ADDRESS TO BOSTON UNIVERSITY SCHOOL OF LAW

RECENT ISSUES IN ANTITRUST AND INTELLECTUAL PROPERTY

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I. WELCOME AND INTRODUCTIONS

Clyde Vanel, Editor-in-Chief:

I would like to welcome everyone to *the Journal of Science and Technology Law*'s annual speaker series. This year we are hosting and featuring former FTC Commissioner Mary Azcuenaga, who will be discussing recent issues in intellectual property and antitrust law. I would also like to recognize our cosponsors for this program: Testa, Hurwitz and Thibeault and Compaq Computer Corporation. We have refreshments on the right side of the room. Immediately after this speech there is a reception in the Tenth Floor Faculty Lounge where we will have hors d'oeuvres and drinks.

The *Journal of Science and Technology Law* was founded in 1995 and was the first electronically published student edited law journal. This volume will be our inaugural volume in book form. In this issue, we will feature this speech, as well as other articles and student notes.

Without further ado, I would like to welcome Dean Cass.

Dean Ronald Cass:

One of my pleasures as Dean is to get to introduce certain speakers to the students and faculty here. I like to introduce famous people to you. And I like to introduce nice people to you. And I like to introduce smart people. It is a pleasure when I can do all three at once. Many of you know the story of the person walking through the graveyard and saw the headstone that read: "Here lies a lawyer and an honest man." He turned to his companion and said, "I see they are burying them two at a time now."

We actually have the great honor of having someone who has all the attributes you would want in a speaker. Mary Azcuenaga was a Commissioner of the Federal Trade Commission for fourteen years. She is one of my few classmates from law school who was able to hold down a job for any length of time. All the rest have had itinerant careers and have been chased from job to job. But Mary was such a success at the FTC that they not only appointed her as a Commissioner, but also asked her repeatedly to stay on. I was a Commissioner, at one point, of another agency and they asked me repeatedly to move on. Almost the same thing.

I think you will enjoy hearing her. She is an excellent speaker. Make sure at the end of the speech you ask for more jokes. Please welcome Commissioner Mary Azcuenaga.

II. BACKGROUND ON INTELLECTUAL PROPERTY AND COMPETITION LAW

Thank you very much, Ron. I am not sure I can live up to that introduction. But it is a great pleasure to be here in Boston on this great autumn day. I would like to thank both Dean Cass and the members of the Editorial Board of the *Journal of Science and Technology Law* who have given me such a warm

welcome to the school. It has been great.

I am an antitrust lawyer, and I am an antitrust lawyer specializing in the intersection between antitrust law and intellectual property law. But I am fundamentally an antitrust lawyer. I thought for the purposes of speaking today, it would be useful for me to get some sense of your background. First of all, how many of you are students? How many of you are members of the faculty? Is there anyone who is not covered in either of those two categories? Okay, are you in business or. . .

Audience:

I am an attorney with Testa, Hurwitz and Thibeault.

Commissioner Azcuenaga:

Now I have to ask for another show of hands. How many of you know something about intellectual property law? And how many of you know something about antitrust? Thank you.

For those of you who don't know anything about antitrust, I think I will talk about it for just a moment because it is not a terribly well understood field of law. Antitrust evolved with our free market economy, and that free market economy, as you know, is the basis for our commercial strength and prosperity. Antitrust came about because we had to have, if you will, certain rules of the road. There are certain kinds of conduct in that free market economy that are not tolerated because they tend to suppress competition.[1] When I use the words "antitrust" and "competition," I use them more or less interchangeably. That is the way they usually used.

Antitrust seeks to prohibit conduct that harms competition, not competitors.[2] What does that mean? If you have never been involved in antitrust law, it is not altogether obvious why that is a fundamental principle of antitrust law. Competition is good, we think, for consumers because it results in goods and services at better prices or better in other ways.[3] What constitutes better may differ, but that is in the consumer's eye and people can debate about that. But we assume that in a truly competitive market we will have better goods and services and at better prices.

So a simple example of antitrust law might be price fixing.[4] Almost everybody knows something about price fixing. I will take a nice clean example, a nice healthy example. Let us talk about the market for milk, and let

[1] *See* 15 U.S.C. § 1 (1994) ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal.").

[2] *See* Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962).

[3] *See* Northern Pac. Ry. v. United States, 356 U.S. 1, 4-5 (1958).

[4] *See, e.g.*, United States v. Socony-Vacuum Oil, Co., 310 U.S. 150, 210 (1940).

us assume that all the people who supply milk to Boston consumers are engaging in a price fixing conspiracy. If they decide to do that, there are some people who will buy milk even if price goes up. So they can agree that they will increase the price for milk. If all of them get together and do it, they probably can increase the price of milk. Now that is not very good for consumers. What if someone cheats on this agreement and lowers the price of milk? Who is that going to hurt? It is going to hurt the competitors, but it is going to increase competition. And it is the competitors who want to be part of that price fixing agreement and keep the price of milk up that are the ones who will be hurt.

So that is why we say that the purpose of antitrust is to keep from harming competition, not competitors. That, I think, is an important backdrop to keep in mind in a number of antitrust cases because competition law is not always intuitive. Sometimes it is counterintuitive; sometimes it hurts competitors and people say: "Well something must be wrong because it is hurting a competitor." But what we want to keep in mind is competition itself and keeping it healthy. Competition is not always pretty, but ultimately, competition benefits consumers.

This is an important time in the evolving history of antitrust and intellectual property law. Increasingly, the valuable products and assets of American businesses are innovations. Companies in industries as diverse as computer hardware and software, biotechnology, aerospace, and pharmaceuticals generate wealth and employment by developing and improving the stream of new ideas and new products. Although these companies range from tiny research boutiques to giant aerospace defense contractors, they all depend significantly on the legal framework protecting the competitive market, in which rights of inventors are protected and in which innovators can profit from their ideas and inventions.[5]

III. INTELLECTUAL PROPERTY LAW AND COMPETITION POLICY ARE COMPLEMENTARY

The legal framework that has sustained this fertile innovation by American corporations over the past two decades has two parts. The first part consists of the intellectual property laws, which secure for a limited time to authors and inventors the exclusive rights to their respective writings and discoveries.[6] The second part is somewhat more obscure. That is the part that I specialize in.

[5] *See* U.S. DEP'T OF JUSTICE & FTC, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 3.2.3 (1995), *available at* <http://www.usdoj.gov/atr/guidelines/ipguide.htm>.

[6] *See* U.S. CONST., art. I, § 8, cl. 8; 35 U.S.C. §§ 1-376 (1994 & Supp. IV 1999) (patents); 17 U.S.C. §§ 101-1332 (1994 & Supp. 1999) (copyrights); 15 U.S.C. §§ 1051-1127 (1994 & Supp. IV 1999) (trademarks). Trade secrets are a matter of state law. *See generally* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 478-79 (1974).

But it is no less important. The antitrust laws, which ensure an open and competitive marketplace, in which inventors can realize the value of their inventions, and antitrust enforcement, are grounded in competition policy, as I said.[7]

Both competition policy and the policy underlying intellectual property law have the same goal: they both have the goal of protecting and seeking to foster an economic environment conducive to technological change and innovation.[8] By eliminating private restraints on trade that diminish rivalry or bar entry, antitrust enforcement can protect the opportunity for entrepreneurs to exploit their innovations commercially. Antitrust enforcement should complement, indeed should reinforce, the value established by the creation of intellectual property rights.

