The Role of Innovation in Competitive Analysis

The Chair's Showcase Program, ABA Section of Antitrust Law Spring Meeting (March 31, 2005)[1]

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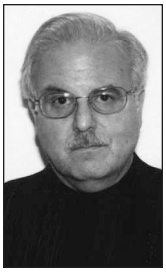

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RICH WALLIS: This program focuses on antitrust and intellectual property (IP)—where the rules intersect, where they diverge, and perhaps where the two disciplines lead to head-on collisions. We will discuss how to manage the "traffic" inherent in these two systems in an efficiency-enhancing manner to promote innovation and yet allow full and fair competition on the merits. This traffic management is a work in progress. The program will focus on the many ways the IP/antitrust interface manifests itself in our practices and in the real world.

We are very fortunate to have a highly talented and diverse panel to tackle the issues. We will explore the IP/antitrust interface, the role of innovation in merger analysis, standard setting, patent settlements in the pharmaceutical industry, and special issues relating to IP licensing.

Our panelists are: Carl Shapiro, the Transamerica Professor of Business Strategy at the Haas School of Business at the University of California at Berkeley. Carl is a Professor of Economics and the Director of the Institute of Business and Economic Research and a Senior Consultant at Charles River Associates. He is a frequent speaker and writer on IP licensing and standards issues and has testified in a number of cases, some of which we will talk about today. Next is Peter Plompen, Senior Vice President and the Competition Counsel for Royal Phillips Electronics of The Netherlands. Peter has broad antitrust experience in consumer electronics, semi-conductors, telecom, IP licensing, and standards organizations. Panelist Debra Valentine is Vice President,

[1] This program has been edited for publication.

Secretary to the Board of Directors, and Assistant General Counsel for United Technologies. She was previously a Partner and Co-Chair of O'Melveny & Myers' antitrust practice group. She had a highly regarded tenure as General Counsel of the Federal Trade Commission and currently serves as a Commissioner for the Antitrust Modernization Commission. Kent Bernard is Assistant General Counsel for Pfizer Inc. He has the lead responsibility at Pfizer for antitrust and competition issues worldwide, and has a huge job of helping to steer corporate, M&A, licensing, and litigation teams on their respective issues. Finally, we have Tim Muris, a long-time friend of and contributor to the Section. Tim has a distinguished record in public service, including a four-year term as Chairman of the Federal Trade Commission. Tim received uniform bipartisan praise for his work at the Commission. Tim is currently Co-Chair of the antitrust and competition practice group at O'Melveny & Myers.

We'll begin our discussion with the IP and antitrust interface. I'll start with Carl. It's been ten years since the IP Guidelines[2] were promulgated, and I would like your views on whether those Guidelines struck the right balance. Do those Guidelines reflect current practice at the agencies? Do they reflect current case law? And what has been the experience under the Guidelines?

CARL SHAPIRO: It was April 6, 1995, almost exactly ten years ago, when the IP Guidelines were issued. These Guidelines relate to the licensing of intellectual property. I liked them ten years ago and I still like them today. In fact, there are some principles articulated in the Guidelines that have become so accepted we don't even talk about them anymore, namely: (1) IP is comparable to other forms of property; (2) there is no presumption that intellectual property creates market power in the antitrust context; and (3) the licensing of IP is generally procompetitive and allows firms to combine complementary assets in ways that serve consumers. So we have a good, solid set of principles, including the principle that an owner of an intellectual property is not required to create competition in the use of his or her own property. Again, we rarely even talk about these things anymore because of the consensus that has grown around those principles.

Probably the key element that has generated the most controversy and will continue to do so is the benchmark that is used for evaluating licensing. The Guidelines say 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. So we compare competition given the license between the parties to competition as if there had been no license. Typically, that does not mean picking away, looking at less restrictive alternatives, and analyzing particular restrictions in the license. And that's a very important principle. I don't think the Europeans see it the same way, and I hope we'll have more discussion on that.

If I had to give some criticisms, they would be muted in comparison with my general view that the Guidelines have held up very well. For instance, the innovation market concept that's in the Guidelines does not appear to have been particularly successful in practice—a subject we're going to talk about later. There's nothing in there that says explicitly that the owner of intellectual property is not required to license that property to others, even if a refusal to license will lead to a monopoly. I think Hew Pate, currently the Assistant Attorney General for Antitrust,[3] would probably like it if such a statement were included in the Guidelines. That omission has caused some

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[2] U.S. Dep't of Justice & Federal Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property (1995), *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm.

[3] *Ed. Note:* R. Hewitt Pate resigned as AAG for Antitrust effective June 30, 2005.

lack of clarity. In addition, and this is not really much of a criticism if you think about conditions ten years ago, but the Guidelines show no real recognition that there are a lot of patents that, as the Federal Trade Commission and many scholars have found, are weak and questionable. The question of how patent weakness affects licensing has become very important. Indeed, this question is key in some of the more current hot topics, such as patent settlements—topics that would have been hard to anticipate ten years ago. Overall, I think that the agencies have followed the Guidelines; I would be curious to hear what the other panelists have to say about that.

Generally, yes, the Guidelines have imposed some discipline at the agencies. However, the case in which I personally felt they departed was the FTC case against Intel back in 1998 or so, in which I did work on behalf of Intel. In that case, I believe that Intel's cross-licensing practices clearly did promote competition in comparison with the lack of such licenses, yet the FTC challenged those licenses. Other people will have their own examples.

What's equally interesting is that in many ways the case law hasn't caught up with the Guidelines.

—Debra Valentine

RICH WALLIS: Tim, reactions? Do you feel as if the Guidelines initially struck the right balance, and are they in the right place now?

TIM MURIS: I think the Guidelines were a very important and sound development. Let me report what the FTC and Justice Department learned about the Guidelines at the hearings that we held on intellectual property. There was very little criticism of the Guidelines, a fact that I think reflects their sound nature. There was concern, however, about issues that were not covered. There was a request for guidance on standards setting and a few additional licensing issues. For industries such as semi-conductors and software, for example, cross-licensing is crucial, given the enormous number of patents that exist. There are some additional issues. We're going to have more to say about the standards and other issues later in this panel. When I left the FTC, the agencies were working on a second IP report, in addition to the one that Carl mentioned that the FTC issued about patents.[4] A lot of good work has been done there, and I hope they finish that project.

RICH WALLIS: Debra, any thoughts on this?

DEBRA VALENTINE: I think what's interesting is the consistency that you're hearing among the panelists that the Guidelines' three major principles—(1) IP is like other property; (2) licensing is procompetitive; and (3) patents don't necessarily confer market power—are correct. I agree that the Guidelines got it right.

What's equally interesting is that in many ways the case law hasn't caught up with the Guidelines. There remain cases from the 1980s, such as *SCM v. Xerox*[5] in the Second Circuit, which held that the patent laws precluded imposing antitrust liability on Xerox for acquiring multiple patents because a relevant market embodying the patented inventions had not yet emerged. In contrast, the Guidelines talk about technology markets and innovation markets where patents can convey market power depending on the facts involved. And while the Guidelines don't apply to merger analysis, certainly the cases that the FTC has been bringing in the pharmaceutical area are not in alignment with the old concept that you can't have a legal violation when there is not yet

[4] To Promote Innovation: The Proper Balance of Competition and Patent Law Policy, A Report by the Federal Trade Comm'n (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

[5] SCM Corp. v. Xerox Corp., 645 F.2d 1195 (2d Cir. 1981).

a product embodying the technology on the market. Further, one of the issues that we've all agreed on—that IP does not necessarily confer market power, but that it all depends on the context—is something with which the courts still haven't caught up. An example is the recent decision from the Court of Appeals for the Federal Circuit in *Independent Ink*,[6] which involved the tying of patented ink jet printing systems to the ink, and reflexively accepted that the patented printing systems conferred market power. The decision reads as if the court is begging the Supreme Court to look at this issue of market power in much the same way that Judge Posner begged the Supreme Court to look at maximum resale price maintenance in his *Khan* decision.[7] To a Guidelines' follower, it is quite extraordinary that we continue to see case law holding that patents automatically confer market power.

One last interesting point is that there are slight differences in the way that the agencies, the federal courts, and the Court of Appeals for the Federal Circuit (CAFC) are developing IP/antitrust principles. For example, in the *CSU v. Xerox*[8] case—where the government filed a brief after CSU had petitioned for certiorari—one observes the federal agencies resisting the three little rigid categories that the CAFC postulated as the only situations in which an IP holder might have to license. Another example is the recent *Telecom Technical v. Rolm Co.*[9] case, where the Eleventh Circuit makes clear that the CAFC's *CSU v. Xerox* case is neither binding nor preemptive, but is merely persuasive. So we may be seeing some divergences and disagreements in the courts over the next couple of years.

