Federal Trade Commission

The Intersection of Antitrust and Intellectual Property:
The Quest for Certainty in an Uncertain World

Remarks of J. Thomas Rosch
Commissioner, Federal Trade Commission

before the

Intellectual Property Litigation: Back to Business

Latham & Watkins LLP
Menlo Park, California

May 18, 2011

I am going to talk today about the quest for certainty in an uncertain world.[1] I will focus on the current debate between Daniel Wall and Amanda Reeves, on the one hand, and Tim Wu, on the other hand, as well as on three amicus briefs the Federal Trade Commission has filed or may be filing respecting the intersection between antitrust law and intellectual property law. My remarks will be posted online on the Commission's website at www.ftc.gov after I make them today.

---

[1] 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, Henry Su, for his invaluable assistance in preparing these remarks.

The hunger for certainty in applying the antitrust laws among antitrust practitioners antedates modern high-tech or pharma issues. After all, it was certainty in the law that was largely responsible for Chief Justice Warren Burger's fondness for rules of *per se* illegality.[1] Arguably at the other end of the spectrum, it was this same interest in certitude that led the Justice Department to champion rules of *per se* legality in its (now withdrawn) 2008 Report on Single Firm Conduct.[2]

However, this quest for certainty (or predictability) has arguably risen to its crest as the intersection between antitrust law and intellectual property law has become fuzzier (or more blurred). My thesis today is that certainty in the law may not be possible in today's world. The notion that antitrust law and intellectual property law are one and the same[3] has been exposed as a fallacy. So has the notion that one should always trump the other, as the Commission's *Schering-Plough* opinion has been read to suggest (by

---

[1] United States v. Topco Assocs., Inc., 405 U.S. 596, 621 (1972) ("The *per se* rules that have been developed are simply directed to the protection of the public welfare; they are complementary to, and in no way inconsistent with, the rule of reason. The principal advantages that flow from their use are, first, that enforcement and predictability are enhanced and, second, that unnecessary judicial investigation is avoided in those cases where practices falling within the scope of such rules are found.") (Burger, C.J., dissenting).

[2] U.S. Dep't. of Justice, Competition and Monopoly: Single Firm Conduct Under Section 2 of the Sherman Act 129 (2008) [hereinafter, Single Firm Conduct Report] (disavowed by the Federal Trade Commission in 2008 and withdrawn by the Department of Justice in 2009), *available at* http://www.justice.gov/atr/public/reports/236681.htm

[3] For example, the notion that a patent monopoly automatically confers market power for antitrust purposes has been debunked. *Compare*

indicating that the strength of a patent may be irreleva

I. Information Markets

That brings me to the current debate between Professor Tim Wu, who is an FTC consultant, and Dan Wall and Mandy Reev

should not and cannot look to the antitrust laws to buttress their views.[13] More specifically, net neutrality in its pure form presupposes that ownership of content and network infrastructure is not concentrated in the same hands—in order to minimize the risk of discriminatory behavior with respect to competing content, infrastructure, or access tools/venues—and there is a large body of law holding that the antitrust laws do not apply unless there is common ownership or control of those multiple functions.[14]

---

1. Remarks before the Broadband Policy Summit IV: Navigating the Dig[illegible] Antitrust [hereinafter, Rosch, Broadband Speech]

So what has triggered this debate between Professor Wu, on the one hand, and Dan Wall and Mandy Reeves, on the other, about net neutrality and competition policy in "markets" relating to the creation and dissemination of information? In his book, Professor Wu makes points that go beyond the net neutrality debate. He suggests that the information dissemination function be separated from the other information-related functions whenever the firm's business model is "closed" as opposed to "open." His thesis is that the "closed" model is inherently "bad" and the "open" model is inherently "good." He further takes the position that the Apple business model is the epitome of a "bad" "closed" system, and that the Google business model is the epitome of a "good" "open" system.[15]