This view of antitrust and intellectual property as complementary has not always been held. In the old days, antitrust enforcers may have seen it as their responsibility to rein in the necessary evil of patent monopolies.[9] The perception of an inherent conflict between antitrust and intellectual property law has receded; at least it did recede earlier in the last decade.[10] And the question to which I may return is whether that is that starting to change again. I think that is a very important policy issue that is arising again today.

One fundamental question in this area is whether intellectual property is like other property for purposes of antitrust analysis. In considering this question it seems to me that we should keep in mind some obvious principles. First, intellectual property has the basic attributes of other property.[11] That is to say,

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[7] *See* Brunswick Corp. v. Riegel Textile Corp., 752 F.2d 261, 266 (7th Cir. 1984) ("The purpose of the antitrust laws as it is understood in the modern cases is to preserve the health of the competitive process . . . .").

[8] *See* Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990); U.S. DEP'T OF JUSTICE & FTC, *supra* note 5, § 1.0.

[9] *See* Roger B. Andewelt, The Antitrust Division's Perspective on Intellectual Property Protection and Licensing—The Past, The Present and The Future, Remarks Before the American Bar Association, Patent, Trademark & Copyright Section, London, England, *reprinted in* 30 PAT., TRADEMARK & COPYRIGHT J. (BNA) No. 739, at 320 (July 25, 1985) ("The [Antitrust] Division's earlier hostility to intellectual property protection appears to be the product of a fundamental misperception that there is an inherent economic conflict between the goals of the antitrust laws and the goals of the laws protecting intellectual property.").

[10] *See, e.g.*, *Atari Games*, 897 F.2d at 1576.

> First, the Division is far more receptive that it has been to expanding the intellectual property protections available to creators of new technologies. Second, the Division has modified its analytical approach for evaluating the antitrust lawfulness of intellectual property licenses in a manner that will result in less antitrust interference with patent licensing.

Andewelt, *supra* note 9, at 319.

[11] *See* 35 U.S.C. § 261 (1994) (stating that patents shall have the attributes of personal

it belongs to someone who has the right to exclude others from using it without his or her consent. However, intellectual property also has attributes that distinguish it from personal property and real property.[12] That is why we have a different word for it. For example, the enforcement of an owner's exclusive right to use physical property may be accomplished more easily than protecting intellectual property, as a practical matter. Intellectual property is intangible and of a limited duration.[13] So there are differences, but it is still a property right.

Antitrust policy makers should certainly remain open to considering new ideas about how the rights associated with intellectual property can be and should be distinguished from the ownership of tangible property in the analysis of antitrust liability. But for now, it seems safe to say that for purposes of antitrust analysis, intellectual property is generally treated like other forms of property. Let me add one qualifier to this general principle, which I hope is not too confusing. To the extent that intellectual property differs from other forms of property, such as in the extent of the duration of the property right, that difference is a fact that is considered with all other facts in the antitrust analysis.

Two other principles seem to be generally accepted under the law and by government antitrust officials. First, the possession of intellectual property rights does not presumptively confer market power.[14] This principle, which seems to run counter to the notion of a patent monopoly, is a very important one to keep in mind. Second, licensing of intellectual property can facilitate efficient commercial exploitation of intellectual property and can help integrate complementary intellectual property.[15] Consumers benefit from licensing because it can expand access to intellectual property by increasing the speed and reducing the cost of bringing innovations to market. And, of course, we assume all this is good.

Anything we might say about the importance of protecting intellectual property, of course, is premised on the assumption that it was properly obtained. Patent protection in the absence of novelty and non-obviousness can harm innovation by eliminating the incentives for the patent holder and others engaged in further pursuit of something that is novel and non-obvious.

The main federal policy these days for the application of antitrust law in the situation in which there is an intellectual property right is contained in one policy document. The courts' opinions, of course, are what ultimately matter.

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property).

[12] *See*, *e.g.*, 14 DONALD S. CHISUM, CHISUM ON PATENTS 8150, § 5(e), at 263 (Supp. 2000) ("[P]atent property is neither real nor ordinary personal property, as is normally subject to the jurisdiction of state judicial authority.").

[13] *See* 35 U.S.C. § 154(a)(2) (1994) (detailing the twenty year patent term).

[14] *See* U.S. DEP'T OF JUSTICE & FTC, *supra* note 5, § 2.2.

[15] *See id.* § 2.3.

But there is one source that is available that is excellent for studying this whole area: the *Antitrust Guidelines for Licensing Intellectual Property*, which were issued by the Department of Justice and the Federal Trade Commission.[16] They were initiated at the Department of Justice, and the Federal Trade Commission joined in issuing them. I commend the guidelines to you for your reading; it is really an excellent document. It has a very appropriate balance, I think, between intellectual property and competition law.

There has been a great deal of discussion in very recent years about whether antitrust law trumps intellectual property law or whether intellectual property law trumps antitrust law.[17] I find that a somewhat disturbing trend because each of them has a role, and it is not a question of which one trumps the other. There is certain conduct that is not allowed with respect to intellectual property and that is fairly well defined in the 1995 Guidelines.[18]

There are some important principles in those guidelines. "As with other forms of property, certain kinds of conduct with respect to intellectual property may have anticompetitive effects against which the antitrust laws can and do protect. Intellectual Property is thus neither particularly free from scrutiny under the antitrust laws nor particularly suspect under them."[19] Those are some of the very fundamental principles in the antitrust guidelines for licensing.

Let me give you a few more. "Market power is the ability to profitably maintain prices above or output below competitive levels for a significant period of time."[20] That is a very fundamental premise of antitrust law. But the market power "does not impose on an intellectual property owner an obligation to license the use of [its] intellectual property to others."[21] Here is another principle from the Licensing Guidelines. "[M]arket power could be illegally acquired or maintained or, even if lawfully acquired and maintained, would be relevant to the ability of an intellectual property owner to harm competition through unreasonable conduct in connection with such property."[22]

IV. THE *XEROX* CASE

Now let's go back to this point that market power does not impose an obligation to license the use of that property to others. Those of you who have

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[16] *See generally id.*

[17] See generally B. Zorina Khan, Symposium on Antitrust and Intellectual Property: Federal Antitrust Agencies and Public Policy Toward Antitrust and Intellectual Property, 9 CORNELL J.L. & PUB. POL'Y 133 (1999).

[18] *See generally* U.S. DEP'T OF JUSTICE & FTC, *supra* note 5, §§ 4.1-.3, 5.1-.7.

[19] *Id.* § 2.1.

[20] *Id.* § 2.2.

[21] *Id.*

[22] *Id.*

studied intellectual property law probably will not find this terribly unusual. But you have to recognize that many antitrust enforcers have not studied intellectual property law. And I do not mean to suggest that we do not know what we are doing, but it is a concept that is not as obvious to us as it is to people who have studied intellectual property law. This came up in a recent case, *Xerox*, which was decided by the Federal Circuit.[23] In that case, the court held just that – that there was no obligation to license intellectual property.[24]

Earlier this month, the Supreme Court asked the government for its views on whether cert should be granted in the *Xerox* case.[25] I do not know what the government will say, obviously, because it has not filed its brief yet. But one person from the government, Chairman Pitofsky of the Federal Trade Commission, has already opined on this case.[26] For those who do not know anything about antitrust, there are two federal antitrust enforcement agencies: the Antitrust Division of the Department of Justice and the Federal Trade Commission.[27] They both enforce the federal laws of antitrust. It is an unusual situation where there are two agencies doing the same thing.

