Federal Trade Commission

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

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before the

Intellectual Property Litigation: Back to Business

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I am going to talk today about the quest for certainty in an uncertain world. I will focus on the current debate between Dan 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.

[*] 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was this same interest in certitude that led the Justice Department to champion rules of *per se* legality in its (now withdrawn) 2008 Report on Single Firm Conduct.[2]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

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[1] United States v. Topco Assocs., Inc., 405 U.S. 596, 621 (1972) ("The *per se* rules that have been developed are similarly 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* Jefferson Parish Hosp. Dist. v. Hyde, 466 U.S. 2, 16 (1984) (dictum) ("[I]f the Government has granted the seller a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power."), *with* Ill. Tool Works, Inc. v. Indep. Ink, Inc., 126 S. Ct. 1281, 1284 (2006) ("The question presented to us today is whether the presumption of market power in a patented product should survive as a matter of antitrust law despite its demise in patent law. We conclude that the mere fact that a tying product is patented does not support such a presumption.").

indicating that the strength of a patent may be irrelevant in condemning a pay-for-delay settlement as an antitrust violation),[4] or as the Federal Circuit's *Cipro* decision has suggested (by adopting a "scope of the patent" test that almost always gives primacy to patent rights in analyzing a pay-for-delay settlement challenged under antitrust law).[5]

Nor is certainty necessarily essential. After all, as Mandy well knows (because we discussed it often as former colleagues), most of the case law under Section 2 of the Sherman Act governing single firm conduct is not "settled."[6] Indeed, the Supreme Court, in describing the way to analyze exclusive dealing agreements, has done nothing more than set out general principles to be considered; it has not undertaken to identify a definitive test to determine whether an exclusive dealing agreement is legal or illegal under the Sherman Act.[7] Similarly, I would suggest that there may not be a "one-size-fits-all" test for deciding cases at the intersection of antitrust and intellectual property law. Rather, each case should be decided on its own merit, taking into account factors on which we can agree.

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[4] Schering-Plough Corp., 136 F.T.C. 956, 1055 (2003).

[5] *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008).

[6] *See, e.g.*, J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Monopolies, Innovation, and Predatory Pricing: Observations on Some Hard Questions in the Section 2 Context, Remarks at the Antitrust 2010 Conference: New Administrations, New Cases, and New Economic Realities in Global Markets (Mar. 25, 2010), *available at* http://www.ftc.gov/speeches/rosch/100325antitrust-cle.pdf; J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Wading Into Pandora's Box: Thoughts On Unanswered Questions Concerning the Scope and Application of Section 2 & Some Further Observations on Section 5, Remarks before the LECG Newport Summit on Antitrust Law & Economics (Oct. 3, 2009), *available at* http://www.ftc.gov/speeches/rosch/091003roschlecgspeech.pdf.

[7] Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320 (1961).

I. Information Markets

That brings me to the current debate between Professor Tim Wu, who is an FTC consultant, and Dan Wall and Mandy Reeves, who as you know represent Apple Computer. The debate concerns Professor Wu's recent book, which is entitled "The Master Switch."[8] Professor Wu proposes in his book that the functions of information creation, dissemination and access be controlled by separate firms, at least under some circumstances.[9] He calls this the Separations Principle.[10]

This proposal is not surprising. It grows out of Professor Wu's longtime advocacy for net neutrality.[11] Nor have I hidden my own views about net neutrality under a bushel.[12] To the contrary, I have publicly opined that supporters of net neutrality

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[8] TIM WU, THE MASTER SWITCH: THE RISE AND FALL OF INFORMATION EMPIRES (2010). For the response from Dan Wall and Mandy Reeves, *see* Daniel M. Wall & Amanda P. Reeves, *The Pro-Competitive Value of Closed Platforms & Walled Gardens: Some Thoughts in Response to Tim Wu*, 3 CPI ANTITRUST CHRONICLE, Mar. 2011, No. 2, at 1 (subscription required).

[9] *ID.* at 304 ("Specifically, what we need is something I would call a Separations Principle for the information economy. A Separations Principle would mean the creation of a salutary distance between each of the major functions or layers in the information economy. It would mean that those who develop information, those who own the network infrastructure on which it travels, and those who control the tools or venues of access must be kept apart from one another.").

[10] *ID.*

[11] "Network neutrality is best defined as a network design principle. The idea is that a maximally useful public information network aspires to treat all content, sites, and platforms equally." Tim Wu, *Network Neutrality FAQ*, TIMWU.ORG (last visited May 9, 2011), http://timwu.org/network_neutrality.html.

