



# Federal Trade Commission

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## **The Role of Static and Dynamic Analysis in Pharmaceutical Antitrust**

**Remarks of J. Thomas Rosch\***  
**Commissioner, Federal Trade Commission**

**at the**

**Fifth Annual In-House Counsel Forum on Pharmaceutical Antitrust**

**New York, NY**

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Good morning and thank you for the opportunity to speak to you today. You heard from a number of my colleagues yesterday regarding the FTC's position on several issues relevant to the pharmaceutical industry, including pay-for-delay settlements, follow-on biologics, and authorized generics. I've previously described my position respecting those issues and my remarks are posted on the FTC's website.<sup>1</sup> Since my colleagues have already covered the nuts-and-bolts of these issues, I'm going to try to offer some unifying principles that help explain the

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\* The views stated here are my own and do not necessarily reflect the views of the Commission or other Commissioners. I am grateful to my attorney advisor, Darren Tucker, for his invaluable assistance in preparing this paper.

<sup>1</sup> J. Thomas Rosch, Commissioner, Fed. Trade Comm., Pay-for-Delay Settlements, Authorized Generics, and Follow-on Biologics: Thoughts on the How Competition Law Can Best Protect Consumer Welfare in the Pharmaceutical Context, Remarks at World Generic Medicine Congress, Washington, D.C. (Nov. 19, 2009), *available at* <http://www.ftc.gov/speeches/rosch/091119worldgenerics.pdf>.

FTC's positions on these issues. I'll also comment with specificity about a few other antitrust topics relevant to the pharmaceutical industry, including refusals to license intellectual property, FDA citizen petitions, product hopping, and bundled discounts.

## I.

It's sometimes said that competition matters should be analyzed using one of two lenses – one focuses on static effects and one on dynamic effects – as though the analysis should not involve assessing both effects. The two effects are different from one another. Static analysis is based on neoclassical economics, which mostly looks at marginal prices and costs in the short run. The goal under a static approach is to avoid transactions or practices that have the effect of increasing prices or reducing output, either of which will reduce short-term consumer welfare. Firms that have some degree of pricing power (prices exceeding the marginal cost of production) are said to have market power and are typically subject to greater antitrust scrutiny than other firms.

In contrast, dynamic analysis focuses on long-run considerations like the creation of new products and services. For those of you that remember your Economics 101 class from college, what I'm talking about is shifting the supply curve out or creating an entirely new supply curve. The person most closely associated with this approach is economist Joseph Schumpeter, who emphasized that a certain amount of protection from competition is necessary for a firm to undergo the risks and costs of innovating and that innovation can have a great effect on consumer welfare.<sup>2</sup> A number of studies have confirmed his insight that technological progress

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<sup>2</sup> Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2100 (3d ed. 2007 supp. 2009) (citing Joseph Schumpeter, *Capitalism, Socialism and Democracy* (1942)).

may benefit consumers to a greater degree than the elimination of noncompetitive prices.<sup>3</sup> The goal under the dynamic approach is to examine how a transaction or practice will affect innovation over time.

Proper antitrust enforcement considers both static and dynamic concepts. Indeed, in its seminal opinion in *United States v. General Dynamics Corporation*,<sup>4</sup> the Supreme Court recognized that static analysis, standing alone, would not suffice in cases involving markets that were not static. That is true of many, if not most, markets today in which producers of computer components or software or pharmaceuticals are the participants. Those markets are dynamic. As the Court indicated, in assessing whether current concentration and market shares are likely to be prologue for any substantial period of time it is appropriate to look at the market's history – at trends, stability over time, entry and repositioning, as well as other indicia that things are likely to change, such as whether and to what extent venture capital is flowing to market participants.<sup>5</sup>

The antitrust agencies condemn price fixing, for example, not only because of its obvious short-term harm to consumers, but also because cartels encourage complacency among suppliers and deaden competitive initiative. As a former assistant attorney general at the DOJ explained: “The essence of cartel behavior is to reduce the competition that spurs dynamic efficiencies and

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<sup>3</sup> See, e.g., Frederic M. Scherer & David Ross, *Industrial Market Structure and Economic Performance* 613-85 (3d ed. 1990); Robert M. Solow, *Technical Change and the Aggregate Production Function*, 39 Rev. Econ. & Stat. 312 (1957); Robert M. Solow, *A Contribution to the Theory of Economic Growth*, 70 Q.J. Econ. 65 (1956). See generally Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. Pa. L. Rev. 761, 813 (2002) (“The consensus among economists since Schumpeter is that the gains achieved from innovative efficiencies dwarf those derived from maximizing allocative efficiency and that innovation is the most important factor in the growth of the economy.”).

<sup>4</sup> 415 U.S. 486 (1974).