The Chairman of the Federal Trade Commission has given a speech in which he questions the *Xerox* opinion, which deals with the obligation to license issue.[28] The Chairman apparently finds the opinion troubling.[29] So it will be very interesting to see what the government will say. That brief will come from the Department of Justice, but no doubt there will be input from the Federal Trade Commission, as there usually is in issues involving antitrust.

"Intellectual property typically is one component among many in a production process that derives value from its combination with

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[23] *In re* Independent Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1324 (Fed. Cir. 2000) [hereinafter *Xerox*].

[24] *See id.* at 1328.

[25] CSU, L.L.C. v. Xerox Corp., 69 U.S.L.W. 3257, 3257 (U.S. Oct. 10, 2000) (inviting the Solicitor General to file a brief expressing the views of the United States on whether cert should be granted).

[26] *See* Robert Pitofsky, Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property, Remarks Before the American Antitrust Institute (June 15, 2000), *available at* <http://www.ftc.gov/speeches/pitofsky/000615speech.htm>.

[27] The Federal Trade Commission "seeks to ensure that the nation's markets function competitively, and are vigorous, efficient, and free of undue restrictions." FTC, *Mission Statement*, June 17, 1999 *available at* <http://www.ftc.gov/ftc/mission.htm>. The Antitrust Division of the Department of Justice seeks to enforce the antitrust laws by prohibiting "a variety of practices that restrain trade, such as price-fixing conspiracies, corporate mergers likely to reduce the competitive vigor of particular markets, and predatory acts designed to achieve or maintain monopoly power." U.S. Dep't of Justice, *Overview*, *available at* <http://www.usdoj.gov/atr/overview.html>.

[28] *See* Pitofsky, *supra* note 26.

[29] *See id.*

complementary factors."[30] And complementary factors of production include:

> manufacturing and distribution facilities, workforces, and other items of intellectual property. The owner of the intellectual property has to arrange for its combination with other complementary factors to realize its commercial value. Often, the owner finds it most [judicious] to contract with others for these factors, to sell rights to the intellectual property, or to enter into a joint venture arrangement for its development, rather than supplying those complementary factors itself.[31]

Moreover, "[l]icensing, cross-licensing, or otherwise transferring intellectual property . . . can facilitate integration of the licensed property with complementary factors of production."[32] And this, in turn, can lead to more efficient exploitation of the intellectual property, which benefits consumers through the reduction of costs and the introduction of new products.[33] Such arrangements also "increase the value of intellectual property to consumers and to the developers of the technology. By potentially increasing the expected returns from intellectual property, licensing also can increase the incentive for its creation and thus promote greater investment in research and development."[34] That is pro-competitive. The antitrust laws, like the intellectual property laws, are concerned with incentives to innovate.

If you know something about intellectual property, of course, I am not surprising you with any of this. But I mention this to emphasize that the fundamental policy document that the antitrust enforcement authorities look to is consistent with the notions of intellectual property law. But what we have seen in the antitrust world in recent years occasionally strays from that document, or from the principles of that document, not in any major way but in a way that is sufficient perhaps to stimulate our interest and possibly cause some concern.

The law does not require that the intellectual property owner create competition in its own technology.[35]

> However, antitrust concerns may arise when a licensing arrangement harms competition among entities that would have been actual or likely potential competitors in a relevant market in the absence of the license . . . . A restraint in a licensing arrangement may harm such competition, for example, if it facilitates market division or price-fixing.[36]

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[30] U.S. DEP'T OF JUSTICE & FTC, *supra* note 5, § 2.3.

[31] *Id.*

[32] *Id.*

[33] *See id.*

[34] *Id.*

[35] *See id.* § 3.1.

[36] *Id.*

V. PATENT POOLS AND PRICE FIXING

A price fixing situation in the intellectual property area can often arise in the context of a patent pool.[37] The FTC consent agreement in the *Summit Technology* case provides a good example of this.[38] Here is a fundamental example in which the antitrust laws were applied to intellectual property in what was basically a price fixing arrangement. The Commission issued a complaint in 1998 challenging a patent pool that had been set up in 1992 by two companies, Summit and VISX, each of which claimed exclusive rights to technology for photorefractive keratectomy (PRK), which is laser eye surgery, and that equipment.[39] They were the only two with the patents necessary to market PRK equipment and they joined together in an agreement that basically said: "All right, we will license this and people can choose either your photorefractive keratectomy equipment, or our photorefractive keratectomy equipment."[40] I love antitrust because you learn about so many different products. But, in any event, they said, "all right, you can pick either one and then you pay the fee, and we will split it up between us."[41]

That scheme was not ideal from the FTC's perspective because, but for that patent pool, presumably each of them would have offered its own equipment and people could have chosen either on the basis of price or other aspects of quality.[42] Absent the agreement, there would have been competition. So the FTC put them under order. It was by consent, but they did put them under order.[43] The FTC order required royalty-free cross-licensing to approximate the competitive conditions that might have prevailed in the absence of the patent pool.[44]

Then the FTC continued with its case against VISX on a patent fraud theory.

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[37] *See* Mark A. Lemley, *Reconceiving Patents In The Age Of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 142-43 (2000) (discussing patent pools as a "new" use of patents).

[38] *See In re* Summit Tech., Inc., FTC Dkt. No. 9286, Final Consent Order as to Summit (Feb. 23, 1999), *available at* <http://www.ftc.gov/os/1999/9903/d09286summit.do.htm>; *In re* Summit Tech., Inc., FTC Dkt. No. 9286, Final Consent Order as to VISX (Feb. 23, 1999), *available at* <http://www.ftc.gov/os/1999/9903/d09286visx.do.htm>.

[39] *See In re* Summit Tech., Inc., FTC Dkt. No. 9286, Complaint ¶¶ 1-13 (Mar. 24, 1998) *available at* <http://www.ftc.gov/os/1998/9803/summit.cmp.htm>.

[40] *See id.* ¶¶ 8-13.

[41] *See id.* ¶ 12.

[42] *See id.* ¶¶ 25-30.

[43] *See In re* Summit Tech., Inc., FTC Dkt. No. 9286, Final Consent Order as to Summit (Aug. 21, 1998); *In re* Summit Tech., Inc., FTC Dkt. No. 9286, Final Consent Order as to VISX (Feb. 23, 1999).

[44] *See In re* Summit Tech., Inc., FTC Dkt. No. 9286, Final Consent Order as to Summit (Aug. 21, 1998); *In re* Summit Tech., Inc., FTC Dkt. No. 9286, Final Consent Order as to VISX (Feb. 23, 1999).

That case was actually tried before an ALJ, Administrative Law Judge, at the Federal Trade Commission. The judge said that that claim had simply not been established by the evidence – it was a matter of the evidence, an evidentiary ruling.[45] Administrative Law Judge Stewart Levin dismissed the complaint, holding that the complaining party failed to meet its burden by establishing clear and convincing evidence that the prior art was withheld with the intent to deceive.[46]

Those of you who studied intellectual property law know much more about prior art than I do, but it is interesting that an administrative agency charged with the enforcement of the antitrust law would get into this sort of thing. That is because it is thought that obtaining patents by fraud is anticompetitive. This is something that goes back to a very fundamental concept.

