What Past U.S. Agency Actions Say About Complexity in Merger Remedies, With an Application to Generic Drug Divestitures

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October 2017
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Abstract: We consider merger remedies of the U.S. Department of Justice’s Antitrust Division and the U.S. Federal Trade Commission between 2008 and 2017. Traditionally one distinguishes between structural and behavioral remedies—and structural remedies are generally considered to be more effective and easier to implement. Our analysis suggests that over time this distinction has become somewhat blurred and a better gradation of remedies may be tied to the complexity of the proposed remedy. Divestitures in the market for generic drugs, in particular, are particularly complex, even though the remedies are of a structural, and so their efficacy is hard to ascertain.

Keywords: Antitrust, Mergers, Structural Remedies, Behavioral Remedies, U.S. Enforcement

¹ Emch (eric.emch@bateswhite.com), Bates White Economic Consulting, Washington D.C.
² Jeitschko (jeitschko@msu.edu), Michigan State University, East Lansing, MI.
³ Zhou (arthur.zhou@bateswhite.com), Bates White Economic Consulting, Washington D.C.
What past U.S. agency actions say about complexity in merger remedies, with an application to generic drug divestitures

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I. Introduction

Structural remedies: good. Behavioral remedies: bad. That, in a nutshell, summarizes nearly two decades of guidance from the Department of Justice (DOJ) and Federal Trade Commission (FTC) about appropriate remedies to merger harm. In this context, “structural remedies” refers to remedies involving the sale of key assets by the merging firms to a third firm in order to create a new competitor to replace the competition lost by the merger.5 “Behavioral remedies,” also known as “conduct remedies,” refers to restrictions on the post-merger conduct of the merged firm designed to prevent the exercise of market power.6

Historically, the antitrust agencies have strongly favored structural remedies over behavioral remedies. Behavioral remedies have been seen as more difficult to design, implement and monitor, and ultimately as less likely to be effective, than structural remedies.7 Structural remedies, in contrast, have been seen as requiring only a targeted intervention to create a market structure that prevents the exercise of post-merger market power. Structural remedies are seen as having the virtue of not legislating a firm to act against its interests, and not requiring substantial ongoing monitoring by the agencies.8

A look back at past settlements by the agencies, however, shows that though they are helpful as a general guide, the simple dichotomy of structural versus behavioral does not illuminate the greyer area into which most remedies, containing both structural and behavioral elements, fall.

Structural remedies usually require some behavioral components to operate effectively and be deemed acceptable by the agencies. These may include, for instance, supply agreements in which the merging parties provide key inputs to the purchaser of divested assets until the purchaser can line up suppliers on its own, contract manufacturing agreements in which the merging party manufactures the divested

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product for the purchaser until manufacturing processes can be transferred and proper approvals obtained, restrictions on interfering with movement of personnel to the purchaser, or agreements to transfer know-how and help defend against future intellectual property (IP) infringement-related suits based on that know-how, among other provisions. Each of these components of a nominally “structural” remedy involves some of the same definitional and monitoring issues as a purely behavioral remedy. If anything, these behavioral elements of structural remedies have become more common over time.

As a guide to what remedies are most functional and will be seen by the agencies as most acceptable, it may be better to think less in terms of structural versus behavioral and more in terms of greater or lesser “complexity.” Complexity might be increased by the sheer number of harms to be remedied. For instance, in 2016, former Assistant Attorney General Bill Baer declared in response to divestiture proposals put forward by the parties in the proposed Halliburton-Baker Hughes merger that the merger was “unfixable.” This was likely due at least in part to the inherent complexity of any proposal designed to remedy harms in the 23 distinct yet linked markets of harm that the complaint alleged.

Alternatively, complexity might be increased by the extent and nature of behavioral components required to make a structural remedy work. For instance, the recent FTC evaluation of the success of past remedies found that generic drug divestitures, though largely successful, were much less successful when the divestiture involved a transfer of manufacturing to the buyer, with accompanying behavioral elements to ensure a smooth transition, rather than just re-contracting with an existing third-party supplier that could begin producing immediately for the buyer. More generally, that study found that divestiture of an “ongoing business,” which is inherently less complex than divesting particular sets of assets that do not necessarily constitute a standalone business by themselves, “are most likely to maintain or restore competition.”

In this paper, we discuss the components of remedy complexity, and how they have differed over time and across agencies. We examine in detail some of the behavioral elements more and less commonly used in structural remedies, and discuss some purely behavioral remedies that likely lie at the outer reaches of the level of complexity that might be acceptable to the agencies. In the final section, we focus on differences in generic drug divestitures as an illustration of the notion that simpler, less complex
remedies are more likely to be both workable and acceptable to the antitrust agencies, and that even remedies that seem simple on their surface can lead to unanticipated difficulties.