<sup>5</sup> *Id.* at 506; see also *Lektro-Vend Corp. v. Vendo Co.*, 660 F.2d 255, 276-77 (7th Cir. 1981); *United States v. Int'l Harvester Co.*, 564 F.2d 769, 777-801 (7th Cir. 1977).

long-term economic growth.”<sup>6</sup> Another good example is the merger context, where the antitrust agencies consider both static and dynamic performance with some regularity. In many transactions, we look not only at a proposed transaction’s immediate effect on prices and output, but also on the deal’s implications to long-run innovation. At the same time, however, public law enforcement agencies must be wary about ex post evidence that may be “trumped up” by the parties and should not look so far in the future that consumers are likely to suffer substantial injury before the changes in the market are likely to occur.

Nevertheless, antitrust enforcement has historically focused more on static than dynamic analysis. I believe that is true for a number of reasons. First is inertia. The antitrust community – both lawyers and economists – has far greater familiarity and comfort with static analysis than dynamic analysis. There is undoubtedly reluctance to abandon what one knows best. Second, there is little incentive for parties to take the time to develop arguments premised on dynamic analysis, given the courts’ and antitrust agencies’ focus on static analysis. Third, there’s the perception – right or wrong – that dynamic analysis is less well developed and more difficult to apply than static analysis.<sup>7</sup> Or, to put a sharper point on that, static considerations are likely to

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<sup>6</sup> Thomas O. Barnett, *Remark: Maximizing Welfare Through Technological Innovation*, 15 *Geo. Mason L. Rev.* 1191, 1202-03 (2008).

<sup>7</sup> For example, it is not clear that greater concentration impedes optimal dynamic performance. See Fed. Trade Comm’n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* Ch. 2 at 12-15 (2003) [hereinafter *FTC Innovation Report*] (“Statistical cross-section studies examining multiple industries have not identified any clear relationship between concentration and innovation.”); see also Statement of Chairman Timothy J. Muris, *Genzyme Corporation / Novazyme Pharmaceuticals, Inc.*, FTC File No. 021 0026 (Jan. 13, 2004), available at <http://www.ftc.gov/os/2004/01/murisgenzymestmt.pdf> (“[N]either economic theory nor empirical research supports an inference regarding the merger’s likely effect on innovation (and hence patient welfare) based simply on observing how the merger changed the number of independent R&D programs. Rather, one must examine whether the merged firm was likely to have a reduced incentive to invest in R&D, and also whether it was likely to have the ability to conduct R&D more successfully.”).

be more measurable. I don't think it is difficult to appreciate that predicting and measuring the long-term effects on R&D and innovation may be more challenging than predicting a transaction or practice's immediate price and output effects.<sup>8</sup>

## II.

Trying to analyze both static and dynamic performance is not unique to antitrust law. Another example where both static and dynamic performance matter relates to the patent system. As the Supreme Court has explained, the Constitution's "Patent Clause reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition . . . ."<sup>9</sup> In addition to years of exclusivity rights, patent holders are accorded certain advantages in litigation – such as the presumption of validity<sup>10</sup> – and the right to license or transfer their patent rights to others. So, the patent system provides a number of incentives for research and innovation – and thus dynamic welfare gains – by helping inventors capitalize on the value of their inventions.<sup>11</sup>

However, from a static, allocative perspective, providing patent rights can be inefficient. The grant of a legal monopoly to an inventor harms consumer welfare insofar as the inventor is able to charge a higher price or reduce output, both of which are detrimental to consumers and result in what economists call a deadweight loss. In addition, a patent holder may spend

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<sup>8</sup> Another problem is that there is no consensus as to how to weigh static and dynamic efficiencies when they point in different directions.

<sup>9</sup> *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

<sup>10</sup> 35 U.S.C. § 282 ("A patent shall be presumed valid.").

<sup>11</sup> U.S. Const. art. I, § 8, cl. 8; (granting Congress the authority to establish a system of patents and copyrights to "promote the Progress of Science and useful Arts"); *Graham v. John Deere Co.*, 383 U.S. 1, 8-9 (1966) (describing a patent as "a reward, an inducement, to bring forth new knowledge").

significant resources obtaining and protecting his intellectual property, and the threat of infringement litigation – whether legitimate or baseless – can act as a barrier to entry by potential competitors.<sup>12</sup> These are also detrimental to consumer welfare.

These static costs may be justified when the promise of a patent helps motivate the investment in (or disclosure of) an invention. It is generally accepted that patents motivating invention (or disclosure) generate more dynamic efficiencies than static losses. But bestowing patents on inventions that would have occurred (or would have been disclosed) without the promise of patent protection results in a windfall to the inventor and higher prices to consumers. Put another way, patenting an invention that would have occurred and been disclosed absent the inducement of a patent is unambiguously detrimental because there is a static consumer loss and no dynamic efficiencies.<sup>13</sup>

What may be less obvious is that providing *overly generous* patent rights may not only harm static efficiency but also dynamic efficiency. As the Supreme Court has explained, our patent system is designed not only “to foster and reward invention” but also to “promote[] disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires.”<sup>14</sup> If patent rights are too generous, innovation costs will

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<sup>12</sup> FTC Innovation Report, *supra* note 7, at Ch. 2 p. 8 (“Patentee suits against entrants for infringement can ‘tax’ entry. The threat of being sued for infringement by an incumbent – even on a meritless claim – may ‘scare . . . away’ venture capital financing.”), and at Ch. 2 p. 11 (“Amassing patent portfolios . . . is, as one commenter noted, a ‘rather costly arms race.’ It generates a ‘lot of resource waste,’ some panelists noted since firms spend ‘a significant amount on legal bills to apply for patents . . . .’”).