I would say, and I am just going to pause here now to talk very generally, that for antitrust law you could actually know everything you need to know about antitrust and intellectual property by remembering a few tests. First, consider whether the intellectual property was obtained in a proper manner, that is, it was not obtained by fraud or some sort of inequitable conduct. If the answer is no, then the antitrust laws may apply.[47] Second, consider whether the holder of the patent or other intellectual property right somehow expanded the scope of the intellectual property right. If not, and if the intellectual property was properly obtained, then there should be no need to apply antitrust law.[48]

Those are two very simple questions. If you can answer them, you may know everything you need to know about antitrust and intellectual property. Then why do we have so much trouble with it? Why do we have so many courses? Why are there so many cases? Why are there so many issues about antitrust and intellectual property law?

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[45] *See In re* VISX, FTC Dkt. No. 9286, Decision (June 4, 1999), *available at* <http://www.ftc.gov/os/1999/9906/index.htm#4>; *FTC Judge Dismisses Remaining Allegations in Complaint Against VISX*, June 4, 1999, *available at* <http://www.ftc.gov/opa/1999/9906/visx.htm>.

[46] *See In re* VISX, FTC Dkt. No. 9286, Decision (June 4, 1999), *available at* <http://www.ftc.gov/os/1999/9906/index.htm#4>; *FTC Judge Dismisses Remaining Allegations in Complaint Against VISX*, June 4, 1999, *available at* <http://www.ftc.gov/opa/1999/9906/visx.htm>.

[47] *See* Argus Chem. Corp. v. Fibre Glass-Evercoat Co., 812 F.2d 1381, 1386 (Fed. Cir. 1987) ("[T]o prevail in an antitrust claim based upon enforcement of an invalid or unenforceable patent, the litigant must establish that the patentee acted in bad faith in enforcing the patent because he knew that the patent was invalid."); SSP Agric. Equip., Inc. v. Orchard-Rite Ltd., 592 F.2d 1096, 1103-04 (9th Cir. 1979) ("[K]nowing and willful patent fraud is required to establish a violation of § 2 of the Sherman Act based on the use of an invalid patent to monopolize or attempt to monopolize a segment of the market.").

[48] *See* 6 CHISUM, *supra* note 12, § 19.04 ("A patent owner may exploit his patent in an improper manner [either] by violating the antitrust laws or extending the patent beyond its lawful scope.").

Part of it is because there are lots of ways in which companies or people can try to expand intellectual property beyond the scope of the initial grant. Part of the reason we have so many cases is because the nature of intellectual property is often difficult and complex. This leads us to a lurking third question which is whether the patent is valid. I will return to this question later in discussing two recent FTC cases involving patent litigation settlements. Patents tend to be highly technical. Most of us cannot just look at a patent for a few minutes and be able to conclude, "this is a valid patent." It is not even easy in many cases to ascertain what the scope of the patent is intended to be. These are difficult matters. So the principles, the very fundamental principles, are easy, but as we start trying to apply them it sometimes gets very difficult.

VI. THE "PENUMBRA" OF SECTION 5

I will not go into the *VISX* case any further, except to mention that it involved fraud in obtaining the patent at issue,[49] and another issue about alleged inequitable conduct under section 5.[50] The inequitable conduct claim is not what we usually see in a Sherman Act case. The allegation is under section 5 of the FTC Act.[51] I will just tell you a little bit about section 5 of the FTC Act. We are perhaps most familiar with cases brought under the Sherman Act sections 1 and 2.[52] Those, of course, are brought by the Department of Justice. The FTC has its own special statute, the Federal Trade Commission Act, and most of its cases are brought under section 5.[53] Section 5 includes conduct that is unlawful under sections 1 and 2 of the Sherman Act, under the Clayton Act,[54] and under the Robinson Patman Act, plus anything else the FTC thinks it covers. Now, I am overstating that to make a point because anything the FTC decides is unlawful can be appealed to a Court of Appeals, and so the FTC must justify it. But essentially, under section 5, if the agency believes that something is anticompetitive, but for one reason or another, it does not meet the standards for a Sherman Act violation or a Clayton Act violation, then the agency can find it unlawful under the broader authority of the FTC Act. I call that the "penumbra of section 5."[55]

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[49] *See In re* Summit Tech., Inc., FTC Dkt. No. 9286, Complaint ¶¶ 14-24 (Mar. 24, 1998) (referring to U.S. Patent No. 5,108,388 in the fraud and inequitable conduct charge against VISX), *available at* <http://www.ftc.gov/os/1998/9803/summit.cmp.htm>.

[50] *See id.* ¶¶ 29-30.

[51] 15 U.S.C. §§ 45 (1994).

[52] *Id.* §§ 1, 2.

[53] *See id.* § 45.

[54] 15 U.S.C. §§ 12-27 (1994 & Supp. IV 1999).

[55] *See* Mary L. Azcuenaga, Shimmers in the Penumbra of the Section 5 and Other News, Address Before the 13th Annual Antitrust and Trade Regulation Seminar National Economic Research Associates, Inc. (July 9, 1992), *available at* <http://www.ftc.gov/speeches/az1.htm>.

The penumbra of section 5, you will not be surprised to learn, is not used very often. But it is there, and it is something to keep in mind. Where something looks bad, the FTC senses it is bad, and it cannot really make a case under another statute, sometimes the Commission will then turn to section 5. But because, as I mentioned earlier antitrust can be counterintuitive, this authority should be used sparingly. It is very important as a policy matter, I think, for the FTC to be very careful in its use of the penumbra of section 5.

VII. INNOVATION MARKETS

Now I want to talk a little bit about another issue that has come up, the so-called "innovation market."[56] It is a rarity, and it comes up mostly in merger law, but it can also arise in other areas. Let me take a moment to define my terms. In many industries, particularly high technology industries, we can identify three types of competition. One is competition with respect to existing goods and services, and I will call these present products.[57] Competition in producing and selling these products is the subject of most antitrust analysis. The second is competition with respect to products that are not yet on the market, but are in research and development, are specifically identifiable, and therefore can be foreseen with reasonable certainty.[58] I call this competition in future products. Most of the merger complaints alleging research and development markets are in this category. Finally there is competition to develop products that have only been envisioned or perhaps not even that. I will call this competition in pure research.[59]

I want to give you some examples of innovation markets, sometimes called "research and development markets." Examples would come primarily from the drug and medical device industries. Most of these cases involve allegations of entities affecting the market for a drug, or rather, the development pipeline for drugs that have not yet reached the market.[60] Another aspect of these cases is that they seem to involve competition among only two or three firms.[61] The structure of the market is a key issue in antitrust law. If you get down to a few firms in a certain industry, people start to get concerned that antitrust issues might arise. In some of these cases, firms were close to bringing the product to

[56] *See* U.S. DEP'T OF JUSTICE & FTC, *supra* note 5, § 3.2.3.

[57] *See* William F. Baxter, *The Definition and Measurement of Market Power in Industries Characterized by Rapidly Developing and Changing Technologies*, 53 ANTITRUST L.J. 717, 717 (1984) (referring to "today's products").