II. The components of remedy complexity

The purpose of a merger remedy is to preserve the efficiencies of a merger while removing the sources of anticompetitive harm. The set of remedies that may be implemented are ones that are both acceptable to the merging parties as not too damaging to the underlying rationale of the merger and acceptable to the agencies as limiting the potential for anticompetitive harm.

As a basic matter, the more complex the remedy, and the more substantial it is relative to the size of the overall merger, the less likely it is to be acceptable to both the agencies and the parties. The agencies may worry about the administrability of a complex remedy, while parties may balk at a remedy that involves substantial portions of the assets involved in the merger. The most attractive remedies are thus structural remedies of existing lines of businesses that are small relative to the size of the overall merger and that require few behavioral components to be effective. In Regal Cinema’s 2009 acquisition of Consolidated Theatres, for example, the DOJ required divestiture of four movie theaters in North Carolina with minimal behavioral components. Similarly, in the recent Emerson acquisition of switchbox manufacturer Pentair, the FTC required the divestiture of a standalone Pentair switchbox business unit to the already-identified buyer Crane Co. When these types of remedies are available, they can provide a relatively easy fix that is acceptable to both the parties and the agencies.

On the other end of the spectrum are intricate behavioral remedies that potentially cover a wide range of disparate assets. When a purely behavioral remedy is the only option, either agency may question whether a remedy is viable at all, and may see blocking the merger as the only way to prevent anticompetitive harm. This presents a particular problem in vertical mergers, where there may be no real structural remedy available, and yet inherent efficiencies in combining complementary goods may mean that there is a good argument for trying to remedy the merger rather than blocking it entirely. For this reason, the agencies tend to be most willing to accept purely behavioral remedies in vertical mergers.

15 The DOJ defines vertical mergers as those involving firms “that do not operate in the same markets, and may not result in an overlap between the assets of the purchaser and the acquired entity.” See “Antitrust Division Policy Guide to Merger Remedies,” U.S. Department of Justice: Antitrust Division, June 2011: 12. The FTC provides a similar definition in its online guidance on the competitive effects of mergers—“vertical mergers involve firms in a buyer-seller relationship” such as a “manufacturer merging with a supplier of an input product.” Also see “Mergers: Competitive Effects,” Federal Trade Commission, available at https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/competitive-effects.
Below we discuss the components of remedies in increasing order of complexity: from the “standard” components of most structural remedies—which include some behavioral provisions—to non-standard structural remedies that sometimes add significant behavioral components, to intricate, purely behavioral remedies that form the outer reaches of what may be acceptable to the agencies.

II.A. Standard components of structural remedies

We reviewed all merger remedies imposed by both agencies in 2008–2009—the end of the Bush administration and the beginning of the Obama administration—and 2016–2017—the end of the Obama administration and the beginning of the Trump administration. Though there are some changes across the two time periods, there is a high degree of consistency both across agencies and over time in remedy design.

With few exceptions, consent decrees expire after 10 years. During that period, the agencies typically require some type of compliance reporting, though the DOJ and FTC differ in both the frequency and method in which this is required. The DOJ usually requires defendants to submit reports or respond to written interrogatories “upon request,” or triggered by specific market events. The FTC, in contrast, often mandates that the defendants submit compliance reports after 30 days, followed by intervals of decreasing frequency until the final judgment term has ended.

The agencies generally reserve the right to establish a divestiture and/or monitoring trustee to ensure that the divestiture is sold to an effective buyer and that the provisions of the remedy are followed by the parties. Sometimes that trustee is named in the final judgement but usually it is not. The assets to be sold to a buyer are typically mandated to be kept separate, distinct, and saleable in the period between the merger and the divestiture – the DOJ calls this a “hold separate” provision.

Since use of divested assets typically involve a level of specific know-how, or, in some cases, specialized knowledge of the relevant supply chain, the agencies typically either mandate or allow the acquirer the option to accept a transitional services agreement whereby the divestor must assist the acquirer of the assets with technical or administrative issues that come up during the transition. When transitional services are stipulated, they range from a period of a couple months to at most two years and need to be provided at cost or at “commercially reasonable” terms.

Both agencies also often place restrictions on the post-merger movement of personnel to ensure that the acquirer does not lose key staff members. These restrictions can include 1) facilitating the buyer’s hiring of key employees from the merging parties and 2) establishing non-interference or non-solicitation

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16 Though the court can choose to grant an extension in the DOJ filings.
clauses to prevent the merging parties from poaching employees who may initially move to the buyer of the assets.\textsuperscript{18}

Even these standard provisions, present in most structural remedies, contain behavioral elements – the level of assistance given in transition services agreements are difficult to monitor, for instance, and “commercially reasonable terms” for services that have never actually been offered may be difficult to determine. A number of nominally structural remedies have gone beyond these standard terms to include a number of additional behavioral elements that the agencies deem are necessary to ensure that the remedy restores competition lost by the merger.