<sup>13</sup> *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007) (“Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress.”).

<sup>14</sup> *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979); *see also Bonito Boats*, 489 U.S. at 146 (“From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement

become excessive because of the need to design around existing patents or, alternatively, to negotiate and pay for licenses from existing patent holders. Independent follow-on inventions in particular will be discouraged.

In theory, there is an optimal level of patent protection that balances the static and dynamic considerations. Researchers have tried to determine whether Congress and the courts have made these tradeoffs correctly,<sup>15</sup> but significant debate remains about even the fundamental question of whether patents are needed to stimulate innovation.

Several studies have found that firms prefer a variety of appropriability mechanisms, such as secrecy and lead time over competitors, to patent protection. An early and relatively small study of 100 firms concluded that patents were essential for innovation in only two of twelve industries: pharmaceuticals and chemicals.<sup>16</sup> A subsequent study of 650 firms found that patents were rated last out of five strategies for protecting new processes, and fourth for

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through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.”); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974) (“When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.”); *White v. Samsung Elecs. Am., Inc.*, 989 F.2d 1512, 1513, 1516 (9th Cir. 1993) (Kozinski, J., dissenting from denial of rehearing en banc) (“Overprotecting intellectual property is as harmful as underprotecting it. Creativity is impossible without a rich public domain. . . . Intellectual property rights aren’t free: They’re imposed at the expense of future creators and of the public at large.”).

<sup>15</sup> For example, there is considerable debate as to the optimal duration and scope of intellectual property rights. See, e.g., Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 Rand J. Econ. 106 (1990); Paul Klemperer, *How Broad Should the Scope of Patent Protection Be?*, 21 Rand. J. Econ. 113 (1990).

<sup>16</sup> Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32, Mgmt. Science 173 (1986).

protecting new products.<sup>17</sup> The same study found considerable variation by industry, with patents more useful for protecting pharmaceuticals and certain chemicals.<sup>18</sup> A third study found that firms protect profits from invention primarily through secrecy and lead time, with patent protection the least important strategy.<sup>19</sup> The study concluded that “patents are unambiguously the least central of the major appropriability mechanisms overall.”<sup>20</sup> Like the other studies, this one found that the importance of patents varied by industry, with medical equipment and pharmaceuticals standing out at the high end and semiconductors and communications equipment at the low end.<sup>21</sup>

A few years ago, the ABA Section of Antitrust Law reviewed the empirical studies and concluded that patents are an important inducement to innovation in only a few industries and that expanding the rights provided by an existing patent system does not increase overall inventive activity.<sup>22</sup> The ABA report found that patents helped stimulate R&D in the pharmaceutical industry in particular but not in some high-tech industries where “the advantages that come with a head start, including setting up production, sales, and service structures and moving down the learning curve, were judged much more effective than patents as an

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<sup>17</sup> Richard C. Levin et al., *Appropriating the Returns from Industrial R&D*, Brookings Papers on Economic Activity 783, 794-95 (1987). The five ways of protecting new processes and products in the survey were lead time, learning curve advantages, complementary sales or service advantages, secrecy, and patents.

<sup>18</sup> *Id.*

<sup>19</sup> Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* (Nat'l Bureau of Econ. Research Working Paper No. 7552, 2000).

<sup>20</sup> *Id.* at 9.

<sup>21</sup> *Id.* Table 1.

<sup>22</sup> ABA Section of Antitrust Law, *The Economics of Innovation: A Survey* § II.E. (2002).



inducement to R&D.”<sup>23</sup> Several other surveys of the empirical data have also concluded that there is little or no link between the degree of patent protection and innovation in many industries.<sup>24</sup>

The most recent study that I’m aware of is by David Abrams, an economist at the University of Pennsylvania.<sup>25</sup> In a paper published last year, he studied the effects of the 1995 TRIPS agreement, as a result of which the United States changed the duration of patent protection from 17 years from the grant date to 20 years from the application date.<sup>26</sup> Abrams concluded that this change increased innovation and overall welfare, but suggested that “biological patents [were] responsible for the bulk of the observed impact of TRIPS.”<sup>27</sup>

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<sup>23</sup> *Id.* For a contrary view, see Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross Country Analysis of Pharmaceutical Patent Protection, 1978-2002*, 89 Rev. Econ. & Statistics 436 (2007) (concluding that patent protection does not stimulate pharmaceutical innovation).