RICH WALLIS: Peter, let's turn to the EU. We've been talking about U.S. Guidelines for IP, and the EU has its block exemption rules. How do they work and do they differ materially from the U.S. IP Guidelines? What do U.S. practitioners advising clients with European businesses need to know about the block exemption?

PETER PLOMPEN: Any system of law enforcement, and especially one involving intellectual property and antitrust, should be seen against the background of the general regulatory structure in which it is being enforced. Europe, as you may know, is not a federal state, but rather a cooperative effort among many European countries. The European Union's competition laws are virtually the only laws that are more or less federal in nature. This has increasingly been true since the modernization effort that took place last year. It is now well-established that European competition law must be taken in account when applying national competition laws of the individual Member States, perhaps even more than individual states in the United States must take federal antitrust laws into account. European law is applicable in Europe where there is an effect on interstate trade within the European Union. Europe is indeed about integration of the economies of all countries belonging to the European Union, and as a consequence, the integration goal is still one of the goals of European competition law. This still has consequences in the application of competition law. Another important factor, different from the U.S., is that in Europe, patents are still national, and not continental. These factors explain why, for instance, in the area of intellectual

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[6] Indep. Ink, Inc. v. Illinois Tool Works, Inc., 396 F.3d 1342 (Fed. Cir. 2005), *cert. granted*, 125 S.Ct. 2937 (2005).

[7] Khan v. State Oil Co., 93 F.3d 1358 (7th Cir. 1996), *vacated*, 522 U.S. 3 (1997).

[8] *In re* Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322 (Fed. Cir. 2000), *cert. denied sub nom.* CSU, L.L.C. v. Xerox Corp., 531 U.S. 1143 (2001).

[9] Telecom Tech. Servs. Inc. v. Rolm Co., 388 F.3d 820 (11th Cir. 2004).

property, enforcement activities have always been very much focused on combating licensing conditions that would re-erect barriers to intra-European trade. That explains, perhaps, the stronger focus on intra-technology restrictions in comparison to the situation in the U.S.

The new block exemption regulation on transfer of technology (the TTBER) came about in April 2004.[10] In certain ways, it is an enormous improvement over the older regime, but in other ways it is not. It is an improvement in that it now clearly sets forth a limited list of specific contractual provisions referred to as "hardcore restrictions," the presence of which in an agreement will cause that agreement to fall outside of the protections of the TTBER. Another improvement is that agreements that fall outside of the TTBER may still be covered by an exemption under Article 81(3) of the European Treaty as long as there is no clear situation of "abuse of dominant position." However, the market share thresholds for the application of the TTBER are problematic in the context of intellectual property and intellectual property licensing, given that parties will be deemed to exceed these thresholds and thereby fall outside the protections of the TTBER. Parties falling within the TTBER are free from harassment in any court in Europe and by any competition authority in Europe. In addition, the new Transfer of Technology Guidelines (the TTG) have a modern economic approach to topics not covered by the TTBER, like patent pools and settlements. Although present, this modern economic approach is not reflected to the same level in the 2000/2001 Guidelines of the Commission relating to vertical and horizontal agreements.

DEBRA VALENTINE: I would like to make one quick comment to put Peter's observation in context within U.S. law. Much like the Vertical Restraint Guidelines the EC released a while ago, these EU Technology Transfer Guidelines move very far toward a U.S.-like rule of reason, grounded in pro- and anticompetitive balancing, and an economically based approach—a very good move in general. Peter is right that once licensing agreements fall outside the 20 percent safe harbor for competitors, or the 30 percent safe harbor for (vertically related) noncompetitors, you have to worry. But the critical point here is that the agreement is not condemned; instead, the analysis progresses to a balancing test as to whether the procompetitive effects outweigh the anticompetitive effects. Finally, one last interesting provision is the safe harbor for all technology markets involving four or more independently controlled technologies. These guidelines sound very similar to those of the U.S., and have moved a long way.

CARL SHAPIRO: Let me focus on where I think there's a real difference between the U.S. and EU. Take a field-of-use or a customer-type restriction. Suppose that I have a great patent that I want to license and I have decided to issue a license to Debra that is only for a certain country or only for a certain type of product using my technology. Now in the U.S., at least under our IP Guidelines, I am clearly adding to competition. Debra would not be allowed to compete without this license so there shouldn't be an issue there. But as I understand the EU Guidelines regarding this restraint, to justify such a restraint—let's say a territorial restraint—it has to be objectively necessary for the existence of the agreement of this type. Evidently, it is not going to be enough for my documents to say "I really need this restriction in order to make this license work for me as a business matter." Instead, it seems that the EU will need to be convinced that in this general type of situation (using some comparison set), licenses will not be achieved without these types of

[10] Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements, 2004 O.J. (C 101) 2, *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_123/l_12320040427en00110017.pdf.

restrictions. That's quite a hurdle as well as a business risk for the patent holder. Am I getting it right? And how do you justify that? Or maybe the European Commission wants to force me to create competition in the use of my own technology? Is that a different principle?

PETER PLOMPEN: Well, the Guidelines are very difficult to read.

Field of use restrictions are normally covered by the TTBER, even if reciprocal between competitors, as long as the restrictions are not a sham cartel as defined by the TTBER. ("Reciprocal license" is European parlance meaning "a license agreement between two parties which cross-license competing technologies.") Only if the cross-license is exclusive or sole, meaning that each licensor is also limited in the exploitation of its own licensed-out technology and not only as to the licensed-in technology, reciprocal fields of use are "hard core" and outside the TTBER. If, on the other hand, there is a field of use restriction in a unilateral licensor/licensee relationship (even if exclusive) or a nonexclusive cross-licensing situation (even if reciprocal), then normally there wouldn't be a problem at all and that arrangement would be covered by the TTBER. Only agreements outside the TTBER require an individual assessment of the license, and a showing that the restriction concerned does not have sufficient negative effects to outweigh the procompetitive effects. In that context, it is important that the Guidelines specifically recognize that anticompetitive effects can only occur regarding competition that would have existed in the absence of the agreement including the restraints concerned. So from our perspective at least, the final outcome of the discussions with respect to field of use was very positive because you're quite right that in earlier drafts of the TTBER, most field of use restrictions fell outside the block exemption.

RICH WALLIS: The complicating issue is that while there is some convergence on Guidelines, the lack of convergence on patent policy creates special problems.

PETER PLOMPEN: Perhaps I can explain that also. In the European Treaty, there is a rule that says there is free circulation of goods within Europe. There is an exemption for patent or IP situations, but through the impact of competition law, there has been a modification of that in the sense that you can only invoke your national intellectual property right against a licensee in another country who is directly putting products in your country's market. If a product has been patented in one country within Europe, as soon as a licensee in another country within Europe has put that product on the market in another European country, the latter country's laws cannot be used anymore to stop the circulation of goods in the country in which the product was patented. Furthermore, because there still is no Europe-wide patent, but only national licenses that could run counter to the economic integration goal of European competition law, there are special rules in European competition law with respect to passive and active imports in other countries by licensees. That's still a typical European situation, although within the Guidelines, there is also a modification: the Commission acknowledges that the European market, to a vast extent, has already been integrated and therefore the consequence of these territorial restrictions on competition may be less than they have been in the past.

RICH WALLIS: Let's shift the discussion to patent pools. Peter, your company was one of the first, if not the first, to create a number of patent pools. How does one deal with the differences between the U.S. and EU models in the treatment of global patent pools, particularly in the way they distinguish between insiders and outsiders. My understanding is that under the EU Guidelines, the treatment of licensees does not depend on whether they are licensors or not. But in the U.S., the

district courts have ruled that differential treatment based on status as a licensor is permissible.

PETER PLOMPEN: Patent pools are the subject of a special chapter in the new TTG, and that is a big benefit because in the past we only had to work on the basis of so-called "comfort letters" in Europe, which were informal messages from the Commission to the parties involved about the way the Commission intended to enforce competition law with respect to a certain project. More often than not, third parties did not have access to the contents of those "comfort letters," and only saw a summary of the notification of a certain plan to the Commission without any changes made to allow the Commission to issue its comfort letter. This was quite different from the business review letters which have been given in the U.S. where you have a clear exposé of the relevant facts and the reasoning of the authorities involved.