---

[15] *Compare* ID. at 291 ("But even if invisible to many consumers, the inescapable reality is that [the Apple iPod, iPhone and iPad] are closed in a way the personal computer never was."), *with* ID. at 295 ("Implicit in [Google's view of interconnections as opposed to exclusive partnerships] is the basic conception of the Internet and Wozniak's idea of the computer as tools that minimize the need for permission. The very same idea animates the Android."). Professor Wu calls Apple and its business partners AT&T and Hollywood "centralizers," who subscribe to a notion of virtue that caters to individual desires and consumption by delivering the "best of everything"—at a price, and Google and Verizon the "apostles of openness," who subscribe to a different notion of virtue that places individual self-expression and self-actualization above other activities in an information economy. ID. at 296.

For a recent industry article contrasting Apple and Google's business models, see Fred Vogelstein, *How the Android Ecosystem Threatens the iPhone*, WIRED, May 2011, at 118, 122, *available at* http://www.wired.com/magazine/2011/04/mf_android/

> . . . Apple exerts complete control over the iPhone. It builds the hardware. It designs the operating system. It runs the marketing campaigns. And it curates and polices its App Store, refusing programs it deems potentially offensive or a threat to its own business. . . .
>
> Android, by contrast, prides itself on its lack of control. It gives away its operating system for free to anyone who want Tc 12h8.perating systemidea a[(th)6(e oissubsctrol. a)1 <<,1 em. It

I should pause here to note that Professor Wu's views are not new—not even at the Federal Trade Commission. More than forty years ago, former Chairman Michael Pertschuk expressed a similar view that the dissemination of information was always in the public interest, and that the antitrust laws ought to be applied with particular zeal whenever the dissemination of information was at issue.

Not surprisingly (since Dan and Mandy were formy former colleagues and I admire them, and Tim is my current colleague and I admire him), I agree with Dan and Mandy in some respects, but disagree with them in others.

To begin with, I agree with Wall and Reeves that the Google business model cannot be considered "open" and therefore "good" *per se*. That may have once been true. But today Google monetizes its business for the most part by attracting advertising, and the kind of advertising

marginal revenue from the sale of its devices may not be sufficient to sustain its shareholder value. Over the long run, like Google, Apple may have to depend on revenue from advertisements (and particular kinds of advertisements like display advertisements) to do that. It remains to be

Perhaps more significantly, the Wall/Reeves thesis is not universally accepted by the economics community. Although innovation at the systems level may always be considered pro-consumer and procompetitive by a proponent of dynamic competition like Professor David Teece, there may be some instances in which standardization and aggressive competition based on price (as opposed to product variety) trump systems innovation (and systems differentiation) as far as consumer welfare is concerned. Besides, what matters most is what the law says, not what economists believe the law should be. And that brings me to the law.

As I say, Wall and Reeves argue that Prof. Wu's view is flawed both as a matter of procedure and as a matter of substance. They argue that it is flawed as a matter of procedure because it would lead to "ex ante" rules of *per se* illegality depending on whether a firm's business model was "open" or "closed."[29] I find this contention to be somewhat ironic. As I say, since 2008 when the Antitrust Division issued its Report on Single Firm Conduct, I had thought that the business community was crying out for rules of certainty and predictability.

But I do agree with Wall and Reeves that Rule of Reason rather than *per se* rule of illegality has been the rule, rather than the exception, in cases involving forward integration like the in-house incorporation of components into systems (and in vertical restraint cases). That said, it is hard to imagine a less predictable rule than the Rule of Reason. Except for identifying the threshold of market power, the Supreme Court has not definitively defined how the Rule of Reason applies,[30] and consequently the regional

---

[29] Wall & Reeves, *supra* note 8, at 7, 9.

[30] *See, e.g.*, Cal. Dental Ass'n v. FTC, 526 U.S. 756, 780-81 (1999) ("As the circumstances here demonstrate, there is generally no categorical line to be drawn

works best in a pure innovation market.[33] Or, as Tim Muris has speculated, it may be because the tools with which we define product markets don't work as well in defining innovation markets.[34] But for whatever reason, antitrust principles have their limitations in this context.