<sup>24</sup> *See, e.g.*, FTC Innovation Report, *supra* note 7, Ch. 2(II)(A)(2), at 11 (2003) (“Empirical study has shown that in some industries, firms often innovate to exploit first-mover advantages, learning-curve advantages, and other advantages, not to gain patent protection.”); *see also id.* ch. 2(I)(A)(1), at 5 (“[A] number of studies have shown that [other] measures typically are more important than patents for protecting appropriability in many industries.”); Cohen, *supra* note 19, at 2 (stating that prior studies “suggest that patent protection is important in only a few industries, most notably pharmaceuticals”); Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 Research Policy 531, 540, 554 (2000) (noting that there is “little empirical evidence” that strengthening patent protection in the 1980s increased innovation and that several studies suggest “that patents are not central to appropriating the returns to R&D in most industries”); Michele Boldrin & David K. Levine, *Does Intellectual Monopoly Help Innovation?* 13 (Working Paper 2009) (“We have identified twenty three economic studies that have examined the issue empirically. The executive summary: they find weak or no evidence that strengthening patent regimes increases innovation; they find strong evidence that strengthening the patent regime increases patenting!”).

<sup>25</sup> David S. Abrams, *Did TRIPS Spur Innovation? An Analysis of Patent Duration and Incentives to Innovate*, 157 U. Pa. L. Rev. 1613 (2009).

<sup>26</sup> Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532(a), 108 Stat. 4809, 4984-85 (1994).

<sup>27</sup> Abrams, *supra* note 25, at 1640.

Thus, it appears that patent protection may stimulate innovation in the pharmaceutical industry to a far greater degree than most other industries. This is not entirely surprising, given the large upfront costs and degree of risk developing a new product and the relative ease of developing copycat products.

### III.

A hotly debated antitrust issue with implications for the pharmaceutical industry is the legal standard for evaluating a firm's refusal to license intellectual property. Section 271(d) of the Patent Act declares that refusing to license a patent cannot be patent misuse, even when done by a monopolist.<sup>28</sup> Likewise, a number of courts have held that a refusal to license intellectual property, standing alone, cannot be an antitrust violation.<sup>29</sup> It has been asserted that a contrary result could reduce the incentives for innovation both by the original inventors, as well as by

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<sup>28</sup> 35 U.S.C. § 271(d) (“No patent owner otherwise entitled to relief for infringement . . . of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . refused to license or use any rights to the patent . . .”).

<sup>29</sup> See, e.g., *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432 (1945) (“A patent owner is not in the position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention. He has no obligation either to use it or to grant its use to others.”); *United States v. United Shoe Mach. Co. of N.J.*, 247 U.S. 32, 57 (1918) (“[A patent’s] strength is in the restraint, the right to exclude others from the use of the invention . . . Its exertion within the field . . . is not an offense against the Anti-Trust Act.”); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) (“[T]he antitrust laws do not negate the patentee’s right to exclude others from patent property.”); *Cygnus Therapeutic Sys. v. Alza Corp.*, 92 F.3d 1153, 1160 (Fed. Cir. 1996) (patentee “under no obligation to license” under antitrust laws); *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1186 (1st Cir. 1994) (“The courts appear to have partly settled an analogous conflict between the patent laws and the antitrust laws, treating the former as creating an implied limited exception to the latter.”); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) (“A patent holder who lawfully acquires a patent cannot be held liable under Section 2 of the Sherman Act for maintaining the monopoly power he lawfully acquired by refusing to license the patent to others.”); *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 647 (9th Cir. 1981) (“The right to license [a] patent, exclusively or otherwise, or to refuse to license at all, is ‘the untrammelled right’ of the patentee.”); *W.L. Gore & Assocs., Inc. v. Carlisle Corp.*, 529 F.2d 614, 623 (3d Cir. 1976) (“right to refuse to license is the essence of the patent holder’s right”).

rivals seeking their own alternatives to the monopolist's patents. Thus, the FTC stated in its 1980 *DuPont* case that the "imposition of a duty to license might serve to chill the very kind of innovative process that led to duPont's cost advantage."<sup>30</sup> Likewise, the Supreme Court has asserted that compelling firms to assist their rivals "may lessen the incentive for the monopolist, the rival, or both to invest in . . . economically beneficial facilities."<sup>31</sup>

Nevertheless, the Ninth Circuit in *Image Technical Services v. Eastman Kodak Co.* held that a unilateral refusal to license intellectual property by a monopolist could violate Section 2 of the Sherman Act if not supported by a valid business justification.<sup>32</sup> In that case, the court found that Kodak's reliance on intellectual property rights as a justification for refusing to license was largely pretextual. This may have been the first time a federal court imposed antitrust liability for the refusal to license a patent.