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—Peter Plompen

Recently, as I already mentioned, a special chapter regarding patent pools has been inserted in the new Guidelines. The way that it is being done, to a large extent, is in conformity with the business review letters over here. Generally speaking, I would say that the rules in Europe and the U.S. are more or less similar with respect to the specific point that you mentioned—the insider/outsider question. I get the feeling that perhaps also this issue originates in the cloudy text of the Guidelines. The TTG explain that if a patent pool includes nonessential patents, the Commission would take into account certain factors when assessing whether such a pool should be allowed or prohibited. One of those factors is whether or not the licensors themselves are also subject to royalty obligations, so that there is not a sort of inner circle of people that does not pay and a circle of outsiders that has to pay. This factor is mentioned only in discussing the situation where the patent pool has a dominant position on the market. I cannot imagine, in view of other language in the Guidelines, that this is meant to exclude cross-licensing agreements as a basis for patent pools. Cross-licensing agreements are recognized in other parts of the Guidelines as sufficient and acceptable in order to allow design freedom to the parties involved. So I would think in Europe the situation is similar to that in the U.S., where one could also act against sham cross-licensing agreements. If there is a real cross-licensing agreement with a real balancing of the interests, I don't think that there is a different situation in Europe than in the U.S.

RICH WALLIS: That's a helpful clarification. Tim, let's talk about the role of innovation in merger analysis and start with a very broad question to you, and maybe get Kent's view on it as well. What impact should innovation and innovation markets have on the analysis of a merger?

TIM MURIS: One would think that we ought to care about diminution in competition in any dimension where it occurs—and that includes innovation. But with innovation we have to proceed very cautiously. Unlike product markets, the relevant economic literature doesn't point to a clear resolution. Let me read a conclusion that I think is relevant today from the FTC's 1996 global competition report on which Debra worked: "economic theory and empirical investigations have not established a general causal relationship between innovation and competition."[11] In fact, the strongest conclusion that they could reach was "[n]o witness maintained that a merger of the only two firms developing a totally new product could *never* have any anticompetitive effects on innovation."[12] This certainly is a weaker conclusion than we would make on product markets.

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[11] Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace, A Report of the Federal Trade Comm'n Staff 16 (May 1996), *available at* http://www.ftc.gov/opp/global/report/gc_v1.pdf [FTC Staff Report]

[12] *Id.* at 16 n.51.

DEBRA VALENTINE: There are also portions of that report that note that virtually all of the business people maintained that competition did drive them to innovate—that they really wanted to be first to market. But I accept your point.

TIM MURIS: My conduct as Chairman indicated that in certain areas there are problems in innovation. That's why we paid attention to pharmaceuticals. Important innovation exists, which I think supports your point. But it also supports the point that there's not a big role for antitrust, in that many innovation situations, probably most, have several players and there is easy entry. Those are cases to which antitrust shouldn't and doesn't pay a lot of attention. In the new drug approval process, however, you have decided differences. There are entry impediments, and in the late stages you often have just a few players. That's the one area that antitrust has focused on, and there it seems highly appropriate to consider reductions in the number of competitors. I don't think you can generalize from that area, however. Finally, even though I think the drug approval area is perfectly appropriate for government intervention, and even though I personally think that the FTC has been appropriately cautious, I understand that the Regulated might have a less sanguine view than the Regulators.

If there's a market for innovation—and you can read **SCM v. Xerox** *as saying that there really shouldn't be for antitrust purposes—it's a little hard to see how you can monopolize it.*

—KENT BERNARD

RICH WALLIS: Kent, I know you have some passion about this issue.

KENT BERNARD: Speaking on behalf of the oppressed minority, our view (my view) of innovation market analysis is that it doesn't deal with innovation, it doesn't deal with markets, and it's never been really useful. If you look at the history of this, innovation markets were created out of a case from 1993, involving truck transmissions in which you didn't need innovation markets at all to get the conclusion.[13] The conclusion was the merger of two companies, the only two companies in the world that made these heavy duty truck transmissions, where it cost a lot of money to get the tooling made and everything else was a problem. You don't need any sophisticated analysis for that one.

If there's a market for innovation—and you can read *SCM v. Xerox* as saying that there really shouldn't be for antitrust purposes—it's a little hard to see how you can monopolize it. I mean, with all due respect to my colleagues, unless I go out and hire all the scientists in the world, I don't know how I'm going to monopolize the market for scientific research. I can hire 50 of the best cancer specialists in the world, but there are 500 more that are going to work for somebody else.

So once you get to innovation market analysis, you try to say "where are we?" When you look at it, you see that the supposed "analysis" is completely off the scale in terms of any other market analysis that is done. For example, normally you would look to see how long it will be until a product comes to market—one year, perhaps two years. If you look at what they've done in the pharmaceutical industry, they've gone back 7 or 10 years before a compound would ever be on a market, if indeed it ever got there at all (the attrition rate is very high). We're getting predictions as to what will happen in seven years with $400 million of research. Based on that, on day one we're saying you have to divest this or some other project will or won't happen. It assumes that you have a better crystal ball than any of the researchers doing the work. That's a little odd. But on "innovation markets," you're really going back a heck of a ways.

[13] United States v. General Motors Corp., Civ. No. 93-530 (D. Del. filed Nov. 16, 1993) DOJ Case 4027, 6 Trade Reg. Rep. (CCH) ¶ 45,093.

TIM MURIS: The FTC has studied this industry as much as any. Even in Phase 1 of clinical trials on average there is a quarter probability a drug is going to succeed. Thus, if you have two people pursuing different approaches to a particular problem and you ignore it, in one out of four cases, if it's a 2 to 1, you will have eliminated competition. Given the entry impediments in the FDA process and given small numbers, there is perfect sense in FTC intervention.

KENT BERNARD: I think that Tim's percentages are high, but the problem there is that you define the rabbit into the hat. What we see is the approach to the problem, which gets defined very, very narrowly, so that, instead of saying there are ten different ways you can treat this medical condition, and there are many people and companies working on it, they say, "No, we will define each way as a market for innovation purposes." At which point you have put the rabbit into the hat. You've said, "Well, there are only going to be these three people playing in this field," when the answer is, if in fact this ever works (and one of the reasons you see that much attrition and you see few players is that it's a high risk "generally-you-fail" proposition—the odds in Phases I and II are not favorable at all). And then you go on to say, "Okay, it's only you and somebody else, and furthermore we think this one approach will succeed, and furthermore if it succeeds, patients would be better served having two people competing here." You know, there are a lot of "and ifs" that go into that. We normally don't have the government deciding which independent research initiatives will succeed or fail.

[I]f you look at what happens with successful drugs, it's very hard to find a better example of where you have significant downward-sloping demand that justifies very narrow product markets.

—*Tim Muris*

TIM MURIS: Sure. But the question you're raising in an antitrust sense is whether it is appropriate to define markets narrowly. Again, if you look at what happens with successful drugs, it's very hard to find a better example of where you have significant downward-sloping demand that justifies very narrow product markets.

KENT BERNARD: With all due respect, no.

TIM MURIS: But look at what happens when a generic enters.

KENT BERNARD: That's a whole other question, and we'll get to it in a moment. If you're dealing for the moment with somebody who is competing in the field of hypertension, which is a nice broad field, there are about ten different ways to attack that. Once you have products on the market, you can then say, "Okay, these groups compete primarily with these—beta blockers with beta blockers, diuretics with diuretics"—but to say at the start that there is only one way we're going to look at treating hypertension is a little odd.

RICH WALLIS: Tim, you will have the last word on this one.

TIM MURIS: One of the nice things from your perspective is obviously the courts get the last word and we'll talk about that later. I would be surprised—in fact I would be shocked—if there weren't FTC innovation cases in which I might have come out differently. Obviously, there are many close calls in these cases. The reason I made the point about generics is because when a generic enters, the price plummets, which is very strong proof that other drugs, even though they're substitutes, don't have the kind of constraining effect that we would like them to have. Therefore, I think it's appropriate to worry in small number cases the way the government has.

RICH WALLIS: Carl and Debra, I would like your views on that. To what extent do the agencies factor in innovation as part of the analysis of dealing with high market shares? Is it enough that markets are evolving rapidly so that traditional concentration measures are less important?