[58] *See id.*

[59] *See id.* at 717-18 (referring to "tomorrow's products").

[60] *See, e.g.*, *In re* Baxter Int'l, Inc., 123 F.T.C. 904, 905-06 (1997); *In re* Ciba-Geigy, Ltd., 123 F.T.C. 842, 844-51 (1997); *In re* Upjohn, Co., 121 F.T.C. 44, 45-46 (1996); *In re* Glaxo PLC, 119 F.T.C. 815, 816 (1995); *In re* Roche Holdings, Ltd. 113 F.T.C. 1086, 1087-88 (1990).

[61] *See, e.g.*, *In re Baxter Int'l, Inc.*, 123 F.T.C. at 906.

market and acquired other firms that might be capable of entering the market or had products in the market already.[62]

In these cases, given the small number of firms involved, the prosecutors could be reasonably confident that the alleged markets were highly concentrated and that a large increase in concentration would result from the merger without having to calculate the level of and increase in market share and concentration, as needed in analyzing the markets for existing products. A careful focus on highly concentrated markets for specifically identifiable future products should help to allay the concern expressed by some commentators that predictions about effects on research and development cannot be inferred from market structure.[63] The competition among firms to be the first to bring to market an important future product, as I have defined the term, is important and may need to be preserved in a highly concentrated market.[64]

Although the relationship may not be well understood, there is some support for the theory that increased concentration in research and development alone can be harmful.[65] As we gain experience in this area, it is important to remember that a sound economic foundation is important to the credibility of antitrust enforcement and that there may still be difficult questions to be resolved. It is striking that almost every case involving a research and development market has been in the pharmaceutical or medical device industry. This fact is explained partly by the luck of the draw because there have been many mergers of pharmaceutical firms in recent years. But luck is only a small part of the equation. Certain characteristics make the pharmaceutical industry particularly likely both to entail research and development markets for specific, well defined future products and to provide evidence in support of such markets. The large investments by drug companies in research and development, the long development time before new drugs are approved for market, and the extensive submissions that must be made to the FDA to obtain such approval are factors that make it possible to identify and analyze future product markets in the pharmaceutical industry.

Some additional background provides a context for evaluating the allegations of research and development markets in the pharmaceutical industry. Spending on research and development by the U.S. pharmaceutical

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[62] *See, e.g.*, *In re Upjohn Co.*, 121 F.T.C. at 46; *In re Glaxo PLC*, 119 F.T.C. at 817.

[63] *See generally* Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 ANTITRUST L.J. 19, 26-33 (1995).

[64] The FTC and DOJ suggest that a market of five comparable competitors would ensure competition. *See* U.S. DEP'T OF JUSTICE & FTC, *supra* note 5, § 3.2.3.

[65] See, e.g., Richard J. Gilbert & Steven C. Sunshine, The Use of Innovation Markets: A Reply to Hay, Rapp, and Hoerner, 64 ANTITRUST L.J. 75, 76-78 (1995); Richard J. Gilbert & Steven C. Sunshine, Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets, 63 ANTITRUST L.J. 569, 574-81 (1995).

industry is enormous, and that is true worldwide as well, of course.[66] Mean total development time for new drug approval, including clinical trials and government review, has climbed to many years.[67] The large investment in new drug research suggests both that pharmaceutical firms are competing to develop new products and that competition in these future products markets will be important to the national economy. As firms get closer to the end of the process, the nature of the relevant markets and the extent of competition becomes more clear.

The pharmaceutical industry is unusual, if not unique, because promising new discoveries cannot be rushed to market. Instead, there are clinical trials and regulatory reviews designed to ensure the safety and efficacy of the new drug before it is allowed on the market.[68] As a proposed new drug moves further along the path of development, the likelihood that it will make it to market increases. Only about one in a thousand drugs screened in pre-clinical studies survives to clinical testing.[69] Of the drugs that enter clinical studies, during which the effect of the drug on humans is studied, only twenty percent ultimately are approved.[70] The drop out rate for proposed new drugs is particularly high in the early phases of the clinical studies. Sixty-seven percent of the new drugs that are eliminated from further development drop out between the start of the clinical trials (typically, testing for one year on non-patient volunteers) and the beginning of Phase III clinical studies (large scale testing for three years on patients).[71]

There have now been a number of innovation market cases. They all seem to fall within my second category – namely competition to develop new products that are not available but that can now be foreseen with a reasonable degree of certainty. The analysis in such cases is similar to merger analysis in

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[66] For example, since 1990, research-based companies have more than tripled their Research and Development expenditures. *See* PHARMACEUTICAL RESEARCHERS AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 2000: R&D—THE KEY TO INNOVATION (2000), *available at* <http://www.phrma.org/publications/publications/profile00/chap2.phtml>.

[67] "During the 1990s, the average length of time required to develop a drug increased to nearly 15 years." *See id.*

[68] *See*, PHARMACEUTICAL RESEARCHERS AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 2000: REGULATORY AND LEGAL ASPECTS OF DRUG DEVELOPMENT (2000) ("[T]he companies and FDA proceed extremely carefully and methodically to ensure that drug benefits outweigh any risks."), *available at* <http://www.phrma.org/publications/publications/profile00/chap3.phtml>.

[69] *See id.* Fig. 3-1.

[70] *See id.* Fig. 3-1.

[71] *See* Mary L. Azcuenaga, The Interaction of Antitrust and Intellectual Property: Adaptations, Aphorisms, and Advancing the Debate, Remarks Before the ALI/ABA Antitrust/Intellectual Property Claims in High Technology Markets (Jan. 25, 1996), *available at* <http://www.ftc.gov/speeches/azcuenaga/alis.htm>.

present product markets and, as many commentators have pointed out, has much in common with potential competition analysis.[72] In contrast, competition in pure research poses a different set of challenges and the government has not ventured far into that difficult terrain. Much of the criticism of research and development markets appears to be based on the inaccurate perception that the cases are challenging concentration in pure research among laboratories. But this is not usually the case. Usually they have involved a specific product, with a specific use that can be identified at the time of the merger.[73]

Analyzing a merger that involves a future product market is not fundamentally different from analyzing one that involves a market for existing products. In the pharmaceutical industry, again, for example, during the course of development and regulatory review, the participants in the market are companies that have announced product-specific research and development projects. In the cases the government has brought, only a small number of firms participated in the market, and other firms that were likely to have the same research capabilities lagged many years behind the market participants in the specific product markets at issue.[74] Under these circumstances, it is easy to understand what the market is and see that the market is highly concentrated. In contrast, it may be much more difficult even to identify who is doing pure research in a field. A chemist in another country may realize an incredible scientific breakthrough that could change an entire industry in the next ten years, and we may not yet know about it. But we can find out which products are working through the Food and Drug Administration's approval process for particular drugs.[75]

Whether innovation markets should play a role in antitrust analysis has been hotly debated. Certainly the concept has become more familiar and I expect we will hear more about it, particularly in the pharmaceutical industry. There have been cases in other industries, but they are few and far between.

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[72] *See generally* Mary L. Azcuenaga, *Mergers: A View From the Federal Trade Commission*, Remarks Before the Practicing Law Institute 25th Annual Advanced Antitrust Seminar (Mar. 15, 1995), *available at* <http://www.ftc.gov/speeches/azcuenaga/pli.htm>.