[12] J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Some Reflections on the Future of the Internet: Net Neutrality, Online Behavioral Advertising, and Health Information Technology [hereinafter, Rosch, Internet Speech], Remarks before the U.S. Chamber of Commerce Telecommunications & E-Commerce Committee Fall Meeting (Oct. 26, 2009), *available at* http://www.ftc.gov/speeches/rosch/091026chamber.pdf; J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Broadband Access Policy: The Role of

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 case law holding that the antitrust laws do not apply unless there is common ownership or control of those multiple functions.[14]

Antitrust [hereinafter, Rosch, Broadband Speech], Remarks before the Broadband Policy Summit IV: Navigating the Digital Revolution (June 13, 2008), *available at* http://www.ftc.gov/speeches/rosch/080613broadbandaccess.pdf.

[13] *See* Rosch, Internet Speech, at 3 ("Second, as I have said in prior remarks, I don't think the antitrust laws (which we at the Federal Trade Commission and the Antitrust Division of the Justice Department jointly enforce), have much, if anything, to offer in these debates."); Rosch, Broadband Speech, at 9 ("Rather, my point is simply that *if* there is consensus that this sort of conduct is problematic, then the antitrust laws—at least as they are currently interpreted by the Supreme Court—are unlikely to offer a solution.").

[14] On his website, Professor Wu broadly ponders "whether network neutrality rules (or laws) are called for in the absence of market power and concentration. . . . Therefore, in a market where vigorous competition exists, will the market itself solve any problems of discrimination?" Wu, *supra* note 11. However, in his book Professor Wu expresses skepticism about whether "net neutrality" should be governed by free market principles at all:

> To leave the economy of information, and power over this commodity, subject solely to the traditional ad hoc ways of dealing with concentrations of industrial power—in other words, to antitrust law—is dangerous. Without venturing into the long, rancorous debate over what, if any, kind of antitrust policy is proper in our system, I would argue that by their nature, those particular laws alone are inadequate for the regulation of information industries. One reason is fairly simple: historically, the application of those statutes has been triggered by manipulation of consumer prices and certain other very particular abuses of market power; but those aren't the most troubling problems in this context. . . .

WU, *supra* note 8, at 303.

So what has triggered this debate between Professor Wu, on the one hand, and Dan Wall and Mandy Reeves, on the other hand, 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]

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[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 worlds 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 wants it—though manufacturers must submit their phones for testing if they want to access its app market or run

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.[16] The Commission's majority and the private bar did not agree, however. So it is not surprising that Wall and Reeves oppose this latest iteration of Chairman Pertschuk's view (particularly given Dan and Mandy's representation of Apple).

The Wall/Reeves opposition is threefold. First, they maintain that Professor Wu's view is illogical.[17] Second, they assert that it is contrary to modern economic thinking.[18] Third, they say that it is flawed as a matter of procedural and substantive antitrust law.[19]

> optimized versions of Google apps. Android doesn't review apps before they're added to its marketplace, pulling them only if users complain, and manufacturers can and do modify the look and feel of the OS on their phones.

[16] *See, e.g.*, A Conversation with Michael Pertschuk, Chairman, Fed. Trade Comm'n, in Washington, DC (Jan. 11, 1979), *published in* AM. ENTERPRISE INSTITUTE, STUDIES IN GOV'T REGULATION NO. 255, at 3-4 (1979) ("We are seeking to improve the flow of information where the marketplace has failed to provide the consumer with the information that in turn enables him to act as the sovereign or disciplinarian of the marketplace.").

[17] Wall & Reeves, *supra* note 8, at 4 ("For starters, while critics are quick to laud open systems and criticize closed systems, what does it mean for a business structure or computing platform to be 'open' or 'closed'?").

[18] *Id.* at 5 ("'Open' and 'closed' also lack any generally accepted legal or economic meaning.").

[19] *Id.* at 7 ("When confronting antitrust issues raised by closed systems, we would caution both agencies that, whatever theory of liability they decide to pursue, liability should turn not on the 'closed' or 'open' nature of the platform, but on the rigorous antitrust analysis needed to confirm that a firm is using its market or monopoly power in a way that causes anticompetitive effects.").