Specifically, let's think about the relevant "markets" for Apple and Google. We might think of online display advertising as

and analyzed accordingly? I have not yet made up my mind about that either. If so, are our antitrust tools adequate to define these "systems" and "components" markets or to distinguish between exclusionary and non-exclusionary conduct in acquiring or maintaining market power in these markets? I don't know about that at this point. One thing I am clear about: I do not think that technology is moving too fast for the Commission to challenge conduct or transactions that we have reason to believe will injure consumer choice.[36]

II. Trilogy of Commission Amicus Briefs

That brings me to a trilogy of Commission amicus briefs that I would like to discuss today. The first is the brief that the Commission filed in *TiVo, Inc. v. Echostar Corp.*, recently decided by the Federal Circuit.[37] The second is the brief that the Commission is about to file in the *K-Dur Antitrust Litigation*, a private plaintiff antitrust case now on appeal in the Third Circuit.[38] The third is a brief that the Commission may have an opportunity to file (or join with the Justice Department in filing) in the *Novo Nordisk* case on petition to the Supreme Court, as to which the views of the United States have been requested.[39]

nary ash a pl500005 Twphge condor the-0.0a i2 a i2 a oThat 0 1 Td3

explained in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,[40] the Patent Clause "itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"[41] The *Bonito* Court further observed that in accordance with the Patent Clause, "the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy."[42]

A. *Tivo v. Echostar*

Recognizing the importance of design-around efforts (which constitute a way to avoid infringement, or in other words, a way to achieve noninfringement), I urged the Commission's filing of an amicus brief in connection with the Federal Circuit's en banc rehearing of *Tivo, Inc. v. Echostar Corp.*, and Mandy Reeves essentially wrote the Commission's brief.[43] The case involved the propriety and conduct of contempt proceedings against a defendant accused of implementing a design-around in an allegedly unsuccessful attempt to get out from under an injunction. Specifically, under *KSM Fastening Systems, Inc. v. H.A. Jones Co.*,[44] the district courts were obliged to hold an

---

[40] 489 U.S. 141 (1989).

[41] *Id.* at 146.

[42] *Id.*

[43] Brief of Amicus Curiae Fed. Trade Comm'n on Rehearing En Banc Supporting Neither Party [hereinafter, FTC Brief], Tivo, Inc. v. Echostar Corp., No. 2009-1374, 2011 U.S. App. LEXIS 8142 (Fed. Cir. Apr. 20, 2011), *available at* http://www.ftc.gov/os/2010/08/100802tivoechostarbrief.pdf.

[44] 776 F.2d 1522 (Fed. Cir. 1985).

product to the infringing product with respect to the features or functions that were the bases of the prior infringement finding.[50] If the design-around product is "not more than colorably different," then it undergoes an infringement analysis that compares its features or functions to the claim limitations at issue, using the previously articulated claim construction.[51]

Thus, the court of appeals discarded the old contempt inquiry under *KSM Fastening* as "unworkable," in favor of a clearer articulation of how contempt proceedings are to be instituted, and what a plaintiff patentee must prove by clear and convincing evidence in order to have the court hold a defendant in contempt for violating the injunction.[52]

B. ***K-Dur Antitrust Litigation***

A second amicus opportunity involves the continuing saga of Schering-Plough Corporation's settlements with Upsher-Smith Laboratories and ESI Laboratories of Schering's infringement claims relating to patent on a controlled-release coating for potassium chloride tablets, which are prescribed for consumers suffering from potassium deficiency. A little background is in order here.

In 1995, both Upsher and ESI sought to introduce allegedly infringing, generic versions of Schering's patented, brand-name product, which is called K-Dur 20. It is important to remember that Schering's patent covered only a particular coating on the tablet that provides for controlled release of potassium chloride; the active ingredient itself is in common use and therefore unpatentable. The generic versions included a

---

[50] *Id.* at *26.

[51] *Id.* at *28-29.

