likewise found that the transaction would diminish competition and, consequently, required divestitures. For example, with regard to generic flutamide, the FTC observed that while both Sandoz and Barr would compete in this market post-deal, the combined Teva/Ivax firm would control more than 60 per cent of the market.[18]

Likely and timely entry by one of the merging parties formed the premise for divestitures in certain markets where there were three or fewer suppliers already on the market. For example, for both clozapine and tramadol/acetaminophen, the market comprised Ivax and two other suppliers with Teva poised to enter. The Commission found that anticompetitive effects were likely because the acquisition 'eliminate[d] Teva's planned entry into the generic tramadol/apap tablet market', and that absent the transaction Teva 'would have offered lower prices to attract customers and ultimately cause the market price of generic clozapine to decrease'.[19]

Two final observations on the Teva/Ivax consent. First, the FTC required divestitures in two instances where suppliers on the market did not offer a full-line of dosages of the product. For amoxicillin clavulanate, the merging parties were among four suppliers on the market but Teva and Ivax were the only suppliers for one formulation. For amoxicillin, the merging parties were among five suppliers but only three suppliers including Teva and Ivax offered three particular formulations.[20] Secondly, for cabergoline, there were no suppliers on the market. A divestiture was, however, required, because Teva and Ivax were in the process of entering that market and were 'two of a limited number of suppliers who are capable of entering the future market for generic cabergoline tablets'.[21]

Novartis/Eon

In early 2005, Novartis acquired Eon Labs for US$1.72bn. The Commission's consent with the parties — entered in July of that year — required the divestiture of three products.[22]

For two of the markets (orphenadrine citrate ER and rifampin oral), Eon and Novartis comprised two of the three suppliers on the market. The Commission found there were no likely entrants into these markets, and that, post-merger, Novartis would control in excess of 70 per cent of the relevant markets.[23] Thus, the FTC required divestitures.

Regarding the remaining divestiture (desipramine hydrochloride), again there were only three suppliers for this product including the merging parties. The Commission found that anticompetitive effects were likely as only Novartis and Eon made all six strengths of the product.[24]

GUIDANCE ON LIKELIHOOD OF DIVESTITURES AND DURATION OF FTC REVIEW

Based on these four recent consents, there is now significant guidance available on the mode of analysis for FTC review of generic drug mergers. In particular, companies entering into such transactions can better anticipate under what circumstances the Commission will require divestitures.

The FTC will limit the scope of the product market to include only generic drugs

In each of these four consents, the FTC limited the market to include only the generic products, excluding any competitive impact by the branded product. The FTC explained its reasons for excluding name-branded competition in Watson/Andrx:

> The number of generic suppliers has a direct and substantial effect on generic pricing, as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for each of the products at issue here, the branded versions no longer significantly constrain the generics' pricing.[25]

In the Barr/Pliva consent, the FTC provided further elucidation, noting in its opinion that branded drugs have limited competitive impact upon the prices of generic drugs. The FTC explained that the branded version of one product — trazodone hydrochloride — sold at 50 times the generic price, and that the branded version of another — triamterene/HCTZ — sold for more than five times the price of the generic equivalent, demonstrating in both instances that the price of the branded version of the products had limited or no correlation to the price of their generic counterparts.[26]

In 'actual competition' markets, the FTC generally will require relief where there are only three generic products on the market

Where both of the merging parties sell generics on the market for the same product (ie 'actual competition' markets), the FTC has required relief where there were three or fewer products on the market (and where there was no more than one likely entrant). The FTC has gone further, however, in some instances, and has required relief even where there were more than three participants on the generic market. For example, in situations in which there were four or more generics on the market but certain of those market participants did not supply all formulations, the FTC has required relief. Thus, in Barr/Pliva (trazodone hydrochloride) and in Teva/Ivax (amoxicillin clavulanate and amoxicillin), the FTC required divestitures even though there were four or five active participants on the market. The market peculiarities in those instances drove the FTC's decision to require divestiture. The Commission's rationale, as stated in Barr/Pliva, was that certain customers prefer to obtain all formulations from one supplier, and thus those suppliers without a full line of products will be of less competitive significance. As a result, the FTC discounted one or more competitors as effective price constraints on the merging parties.

The FTC required relief even when market realities suggested that four or five active suppliers on the market could not constrain post-merger consolidation. In Barr/Pliva (triamterene/HCTZ), the agency stated that certain of the five suppliers on the market may have had a 'more limited competitive significance in the market' than Barr and Pliva. No more detailed explanation was provided.[27] Similarly, in Teva/Ivax, the Commission required divestitures for three markets (propoxyphene hydrochloride, nicardipine hydrochloride, and flutamide) when there were four competitors on the market.[28]

In 'potential competition' cases, the FTC generally will require relief when entry by one or both of the merging parties is likely, and the market is concentrated

In markets with three or fewer generic competitors — and when only one of the merging parties was on the market, and the other was poised to enter in a timely manner — the FTC has required divestitures. The agency's consents generally indicate that relief will be required only when entry by one of the merging parties is likely, and the other merging party is also one of a limited number of firms positioned to enter. For example, in Watson/Andrx, relief was required in seven drug markets where Watson was one of two or three suppliers on the market, and Andrx was 'one of a limited number of firms' developing competitive products and was 'well-positioned to enter the markets in a timely manner'.[29]

Finally, the FTC required divestitures in markets where there were no generic products on the market, but both merging parties were viewed as likely and timely entrants. These are the 'future competition' matters noted above.