\section*{II.B. Non-standard behavioral elements of structural remedies}

Adding additional behavioral components to a nominally structural remedy adds to its administrative complexity, but may be required to make the remedy workable in the eyes of the agencies. Three of the most common of these “non-standard” behavioral elements include 1) the provision of a supply and/or tolling agreement 2) mandatory licensing arrangements 3) firewalls.

Depending on the nature of the firms and the merger agreement, the agencies may require as part of a consent decree a supply and/or contract manufacturing agreement that guarantees a buyer a supply of key inputs, or the product itself, until it can establish its own supply relationships and manufacturing capabilities. For example, in generic drug mergers, it is not atypical for the FTC to require that the merging parties initially supply the final product and/or drug ingredients to the buyer at “economically reasonable terms” to assist the smooth transition of production and sales.\textsuperscript{19} Typically, these agreements expire after a period of time that the agencies deem sufficient for the acquirer to begin producing the product on its own. For example, the consent decree in the ChemChina – Syngenta merger (2017), obligated the merging parties to supply finished crop protection products for up to two or three years (depending on the active ingredient in the product), at the option of the buyer.\textsuperscript{20} This provision is designed to give the buyer time to gain the institutional knowledge and/or manufacturing know-how required to eventually produce the finished good independently of the seller.

Mandatory licensing provisions requires the merging parties to license certain intellectual property (IP) to the buyer on reasonable terms, or for free, which gives the buyer the means to produce and in some cases continue to develop the divested product.\textsuperscript{21} For example, in the recent Danone-WhiteWave dairy products

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{18} Sometimes these restrictions are accompanied with time expirations, such as in the McCormick-Unilever merger; the merging parties cannot interfere with hiring key employees for a period of one year. Decision and Order, \textit{In re McCormick & Company, Incorporated, a corporation} (C-4225), Federal Trade Commission (D.D.C. Sep. 12, 2008) at 14.
\item \textsuperscript{19} For example, in the 2016 Mylan-Meda merger, the FTC required that the merging parties supply any requested Contract Manufacture Product at “supply cost”. \textit{See Decision and Order, In re Mylan N.V., a corporation} (C-4590), Federal Trade Commission (D.D.C. Sep. 7, 2016) at 20.
\item \textsuperscript{21} On some occasions, the FTC stipulates that the merging parties cannot sue the acquirer for IP products related to the
\end{itemize}
\end{footnotesize}
merger, the divestiture package included a non-exclusive, perpetual, and royalty-free license to use the Brown Cow Greek Formula, which allowed the acquirer to produce certain Stonyfield dairy products.22 Further complexity can occur if licensed (or transferred) IP is the subject of a patent infringement suit. One might imagine that the acquirer of new IP would lack important information that would allow it to defend itself against patent infringement claims, so remedies sometimes include a provision whereby the merging parties must provide knowledgeable individuals to assist the buyer in its defense of any patent claims. For instance, in the 2009 Pfizer-Wyeth merger, the FTC required that the merging parties provide such individuals to the buyer, at no cost, in the event of a patent infringement suit.23

In instances where the dissemination of certain information within a firm could facilitate anticompetitive behavior, the agencies may deem it necessary to implement an information firewall. For instance, in the 2016 merger of AMC and Carmike Cinemas, in addition to requiring the merged entity to divest movie theaters in 15 local markets, AMC was required to divest most of the ownership and all of its governance rights of National Cinemedia (“NCM”), a preshow services and cinema advertising firm, because Carmike owned significant equity in a competitor of NCM, Screenvision.24 The merged firm was allowed to retain up to 4.99% ownership of NCM, without governance rights, but was required to implement and maintain firewalls to ensure that it did not act as a conduit for NCM or Screenvision’s competitively sensitive information.25

One can imagine some of the problems normally ascribed to purely behavioral remedies being caused by behavioral provisions of mostly structural remedies. For supply or contract manufacturing agreements, there can be issues of timeliness or quality of supply or of how to determine the price paid. For licensing or other technology transfer arrangements, delineating all the relevant IP can be challenging, and if the buyer subsequently becomes embroiled in IP litigation, determining whether the seller is providing an appropriate level of assistance to the buyer may not be an easy thing to determine. Firewalls can be difficult to monitor and enforce. These behavioral provisions are included to protect against dimensions of possible remedy failure, but they add to the complexity of the remedy.