Not surprisingly (since Dan and Mandy were my 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 that is most lucrative for it may not depend as much on "tracking" consumer preferences as its rivals depend on such tracking. As Wall and Reeves point out, the "mechanics behind" Google's products for monetizing advertising, including its dominant "search" capability that it uses to attract eyeballs (which in turn attract display advertisements), are "tightly held 'closed' secrets."[20] Beyond that, Google has reportedly progressively "closed" its "open source" code for its Android releases in order to protect certain Android manufacturers whom it favors. Thus, it cannot accurately be said today that Google's business model is entirely "open."

On the other hand, it may well be accurate to describe Apple's system as "closed." Wall and Reeves make much of statistics showing that most of Apple's revenue comes from sales of its devices like the iPad and the iPhone and from the apps that are available for those devices.[21] They further assert that Apple's business model is "open" because third-party app developers, not Apple itself, develop the apps.[22] But such statistics at best reflect the situation *at this very moment*. Arguably, Apple's

[20] *Id.* at 4.

[21] *Id.*

[22] *Id.* at 5.

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 its revenue from advertisements (and particular kinds of advertisements like display advertisements) to do that. It remains to be seen if Apple will be any more "open" than Google in sharing the mechanics for generating its advertising revenue.

As for revenue generated by app developers, Apple demonstrated in connection with the AdMob saga that it can switch from an "open" business model to a "closed" one in a heartbeat.[23] Apple deprived AdMob of virtually all of its value when it prohibited app developers from sharing with AdMob the "tracking" data the developers had on the Apple platform. Although Apple asserted that this was done in order to protect consumers, it abandoned the prohibition once the Commission cleared Google's acquisition of AdMob (which the Commission had to do because no court or agency could block acquisition of a valueless AdMob with a straight face).

Wall and Reeves also argue that Professor Wu's thesis ignores the difference between components competition and systems competition, which can be central to a meaningful economic analysis of high tech product markets today.[24] I agree that it can be useful to differentiate between these two kinds of competition. I also agree that

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[23] *See* Press Release, Fed. Trade Comm'n, FTC Closes Its Investigation of Google AdMob Deal (May 21, 2010), http://www.ftc.gov/opa/2010/05/ggladmob.shtm.

[24] Wall & Reeves, *supra* note 8, at 5. Joseph Farrell, currently Director of the Commission's Bureau of Economics, wrote a paper in 1998 with two co-authors describing the relevance of components competition and systems competition to markets for products that involve more than one stage or component of production. Joseph Farrell, Hunter K. Monroe & Garth Saloner, *The Vertical Organization of Industry: Systems Competition versus Component Competition*, 7 J. ECON. & MGMT. STRATEGY 143, 144 (Summer 1998). For such products, it can be useful to consider not only competition at the final product stage (systems competition), but also at the intermediate stage(s) involving one or more components that go into the final product.

components beget differentiated systems and that some differentiated systems are extremely beneficial to consumers. But Wall and Reeves go one step further: they contend that modern economic analysis treats systems differentiation (as, for example, in the case of the iPhone versus an Android device) as almost always beneficial, presumably because such innovation in systems attracts investment.[25] This is a variation, it seems to me, on Part II of Mr. Justice Scalia's opinion in *Trinko,* which has been interpreted as saying that monopoly power is good because it attracts investment.[26] Quite apart from the fact that the thesis is contrary to Section 2 of the Sherman Act, which condemns not only the creation, but also the maintenance, of monopoly power, as I have elsewhere observed[27] Part II of the *Trinko* opinion was dictum because it was not necessary to the decision in the case. Indeed, the case only required the Court to decide whether an alleged exercise of monopoly power was lawful when it was subject to regulation by a Public Service Commission.[28]

[25] Wall & Reeves, *supra* note 8, at 6 ("Systems competition increases consumer choice by providing consumers with more differentiated products and it drives innovation and differentiation at the broader systemic level. We are better off in a world with PCs that offer differentiated components *and also* Macs and iPhones—and all the product improvements that the presence of this aggressive systems competition has inspired—than in a world of component competition alone.").

[26] Verizon Communc'ns Inc. v. Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) ("The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts 'business acumen' in the first place; it induces risk taking that produces innovation and economic growth.").

[27] *See* J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, A Modest Proposal for Modest Antitrust Decisions at the Supreme Court, Remarks before the ABA Section of Antitrust Law 56th Annual Spring Meeting (Mar. 27, 2008), at 7, *available at* http://www.ftc.gov/speeches/rosch/080327modest.pdf.

[28] *Trinko,* 540 U.S. at 412.