When confronted with a similar issue a few years later in the *Xerox/ISO* case, the Federal Circuit rejected the Ninth Circuit's approach.<sup>33</sup> The Federal Circuit concluded that the refusal to license intellectual property cannot be an antitrust violation regardless of the reason for the

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<sup>30</sup> *In re E.I. DuPont de Nemours & Co.*, 96 F.T.C. 653, 748 (1980); see also Department of Justice/Federal Trade Commission Guidelines for the Licensing of Intellectual Property (1995) § 2.2, reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132 (an intellectual property owner has no general duty to license its protected product).

<sup>31</sup> *Verizon Communs. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407-08 (2004).

<sup>32</sup> 125 F.3d 1195 (9th Cir. 1997).

<sup>33</sup> See *In re Independent Service Organizations Antitrust Litigation (ISO)*, 203 F.3d 1322 (Fed. Cir. 2000); see also *Intel v. Intergraph*, 195 F.3d 1346 (Fed. Cir. 1999); *Image Technical Services, Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997). Chief Justice John Roberts represented the plaintiffs on appeal in both the *Xerox* case and the *Intel* case when he was in private practice.

refusal.<sup>34</sup> The court explained that we “will not inquire into [the patent holder’s] subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may have an anticompetitive effect, so long as that anticompetitive effect is not illegally extended beyond the statutory patent grant.”<sup>35</sup>

The Seventh Circuit likewise rejected the Ninth Circuit’s approach in a 2006 decision in favor of the Federal Circuit’s approach.<sup>36</sup> And, arguably, a more significant development was the Supreme Court’s 2004 *Trinko* decision,<sup>37</sup> which suggests that the Court may not look favorably on the Ninth Circuit’s approach. In *Trinko*, Justice Scalia wrote that monopolists do not have a duty to deal with rivals except under narrow circumstances.

That said, the circuit split remains, and it cannot be that that *Trinko* resolved the split because that portion of Justice Scalia’s opinion was dictum, not holding. Nor can it be said that the federal enforcement agencies have reached a consensus on the issue. In 2007 the FTC and DOJ issued a report on antitrust enforcement and intellectual property rights that weighed in on this subject. The report concluded that “antitrust liability for mere unilateral refusals to license patents will not play a meaningful part in the interface between patent rights and antitrust protections.”<sup>38</sup> However, as the Commission majority explained in criticizing the DOJ’s 2008

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<sup>34</sup> The opinion suggested that a patent holder would be subject to antitrust liability under only three circumstances: (1) where it had fraudulently obtained the patent; (2) where it had fraudulently engaged in infringement litigation; and (3) where it had attempted to enlarge the scope of its patent by, for example, tying the sale of the patented good to the sale of an unpatented good. *ISO*, 203 F.3d at 1327.

<sup>35</sup> *Id.* at 1327-28

<sup>36</sup> *Schor v. Abbott Labs.*, 457 F.3d 608 (7th Cir. 2006).

<sup>37</sup> *Verizon Communs. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

<sup>38</sup> U.S. Dep’t of Justice & Fed. Trade Comm., *Antitrust Enforcement and Intellectual Property Rights: Protecting Innovation and Competition* 30 (2007).

report on single firm conduct,<sup>39</sup> the word “mere” must be emphasized: if and to the extent that the refusal to license does not stand alone, it may be challenged, if employed by firms with monopoly power.<sup>40</sup>

#### IV.

A few years ago, four FTC officials, including the then-Director and Deputy Directors of the FTC’s Bureau of Competition argued that combating what they called “cheap exclusion” should be an enforcement priority for the FTC.<sup>41</sup> They defined cheap exclusion as “conduct that costs or risks little to the firm engaging in it” and “does not raise any cognizable efficiency claims.”<sup>42</sup> They asserted that the FTC’s enforcement resources should be directed toward this type of conduct (compared to other types of exclusionary conduct) because of the frequency of its use, the relative ease of the antitrust analysis, and the low risk of investigating what turns out to be a pro-competitive practice.<sup>43</sup> Cheap exclusion involves conduct with no plausible benefits – static or dynamic – and thus does not present the analytical challenges we’ve seen in some other contexts.

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<sup>39</sup> U.S. Dep’t of Justice, *Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act* (2008).

<sup>40</sup> Statement of Commissioners Harbour, Leibowitz and Rosch on the Issuance of the Section 2 Report by the Department of Justice at 8-9 (Sept. 8, 2008), *available at* <http://www.ftc.gov/os/2008/09/080908section2stmt.pdf>.

<sup>41</sup> *See* Susan A. Creighton, D. Bruce Hoffman, Thomas G. Krattenmaker & Ernest A. Nagata, *Cheap Exclusion*, 72 *Antitrust L.J.* 975 (2005) [hereinafter Creighton, *Cheap Exclusion*]; *see also* Susan A. Creighton & Thomas G. Krattenmaker, *Appropriate Role(s) for Section 5*, *Antitrust Source*, Feb. 2009, at 7, <http://www.abanet.org/antitrust/at-source/09/02/Feb09-Creighton2-26f.pdf> (“Section 5 could be a significant tool in preventing cheap exclusion, although most forms of cheap exclusion can and should be reached via straightforward application of the Sherman Act.”)