II.C. Purely behavioral remedies

In some cases a structural remedy may not be possible. Vertical mergers, for instance, are often not amenable to structural remedies.26 In that case, when the agencies face an anticompetitive merger, they

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25 Id.
26 In horizontal mergers, to alleviate the loss in head-to-head competition resulting from one of the merging parties effectively “exiting” the market, it is not surprising that remedies consist of selling off overlapping assets to a viable competitor that is intended to restore the lost competition. Vertical mergers, by definition, do not involve combining ownership of direct
may confront a choice between implementing a purely behavioral remedy and simply blocking the merger. In certain cases, especially when expected efficiencies are high, it may make sense from the agency’s perspective to try to design a purely behavioral remedy despite the challenges inherent in such a remedy.

In its 2011 Antitrust Division Policy Guide to Merger Remedies, the DOJ seemed to open the door to increased use of behavioral remedies relative to its earlier 2004 guidance, in particular with respect to vertical mergers. The Guide advised that “conduct remedies can be an effective method for dealing with competition concerns raised by vertical mergers.”27 The guidance as a whole was interpreted by some as the DOJ endorsing behavioral remedies to a greater degree than either agency had previously.28

Around this time, the DOJ implemented a number of complex behavioral remedies for vertical mergers—for instance in the Comcast-NBC, Google-ITA, and GrafTech-Seadrift Coke merger—that seemed to represent a greater level of behavioral complexity than the DOJ had historically found acceptable. These types of remedies may represent the outer bound of the level of complexity acceptable to the agencies.

II.C.1. Comcast-NBC Universal

In late 2009, the DOJ and the Federal Communications Commission (FCC) began reviewing the acquisition by Comcast, a large multi-video programming distributor (“MVPD”), of a 51% stake in NBC Universal (“NBCU”), a large creator of video programming content. In early 2011, the DOJ allowed the acquisition to proceed after imposing a number of behavioral conditions to address concerns that the merged firm would harm competition by foreclosing access to NBCU content by emerging online video distributors (“OVDs”) that competed with Comcast (the FCC at the same time imposed its own set of conditions). The DOJ consent decree required the merged firm to provide all video programming it provides to any MVPD to OVDs on “economically equivalent” terms.29 It also included anti-retaliation provisions designed to prevent the merged entity from “retaliating” or “punishing” any broadcast network, cable programmer, production studio, local television station, or network affiliate for providing programming to a MVPD or OVD competitor.30

These provisions depend on oversight and review of potential ambiguous terms like “economically equivalent” and “retaliation.” Retaliatory behavior can occur in several different forms (e.g., foreclosure

competitors. Instead, the agencies are more concerned with issues such as vertical foreclosure or the denial or degradation of a competitor’s access from the upstream component of the supply chain.

30 Final Judgment, United States of America et al. v. Comcast Corp. et al. (1:11-cv-00106), Department of Justice, (D.D.C. Sep. 01, 2011) at 19.
of access, raising prices), so, accusations of retaliation would need to be reviewed on a case-by-case basis. Though the decree was approved, the court was skeptical of the efficacy of some of its provisions:

Because of the way the Final Judgement is structured, the government’s ability to “enforce” the Final Judgement and, frankly, this Court’s ability to oversee it, are, to say the least, limited. . . . And despite the Government’s assurances that “this Court retains jurisdiction to issue orders and directions necessary and appropriate to carry out or construe any provision of the Final Judgement,” Supp. Stmt. At 6, and “to enforce compliance, and to punish violations of its provisions,” . . . I am not completely certain that these safeguards, alone, will sufficiently protect the public interest in the years ahead. 31

II.C.2. Google-ITA

In 2011, the DOJ allowed the merger of Google and ITA, the latter being a provider of a back-end airfare pricing and shopping system called QPX. This was a vertical merger because Google planned to create a consumer-facing airfare search product and to use ITA on the back end of its product, as a number of consumer-facing airfare search firms (e.g., Kayak, Orbitz) already did. 32 The DOJ concluded that the merger would give Google the incentive and ability to use its ownership of ITA to foreclose competitors in “comparative flight search services” by degrading or denying access to QPX and related software. 33 To alleviate concerns that Google would leverage its ownership of ITA by degrading flight search rivals’ access to ITA products and thereby harming competition, the DOJ imposed a number of behavioral restrictions, including mandated licensing, firewalls, and provisions to ensure continued investment in ITA’s pricing and shopping software for use by firms other than Google. Among these was a requirement that the merged entity devote “substantially as many (or more) engineering resources (in terms of budget and full-time-equivalent employees) to the research and development and maintenance of QPX and the InstaSearch service” compared to the two years prior to the acquisition. 34

The enforceability of these provisions seems difficult. One commentator contemporaneously flagged possible risks of these provisions, which highlight the inherent difficulty in envisioning and covering every possible scenario when designing complex behavioral remedies.