DEBRA VALENTINE: Let me address that more broadly than just innovation markets. Obviously, parties often come to the agencies and say, "Look, change is happening so rapidly in this market that you shouldn't worry about this merger." And it's very, very true that the agencies and the Guidelines themselves take innovation into account in myriad ways in defining product markets. One can look at whether a buyer shifts purchases based on features like product quality or product features that are important competitive variables in a market undergoing a lot of innovation. The *General Dynamics*[14] principles are captured in Section 1.52 of the Guidelines, pursuant to which the agencies consider whether reasonably predictable or ongoing changes in the market conditions should affect how to interpret market concentration and market share data.

I agree that Debra is posing the key question: "Are there predictable effects in future goods markets."

—Carl Shapiro

I think there are lots of ways that the agencies think about innovation. But at the end of the day you always return to the simple question: "Given what the facts are, given what we know, what is reasonably predictable, what is the reasonably foreseeable effect of this transaction on competition?" It is really a question of reasonable foreseeability. Thus, if an innovation is on the very near horizon and is going to displace and disrupt the relevant market within two years, there's not a very solid basis for enforcement action in that case. On the other hand, if a party simply claims that there is a brilliant Schumpeterian theory of innovation, demonstrating that all market power will be eroded over time, that's not a reasonable basis for allowing a merger in a highly concentrated market where no likely entry exists within the foreseeable future. Michael Porter said something very thoughtful in this respect—if one simply relies on Schumpeterian theory then one will dramatically underestimate the time between monopoly displacing occurrences, even in high-tech markets. I think that's true, and I think you've got to be alert to that. On the other hand, if a market is very dynamic, an agency should require increasing certainty as to likely anticompetitive effects before intervening. If you're uncertain, that's an appropriate time to hold your hand. The one exception to that would be a tipping market, in which case an agency may well want to intervene early.

CARL SHAPIRO: Instead of focusing on the buzz word of "innovation markets," I would like to bring the discussion back to potential competition. I think the part we can agree on ultimately is that we care about what's going to happen in real markets where products are sold. To some extent the innovation market concept is kind of a sleight of hand: We'll say there's a market now because people are spending money on R&D, and then if we have concentration there, then the government has a case. Obviously, this is going to make it easier for the government to bring cases. But I agree that Debra is posing the key question: "Are there predictable effects in future goods markets." Part of your comment asks: "Even if all the people pursuing this line of research were to merge would they have any power to slow down innovation or raise prices, given that they have to compete against other products?" That's a fair question. But it may be hard to tell, if the future competition is years away and involves products whose attributes are not yet fully defined. It is not a coincidence these issues have come up in the FDA context where we tend to know who the players are years in advance. In many other sectors of the economy there is greater uncertainty

[14] United States v. Gen. Dynamics Corp., 415 U.S. 486 (1974).

about who is currently doing relevant R&D, the likely timing of those projects, or who is going to enter surprisingly from some other market. If we cannot accurately identify the most relevant current lines of innovation and say something about their likely timing and success, it is harder to build a strong case based on loss of innovation and subsequent loss of future product market competition as distinct from the loss of current and imminent product market competition.

RICH WALLIS: So what time horizon is appropriate, Carl?

CARL SHAPIRO: The easy answer is that the time horizon depends on the industry. If we are talking about a weapons system for the Defense Department, DOD is likely to say: "We plan to introduce this weapons system in eight to ten years, and we're trying to make sure that multiple contractors have the necessary capabilities over that time frame." The time horizon can be very long in this setting. In the pharmaceutical case, the horizon may be three to five years depending on which phase of the research process the players are in. More generally, the principle is that you should go as far out in time as the industry participants do in their own planning. If the government can't or won't look as far out as the industry does, the incentive then is for the players to consolidate, and reduce competition, when those effects are within the planning horizon of the companies but not the government.

DEBRA VALENTINE: I'm actually glad you mentioned the DOD. I believe that Kent is right where the activities involve pure innovation, R&D—where it's totally unpredictable what will develop. One might think there are two innovating firms, but there might be 200, and if two parties merged you wouldn't know who was left. In contrast, I think that in pharmaceuticals and defense, where you have government review, government oversight, and government involvement, the agencies know far more about who has capabilities and how many years are required before products are brought to market.

KENT BERNARD: Can I make one suggestion? We don't want to get any closer to government planning of innovation and you're coming awfully close to that when you're suggesting that five or seven years out you can predict which approaches will work. The only problem with looking at the planning cycle of the company is that if you know that you're looking at ten years from "eureka" to what you hope is the end of the product, you're going to plan and you're going to track early. The attrition rate is going to be phenomenal but you're going to do it.

I think the thing that's getting lost here, and it has to just by virtue of the size of the group, is that this analysis will differ depending upon the facts you're actually looking at. If you're looking at something where everybody knows what the condition is and how to cure it and only two people are working on the pill, then maybe you can do these kinds of things. But if you're looking at some of the emerging disease states—various cancers and things—nobody's quite sure how they happen, or how they work. You've got a lot of very informed speculation running around doing different things. That's when it becomes, in my view, dangerous from a competition regulation standpoint to decide five years out which approach is going to work and then make sure that we have various people pursuing that one narrow approach.

TIM MURIS: This is more than informed speculation. You can see in your company and other companies' documents who they think they are competing with, particularly in the later phases.

KENT BERNARD: Different issue. I'm not saying whom I compete with. I'm saying if my approach is to do X to kill cancer, that may not be the best approach to do it. I may think there are three other people doing that approach. I will also know there are seven other people doing these other approaches and they may be right and we may be wrong.

CARL SHAPIRO Ultimately down the road that may be true in some situations. Clearly, it is a relevant issue, depending upon the fact pattern in a given case. For example, consider Phase 3: my understanding is that drugs in Phase 3 have a 70 percent probability of being successfully introduced. I have seen company documents that essentially say, "We're in a race with Company X." If two companies that are racing in Phase 3 seek to merge, I would certainly hope and expect that the government would look at that very carefully. I think you will have to show, using documents from the ordinary course of business, or some other convincing evidence, that within some relevant time period that the government would worry about, that these other seven approaches are going to be relevant. In the Phase 3 case I think that's highly unlikely to be true.

KENT BERNARD: Let me give you the contrary view to that since I'm surrounded by FTC people—or people who at some point in their life were FTC people. And that is this: You're saying that you will know what's going on, where they are coming down to. In fact, in many cases, you will be there saying "I've got a concept," or "I'm putting something in it," but you're working on a slightly different concept toward the same thing. I would just make the point (and then I'll let you explain *Genzyme*[15]) that there are times when combining the research programs in fact leads to more resources being put behind them. That's because, if you've got one compound (and I'm going to get fact specific here but not refer to a particular Pfizer compound) and that compound's very effective, but very toxic, in a particular approach, and you've got another compound that is less effective, but less toxic, then if I combine those two research programs, I may find a way around the toxicity problem for mine or a way around the effectiveness of this problem for yours, which I would not have had any chance of finding if you're independent and I'm independent. Combining them may lead to a product which can actually help cure cancer rather than end up with two programs, neither of which will accomplish the goal. That's the only point I was making.

RICH WALLIS: That leads me to the final question in the area, Tim, and it's for you. Are there times that you see a reduction in R&D as an efficiency rather than a competitive effect? If so, in what circumstances do you see that happening?

TIM MURIS: Again, there's no theoretical or empirical consensus on when a reduction in the number of innovators makes a difference. Debra's report,[16] which I've tried to defend, makes that point. A merger can lead to greater efficiency and innovation. Look at pharmaceuticals. The FTC's evidence—there's a caveat I'll get to—suggests that larger firms are more efficient and that larger firms are better at producing successful drugs. The caveat is that this evidence has been developed during a period of mergers, and it's impossible to exclude the explanation (although I think

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[15] FTC File No. 0210026, Closing of the Investigation of Genzyme Corp. Acquisition of Novazyme Pharm., Inc., *available at* http://www.ftc.gov/opa/2004/01/genzyme.

[16] *See* FTC Staff Report, *supra* note 11.

it's probably not the right explanation) that firms are merging to improve their product pipeline. If that's true, then the successful drugs cause large firms and not vice versa. The nature of economic analysis is it's impossible to exclude that explanation. But I think the evidence points much more to the conclusion that large firms are better with innovation. I made this point in front of several senators once and got attacked for it, but there's no other industry where the reality of the good the pharmaceutical industry does for society is at such variance with the public's perception of the industry. Maybe people like to turn on winners, I don't know. Problems can exist, but a government monopsony as some have suggested in the Medicare program would be a disaster for future consumers and for the future health of America. Again, with the drug industry some competitive problems do exist.