<sup>42</sup> Creighton, *Cheap Exclusion*, *supra* note 41, at 977.

<sup>43</sup> *Id.* at 977-78.

The FTC has investigated alleged cheap exclusion in the pharmaceutical industry. An early example involved brand companies improperly listing patents in the Orange Book and then filing infringement actions against ANDA applicants. As a result, the brand companies were able to obtain 30-month stays of the ANDA approval. The FTC entered into consent agreements with two companies engaged in this practice resolving the FTC's concerns.<sup>44</sup> Like other examples of cheap exclusion, making false Orange Book filings involves highly asymmetric costs, that is, the cost to the brand company of making a false filing was trivial compared to the benefit.

Another type of cheap exclusion we have seen in the pharmaceutical sector is “product hopping” or “product switching.” This is the practice of introducing new patented products with minor or no substantive improvements by brand companies in the hopes of preventing substitution to lower-priced generics.<sup>45</sup> The practice is most likely to arise when generic entry is imminent.

Of course, the antitrust laws don't seek to discourage the introduction of new products or product line extensions.<sup>46</sup> Here the concern is that the new product is, in a sense, a sham whose

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<sup>44</sup> *Biovail Corp.*, FTC Docket No. C-4060 (Oct. 2, 2002) (consent order), *available at* <http://www.ftc.gov/os/2002/10/biovaildo.pdf>; *Bristol-Myers Squibb Co.*, FTC Docket No. C-4076 (Apr. 14, 2003) (consent order), *available at* <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>. Congress also addressed this abuse by passing the Medicare Prescription Drug Improvement and Modernization Act of 1993, which precludes successive 30-month stays in most circumstances. *See* 21 U.S.C. § 355(j)(5)(B).

<sup>45</sup> Mark A. Lemley, *Ignoring Patents*, 2008 Mich. State L. Rev. 19, 30 (product hopping involves “[p]atent holders . . . changing the product they sell and restarting the regulatory clock once their patent on the existing product expires or is invalidated”).

<sup>46</sup> Many courts are reluctant to find that product improvements by themselves violate Section 2, even if done by a monopolist and competitors are harmed as a result. *See, e.g., Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, -- F.3d --, 2010 WL 22693 (9th Cir. 2010) (“Absent some form of coercive conduct by the monopolist, the ultimate worth of a genuine product improvement can be adequately judged only by the market itself.”).

only purpose is to delay generic competition without any consumer benefits. Thus, the practice results in a significant static welfare loss without any plausible dynamic benefits.

Product hopping concerns are relatively recent and, as a result, there are few litigated cases and enforcement actions in this area. In 2005, the FTC filed a complaint in federal District Court alleging that Warner Chilcott had entered into an agreement with Barr to forestall generic entry for the birth control product Ovcon.<sup>47</sup> While the case was pending in court, the FTC learned that Warner Chilcott intended to launch a new, chewable version of Ovcon and stop selling the tablet version of Ovcon, in order to convert consumers to the new product. Such a strategy would have essentially destroyed the market for generic Ovcon because if regular Ovcon were unavailable, generic substitution at the pharmacy would be unavailable. To prevent that development, the FTC filed for a preliminary injunction to require Warner Chilcott to continue to make regular Ovcon. The day that the FTC filed its motion, Warner Chilcott waived the exclusionary provision in its agreement with Barr that prevented Barr from marketing its generic version of Ovcon, and Barr then announced its intention to start selling a generic version of the product. The Commission and Warner Chilcott subsequently entered into a final order requiring Warner Chilcott to take steps to preserve the market for the tablet form of Ovcon providing Barr the opportunity to compete with its generic version.

In *Abbott Labs. v. Teva Pharmaceuticals U.S.A., Inc.*,<sup>48</sup> Teva alleged that Abbott had “responded to the threat of generic entry . . . by changing the formulation of TriCor, not to improve the product, but simply to prevent generic formulations from becoming AB-rated for

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<sup>47</sup> Complaint for Injunctive and Other Equitable Relief, *FTC v. Warner Chilcott Holdings Company III, Ltd*, Civil Action No. 1:05-cv-02179-CKK (D.D.C. Nov. 7, 2005), *available at* <http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf>

<sup>48</sup> 432 F. Supp. 2d 408 (D. Del. 2006).

substitution with TriCor.”<sup>49</sup> The district court denied Abbott’s motion to dismiss, explaining that “an antitrust inquiry into the benefits provided by Defendants’ product changes is appropriate.”<sup>50</sup> Relying on the balancing test from the *Microsoft* decision, the court explained that “if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.”<sup>51</sup> Applying this test, the court found that plaintiffs had adequately alleged anticompetitive harm because Abbott had allegedly barred competitors from the most cost-efficient means of distribution. (Earlier this year 24 states reached a \$22.5 million settlement with Abbott and Fournier to resolve their own claims involving TriCor product hopping.)<sup>52</sup>

A different result occurred in *Walgreen Co. v. AstraZeneca Pharmaceuticals*,<sup>53</sup> where a federal district court granted defendant’s motion to dismiss a “product hopping” claim. Plaintiffs alleged that as the branded drug Prilosec was about to lose patent protection, AstraZeneca introduced Nexium, a drug that was “virtually identical” to Prilosec but offered no incremental medical benefits. However, unlike the situation in *Abbott Labs. v. Teva*, the case did not involve

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<sup>49</sup> *Id.* at 415.

