Federal Trade Commission

The Role of Static and Dynamic Analysis in Pharmaceutical Antitrust

Remarks of J. Thomas Rosch*
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at the

Fifth Annual In-House Counsel Forum on Pharmaceutical Antitrust

New York, NY

February 18, 2010

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.[1] 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

* 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.

[1] 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,

may benefit consumers to a greater degree than the elimination of noncompetitive prices.[3] 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*,[4] 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.[5]

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

be more measurable. I don’t think it is difficult to appreciate that pr

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.[12] 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.[13]

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."[14] If patent rights are too generous, innovation costs will

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[12] 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 . . . .'").

[13] *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.").

[14] *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,[15] 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.[16] 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.").

[15] 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).

[16] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32, Mgmt. Science 173 (1986).

protecting new products.[17] The same study found considerable variation by industry, with patents more useful for protecting pharmaceuticals and certain chemicals.[18] A third study found that firms protect profits from invention primarily through secrecy and lead time, with patent protection the least important strategy [19] The study concluded that "patents are unambiguously the least central of the major appropriability mechanisms overall."[20] 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.[21]

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.[22] 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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[17] 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.

[18] *Id*.

[19] 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).

[20] *Id*. at 9.

[21] *Id*. Table 1.

[22] ABA Section of Antitrust Law, *The Economics of Innovation: A Survey* § II.E. (2002).

inducement to R&D."[23] 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.[24]

The most recent study that I'm aware of is by David Abrams, an economist at the University of Pennsylvania.[25] 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.[26] 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."[27]

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[23] *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).

[24] *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!").

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

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

[27] 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

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."[30] 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."[31]

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

refusal.[34] 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."[35]

The Seventh Circuit likewise rejected the Ninth Circuit's approach in a 2006 decision in favor of the Federal Circuit's approach.[36] And, arguably, a more significant development was the Supreme Court's 2004 *Trinko* decision,[37] 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."[38] However, as the Commission majority explained in criticizing the DOJ's 2008

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[34] 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.

[35] *Id.* at 1327-28

[36] *Schor v. Abbott Labs*., 457 F.3d 608 (7th Cir. 2006).

[37] *Verizon Communs. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

[38] 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,[39] 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.[40]

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.[41] 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."[42] 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.[43] Cheap exclusion involves conduct with no plausible benefits

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.[44] 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.[45] 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.[46] Here the concern is that the new product is, in a sense, a sham whose

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[44] *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).

[45] 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

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.[47] 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 toyeasteps 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.*,[48] 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

[47] Complaint for Injunctive and Other Equitable Relief, FTC v. Warner Chilcott Holdings

substitution with TriCor."[49] The district court denied Abbott's motion to dismiss, explaining that "an antitrust inquiry into the benefits provided by Defendants' product changes is appropriate."[50] 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."[51] 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.)[52]

A different result occurred in *Walgreen Co. v. AstraZeneca Pharmaceuticals*,[53] 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

[49] *Id.* at 415.

[50] *Id.* at 422.

[51] *Id.*

[52] 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).

[53] 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.[54] 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.[55] Citizen petitions are submissions designed to alert the FDA to possible scientific and safety issues related to regulated products or agency procedures.[56] 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.[57] In particular, the report found

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[54] *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

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*,[60] 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.[61]

The Third Circuit took up the issue of bundled rebates again in *LePage's Inc. v. 3M Co*.[62] 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.[63] Instead, the Ninth Circuit declared that a plaintiff challenging a monopolist's bundled pricing "must establish that, after

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[60] 920 F. Supp. 455 (S.D.N.Y. 1996).

[61] *Id*. at 469.

[62] 324 F.3d 141 (3d Cir. 2003) (en banc).

[63] *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."[64] 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."[65]

However, in a perceptive analysis written by District Court Judge Claudia Wilkin in *Meijer, Inc. v. Abbott Laboratories*,[66] 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

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

[65] *Id*. at 906.

[66] 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.