RICH WALLIS: Let's shift the discussion to standard setting. Carl, you testified in the Unocal case. Can you describe the economic issues in *Rambus*[17] and *Unocal*?[18]

CARL SHAPIRO: Let me just give a very quick précis of the *Unocal* case, which is right now awaiting a decision from the Administrative Law Judge. I testified on behalf of complaint counsel. The allegation is that Unocal willfully deceived the California Air Resources Board (CARB) back in the early '90s when they were setting the rules for reformulated gasoline. In particular, complaint counsel alleges that Unocal initially represented that its technology would be available on a nonproprietary basis and then later, after the regulations were in place, and Unocal received a number of patents covering its technology, Unocal sought significant royalties. Hundreds of millions of dollars are at stake, because in the intervening time, the refiners in California spent billions of dollars to invest and comply with these reformulated gasoline regulations.

So the economic issue in the case (there are many other interesting legal issues, including *Noerr Pennington* issues that I will not address) is one of opportunism. Suppose that a company participates in a standard-setting process, misleads others in that process, and then later attempts to enforce intellectual property rights that are essential for that standard. Does that company have market power? Is such behavior anticompetitive? The *Unocal* case, in fact, seems pretty straightforward to me if CARB and the other refiners really were deceived as claimed. There is no business justification for lying, no efficiency associated with deceptive conduct. Plus, refiners made these huge investments to comply with the regulations that clearly put Unocal in a much stronger bargaining position vis à vis the refiners. Therefore, Unocal could be expected to negotiate much higher royalties after the fact, leading ultimately to higher gas prices. Unocal argues that they did not engage in deceptive conduct; and they make a number of other arguments that I will not go into.

The key economic concept in the case involves opportunism, or lock-in as some would call it: initially CARB and the refiners have more flexibility in their choice of technology, but then a standard is set, investments are made, and it becomes much harder to reverse the earlier choice of technology. Therefore, a company that controls technology that is essential to the standard can have quite a lot of market power. If that enhanced market power is achieved through deception, it seems to me extremely hard to defend. If it is achieved through just being quiet, let's say participating in the standard-setting process and not saying anything, then there are questions about

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[17] Rambus Inc., FTC Docket No. 9302, *available at* http://www.ftc.gov/os/adjpro/d9302.

[18] Union Oil Co. of Cal., FTC Docket No. 9305, *available at* http://ftc.gov/os/adjpro/d9305.

whether the company took on certain duties by being part of that process and questions about just what the standard-setting organization required in terms of disclosures.

There can be different views about what constitutes "fair, reasonable, and non-discriminatory" royalties. There can be disputes about exactly what participants are required to disclose. Those are some of the issues that came up in *Rambus* and will continue to come up. But the basic economics of opportunism—the shift that leads to a company having greatly enhanced power after the standard is in place, even if there had previously been many good choices for technology, is fundamental to all of these cases. Fortunately, there is a huge literature about opportunism, and the concept is quite well understood by economists. But we will have many different fact patterns in terms of what the challenged conduct was. Is it acceptable to simply participate and stay quiet and then later try to assert your patent? Is it acceptable not to disclose a patent application? Those are the sort of things where there are boundary lines and private standard-setting organizations have not necessarily been clear about exactly what they expect of their participants. That lack of clarity has led to patent disputes and antitrust disputes.

A standard-setting organization should be able to negotiate ex ante detailed provisions regarding licensing for any patented technology that does exist and is disclosed. Per se treatment of such provisions, which some people are afraid may exist, is completely inappropriate unless there's a sham.

—Tim Muris

RICH WALLIS: Tim, a couple of follow-up questions and then you can talk as broadly on this area as you would like. The follow-ups: Does it make a difference whether specific disclosure is required? Secondly, do you have perspectives on what constitutes a reasonable and non-discriminatory price? How do you get comfortable if you're an agency, how do you get comfortable if you're a party, with what is reasonable and non-discriminatory?

TIM MURIS: Those are crucial questions. Even though I'm not technically under any obligations, I don't want to say any more about *Rambus* and *Unocal* than I said publicly while I was Chairman. There are complex theories in both cases, particularly in *Rambus*. The case involves an alleged disclosure requirement, and the complaint is extremely detailed. Even if you just glance at it, I think you understand that there are many facts that the complaint counsel will have to show to prove the complaint. *Unocal*'s not quite so detailed, but it does have the additional complications of *Noerr*. The Commission spoke on those issues in an opinion I authored last summer.[19] If the Commission overrules the ALJ and finds against Unocal, that issue is going to a circuit court and ultimately the Supreme Court.

On the second question that you raised, I think that's beyond those cases but it's extremely important. A standard-setting organization should be able to negotiate ex ante detailed provisions regarding licensing for any patented technology that does exist and is disclosed. Per se treatment of such provisions, which some people are afraid may exist, is completely inappropriate unless there's a sham. I hope that the second IP report that I mentioned addresses those issues. That would be a very important statement coming from the government.

PETER PLOMPEN: I just wanted to compare the situation in Europe. In Europe, in the new Guidelines for transfer of technology licensing, there is a specific chapter on patent pooling but there is no specific rule with respect to the situation that you described in *Unocal*. The Commission has only limited experience in this area. Whenever you have participated in a standardization process, there was probably going to be a debate about whether excluding companies from the talks, or

[19] Union Oil Co. of Cal., FTC Docket No. 9305, Opinion of the Commission (Muris, Ch.) (July 7, 2004), *available at* http://www.ftc.gov/os/adjpro/d9305/040706commissionopinion.pdf.

discussing licensing conditions was in itself anticompetitive or not. In the end, the only way to receive a reliable answer was to prompt the Commission to intervene on the basis of competition law, which of course was not always an attractive alternative.

In the area of pools related to standards as such, it would be good if there were an advance agreement on the royalty to be set by the pool. But it is sometimes very difficult to do that because when setting a standard, often the patent rights involved are not yet granted. They are often only patent applications and may only be granted some years later. The other thing is that the TTG provide for a more favorable treatment for patent pools including only so-called essential patents, or only a minority of non-essential patents. The question whether a patented technology is essential or not is also often highly debated. We have had discussions in Europe and in Taiwan about this issue, but it's very difficult in that it also has to do with the availability of alternatives for certain choices that you are making or have made in the standardization process. I would submit that it is important that competition law enforcers focus on the essentiality criteria used for including patents in a pool when setting up the pool and do not intervene ex post when new alternatives for historic choices may have come up.

Second, when you are debating royalties, at least in Europe at the moment, the rule is that you should only have those discussions with licensors and not licensees. And if I recall correctly, in the recent business review letter here in the U.S. with respect to the 3G patent pool[20] and also in Europe, the system that has been set up is explicitly such that the combination of licensors and licensees can talk about the general licensing structure, but not as such on the royalties to be set for some of the pool licenses. The royalties are set only by the licensors.

DEBRA VALENTINE: I wanted to throw one more element into the mix. I want us to return to *Dell*,[21] which was a bellwether in establishing the proposition that a misleading non-disclosure of patents to a standard-setting organization can undermine that patent holder's ability to enforce those patents and could violate the antitrust laws. (And that is a subject you could speak more easily about, Tim.) What you had in *Dell* was as follows: each participant in VESA (the Video Electronic Standard Association) was asked to sign a statement that the proposed standard for the VL-bus did not rely upon any patents that that particular firm held. Dell did not state that the standard read or relied on its patents. Consequently, the FTC (not a court) found that Dell's misleading failure to disclose its patent interests led to liability.

Now, the thing I want to add to the mix here is if we're talking about this kind of behavior as essentially monopolization, we're not talking about profit sacrifice. This isn't costing anybody anything. And I think it's very important to think about, especially for those who might be arguing that profit sacrifice should always be the standard in terms of how we think about exclusionary conduct and monopolies. There's a lot of cheap exclusion. It could be fraud on the patent office, which doesn't cost much, or putting a torch to your competitor's factory, or lying in your standard-setting organization, when there is a duty to disclose. As Carl said, there is generally no legitimate business reason not to disclose, and it's very cheap not to do so. I think that's a problem. I think it probably should be an antitrust violation.

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[20] Business Review Letter from Assistant Attorney General Charles A. James to Ky P. Ewing, Jr. (Nov. 12, 2002), *available at* http://www.usdoj.gov/atr/public/busreview/200455.pdf.

[21] *See* Press Release, FTC (June 17, 1996), *available at* http://ftc.gov/opa/1996/06/dell2.