The length of an FTC investigation is related to the number of markets at issue

The FTC has gained considerable experience in reviewing generic drug mergers over the past two years. This experience should help expedite review of these transactions, as often the same staff attorneys and economists will be involved in generic drug merger reviews. Based upon these past investigations, companies engaged in generic drug mergers with overlaps should expect the length of the investigation to last approximately three to six months.

The number of products involved likely will have an impact on the duration of the investigation. It is no accident that Watson/Andrx (13 products divested) and Teva/Ivax (15 products divested) were the longest investigations, at approximately five and a half and six months, respectively. In comparison, the review of Barr/Pliva (three generic products divested) took three and a half months and Novartis/Eon (three products divested) took approximately five months. The more product markets to investigate, the longer the investigation likely will last.

CONCLUSION

In light of recent consolidation in the generic drug industry, future generic drug mergers will likely be subject to continued scrutiny by the FTC. Mergers between major firms will almost certainly result in divestitures, and even acquisitions of and among smaller firms could be seen as leading to anticompetitive effects depending on the number of competitors in the individual product markets at issue. Divestitures are almost certain to be required where the number of competitors drops from three to two (absent, of course, a showing of likely and timely entry by others) and will also be required under certain circumstances (eg limited competition on certain formulations) where the number of competitors drops to four or five.

As noted above, the FTC has gained considerable experience over the last two years in reviewing these transactions. This should benefit the parties to these transactions as the analysis should be more predictable, and the review time should be shorter as both the Commission staff and outside counsel gain experience in this area.

References and Notes

1. For background on these deals and other deals reviewed by the FTC, the FTC publishes a semi-annual report entitled 'Overview of FTC Antitrust Actions in Pharmaceutical Services and Products', which details all pharmaceutical matters challenged by the Commission. It is available at www.ftc.gov/bc/0608rxupdate.pdf.
2. This occurred in Baxter/Wyeth (FTC 2003 consent order) and in Hoechst AG/Marion Merrell Dow (FTC 1995 consent order).

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3. In 2004, the FTC released data detailing challenges (ie brought suit or obtained a consent agreement) to mergers covering the years 1996–2003. This data provides information regarding FTC merger challenges for all industries, including the pharmaceutical industry. The report detailing this information is available at www.ftc.gov/os/2004/08/040831horizmergersdata96-03.pdf.
4. The FTC's 'consent package' for each of the transactions is available on the FTC website (by searching under 'Past Commission Actions' at www.ftc.gov/ftc/formal/htm). The most pertinent documents in each 'consent package' are the Complaint, Decision and Order, and Analysis to Aid Public Comment. The 'Analysis' statement is not considered an 'official interpretation' of the other documents, but is intended to be a plain English explanation of the Order to facilitate public comment and often is more expansive in providing the rationale for relief than the Complaint. When the parties and the FTC reach agreement on a consent, the consent is placed on record for a 30-day public comment period. For most transactions, no public comments are received, and the order is formally entered soon after the period expires.
5. Divestiture of one branded product for organ preservation solutions also was required.
6. Watson/Andrx 'consent package', available at www.ftc.gov/os/caselist/0610139/index.htm.
7. Watson/Andrx Analysis to Aid Public Comment, at p. 4.
8. In that market (hydrocodone bitartrate/ibuprofen) there were three competitors on the market and one likely entrant constituted the fourth competitor. Watson/Andrx Analysis to Aid Public Comment, at p. 4.
9. Under the joint Federal Trade Commission/Department of Justice 'Merger Guidelines,' entry is considered timely if it occurs within a two-year period.
10. Watson/Andrx Analysis to Aid Public Comment, at p. 3.
11. *Id.*
12. Barr/Pliva 'consent package', available at www.ftc.gov/os/caselist/0610217/0610217.htm.
13. Barr/Pliva Analysis to Aid Public Comment, at p. 2.
14. *Id.*
15. *Id.*
16. Teva/Ivax 'consent package', available at www.ftc.gov/os/caselist/0510214/0510214.htm.
17. Teva/Ivax Analysis to Aid Public Comment, at p. 3.
18. This observation relating to a specific high market-share figure should not be over-emphasised. The FTC Complaint and Analysis to Aid Public Comment in these consents does not uniformly provide such figures, and the more relevant factor appears to be the number of overall competitors left in the market post-deal. If a merger reduced the number of competitors in a market from four to three, and the two merging parties had a minimal share, the transaction would, however, pose less competitive concerns in that market.
19. Teva/Ivax Complaint at ¶¶ 21–22.
20. *Id.* at ¶¶ 11 and 17.
21. *Id.* at ¶ 25.
22. Novartis/Eon 'consent package', available at www.ftc.gov/os/caselist/0510106/0510106.htm.
23. Novartis/Eon Analysis to Aid Public Comment, at p. 2.
24. *Id.* at pp. 1–2.
25. Watson/Andrx Analysis to Aid Public Comment, at p. 2.
26. Barr/Pliva Analysis to Aid Public Comment, at p. 2.
27. Barr/Pliva Analysis to Aid Public Comment, at p. 2.
28. Teva/Ivax Analysis to Aid Public Comment, at pp. 3–4.
29. Watson/Andrx Analysis to Aid Public Comment, at p. 3.