. . . as confident as the DOJ appears, the following risks were not adequately addressed:

32 For discussion, see John Kwoka, Mergers, Merger Control, and Remedies (Cambridge, MA: MIT Press, 2015), 136.
34 Final Judgment, United States of America v. Google Inc. and ITA Software, Inc. (1:11-cv-00688 (RLW), Department of Justice, (D.D.C. Oct. 05, 2011)) at 15–16. InstaSearch was one of ITA’s products that was used to reduce response times for innovative flight features that enabled consumers greater flexibility in their search for fares. See Complaint, United States of America v. Google Inc. and ITA Software, Inc. (1:11-cv-00688 (RLW), Department of Justice, (D.D.C. Apr. 08, 2011)) at 11.
• Google will provide competitors with its latest code but will it provide timely notification of changing code specifications and interface designs? . . .

• Google has agreed that it will not perform data mining on competitors but, really, is it possible to know if Google were abusing competitors’ sensitive information? . . .

• Google has promised to provide its competitors with fair access to ITA’s latest software, but will Google provide these competitors with fair access to the customers they are all seeking to serve? Nowhere does the decree explicitly mention Google’s future obligation to provide other firms with access to customers by ensuring that Google will not preference its own offerings by placing them higher on the search page. 35

II.C.3. GrafTech-Seadrift

In April 2010, the graphite electrodes manufacturer GrafTech International announced its intention to acquire Seadrift Coke. Seadrift was a major supplier of petroleum needle coke, one of the key inputs into the production of graphite electrodes. 36 The DOJ identified a potential vertical concern in that GrafTech was a buyer and would continue to be a buyer of petroleum needle coke from one of Seadrift’s main competitors, Conoco. Part of GrafTech’s agreement with Conoco involved a most-favored nation (MFN) pricing agreement with accompanying audit rights, including the right to access cost information, production schedules, and third-party pricing information. The DOJ was concerned that if GrafTech routinely acquired this information about one of Seadrift’s main competitors, it could use that information to coordinate pricing and output in the market for petroleum needle coke. 37

To resolve that concern, the DOJ and the parties agreed to modify the Conoco supply agreement with GrafTech to eliminate its audit and MFN provisions, and to not include such provisions in any future contract with Conoco. The DOJ also added a variety of transparency provisions, mandating that defendants were required to provide to the DOJ quarterly update on contracts between defendants and Conoco relating to the provision of petroleum needle coke, Seadrift's projections of demand and sales, year-to-date production and sales of petroleum needle coke, and changes to production capacity or other major capital projects by Seadrift. 38 In addition, if Seadrift made a change in its capacity and production that caused annual output to shift by more than 10%, the merging parties were required to report outside

of the normal quarterly reporting. Finally, various provisions of the consent decree instituted firewalls between certain Seadrift and GrafTech employees.

II.C.4. Summary

These behavioral remedy provisions may fall on the more complex end of those acceptable to the agencies. They all occurred around the time of the revision of DOJ’s merger guidance in 2011. It is difficult to know until the new administration has begun to review whether these types of complex behavioral remedies of vertical mergers will continue to be acceptable under current DOJ and FTC leadership.

III. Differences in remedy complexity across time and agencies

With the possible exception of the vertical mergers in the 2010–2012 period, the types of remedies the agencies accepted and their standard provisions have been fairly consistent in recent years. The most important change seems to be the increasing frequency of identifying the buyer of a particular package of assets in the consent decree itself — a so-called “upfront buyer” provision — as opposed to identifying the buyer after the consent decree has been filed. The DOJ went from identifying zero upfront buyers in the 2008–2009 remedies to identifying up-front buyers for 50% of its cases in the 2016–2017 period, and the frequency at the FTC increased significantly as well. The change in frequency in use of upfront buyers from the 2008-2009 period to the 2016–2017 period across the two agencies is shown in Figure 1.

**Figure 1. Up-front buyers are increasingly used**

<table>
<thead>
<tr>
<th>Year</th>
<th>DOJ</th>
<th></th>
<th>FTC</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td>% Yes</td>
<td>No</td>
</tr>
<tr>
<td>2008–2009</td>
<td>20</td>
<td>0</td>
<td>0%</td>
<td>10</td>
</tr>
<tr>
<td>2016–2017</td>
<td>5</td>
<td>5</td>
<td>50%</td>
<td>5</td>
</tr>
<tr>
<td>All four years</td>
<td>25</td>
<td>5</td>
<td>17%</td>
<td>15</td>
</tr>
</tbody>
</table>

Another change over time has been the increasing use of transitional services agreements across both the DOJ and FTC: 76% of the cases reviewed in 2016–2017 compared to only 52% in 2008–2009, as shown in Figure 2.