CARL SHAPIRO: Let me pose these questions from a counseling perspective. Many of you probably work with companies that are participating in standard-setting organizations and which are trying to decide whether to put their weight behind a particular technology. Such companies do not want to find out in two years that another industry participant is coming after them for exorbitant royalties, alleging that they are engaging in patent infringement by complying with the standard. So industry participants have a great desire to know not just that any patents will be licensed on fair, reasonable, and non-discriminatory terms, but also what those nice-sounding words actually mean for a particular technology or patent. Does it mean royalty free? Does it mean 1 percent of revenues? If so, what will be the basis on which revenues are measured? I always advise industry participants who will be licensees to nail down these terms and conditions as best as they can at an early stage, before the standard is set and their bargaining power erodes.

I don't see why one size fits all when it comes to rules governing standard-setting organizations.

—Carl Shapiro

The other related problem is that participants who have intellectual property rights may not disclose them, in part because they would rather negotiate later when their bargaining power is greater. Many standard-setting organizations require disclosure of relevant patents, but the treatment of pending patents varies a great deal across organizations. Indeed, Debra, some participants ask why they should have to disclose patent applications, since under the patent laws most patent applications are not disclosed until 18 months after the application is filed.

I said earlier that lying is hard to defend. But as to non-disclosure, people argue that there are costs to requiring disclosure of pending patents. And I think the standard-setting organizations and individual companies have to design the rules under which they want to operate. I don't see why one size fits all when it comes to rules governing standard-setting organizations. One standard-setting organization may say it's going to require either disclosure of pending patents or a commitment to offer them royalty-free. Under the disclosure requirement, suppose that I say: "I have a pending patent, but the patent application itself is confidential and I am not going to show it to you or describe it to you." At least the other participants in the standard-setting process are on notice, and they might say, "Well you better tell me or I am not going to support this particular specification, because I am not prepared to leave myself at your mercy."

RICH WALLIS: Does anyone have any concerns if a standard-setting organization demands that participants agree to reasonable license fees to have the patents included in the standard? Is everybody comfortable with that approach?

TIM MURIS: To the extent people are concerned about antitrust laws, they shouldn't be; again, with the exception of some sort of sham problem. Obviously, you can have problems with standard-setting organizations. A problem we addressed when I was at the FTC in the '80s, was about the standard being set up purposely to exclude—for example, where the standard has a particular benefit like in a building code and it excludes plastic pipe. That's a different issue and a different problem; but with those caveats I don't have any problem.

RICH WALLIS: Does any of this analysis change depending on the industry?

DEBRA VALENTINE: Hold it. Are we saying that everybody could agree ex ante that the royalty—instead of being between 5 and 10 percent is going to be X dollars. We're going to literally agree on the price?

CARL SHAPIRO: Personally, I think that it is not enough simply to require ex ante that the royalties

be "fair, reasonable, and non-discriminatory." That language invites subsequent disputes. What company would sign to a licensing agreement under those terms and then make major investments that rely on using the patented technology? Please tell me so I can be sure not to invest in any such companies. The terms "fair, reasonable, and non-discriminatory" can be subject to very different interpretations by different parties based on their subsequent commercial interests. Given the conflicting incentives within the association, I don't think personally there is a problem with setting a rate.

DEBRA VALENTINE: The moment you have the five largest firms agreeing that the price is going to be X and essentially forcing the three small firms into agreeing to that price, that's a problem.

TIM MURIS: No, I don't think that's the way the normal standard-setting organization works. I agree with Carl that one size doesn't fit all here. If the standard-setting organization wants to pass a rule that says "we love opportunism"—it seems like a strange rule—and people participate with their eyes open, that's okay.

CARL SHAPIRO: Or they can do what the World Wide Web Consortium (W3C) has done and adopt a policy directed towards ensuring that patents are licensed on a royalty-free basis. That approach is not going to work in a lot of other contexts, but the W3C has adopted such a policy.

PETER PLOMPEN: Let me quote from the European Technology Licensing Guidelines No. 225: "Undertakings setting up a technology pool that is compatible with Article 81, and any industry standard that it may support, are normally free to negotiate and fix royalties for the technology package and each technology's share of the royalties either before or after the standard is set. Such an agreement is inherent in the establishment of the standard or pool and cannot in itself be considered restrictive of competition and may in certain circumstances lead to more efficient outcomes. In certain circumstances it may be more efficient if the royalties are agreed before the standard is chosen and not after the standard is decided upon. . . ." [22]

TIM MURIS: Debra, it's also important that Carl and I are not saying that everything is per se illegal.

DEBRA VALENTINE: I agree it should not be per se illegal.

TIM MURIS: And it shouldn't be per se legal either. I'll let Carl speak for himself, but I'm not going the extra step to say situations where there is a problem don't exist.

RICH WALLIS: Does this analysis change in the standard-setting organization if it is a regulated industry or a network industry or an emerging industry as opposed to a mature industry, Tim?

TIM MURIS: Industry context will matter in certain senses. With regulation, you obviously have the *Noerr* issues. You could lack antitrust jurisdiction depending upon the nature of the regulation even at the state level because of the state action issue. The reasons for having a standard can

[22] *See supra* note 10.

be greater in a network industry or a nascent industry and so can the opportunity for mischief. There is the problem that we have talked about with exclusion, but I think you can oversell that point. Network effects are ubiquitous. I'm in the network of Diet Coke and Diet Pepsi drinkers and I'm not a Tab drinker. There are definitely increasing returns to scale from the fact that some of those products are ubiquitous.

RICH WALLIS: We're going to talk more about compulsory licenses, generally, later in the program but, Debra, in a standard-setting organization, how do you feel about compulsory licensing? Is it appropriate under any circumstances?

DEBRA VALENTINE: I don't think I know what relief the Commission asked for in *Unocal* and *Rambus*. It's interesting that the relief in *Dell* was not compulsory licensing; it was prohibiting the patent holder from enforcing the patent against others in the standard-setting groups. I think if we agree that when there is misleading conduct within a standard-setting organization—conduct that has no basis other than harming competition and essentially gaining monopoly power—then you have a reason to require licensing. The clever thing about *Dell* was that Dell was allowed to enforce its patents against firms in contexts other than those relating to the standard-setting organization's activities.

CARL SHAPIRO: It seems to me the general principle to apply if somebody has misbehaved in the standard-setting process is to try to restore competitive conditions, which requires trying to determine what the licensing terms would have been ex ante, when industry participants had more choices, i.e., when the relevant technology market was more competitive. In *Unocal*, since Unocal had (allegedly) represented that its technology would be nonproprietary, the remedy requested is that they not be able to enforce the patent for California gasoline, but they could still enforce it outside California. In another context, you might well find that the competitive price was not zero, but some other number. In many cases, it is going to be hard to get a good estimate of the ex ante competitive royalty rate. That is one of the problems with these cases. At the beginning, industry participants can, in principle, evaluate the different technologies and negotiate and bargain over licensing terms. The outcome of that process is our "competitive benchmark" without the deception or other anticompetitive conduct. To reconstruct that—in the *Unocal* case it is now more than a dozen years—is very hard. I do not know how hard that estimation exercise was in the *Rambus* case, but that would be the principle. I suppose one might use a shortcut and set the royalty rate at zero if a company acted deceptively, not unlike some concepts in the area of patent misuse, but I don't see why the competitive price would always be zero.

DEBRA VALENTINE: In addition, since this is a nascent area, we do all need to be sensitive to encouraging broad-based participation in these standard-setting organizations. It's really a question of how to address the very extreme abuse of these organizations.

KENT BERNARD: The point that I was going to make is we're all antitrust lawyers and we're talking about antitrust. There is the old saying that to a man with a hammer, everything looks like a nail. Antitrust may not be the remedy to a lot of what we're talking about here. Debra gave the example of blowing up somebody's factory. You can bring a Section 2 case about that, but there are probably other laws that are more applicable than that. When we are looking at deliberately lying to set a standard, maybe we shouldn't limit ourselves in terms of remedy to an antitrust remedy

on these things. You may not be limited to a reasonable royalty. You may be talking about any number of different things, and those of you who deal with the state attorneys general will know that they're extremely creative about coming up with theories which God probably never intended but that can be applied across different contexts. I'm not recommending that, I'm simply stating it because antitrust compulsory licensing—whatever on earth a reasonable royalty might be ex post, and I agree with you, that's almost impossible to figure out—these are kind of blunt instruments and they may not be the best instruments for dealing with this.

Hatch-Waxman involves difficult issues at the interplay of antitrust and patent law. The courts have split on the appropriate responses to these settlements but I doubt, however, that the Eleventh Circuit has had the last word. First, the opinion is based on an astonishing clear legal error that destroys the premise of much of its argument about Hatch-Waxman.