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 Professor 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 the Rule of Reason rather than a *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

appellate courts (including some pretty sophisticated ones like the D.C. Circuit in the *Microsoft* case) have not done so.

Please do not misunderstand me. I take very seriously the Wall/Reeves position regarding the substantive law. I agree with them entirely that whether a business model is "good" or "bad" ought to be decided, not on the basis of whether it champions an "open" or "closed" system, but on whether a firm is operating in a highly concentrated market and, if so, whether the firm's practices or transactions comport with the Sherman Act (putting to one side Section 5 of the Federal Trade Commission Act).[31] It seems to me that Professor Wu, like numerous antitrust lawyers before him, has succumbed to the temptation to try to identify "bright line rules."

However, I am concerned that Wall and Reeves insist on applying antitrust principles in a context where their suitability is at least suspect. As I have observed before, where high-tech (or pharma) is involved, innovation is an important, non-price dimension of competition, but no litigated case (private or public) has ever held there can be an antitrust violation where there is no product (or service) market, only an innovation market.[32] That may be because we just don't know whether competition or collaboration

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between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.").

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

[32] *See* J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Some Thoughts on the Role of Intellectual Property in Innovation Market Cases and Refusals to License, Remarks at the Conference on Antitrust and Digital Enforcement in the Technology Sector (Jan. 31, 2011), at 3-15, *available at* http://www.ftc.gov/speeches/rosch/110131technologysector.pdf; J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Intel, Apple, Google, Microsoft, and Facebook: Observations on Antitrust and the High-Tech Sector [hereinafter, Rosch, High-Tech

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 a "systems" market because it largely funds the "components" upon which Apple and Google depend in order to attract the "eyeballs" essential to sustain that advertising. It is arguable that the systems market is highly concentrated today: if one considers only the advertising market today, for example, it is arguable that there are only three or four major players—Google, Microsoft, Apple and perhaps, Facebook.[35]

Has Google acquired (lawfully or unlawfully) monopoly power over a "component" market because of its dominance in the search market, which is used to attract those eyeballs? I have not yet made up my mind about that. If so, does this mean that another means of attracting those eyeballs, such as Apple's accumulation of apps and its development of platforms like iPads and iPods, should also be treated as components

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Speech], Remarks at the ABA Antitrust Section Fall Forum (Nov. 18, 2010), at 9-10, *available at* http://www.ftc.gov/speeches/rosch/101118fallforum.pdf.

[33] *Id.*

[34] *See* Stmt. of Timothy J. Muris, Chairman, Fed. Trade Comm'n, Genzyme Corp.-Novazyme Pharms., Inc., FTC File No. 021-0026 (Jan. 13, 2004), *available at* http://www.ftc.gov/os/2004/01/murisgenzymestmt.pdf.

[35] *See* Mike Swift, *Facebook Shows Growth in Display Ads*, SILICONVALLEY.COM (May 5, 2011, 2:07 PM) (reporting that Facebook had 346 billion ad views ("impressions") during the first quarter of 2011, nearly 33 percent of all Internet display ad views), http://www.siliconvalley.com/social-networks/ci_18001513.

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 this 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]

Let me begin by reminding everyone that the patent monopoly granted by the Constitution and the Congress is not absolute. More specifically, as the Supreme Court

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[36] *See* Rosch, High-Tech Speech, *supra* note 32, at 4-5.

[37] No. 2009-1374, 2011 U.S. App. LEXIS 8142 (Fed. Cir. Apr. 20, 2011).

[38] *In re* K-Dur Antitrust Litig., *appeal docketed*, Nos. 10-2077, 10-2078, 10-2079 & 10-4571 (3d Cir. appeal filed Apr. 12-13, 2010).

[39] Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, 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).

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

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[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).

alleged infringer (and contemnor) in contempt if they determined in a summary proceeding that the design-around did not provide a product that was "colorably different" from the original product admitted or found to infringe.[45] As you probably know, the Federal Circuit recently issued its en banc decision.[46] I am heartened by the fact that the decision fairly well tracks the points made in the Commission's brief.