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39 *Id.* at 6–7.
40 *Id.* at 7–8.
42 While the period of comparison used is 2011 and 2015, Dechert LLP’s Gregory Luib has also pointed out the increased frequency in which the agencies require the use of upfront buyers. See Gregory Luib, “The Antitrust Agencies’ Recent Merger Challenges: Is the Remedial Tail Wagging the Dog?”, *The Threshold*, Summer 2016 at 41.
Figure 2. Transitional services agreements are increasingly mandated (“yes”)

<table>
<thead>
<tr>
<th>Year</th>
<th>No</th>
<th>Yes</th>
<th>% Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008–2009</td>
<td>20</td>
<td>22</td>
<td>52%</td>
</tr>
<tr>
<td>2016–2017</td>
<td>7</td>
<td>22</td>
<td>76%</td>
</tr>
</tbody>
</table>

While remedies are usually similarly structured across agencies, our review of recent remedies indicates that, in general, the FTC may be more willing than the DOJ to accept behavioral components of structural remedies. For instance, as shown in Figure 3, supply or toll agreements accompanying a structural remedy are much more common in FTC remedies than in DOJ remedies. In addition, FTC is nearly three times as likely to use an upfront buyer in the set of recent remedies we reviewed. These differences between DOJ and FTC remedies could also be a function of the differences in types of mergers reviewed across agencies, however.

Figure 3. Comparison of select remedy elements between the DOJ and FTC (2008–2009 and 2016–2017)

<table>
<thead>
<tr>
<th></th>
<th>Transitional services provided?</th>
<th>Up-front buyer identified?</th>
<th>Supply or toll agreement?</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOJ</td>
<td>52%</td>
<td>21%</td>
<td>16%</td>
</tr>
<tr>
<td>FTC</td>
<td>68%</td>
<td>63%</td>
<td>56%</td>
</tr>
</tbody>
</table>

Along with a higher prevalence of certain behavioral components, the FTC generally has more stringent reporting requirements than the DOJ. The FTC usually requires merging entities to proactively file written compliance reports at a regular intervals until the 10-year term of the Decision and Order has expired. The DOJ, instead, commonly requires the submission of compliance affidavits, which only need to be filed until the divestiture itself has been completed. Additionally, the FTC far more frequently than the DOJ establishes at the time of the remedy a monitoring trustee to oversee compliance with remedy orders.43

IV. Generic drug divestitures

In both of its merger remedy effectiveness studies, the FTC singled out pharmaceuticals for separate discussion.44 We now review some of the issues that arise concerning the complexity and efficacy of these remedies.

IV.A. Complicating factors in the enforcement in pharmaceuticals competition

Divestitures in the pharmaceuticals industry raise some issues particular to that industry. Within the space of drug competition, there is a distinction between what is sometimes called therapeutic competition and competition between bio-equivalents. The former concerns competition between different branded drugs that target the same diseases. Rather than competing on price, the main nexus of competition in therapeutic competition is the clinical profile of the drugs, including the means of administering the drug, possible side effects, possible interactions with other drugs or treatments, etc. As a result, market definition and competitive effects assessments, around which remedies are based, can be difficult. The analysis is further complicated by the importance of patents. If a merger is found to raise competitive concerns that might be alleviated by a divestiture, the potential for future IP litigation raises additional issues, as the acquirer of the divested asset may not be in the same position as was the original owner to defend itself.

In contrast to therapeutic competition, competition between bio-equivalents concerns competition between generic drugs, or between generics and an incumbent brand. One might expect that, similar to therapeutic competition, a set of generics that target the same diseases are first identified as the potential relevant product market and that clinical profiles and other characteristics of the drugs determine the extent of the product market. However, in practice the analysis is much simpler. Bio-equivalents share the exact same active ingredients, and the large buyers—doctors, hospitals, pharmacies, wholesalers and retail chains—stock all variants of a drug and do not substitute between different delivery methods of an active ingredient. Therefore, the relevant product market is characterized by an active ingredient (molecule) and delivery method. Moreover, and in contrast to therapeutic competition, by the nature of the products, potential IP litigation does not raise to the level of concern as it does with therapeutic competition, at least for the case of products already in production. As a result, competition between bio-equivalents is largely based on price, with the market often evolving into two-tier price competition: incumbent branded variant of the drug able to command a price-premium with multiple generics at a lower price point. This suggests that assessing competitive effects and devising remedies when needed may be straightforward when it comes to competition in the generic drug market. However, despite a features that would otherwise suggest a commodity-like market, merger remedies in generic drugs are not straightforward, due in part to regulatory oversight of the markets.