<sup>50</sup> *Id.* at 422.

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

<sup>52</sup> Press Release, California Dep’t of Justice, California and 23 States Reach \$22.5 Million Settlement Against Pharmaceutical Companies that Blocked Generic Drugs (Jan. 7, 2010), *available at* <http://www.ag.ca.gov/newsalerts/release.php?id=1844>. The states alleged that Abbott and Fournier forced customers to convert to new formulations of TriCor before generic entry by “reformulating TriCor with only minor changes to a form and dosage strength, which did not provide any significant new clinical benefit” and by “removing the old TriCor formulation from the market, so as to make it commercially unavailable by the time a generic competitor could enter the market.” First Amended Complaint ¶ 4, *Florida v. Abbott Labs.*, Case No. 08-155 (SLR) (D. Del. Apr. 18, 2008).

<sup>53</sup> 534 F. Supp. 2d 146 (D.D.C. 2008).



the withdrawal of a product from the market. The court found this distinction to be significant.<sup>54</sup> The court stressed that AstraZeneca had not limited consumer choice by withdrawing any product from the market. To the contrary, the court found that AstraZeneca had *added* choices.

Another potential type of cheap exclusion in the pharmaceutical industry is the improper filing of citizen petitions to delay the FDA's approval of ANDAs.<sup>55</sup> Citizen petitions are submissions designed to alert the FDA to possible scientific and safety issues related to regulated products or agency procedures.<sup>56</sup> Generic pharmaceutical companies have alleged that brand companies have improperly used citizen petitions to block or delay their entry by raising frivolous or untimely concerns about ANDA filings.

In a 2002 report, the FTC recognized the potential for misuse of citizen petitions, but concluded that no actual anticompetitive effects had resulted.<sup>57</sup> In particular, the report found

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<sup>54</sup> *Id.* at 151 (“The elimination of choice was a critical factor in the court’s decision to deny Abbott’s motion to dismiss the complaint.”). The *Abbott v. Teva* court also noted the importance of this distinction. 432 F. Supp. 2d at 421 (“[W]hen the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate.”), and at 422 (“But here, according to Plaintiffs, consumers were not presented with a choice between fenofibrate formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations.”).

<sup>55</sup> For a more detailed review of this issue, see Darren S. Tucker, *FDA Citizen Petitions: A New Means of Delaying Generic Entry?*, *Antitrust Health Care Chronicle*, Nov. 2006, available at <http://ssrn.com/abstract=1531776>.

<sup>56</sup> 21 C.F.R. § 10.30; *see also* section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355.

<sup>57</sup> Fed. Trade Comm., *Generic Drug Entry Prior to Patent Expiration* 65-68 (2002) (the citizen petitions studied “did not affect the timing of generic entry”). In March 2000, the FTC submitted comments to the FDA explaining how the cost of filing an improper citizen petition is negligible compared to the value of securing a delay of a rival’s entry. *See* Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration, FDA Docket No. 99N-2497 (Mar. 2, 2000), available at <http://www.ftc.gov/be/v0000005.pdf>; *see also* Jon Leibowitz, Commissioner, Fed. Trade Comm., Remarks at the Second Annual In-House Counsel’s Forum on Pharmaceutical Antitrust (Apr. 24, 2006), available at

that citizen petitions did not affect the timing of generic entry. To date the FTC has not brought an enforcement proceeding on these grounds, and private plaintiffs have generally not fared well in court.<sup>58</sup>

## V.

The final topic I'd like to discuss is the antitrust analysis applied to bundled rebates, which are similar to volume discounts but awarded when a customer makes a sufficient number of purchases across product lines. The concern with bundled rebates is largely a static one, namely that the rebates may be so large that it would be economically irrational to purchase a single product from another customer, regardless of the merits of the competing product. The justifications for bundled rebates are also largely static, namely that they reduce prices to consumers.

This is a matter about which the courts have struggled to articulate a consistent framework. In *SmithKline Corp. v. Eli Lilly & Co.*,<sup>59</sup> the Third Circuit condemned Eli Lilly's

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<http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf> (noting that that citizen petitions are low cost to file in comparison to the "value of securing even a brief delay in a rival's entry").