[52] *Id.* at *22-29. *Cf.* FTC Brief at 10-19.

release mechanism that Upsher and ESI each believed to be a design-around of Schering's patent. Instead of proving noninfringement in court, both Upsher and ESI settled with Schering on terms that included payments by Schering ($60 million to Upsher and $15 million to ESI) and agreements by Upsher and ESI to delay the marketing of their generic versions for some period of time.

Through administrative litigation, the Commission found that Schering's agreements violated Section 5 of the FTC Act.[53] But on appeal, the Eleventh Circuit set aside the Commission's decision, holding, among other things, that "there has been no allegation that the '743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were 'shams.'"[54] On this basis, the Eleventh Circuit concluded that "[b]y entering into the settlement agreements, Schering realized the full potential of its infringement suit—a determination that the '743 patent was valid and that ESI and Upsher would not infringe the patent in the future."[55]

In my view, the Eleventh Circuit missed the point. First, even if the K-Dur patent were valid, Schering was still not entitled to exclude from the market generic versions with release mechanisms that do not infringe. Second, the fact that Schering may have had "probable cause to institute legal proceedings" against Upsher and ESI for patent infringement,[56] as the Hatch-Waxman Act expressly entitles it to do,[57] does not answer

---

[53] Schering-Plough Corp., 136 F.T.C. 956, 1076-91 (2003).

[54] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1068 (11th Cir. 2006).

[55] *Id.* at 1075.

[56] *See* Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 62 (1993) ("The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation. The notion of probable cause, as understood and applied in the common-law tort of wrongful civil

the question of whether the *settlement agreements*, as opposed to the *underlying litigations*, are anticompetitive. Even lawfully instituted litigation should not immunize the terms and conditions of any ensuing settlement agreement from antitrust scrutiny. The Eleventh Circuit's approach in *Schering-Plough* was therefore flawed.

Now a different Circuit—the Third Circuit—will have the chance in *K-Dur Antitrust Litigation*[58] to describe its own approach to evaluating whether Schering's settlement agreements with Upsher and ESI are anticompetitive. As the Commission has argued before, these agreements can be viewed as a form of horizontal market allocation: in essence, Schering has taken the monopoly profits that it expects to earn from the additional period during which Upsher and ESI have agreed not to introduce their generic versions of K-Dur, and agreed to split them with its potential generic competitors. Such a bargain is not, as the Eleventh Circuit has said, "a natural byproduct of the Hatch-Waxman process."[59] What the Hatch-Waxman Act instead intended was that generic competitors like Upsher and ESI have sufficient incentive through the grant of 180 days of marketing exclusivity to challenge Schering's patent on invalidity and/or noninfringement grounds. Settlement agreements of this sort therefore can be viewed as presumptively anticompetitive, which would put the burden on the parties to come forward with any evidence showing how and why the agreement is not anticompetitive.

The Commission is therefore filing an amicus brief to express its views on the proper analysis of pay-for-delay agreements. If you take a look at the brief (which will be posted on the Commission's website at www.ftc.gov after it has been filed with the Third Circuit), you will see that it describes and calls the "middle course," which is to say that such agreements should not be viewed as *per se* lawful, as the Second and Federal Circuits have held,[60] or *per se* unlawful, as the Sixth Circuit has held, at least under some circumstances.[61] Instead, such agreements should be viewed as presumptively unlawful, and adjudged under a truncated Rule of Reason whereby the burden first is on the settlement parties to provide evidence that the payment of consideration to the generic competitor was for some legitimate reason other than delayed entry. If the parties come forward with some evidence to justify their settlement agreement, then the burden would shift back to the Government or the private plaintiff to prove that the agreement has, on balance, anticompetitive effects. We will see if the Third Circuit adopts the Commission's approach instead of following one of the other Circuits.

C. *Novo Nordisk v. Caraco*

A third amicus opportunity involves the litigation in *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories*, currently on Caraco's petition for a writ of certiorari filed

---

[60] *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212-13 (2d Cir. 2006). *See also* Asahi Glass Co., Ltd. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003).