[73] *See, e.g.*, *In re* Hoechst AG, 1996 FTC Lexis 370, *3 (1996); *In re* Upjohn, Co., 121 F.T.C. 44, 46 (1996); *In re* Glaxo PLC, 119 F.T.C. 815, 816-17 (1995). *But see In re* Ciba-Geigy, Ltd., 123 F.T.C. 842, 844-46 (1997).

[74] *See, e.g.*, *In re* Baxter Int'l, 123 F.T.C. 904, 906 (1997); *In re* Ciba-Geigy, Ltd., 123 F.T.C. at 844-49; *In re* Upjohn, Co., 121 F.T.C. at 45-46; *In re* Glaxo PLC, 119 F.T.C. at 816-17; *In re* Roche Holdings, Ltd. 113 F.T.C. 1086, 1087-88 (1990).

[75] Drugs may not be introduced into interstate commerce without federal approval by application. *See* 21 U.S.C. § 355(a) (1994). The FDA is charged with evaluating such applications. *See* 21 U.S.C. § 355(c) (1994 & Supp. IV 1999).

VIII. MONOPOLIZATION

One of the main focal points in antitrust today is, of course, the *Microsoft* case.[76] That is how many people have come to know what antitrust is, other than price fixing and merger law. I am not going to talk about the *Microsoft* case to any great extent. I should and do disclose that my firm represents Microsoft in a number of class action lawsuits in California. Both the Assistant Attorney General and the lawyers who represent Microsoft in the government case have cautioned that one should not reach any conclusions about the case unless he or she knows the evidence. It has been my experience that everyone has an opinion on the *Microsoft* case, and most of those opinions are pretty strong. I have an opinion on the *Microsoft* case, and I am not here to tell you about that. But I would say, for the purposes of speaking about antitrust and intellectual property law, that cases like this are not as obvious as they may appear in the popular press. Some of the trials go on for many months. Antitrust law, for those of you who have not taken it, involves very specific conduct that has to be examined as well as extensive examination of the competitive context in which it occurs. Various elements must be established to make a case. The *Microsoft* case involves numerous factual, legal and procedural issues. I would join in the precaution that others have given before me to keep an open mind unless and until you have the opportunity to study it in detail. It is a case that will have long lasting impact in the antitrust world.

One of the theories in the *Microsoft* case is monopolization,[77] which is an important theory in the high tech industry. Let me segue from this to discuss monopolization and monopoly power more generally. The offense of monopolization under our law has two elements. First, the possession of monopoly power in the relevant market must involve "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident."[78] That is to say, you can have monopoly power; just having monopoly power itself is not a violation of the antitrust laws.

Second, a monopolization claim requires proof of deliberate conduct that could be characterized as predatory, anticompetitive or exclusionary.[79] In characterizing conduct as predatory, it is important to consider whether it has an adverse impact on consumers and not just on competing firms, and whether

[76] United States v. Microsoft Corp., 87 F. Supp. 2d 30, 35 (D.D.C. 2000), *appeal denied*, 121 S. Ct. 25, 25 (2000) (remanding the case to the U.S. Court of Appeals for the District of Columbia Circuit).

[77] *See Microsoft*, 87 F. Supp. 2d at 35 (stating the charge of illegal monopolization practice under the section 2 of the Sherman Act).

[78] United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1965).

[79] *See* Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456-57 (1993).

it has impaired competition in an unnecessarily restrictive way.[80] The legal offense of an attempt to monopolize requires proof that the defendant engaged in predatory or anticompetitive conduct with a specific intent to monopolize and with a dangerous probability of success.[81]

It may seem curious even to mention monopolization in connection with technologically driven, innovative markets because products in these markets change rapidly, and shares in some of these markets may shift rapidly as one firm's innovation supersedes another's. In an environment in which new, innovative products leap-frog over their predecessors, one monopolist may rapidly be displaced by another. Market share measurements over a period of time in such an industry could be markedly different from market share measurements at one instant in time.

As we all know, there are numerous examples of companies with large market shares in various high-tech industries whose conduct often comes under antitrust scrutiny once they attain a high market share. There are also numerous legal and economic theories about monopolization. For example, the significance of path dependency economic theories and theories of network effects have been debated extensively over the last several years.[82] Not only are people trying to innovate to create new inventions and get new intellectual property rights, but the government is trying to deal with new high-tech industries and is trying to innovate and develop its own new approaches to things. We can expect to see continued and vigorous debate in this area.

IX. ANTITRUST ISSUES IN THE SETTLEMENT OF PATENT LITIGATION

Now, I want to talk a little bit about some recent cases that the FTC has brought. They have involved, once again, the pharmaceutical industry. It is not just the pharmaceutical industry that has intellectual property issues, but there has been an interesting issue in the pharmaceutical industry involving branded pharmaceuticals and generic pharmaceuticals. Earlier this year, the FTC charged four pharmaceutical manufacturers with violations of section 5 of the FTC Act.[83] The branded drug manufacturers, of course, are the patent holders. They allegedly paid huge sums of money, millions and millions of dollars, to generic manufacturers to delay bringing products to market.[84] These

[80] *See* 3 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW § 650c (1996).

[81] *See id.* § 651a.

[82] *See generally* Daniel J. Gifford, *Java and Microsoft: How Does the Antitrust Story Unfold?*, 44 VILL. L. REV. 67, 90-96 (1999).

[83] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶¶ 40-43 (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/05/abbottgenevacomp.htm>; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶¶ 36-39 (Mar. 16, 2000), *available at* <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

[84] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶¶ 26, 27; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶¶ 23, 24.

agreements were reached during the course of patent litigation.[85]

One of the cases was settled, and that case was against Abbott Labs and Geneva Pharmaceuticals.[86] Abbott has a product, terazosin HCL, which is a drug used to treat hypertension and benign prostatic hyperplasia (enlarged prostate).[87] Obviously, an important drug. The other case was brought against Hoechst Marion Roussel, which is now Aventis Pharmaceuticals, over similar payments to a firm called Andrx not to market generic drugs that compete with Hoechst's Cardizem-CD, which is a diltiazem product that is taken daily to treat hypertension and chronic chest pain (angina).[88] The FTC viewed these payments, basically, as a payment in exchange for an agreement not to compete. And yet, they were in settlement of patent litigation.

Well, what do we know about the settlement of patent litigation and the antitrust laws? The Antitrust Guidelines for the Licensing of Intellectual Property talk about settlements, and they say "[s]ettlements involving a cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements."[89]

> "[However,] when such cross-licensing involves horizontal competitors . . . the Agencies will consider whether the effect of the settlement is to diminish competition among entities that would have been actual or likely potential competitors in the relevant market in the absence of the cross-license. In the absence of offsetting efficiencies, such settlements may be challenged as unlawful restraints on trade.[90]

This is really not cross-licensing, but it is settlement of patent litigation. We know that settlements can be pro-competitive. We know that there is lots of patent litigation out there, and settlements occur all the time. Sometimes they raise issues and here the settlements did not fare so well.

Once again in the pharmaceutical industry we have a special situation, in this case, something called the 1984 Hatch-Waxman Act.[91] It is a complex statute that in certain cases enables the manufacturer of a generic pharmaceutical to market a generic drug before the expiration of a patent relating to the brand name drug on which the generic is based and also to be

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[85] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶¶ 28, 29; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶¶ 24, 25.

[86] *See In re* Abbott Labs., Inc., FTC Dkt. No. C-3945, Decision and Order (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/05/c3945.do.htm>.

[87] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶ 10.

[88] *See In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶ 12.

[89] U.S. DEP'T OF JUSTICE & FTC, *supra* note 5, § 5.5.

[90] *Id.*

[91] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355, (1994).

protected from follow-on competition for 180 days.[92] This legislation was designed to reward those who challenge pharmaceutical patents as invalid or who promote similar products on the ground they do not infringe the patents.[93] In this context, the FTC said that payments of the nature involved in the *Abbott Laboratories* and *Hoechst* cases raise barriers to entry, which make it more difficult for new competition to come in.[94] Such agreements would delay entry for the first generic, or follow-on generic drugs.[95]

The two cases are similar. In each case, the generic manufacturer had sought FDA approval to manufacture the generic version of the branded product.[96] In each case the generic manufacturer was sued by the manufacturer of the branded drug for patent infringement.[97] These suits delayed the FDA approval process.[98] Under Hatch-Waxman, when patent infringement actions are filed by a holder of the patent, the FDA stays its approval to market the generic drug for thirty months or until the suit is resolved.[99]

The payments to the generic companies were payments for the promise not to market the generic until the lawsuits and all the appeals were over.[100] Even though Geneva, which is the generic manufacturer, prevailed in district court on summary judgment, it still did not start to market the product at that point because of the agreement.[101] Later on, after the FTC began to investigate them, the parties cancelled the agreement.[102] In reaching the settlement with Abbott and Geneva, an apparently important factor to the FTC was its

[92] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (Supp. IV 1999).

[93] *See* Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1063-66 (D.C. Cir. 1998); Mylan Pharms., Inc. v. Henney, 94 F. Supp. 2d 36, 40 (D.D.C. 2000). The legislative record suggests that Title I of the Hatch-Waxman Act (the relevant portion here) was intended to streamline the generic drug approval process. *See* H.R. REP. NO. 98-857, pt. 1, at 14-15 (1984).

[94] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶ 34 (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/05/abbottgenevacomp.htm>; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶ 29 (Mar. 16, 2000), *available at* <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

[95] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶ 36; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶ 30.

[96] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶ 16; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶¶ 17, 19-20.

[97] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶ 18; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶¶ 18-19.

[98] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶ 19; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶¶ 18-19.

[99] *See* 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. IV 1999).

[100] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶ 26; *In re* Hoechst Marion Roussel, Inc., FTC. Dkt. No. 9293, Complaint ¶ 23.

[101] *See In re* Abbott Labs., FTC Dkt. No. C-3945, Complaint ¶¶ 31-32.

[102] *See id.* ¶ 33.

conclusion that the agreement was not justified by any countervailing efficiency.[103] Now efficiency in antitrust law is not just an efficiency as we normally think of it in savings or dollars and cents, but it is also any justification, any valid justification, an economic justification, a business justification.[104] So the FTC said it saw no justification when it said it saw no countervailing efficiency.[105] The agreements imposed restraints, the FTC alleged, beyond what likely would have been available in a court ordered preliminary injunction.[106] The agreements prevented Geneva from relinquishing its exclusivity rights and prevented Geneva from developing and marketing non-infringing products.[107] Notice that the FTC is talking about going beyond the scope of the intellectual property rights. The Commission ultimately pointed out that the agreements are not approved by most of the courts.[108]

Let me pose a question: What if the patents of the branded drug companies are valid? What should be done in that situation? If the patents are invalid, the cases involve agreements not to compete, which are clear violations of the antitrust laws. These cases get complicated when the validity of the patents is unclear. That is why they often settle: they are settled to reduce a private risk. The question is: Is the reduction of a private risk an efficiency sufficient to offset liability? Apparently, in this case, the FTC said no. The consent agreement does not tell us a great deal about how the FTC analyzed the issue.[109]

Let me pose some questions about these cases. Do they necessarily assume the patents of the branded manufacturers are invalid? If not, should they? Should invalidity of the patents be an element of the case that must be pleaded and proved? If not, why hot?

In addition to enjoining agreements to give up Hatch-Waxman exclusivity

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[103] *See In re* Abbott Labs., Inc., FTC Dkt. No. C-3945, Agreement Containing Consent Order (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/03/abbottagreement.htm>; *In re* Geneva Pharms., Inc., FTC Dkt. No. C-3946, Agreement Containing Consent Order (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/03/genevaagre.htm>; FTC, *Analysis to Aid Public Comment*, Mar. 16, 2000, *available at* <http://www.ftc.gov/os/2000/03/genevaabbpttanalysis.htm>.

[104] *See* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY § 1.3a (2d ed. 1999).

[105] *See* FTC, *supra* note 103.

[106] *See id.*

[107] *See id.*

[108] *See id.*

[109] *See In re* Abbott Labs., Inc., FTC Dkt. No. C-3945, Agreement Containing Consent Order (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/03/abbottagreement.htm>; *In re* Geneva Pharms., Inc., FTC Dkt. No. C-3946, Agreement Containing Consent Order (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/03/genevaagre.htm>.

rights,[110] the remedy in the *Abbott* case requires that notice be given to the FTC in the event of certain interim settlements of patent litigation so the FTC can go in and present its views to the court.[111] Does this mean that the FTC would take a position on the validity of the patent or the merits of the infringement? The other case, the *Hoechst* case, is still ongoing.

What does this tell us about settlement of patent litigation and antitrust policy? Bill Baxter suggested in the early 1980s that the antitrust agencies should engage in routine review of patent litigation settlements.[112] Nothing was done at that point. Just a few years ago, then Assistant Attorney General Joel Klein proposed an expansion of the Hart-Scott-Rodino Premerger Notification Act to require that settlements of infringement suits be filed with the Department of Justice, and then the Department of Justice could either try to block the settlements on public interest grounds or step into the defendant's shoes and continue the litigation.[113] These are remarkable suggestions. They may be good ones, maybe not. The first question that comes to my mind is: where will the Department of Justice get resources to do this? The next question that comes to mind is: To what extent, if at all, should antitrust enforcers take positions on the validity of patents? Those of you who have studied patents know that it is not always that easy to figure out who is right and who is wrong in patent disputes.

I am not suggesting that these cases are not theoretically sound. They are theoretically sound – at least, they can be theoretically sound – but they are not easy. Unless the enforcement agencies know more about the validity of particular patents than the Patent and Trademark Office does, the cases run the risk of being counter productive.

The FTC staff weighed in on this issue last year, by filing a "Comment" with the FDA.[114] The staff suggested that the FDA require that patent

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[110] *See In re* Abbott Labs., Inc., FTC Dkt. No. C-3945, Decision and Order (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/05/c3945.do.htm>; *In re* Geneva Pharms., Inc., FTC Dkt. No. C-3946, Decision and Order (May 22, 2000), *available at* <http://www.ftc.gov/os/2000/05/c3946.do.htm>.

[111] *See In re* Abbott Labs., Inc., FTC Dkt. No. C-3945, Decision and Order (May 22, 2000); *In re* Geneva Pharms., Inc., FTC Dkt. No. C-3946, Decision and Order (May 22, 2000).