<sup>58</sup> See, e.g., *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, Case Nos. 5:03-00887-MRP (PLA) and 5:04-00333-MRP (PLA) (C.D. Cal. Feb. 17, 2009) (unpublished opinion dismissing antitrust counterclaim that Aventis filed a materially false citizen petition delaying generic entry; court ruled that plaintiff failed to show that conduct was beyond the protection of *Noerr*); *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, Case No. 07-cv-07343 (S.D.N.Y. Nov. 21, 2008) (jury verdict in favor of Sanofi on the ground that its citizen petition was not baseless under *Noerr*). But see *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (reversing dismissal of antitrust claim on the basis that allegations in the complaint "indicate the plaintiffs could plausibly show the citizen petition to have been a sham" and noting "the possibility that the sham petition caused a delay in generic competition"); *Roxane Labs., Inc. v. Smithkline Beecham Corp.*, Civil Action No. 09-CV-1638, 2010 WL 331704 (E.D. Pa. Jan. 26, 2010) (generic company had antitrust standing to challenge citizen petitions allegedly intended to delay FDA approval of its ANDA filing).

<sup>59</sup> 575 F.2d 1056 (3d Cir. 1978).

discount on a bundle of three products, two of which were available only from Eli Lilly. The bundle violated the Sherman Act, according to the court, because the defendant linked the sale of products for which it faced no competition with products that did face competition.

The next important bundled discount case was *Ortho Diagnostic Systems v. Abbott Laboratories*,<sup>60</sup> which again involved a company's bundling of products that faced competition with products available only from the company. The district court articulated a more restrictive test for liability than the *Eli Lilly* court, holding that the plaintiff:

must allege and prove either that (a) the monopolist has priced below its average variable cost or (b) the plaintiff is at least as efficient a producer of the competitive product as the defendant, but that the defendant's pricing makes it unprofitable for the plaintiff to continue to produce.<sup>61</sup>

The Third Circuit took up the issue of bundled rebates again in *LePage's Inc. v. 3M Co.*<sup>62</sup> In that case, the jury found that the defendant's exclusive dealing agreements and bundled discounting program violated Section 2 of the Sherman Act. The en banc Third Circuit affirmed the jury's verdict after it concluded that these arrangements allowed 3M to exclude LePage's from the market. The court found that it was impossible for LePage's to meet 3M's discounts because it did not sell the same array of products and also pointed to evidence that 3M's policies were intended to exclude competitive rivals.

In its 2007 decision in *PeaceHealth*, however, the Ninth Circuit rejected *LePage's* and held that defendant's bundling practices did not violate Section 2.<sup>63</sup> Instead, the Ninth Circuit declared that a plaintiff challenging a monopolist's bundled pricing "must establish that, after

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<sup>60</sup> 920 F. Supp. 455 (S.D.N.Y. 1996).

<sup>61</sup> *Id.* at 469.

<sup>62</sup> 324 F.3d 141 (3d Cir. 2003) (en banc).

<sup>63</sup> *Cascade Health Solutions v. PeaceHealth*, 502 F.3d 895 (9th Cir. 2007).

allocating the discount given by the defendant on the entire bundle of products to the competitive product or products, the defendant sold the competitive product or products below its average variable cost of producing them.”<sup>64</sup> The court explained that its new test was intended to make “bundled discounts legal unless the discounts have the potential to exclude a hypothetical equally efficient producer of the competitive product.”<sup>65</sup>

However, in a perceptive analysis written by District Court Judge Claudia Wilkin in *Meijer, Inc. v. Abbott Laboratories*,<sup>66</sup> the assertion was made that average variable cost would not be the appropriate cost standard in cases involving pharmaceutical products, whose costs were mostly fixed or sunk upfront costs; the court reasoned that in such a case, the average variable cost would be *de minimis* so that the price of the competitive product would always exceed its measure of cost, however the discount was allocated. Unfortunately, although Judge Wilkin certified her decision to the Ninth Circuit for interlocutory review, subsequent events made the case moot.

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Notwithstanding the unsettled standards in some of the areas I’ve discussed today, the FTC remains committed to investigating and, where appropriate, challenging conduct in the pharmaceutical industry that harms competition. In doing so, however, the Commission will

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<sup>64</sup> *Id.* at 912. The court did not require proof of recoupment, a requirement in a single-product predatory pricing case.

<sup>65</sup> *Id.* at 906.

<sup>66</sup> 544 F. Supp. 2d 995, 999-1005 (N.D. Cal. 2008) (“Thus, as applied here, the *Cascade* rule does not achieve its stated goal of prohibiting equally efficiency competitors. This failure is attributable to the unique structural characteristics of the pharmaceutical industry, where fixed costs in the form of investment in research and development dwarf variable costs.”); *see also id.* at 1004 (“[U]sing average variable cost as a gauge of anticompetitive pricing leads to an exclusive concern with promoting manufacturing efficiency. But such a concern is not relevant” in the context of competition with a patented drug.).

take into consideration both short-term (static) and long-run (dynamic) consumer welfare. While we will rely on economic theory when weighing these considerations, I will probably accord greater weight to empirical data and the parties' intent.