Production and distribution of a drug by a new market participant requires FDA approval. This process can take years and is further complicated because most pharmaceuticals are produced in plants in which several drugs are manufactured. Part of the FDA approval process concerns the production facility, and when individual drugs are divested the regulated assets require a more cumbersome review process when production is moved to another location—as is routinely the case. Indeed, when the transfer of production

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is required, filing the Drug Master Files (DMFs) with the FDA and stability and other testing easily takes several years.

The transfer of production from one manufacturer to another has additional implications for production costs, as both scale on scope economies play an important role in the manufacture of generics. Thus, when a drug is divested to a smaller rival, scope economies that were present with the divestee may not transfer, putting the acquirer at a cost disadvantage. Similarly, whether the acquirer is able to effectively replace the competition that is otherwise lost due to the merger may require that a sufficient scale of production and sales are achieved.

The bottom line is that even what may appear as standard horizontal product line divestitures can be quite complex in the context of pharmaceuticals, even in the case of generic drugs. As a result, two of the three “non-standard” behavioral elements of structural remedies that we identity in section II.B are common in the context of merger remedies in generic drug divestitures: the provision of a supply and/or tolling agreement, and mandatory licensing arrangements. To illustrate this we briefly consider specific mergers of generic drug manufacturers.

**IV.B. Mergers in generic drug transactions**

The FTC’s 2017 merger remedies study reviews the efficacy of merger remedies imposed from 2006–2012. It includes 24 orders involving pharmaceutical mergers, the majority of which pertain to prescription generic drugs. In our two benchmark periods, 2008–2009 and 2016–2017, we overlap with the FTC study on two mergers in the earlier period. In addition, we report on one transaction (i.e., Teva-Allergan) that was beyond the 2012 scope of FTC study. Our small sample of only three transactions does not yield strong conclusions concerning trends; however, there are some noteworthy differences among the three transactions that also dovetail with the FTC study.

**IV.B.1. Sun-Taro**

In 2008, Sun Pharmaceutical Industries announced its intention to acquire Taro Pharmaceutical Industries. In the FTC’s complaint, the agency alleged that relevant lines of commerce were three oral forms of carbamazepine tablets – immediate-release, chewable, and extended-release. The FTC identified Torrent Pharmaceuticals (“Torrent”) as the most suitable upfront buyer for two reasons: one, due to its position as a “growing generic manufacturer,” and two, its lack of presence in the carbamazepine tablet market.

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47 Complaint, In re of Sun Pharmaceutical Industries LTD., a corporation (C-4230), Federal Trade Commission, (D.D.C. Aug. 12 2008) at 3. Carbamazepine is a medication used to control and prevent epileptic seizures, nerve pain, and bipolar disorder.
48 “Analysis of Agreement Containing Consent Orders to Aid Public Comment,” In re of Sun Pharmaceutical Industries Ltd.,
Competitive concerns in the Sun-Taro transaction were tied to oral solids—generally the largest group of generics that are subject to divestiture orders and frequently also the least complex transfers. To ensure the effective transfer of divested assets in the Sun-Taro transaction, the FTC stipulated the provision of a tolling agreement, mandatory licensing of relevant IP, and transitional services to enable Torrent to obtain all of the necessary approvals from the FDA.49

IV.B.2. Teva-Barr

Also in 2008, Teva Pharmaceuticals entered into an agreement to acquire Barr for $8.9 billion. In its complaint, the FTC evaluated a total of 29 generic pharmaceutical products across various drug forms including oral solids (e.g., trazodone HCI tablets), oral liquids (e.g., cyclosporine liquid), and injectables (e.g., deferoxamine injection).50 Given that some of the 29 overlapping drugs were being developed but yet to be produced and sold, one of the FTC’s concerns was the threat to or elimination of future competition due to the merger.51 To address anti-competitive concerns, the FTC ordered the divestiture of an assortment of generic drugs to the two upfront-buyers: Watson Pharmaceuticals (now Actavis) and Vintage Pharmaceuticals.52

The 2008 Teva-Barr transaction raised concerns tied to liquid orals and injectables, which are generally understood to be harder to successfully divest than oral solids. Along with the divestiture, the FTC required the merging parties to supply the divestiture product “for a period of time sufficient” to allow the acquirers to obtain all relevant product approvals necessary to manufacture the divested product in commercial quantities.53

IV.B.3. Teva-Allergan

In mid-2015, Teva Pharmaceuticals announced its intentions to purchase Actavis Generics, Allergan’s generic pharmaceutical business, for $40.5 billion. At the time, the deal combined the world’s largest generic-drug company by sales with the third-largest competitor in generic drugs.54 Additionally, the deal


alone represented nearly 90% of the value of all generic drug pharmaceutical deals in 2016. The FTC identified concerns in a record total of 79 relevant product markets across a broad variety of drug forms including oral solids, oral liquids, injectables, creams, transdermal patches and films, and gels. Due to the sheer number and breadth of overlapping generic drugs, the FTC identified 11 divestiture buyers.