[112] *See* William J. Baer & David A. Balto, *New Myths and Old Realities: Recent Developments in Antitrust Enforcement*, 1999 COLUM. BUS. L. REV. 207, 256 ("[William Baxter] argued that a mechanism needs to be established to notify antitrust authorities whenever competitors settle significant patent disputes.").

[113] *See* Joel I. Klein, Cross Licensing and Antitrust Law, Address Before the American Intellectual Property Law Association (May 2, 1997), *available at* <http://www.usdoj.gov/atr/public/speeches/1123.htm>.

[114] *See generally* COMMENT OF THE STAFF OF THE BUREAU OF COMPETITION AND OF POLICY PLANNING OF THE FTC BEFORE THE FDA, *IN RE* 180-DAY GENERIC EXCLUSIVITY FOR ABBREVIATED NEW DRUG APPLICATIONS (Nov. 4, 1999), *available at*

litigation settlements between branded drug manufacturers and generic drug manufacturers be filed with the FDA and be made accessible to the FTC.[115] This is the same sort of idea that the Assistant Attorney General proposed: Make sure the files are where we can see them, and we can do something about them. It remains to be seen whether this would be a good use of enforcement resources. The proposal is similar to the Hart-Scott-Rodino Premerger Notification Program, where many mergers are pre-reported to the agencies, and only a tiny fraction are challenged.[116] Of course the question is not how many challenges would result but what the standard for challenge would be. Certainly it is a proposal that merits the attention of the intellectual property community.

X. OTHER NOTABLE CASES PENDING BEFORE THE COURTS

A. *Intergraph Corp. v. Intel Corp.*

There have been a couple of very important cases that I will mention briefly. A particularly important case, the *Intergraph-Intel* case, came down from the Federal Circuit about a year ago.[117] That case had numerous issues in the intellectual property area.[118] I commend it to you. If you are to read one case and only one case on antitrust and intellectual property law, that would be a good one. The case addresses the question of whether Intel was going beyond the scope of its intellectual property rights. The Federal Circuit dismissed the case.[119] There were various theories, ranging from essential facilities to monopoly leveraging, and all of those were rejected, one-by-one, by the Court of Appeals for the Federal Circuit.[120] Finally, the Federal Circuit rejected the plaintiff's argument that if you put them all together, that would constitute a

<http://www.fda.gov/ohrms/dockets/dailys/110899/c000059.pdf>.

[115] *See id.* at 12.

[116] For example, in 1999, the antitrust enforcement agencies received 4,642 filings, and only challenged 77 transactions. *See* FTC & U.S. DEP'T OF JUSTICE, ANNUAL REPORT TO CONGRESS: FISCAL YEAR 1999 at 2-3, *available at* <http://www.ftc.gov/os/2000/08/hsrreport1999.pdf>.

[117] Intergraph Corp. v. Intel Corp., 195 F.3d 1346 (Fed. Cir. 1999).

[118] In *Intergraph v. Intel*, Intel, the manufacturer of graphics workstations, sued Intel, maker of microprocessors used in workstations, for patent infringement and antitrust violations. *See id.* at 1349-51. Intergraph alleged, among other claims, that Intel used its intellectual property in restraint of trade. *See id.* at 1362-63.

[119] *See id.* at 1367 (holding that the plaintiff did not show a substantial likelihood of success in establishing that the defendant violated the antitrust laws).

[120] *See id.* at 1352-66 (rejecting theories of Intel as a monopolist, essential facility, unlawful leveraging, coercive reciprocity and tying, use of intellectual property to restrain trade, conspiracy and termination of non-disclosure agreements to restrain trade).

violation of the law.[121] That is what we often call the "monopoly broth" argument. If you cannot quite make a case on any one of a number of theories, we throw all the theories together and these "not quite" violations on various theories together amount to one violation.

This does not seem like a proper application of antitrust law and the Federal Circuit so held. A few months before the Federal Circuit ruled, the Federal Trade Commission reached a consent agreement with Intel and issued an order prohibiting the very same conduct at issue in *Intergraph.* The last time I checked, which was not long ago, the Federal Trade Commission had not revisited that order. The FTC has the authority sua sponte to reopen and vacate its order based on the *Intergraph* case. Interestingly, it has not done so.

B. *The* Xerox *Case*

I see I have gone almost to the length of my time here, so I will say that the *Xerox* case, which is currently pending on petition for Writ of Certiorari before the Supreme Court, could be one of the most important cases ahead.[122] The other thing I would say in terms of the issues that are important today is to watch the antitrust agencies very carefully. There are little signs that they think that antitrust law is more important that intellectual property. To the extent that that is true, it will influence the kinds of cases they bring, and it will influence the kinds of remedies that they will propose or impose. Ultimately it can, depending on how far they go, affect the entire incentive structure that has been developed over time in these two areas of the law.

Thank you.

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[121] *See id.* at 1366-67.

[122] CSU, L.L.C. v. Xerox Corp., 69 U.S.L.W. 3257, 3257 (U.S. Oct. 10, 2000); *In re* Independent Serv. Orgs. Antitrust Litig., 203 F.3d 1322 (Fed. Cir. 2000).

XI. QUESTION AND ANSWER SESSION

Clyde Vanel:

Thank you, Commissioner. We will open up the floor and have a short period of questions and answers. Also, we have refreshments to the right, and we will be having a reception upstairs on the Tenth Floor. The floor is open for any questions.

Audience: Professor Michael Meurer:

Ward Bowman wanted to go further than Klein and Baxter and suggested that it would be good competition policy to give the DOJ the authority to challenge the validity of any patent. The rationale is that successful invalidation of a patent is kind of a public good that you would expect would be under-provided by private parties. Apart from the issue of cost, I wonder what you think about a policy allowing the FTC or the DOJ Antitrust Division to challenge patents that are important, but of questionably validity?

Commissioner Azcuenaga:

Well, I think either it should be done all the way or it should not be done at all. The reason I say that is that obviously the scope of a patent, the grant of a patent, is very important to competition law in that it be done properly. I know there have been criticisms of the Patent and Trademark Office (PTO) and whether they have been granting patents that are too broad. A few years ago, the staff of the Federal Trade Commission filed an advocacy piece with the PTO saying the PTO should not grant patents that are overbroad. That is basically what it said. From both a competition perspective and from an intellectual property perspective, that is correct.

But who decides that? What I worry about is the antitrust agencies starting to do this on a case-by-case basis without actually getting into it to the extent that they need to in order to know the background for any particular patent. I think it is always easy to say, let's support follow-on inventions, for example, and try to decrease the scope of established patent rights so we can make things easier for follow-on inventors. Follow-on inventions can almost always provide new competition. New competition is good for consumers in the short term, but the whole system is set up to protect incentives in the long term. The pharmaceutical industry is a very good example of that because it costs so much to develop pharmaceuticals; a new drug takes very, very long to develop and is terribly expensive. I think the issue of whether patents are correctly granted in the first place is important to competition policy. It seems to me that the Patent Office is the first place to look to get the job done right. If there is a problem there, I guess as a matter of public policy, someone has to correct it, and maybe the competition agencies could, but they would have to replicate,

indeed, improve on the scientific and technical capabilities of the Patent Office. I guess I would prefer to see the Patent Office improve this process, if indeed there is a problem.