—Tim Muris

RICH WALLIS: One thing that is truly a hot topic right now is patent settlements, in the pharmaceutical industry in particular. I'll ask Tim to talk about what the generic drug cases brought by the FTC entailed and to discuss briefly the *Schering* decision.[23]

TIM MURIS: Let me give you the overview, and then make a few points about *Schering*. The Commission has had two generations of cases involving generic competition. The first is like *Schering*, in which there was an agreement, a Section 1 case, where the branded drug maker pays the generic competitor to delay the generic's entry. There were several of these cases brought under Bob Pitofsky's Chairmanship, which, with follow-on class actions, stopped this practice. The second generation, which occurred in my Chairmanship, involved unilateral behavior by the branded drug to exclude generic competition. Probably the best example involved the Commission and the states taking a very tough stance against Bristol-Myers Squibb.[24] (Obviously *Mylan*[25] involves somewhat similar issues.) Bristol-Myers, for example, went to the PTO and said "X"—it's not worthwhile getting into the details—to get a patent. Then they went to the FDA and they said literally "not X" to get the patent listed in what's called the Orange Book, to be able to exclude generic competition. We thought that that wasn't kosher and Bristol-Myers, after a management change, decided to exit that business. Because there is so much money involved from excluding generics, the tactics have continued to evolve and I think so will the antitrust response.

Now, *Schering*. The case also involves the Hatch-Waxman statute,[26] and I'll begin with the only conciliatory note to the Eleventh Circuit that I will provide. Hatch-Waxman involves difficult issues at the interplay of antitrust and patent law. The courts have split on the appropriate responses to these settlements but I doubt, however, that the Eleventh Circuit has had the last word. First, the opinion is based on an astonishing clear legal error that destroys the premise of much of its argument about Hatch-Waxman. In essence, the court assumed that the generic was infringing. That's just wrong. There is an assumption of validity, but the patent holder has to prove infringement. Second, if there's one clear message from Congress in passing Hatch-Waxman, it was to increase the sale of generics. Yet the Eleventh Circuit seems to find an unrestricted right to buy off generic challengers. That conclusion is fundamentally at odds with the congressional Hatch-Waxman purpose. Third, the court attacks the Commission for lacking empirical foundation. That's particularly surprising given the studies the Commission has done in this area. The Commission's Hatch-Waxman study, for example, on which it relies, surveys the universe of generic entry before

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[23] Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

[24] *See, e.g.*, FTC Analysis to Aid Public Comment, In the Matter of Bristol-Myers Squibb Company, File Nos. 001 0221, 011 0046, and 021 0181, *available at* http://www.ftc.gov/os/2003/bristolmyersanalysis.htm.

[25] *See, e.g.*, FTC v. Mylan Labs, Inc., 62 F. Supp. 2d 65 (D.D.C. 1999).

[26] 35 U.S.C. §§ 155–56.

patent expiration.[27] It's not just a sample, it's the universe. Ironically, the Eleventh Circuit makes an empirical statement itself that is demonstrably false—that the Commission's opinion would stop these settlements. Such settlements now must be reported to the government, and a Commission report shows that many settlements still occur between branded and generics without these payments.

Finally, the Eleventh Circuit stands on its head the well-accepted rule about deferring to agency fact finding. The Eleventh Circuit does defer, but it's to the Administrative Law Judge (ALJ), not to the legal fact finder. The Commission, as the law provides, engaged in an extensive de novo review. The relevant factual analysis in the Commission's opinion takes 40 pages, and it represented months of hard work by a team of lawyers under Tom Leary's able supervision. The court, in 3½ pages, waves its hand at that work largely in deference to the ALJ. I don't think that view will stand, and I don't think much else of the Eleventh Circuit's opinion will ultimately stand, whatever happens to this particular case. I am willing to concede this is a complex area and that, ultimately, Congress may even revisit it.

KENT BERNARD: I'm going to agree with 98 percent of what Tim just said. Perhaps one or two adjectives are different. Clearly the Eleventh Circuit had a different idea of a standard of review, and while I love patents in general, I do agree that the presumption of infringement was kind of gutsy. For those of you who do not live in this particular fish bowl, let me just give you thirty seconds. Hatch-Waxman changed the patent laws—it changed a few things so that a generic could challenge a patent on an innovator drug basically with no risk. They didn't have to try to launch. They didn't have to do anything. They could do all their testing for FDA approval without infringing. Hatch-Waxman set up a different model, and various people have commented on the economics.

The other thing that happened is that most states—and almost all private insurance companies—have mandatory generic substitution. So if a generic of a product comes out on Day 1, almost all of the prescriptions that are written for the branded product automatically are converted by operation of law to prescriptions for the generic. Unless the doctor goes through a lot of hoops, the prescriptions automatically are moved over to the generic without anybody doing anything.

So you sort of have the government rewriting the rules of the marketplace, which governments do all the time. The facts of *Schering*, though, are a little weird in the sense that there was a suit that was settled and *Schering* let the alleged infringer in five years before Schering's patent expired—that concept, by the way, is the norm, you split the difference on patents. Then there was a second set of facts (and I have nothing to do with *Schering*—this is all public record), and that was *Schering* paid money to the alleged infringer—and this is highly disputed, obviously, in the case—got some stuff back, licenses back to things, and the case revolved around the question of how you treated that transaction. I don't think anybody was really worried about the split-the-difference in terms of when your license starts. It was this other chunk and was there a payoff to keep them out—meaning that they would have come in earlier than five years before the patent expired, were they getting value for it, how did it go. There's a very interesting dynamic in a lot of these cases and I'm speaking of this not in a specific case—the economic nature of the system is that when a generic drug comes on the market, the harm to the brand name company is

[27] Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

greater than the benefit to the generic company. That's just an artifact of the way that system works after the first 180 days and I'm not going to make that distinction, which is why the first generation of cases looked so attractive to the participants in them until somebody woke up. When you come on the market, I'm going to lose $100 and you're going to make $30. So why don't I pay you $50 to stay off the market and we're both happier? It makes perfect sense until you figure out that it's got to be illegal as heck, and it was. But that generation sort of went away.

With the settlements that are being reported now, and they all have to be, I have to believe that 98 percent of them are pretty vanilla because nobody seems to ask any questions. There's a way of doing it. This case had just weird facts. The question to me is what does it mean now to have the *Schering* decision? Well, it means, obviously, we're going to wait and see what happens if certiorari is petitioned for. But you have the *Schering* case, and you have some of the other cases that found those kinds of agreements were per se antitrust violations. So the question for me as counsel for a company is not how do I deal with an FTC attack. If I have to deal with an FTC attack, the answer is simple: I appeal it to the Eleventh Circuit. But that's not rocket science; everyone in this room could do that one. The question is, what am I going to do with the 35 class actions that are filed not only in the Sixth Circuit, but in 19 different courts, depending upon where the plaintiff has his home office. They're not going to be bound by the Eleventh Circuit. So I think the lesson right now is this thing has seriously unsettled the law of settling, at least temporarily.

The question to me is what does it mean now to have the Schering *decision? Well, it means, obviously, we're going to wait and see what happens if certiorari is petitioned for.*

—*Kent Bernard*

My personal view is that at least on the standard of review, this case has got to go up to the Court. What happens after that is an open game. As I said, I tend to agree with Tim on most of this. But the standard of review thing just sort of stopped me the first time I read the case. It's like they went through the whole thing and said, well, the FTC found facts but it wasn't supposed to do that. The Administrative Law Judge found the facts; you were just supposed to sort of see if there was substantial evidence supporting the Administrative Law Judge, which is 180 degrees reversed from the actual legal standard.

RICH WALLIS: Carl, several questions. I'll let you expand on the discussion generally, but when you're talking about reverse payments, the courts are not doing in-depth analysis of the strength of the patents that are involved. Is that an issue from an economic perspective?

CARL SHAPIRO: I think ultimately it has to be. The question is how do you get there. I'll continue to use *Schering* as the vehicle. I've heard from the other end of the table here that there was a presumption of infringement, which is gutsy. There was a standard of review that is unusual. Those are mostly legal issues. On economics, I was taken aback in a completely different dimension, which is the notion that if the agreement stays within the scope of the patent, then it's basically okay. This can include some obviously and blatantly anticompetitive agreements not to compete. Yet it appears that the Eleventh Circuit would consider such agreements to be legal, or at least might find them to be legal, when it is crystal clear that the economics are just like you said—the monopoly profits are a lot bigger than the competitive profits, so there are strong incentives to agree not to compete if this is permitted. Of course, for the very same reason, consumers are benefiting a lot when the generic is offered, so there is money to be had if the incumbent can pay off the potential entrant to go away or come in later. These are very basic arguments in antitrust economics, yet the court seemed unaware of them as they apply to the use of reverse payments.