[61] *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 909 (6th Cir. 2003). The D.C. Circuit has also suggested that pay-for-delay settlements might be viewed as an attempt to allocate market share among competitors and to preserve monopoly rents for themselves. Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809, 811 (D.C. Cir. 2001)

with the Supreme Court.[62] This case involves another aspect of the Hatch-Waxman process, the so-called "Section viii" carve-out by which a generic competitor can certify that it does not intend to seek approval of its generic drug for any patented methods of use listed in the Orange Book.[63] Through this carve-out procedure, a generic competitor can avoid the expense and delay associated with infringement litigation that typically ensues following a Paragraph IV certification of patent invalidity or noninfringement,[64] and its generic product can enter the market much sooner, which benefits consumers.

In *Novo Nordisk*, the generic competitor Caraco sought to introduce its own version of a diabetes drug called repaglinide. Novo Nordisk's main patent on the compound, the '035 patent, was due to expire on March 14, 2009. Another Novo Nordisk patent, the '358 patent, would not expire until June 12, 2018, but that patent covered only the combination of repaglinide with another compound called metformin. Accordingly, in April 2008, Caraco asked the FDA at least to approve the use of its generic version of repaglinide as a *standalone* drug, which would no longer be a patented use after the expiration of the '035 patent, and *not as a combination* with metformin, which would still infringe the '358 patent. The FDA's approval of this request would have allowed generic repaglinide to be marketed by Caraco to consumers as a standalone drug immediately after March 2009, instead of being delayed pending the resolution of Paragraph IV infringement litigation with Novo Nordisk, or the lifting of the 30-month stay, whichever is earlier.

---

[62] 601 F.3d 1359 (Fed. Cir.), *rehearing denied*, 615 F.3d 1374 (Fed. Cir. 2010), *petition for writ of certiorari filed*, No. 10-844 (U.S. filed Dec. 23, 2010).

[63] 21 U.S.C. § 355(j)(2)(A)(viii) (2009).

[64] 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV) & (j)(5)(B)(iii) (2009).

The FDA initially agreed to Caraco's request,[65] but then Novo Nordisk got the agency to change its mind by revising the "use code" that is supposed to identify the patented methods of use published in the Orange Book,[66] so that the "use code" for the '358 patent on its face ostensibly covers the generic version of repaglinide as a standalone drug.[67] Because the FDA's stated policy was to rely on the "use code" to decide whether a Section viii carve-out was appropriate, the FDA reversed its position and denied Caraco's carve-out request.[68]

The issue on appeal to the Supreme Court is whether a generic competitor like Caraco, given the FDA's response to its carve-out request, can use the so-called "counterclaim" provision under the Hatch-Waxman Act to ask a district court to order the correction or deletion of an allegedly inaccurate or overbroad "use code."[69] The majority

---

[65] Food & Drug Admin., Ltr. Resp. to Novo Nordisk's & Caraco's Citizen Petitions (Dec. 4, 2008), *available at* http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064807cd390&disposition=attachment&contentType=pdf

[66] *See* 21 C.F.R. §§ 314.53(b)(1) ("For patents that claim a method of use, the applicant shall submit information only on the patents that claim indications or other conditions of use that are described in the pending or approved application."), (c)(2)(ii)(P)(3) ("The description of the patented method of use as required for publication.") & (e) ("FDA will publish in the list the patent number and expiration date of each patent that is required to be, and submitted to FDA by an applicant, and for each use patent, the approved indications or other conditions of use covered by a patent.") (2010).

[67] The use code for the '358 patent was changed from "[u]se of repaglinide in combination with metformin to lower blood glucose" to "[a] method for improving glycemic control in adults with type 2 diabetes mellitus."

[68] Food & Drug Admin., Ltr. Resp. to Novo Nordisk's Pet. for Reconsideration (June 16, 2009), *available at* http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064809d2325&disposition=attachment&contentType=pdf

[69] 21 U.S.C. § 355(j)(5)(C)(ii)(I)(bb) (2009).

Second, in the *K-Dur* case, the Commission will argue that the strength of the