Importantly, the Federal Circuit acknowledged the importance that the contempt analysis should balance "the policy that legitimate design-around efforts should always be encouraged as a path to spur further innovation," with the need to ensure that "an assertion that one has permissibly designed around a patent" is not "used to mask continued infringement."[47] Briefly, the Federal Circuit held that in order to initiate contempt proceedings, the plaintiff patentee must provide the trial court with "a detailed accusation from the injured party setting forth the alleged facts constituting the contempt."[48] In the proceedings, the patentee bears the burden of proving by clear and convincing evidence that "the newly accused [design-around] product is not more than colorably different from the product found to infringe and that the newly accused product actually infringes."[49] The "colorable differences" analysis compares the design-around

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[45] *Id.* at 1526-27.

[46] Tivo, Inc. v. Echostar Corp., No. 2009-1374, 2011 U.S. App. LEXIS 8142 (Fed. Cir. Apr. 20, 2011). The parties have subsequently settled the matter (on terms that call for the Dish Network and Echostar to pay $500 million to Tivo) but the Federal Circuit is not going to withdraw its opinion or dismiss the appeal. *See* Tivo, Inc. v. Echostar Corp., No. 2009-1374, 2011 U.S. App. LEXIS 9632 (Fed. Cir. May 10, 2011) (denying the parties' motion to dismiss the appeal).

[47] *Id.*, 2011 U.S. App. LEXIS 8142, at *27-28. *Cf.* FTC Brief at 9-10.

[48] *Id.* at *23.

[49] *Id.* at *25.

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 trial 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 a 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 noninfringing, 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

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[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.

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proceedings, [7] requires the plaintiff to prove that the defendant lacked probable cause to institute an unsuccessful civil lawsuit and that the defendant pressed the action for an improper, malicious purpose.").

[57] 21 U.S.C. § 355(j)(5)(B)(iii) (2009).

[58] *In re* K-Dur Antitrust Litig., *appeal docketed*, Nos. 10-2077, 10-2078, 10-2079 & 10-4571 (3d Cir. appeal filed Apr. 12-13, 2010).

[59] *Schering-Plough*, 402 F.3d at 1075.

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 what I call 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 that 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.

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[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 publicly listed 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] A majority

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[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 those 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 is, 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).

of the Federal Circuit panel that heard this case held that the counterclaim provision can be used only to correct or delete patent numbers or expiration dates listed on the Orange Book that are inaccurate.[70] The Supreme Court has asked the Solicitor General for the United States' views on whether Caraco's petition should be granted, and the Commission is providing its input.

We will have to see whether the high Court takes this case, and if so, whether the Commission will submit its own brief or join in a brief with the Justice Department. I can't speak for the Commission or the Solicitor General but in my view, this is another example, as in *Tivo* and *K-Dur*, in which a court has to balance the interests of the patent holder in preventing infringing competition against the public's interests in seeing that noninfringing products, whether they be design-arounds or carved-out uses, are not deterred or delayed from entering the market.

Conclusion

In conclusion, let me summarize the teachings of these three amicus briefs. In the *Echostar* case, the take-away is that the patent monopoly is not absolute, even in contempt proceedings: the patentee must show by clear and convincing evidence that the alleged contemnor has not designed around the infringing feature originally alleged by the patentee. If the patentee does not do so, i.e., if the design-around results in noninfringement, then the alleged contemnor cannot be held in contempt. Thus, the Federal Circuit's holding in *Cipro* is wrong: the patent laws do not confer monopoly power absolutely; they only confer the power to exclude *if there is infringement*.

[70] Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359 (Fed. Cir.), *denied*, 615 F.3d 1374 (Fed. Cir. 2010). Judge Dyk dissented from the panel's majority opinion and also joined in Judge Gajarsa's dissent from the Court's decision to deny rehearing *en banc*.

Second, in the *K-Dur* case, the Commission will argue that the strength of the patent must therefore be considered at the intersection of antitrust and intellectual property. This is a fact-specific test so that a lawsuit challenging a settlement at that intersection can't be considered either *per se* legal or *per se* illegal, although it can be considered "inherently suspect" if it involves a payment going the "wrong way" (from the patentee to the alleged infringer) and there is a delay in the alleged infringer's entry. Under these circumstances, the burden should shift to the patentee to justify the settlement.

Third, as I say, I can't predict what the Supreme Court will do with the *Novo Nordisk* case, or what the Commission will say about it. But I can tell you this: consistent with our custom and practice, the Commission will be an "honest broker," that is serving as a true amicus trying to help the Court rather than any of the parties.

That is what I meant when I said "one size may not fit all." The quest for certainty will continue, but certainty is not the only objective of the law. There are higher objectives that must be accommodated, even if we must live with some uncertainty in order to achieve them.

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Thank you for listening. I look forward to your questions.