The transaction was viewed by many as symptomatic of the increased consolidation in the generic drug market. In recognition of the complications that often arise in connection with the transfer of manufacturing of drugs and given that these acquirers had limited experience in manufacturing the divested products, Teva was required to supply the acquirers with the active pharmaceutical ingredient for a period of at least four years at commercial quantities.

### IV.C. Efficacy of merger remedies in generic drug competition

Given the main thesis of our paper, namely that the likely effectiveness of a divestiture is more tied to the complexity involved than a superficial distinction between structural versus behavioral remedies, we now assess what can be said about the impact of divestiture orders in the pharmaceutical industry—specifically in regard to generic drug mergers.

In reviewing the recent FTC remedies study, in all cases in which third-party manufacturing agreements existed that could simply be transferred to an acquirer, the FTC found that the acquirer did have a presence in the market post-divestiture. As the FTC notes, these divestitures do not require transfer of manufacturing with the attendant complexities. In contrast, in cases where the transfer of manufacturing was required, more than a third of the acquired drugs failed to be brought to market by the acquirer; and this rate raises to above 70% of transfers that did not result in the acquirer bringing the drug to market in the case of drugs that were not oral solids (e.g., oral liquids, injectables, dermatologicals, ophthalmics, or systemics). That is, as the manufacture of a drug becomes more complex, the successful transfer also becomes less likely. Thus, while a proposed remedy in generic pharmaceuticals may appear to be

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58 Decision and Order, In re of Teva Pharmaceutical Industries LTD., a corporation; and Allergan PLC, a corporation (C-4589), Federal Trade Commission, (D.D.C. Sep. 7, 2016) at 75–76.


60 Id., at 31.
straightforward in that it is structural and has an up-front buyer, its implementation may nonetheless be complex and less likely to result in a successful remedy.

IV.D. Criteria for success used in FTC study

The role of complexity in the generic drug divestiture process is clouded by the criterion the FTC uses to evaluate these divestitures in its 2017 study. The purpose of divestitures is to preserve or restore competition that is lost due to the merger.\(^{61}\) This is the criterion used throughout most of the 2017 FTC study.\(^{62}\) However, in the assessment of pharmaceutical orders, the study defines success as “the buyer sold the product in the market post-divestiture,” whether or not it replaced lost competition.\(^{63}\) Indeed for the case of pipeline drugs, a mere transfer of the assets was considered a success.\(^{64}\)

Given the complexity involved in these cases, it is hard to find fault in the use of alternate measures of what constitutes a success. However, the instance of a sale does not speak to the competitive impact of the buyer, let alone the preservation or restoration of competition lost due to the merger.

One can imagine more informative (albeit also imperfect) metrics to shed light on the potential efficacy of divestitures in the context of merger review in generic drug markets. Most importantly, of course, is determining prices. A complicating factor here is that list and sales prices differ and thus prices may be hard to ascertain. Similarly, market share data would also be indicative of the successful establishment of a buyer post-divestiture. Related to this is the question of the incidence and extent of possible supply disruptions that periodically plague the industry.\(^{65}\)

Another critical dimension is to consider appropriate timeframes. How quickly does a buyer manage to establish itself? And does the presence of the buyer manifest itself in substantial market share several years post-transaction? These data, too, may not always be readily available. However, these questions become all the more important with the market for generics becoming increasingly consolidated; especially given the studies that suggest that this consolidation is directly impacting competition and prices, and that generic remedies are often not effective.\(^ {66}\)

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\(^{63}\) Id., at 30

\(^{64}\) Id., footnote 44.


Of course, a ready corollary to supply disruptions, increased concentration and increased prices in a complex market, is that determining the appropriate but-for world is a hard undertaking. Ultimately, though, the criteria and metrics used to determine potential harm to competition in the course of the merger review should also be the criteria and metrics that are employed to determine whether a particular divestiture can viewed as successful.

V. Conclusion

The lines between structural and behavioral remedies have become somewhat blurred. In thinking about the acceptability and ultimate success of a divestiture, it may be more useful to think in terms of the complexity of the divestiture, which may have many dimensions, rather than making a simple differentiation between structural and behavioral remedies. The generic drug market in particular, highlights the degree to which the distinction between structural and behavioral itself is perhaps blurred. And, more to the point, it highlights how “structural” remedies can be quite complex and hard to evaluate.
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