DEBRA VALENTINE: But the Eleventh Circuit would allow that.

CARL SHAPIRO: It appears the Eleventh Circuit would allow an incumbent monopolist to pay a potential entrant to stay off the market, so long as the potential entry *might* be infringing a patent held by the incumbent. The economic analysis here is actually pretty straightforward. Aside from the rationale of protecting its monopoly profits, why is the patent holder willing to pay? Because otherwise entry is going to happen either sooner or with greater likelihood. If everyone knew that the patent was absolutely valid, the generic company would never come in until the patent ends, or perhaps the patent holder would obtain a preliminary injunction to stop entry. In neither case would the patent holder pay all that money to the generic supplier.

KENT BERNARD: The only point to make in there is that under normal circumstances that is right, but under Hatch-Waxman, it is different because in that context all that I can do in that suit, basically, is to lose. If I beat the generic, it doesn't cost him anything. When you're looking to settle a case, there's really not the balance of power that you would see in a normal patent infringement suit where the infringer is at risk for damages and I'm at risk for loss. Here, he's at risk for nothing, and other courts have picked up on that. How far it goes, however, I have no clue.

CARL SHAPIRO: There's another discussion about other industries and other situations in which the alleged infringer has already entered the market prior to the settlement. Even defining what is a "reverse payment" is tricky if the alleged infringer has some potential liability for prior patent infringement. We're not going there now. But the *Schering* case is very clean in this sense: the generic supplier is not yet in the market it is threatening to enter, so the incumbent pays the generic to delay or not come in until the patent has expired. That's pretty blatant, and it seems like the Eleventh Circuit would allow those sort of things. That surprised and disappointed me. But there is another whole angle in the *Schering* case: Did Schering in fact make such reverse payments? Because the *Schering* case does not involve a simple cash payment, but rather a more complex side deal involving licensing. From my perspective that leads to a genuine fact question: Did Schering overpay for the licensing rights it obtained so that we effectively have a reverse payment, or not? I have to say, it is rather clever for the companies involved to design the transaction this way. Did they find an ingenious way to settle their dispute by bringing in the gains from trade associated with another licensing transaction? Or did they just design a more complex transaction to hide a reverse payment? On this point, the Commission delved deeply into the facts, which the Eleventh Circuit sees differently. Unlike some of the conceptual points we have been discussing, these factual issues are not of much interest outside the case itself.

DEBRA VALENTINE: One thing that's extraordinary now is how much uncertainty remains. Everyone agrees that the early cases, such as *Hoechst-Andrx*,[28] which involved a simple sharing of monopoly profits and then tying up the 180-day exclusivity period, are probably gone. Nobody's going to do that anymore. *Schering* added two interesting complications. One was the additional payment for marketing rights over in Europe, which was and is going to be hard for the fact finders to value going forward. *Schering* also involved—and this has almost gotten lost in the process—a second entrant. How do you figure out whether preventing a second entrant for a few months is anticompetitive and how do you measure what the likely anticompetitive effect of that is? The one

[28] *See* Press Release, FTC, Consent Agreement Resolves Complaint Against Pharmaceutical Companies Hoechst Marion Roussel, Inc. and Andrx Corp. (Apr. 2, 2001), *available at* http://www.ftc.gov/opa/2001/04/hoechst.

last thing about *Schering* that I hope the FTC pays attention to is that the court seized on that bizarre footnote 12 in *California Dental*[29] about how you must prove effect—it can't be likely or probable—and raised that to the centerpiece of its analysis. That cannot be something that the agencies are going to like having to do whether it's in cases like *Intel*, or *Microsoft*, or *Schering*.

TIM MURIS: Yes, but the irony here of course is that there's ample evidence of the effect of generic entry.

DEBRA VALENTINE: Yes, but you don't want that as a standard even though you could meet it here.

TIM MURIS: No, but we did think that per se treatment was inappropriate. Particularly when Hatch-Waxman was passed, the essentially bankrupt generic was a real concern. It is less so now because of the generic industry's health. The Commission allows for $2 million to be paid, essentially for legal fees. Particularly after spending time in O'Melveny, maybe $2 million is too small. Of course, there's a lot of room between 2 and 60—the payment in *Schering*—and the correct number is much closer to 2. As a matter of doctrine I think it was appropriate, particularly at the beginning, to say this is rule of reason. It turns out that you can show through demonstrable economic evidence the required economic effect. Thus, I understand your point, but even there the court has got it wrong.

CARL SHAPIRO: There is very clear economic evidence: if they were going to come in, we know that would have led to lower prices. But that still leaves the question of whether they really would have come in. If the patent was absolutely valid, then maybe they would never have come in, or at least not until the patent expired, which goes back to your earlier question. If the patent holder—the brand company—is making a large payment, then I think it is very reasonable to infer at least that they were afraid of losing, they were afraid of earlier entry or more likely entry, and thus we can see the anticompetitive effect of the reverse payment. Given that we know entry leads to these price effects, that's how you prove and hopefully meet this condition to establish effect.

TIM MURIS: The Commission's opinion says that delaying entry is not the problem. You can settle, and some appropriate settlements do delay entry. The problem is the payment for delayed entry. I've always thought, and I'm in the minority in this, that the term "reverse" adds nothing to the analysis. But the payment of this large sum to delay entry is the real problem in this context. One should proceed as the Commission did, using a rule of reason analysis. At the end of the day, there is still uncertainty. If the Eleventh Circuit view prevails, and it'll have to be determined by the Supreme Court because of other circuits, then I predict there will be ten bills introduced the next day in Congress to overturn the decision. But before one passes there may be ten bad settlements.

CARL SHAPIRO: Tim, would you be against any settlements that involved these side licensing deals?

TIM MURIS: Absolutely not. The question about side-licensing deals is whether they are legitimate or even look close to being legitimate. You shouldn't second guess them if they appear reason-

[29] California Dental Ass'n v. FTC, 526 U.S. 756, 775 n.12 (1999).

able. The reason the Commission's opinion goes to such great lengths on the side payment was to prove that it was bogus.

CARL SHAPIRO: As I recall, your predecessor at the FTC said that that was so much work involved that these side deals should not be allowed at all if there was anything of value going from the patent holder to the generic firm. I gather you are not going there.

TIM MURIS: No. In fact the opinion is about doing the hard work. Most of the effort that Tom Leary put in was on that very hard factual question. The ALJ is under a distinct disadvantage compared to the Commission. We could put our best people on that factual record, and we did; that's one of the many reasons why the Commission is the de novo fact finder. It took a lot of hard work by some of our best people. For example, Michael Wrobleski, who received the Chairman's award—it's given annually to someone who does extraordinary work at the Commission—was one of those people, which indicates how important the case was.

The scarier thing to me than the Eleventh Circuit's opinion, assuming that that judgment just gets affirmed and nothing changes, is that the next time I settle a case, the first suit that's brought is going to reexamine the strength of my patent to determine whether my settlement is valid.

—KENT BERNARD

KENT BERNARD: From Schering's position, someone must have looked at the situation and said, "Okay, I want to settle this thing and here are the terms. But the other side is saying that they are not interested in simply settling this, they want another revenue stream, which is why they are pushing me to license this other stuff from them." Now, even if the side transaction is arguably legitimate on its face—the fact is you will always find six memos in the file that say, "Why are we doing this and why are we doing a business deal with them?" The reason we're doing it, and doing it with them, is because it's part of a larger transaction. You have to step back and ask if that's reasonable, if it's not so far beyond the pale, you almost have to let that process happen because the other approach is just to say you can never do it and that doesn't make any sense. The scarier thing to me than the Eleventh Circuit's opinion, assuming that that judgment just gets affirmed and nothing changes, is that the next time I settle a case, the first suit that's brought is going to reexamine the strength of my patent to determine whether my settlement is valid. I cannot for the life of me figure out what the standard would be for that. If you think I had an 80 percent chance of winning the patent case, does that mean I can keep you out for sixteen months? Is it twelve versus twenty? You've got to make it up as you go along. That can't happen. There will be no settlement.

RICH WALLIS: Let's now talk about licensing terms. Debra, talk about compulsory licensing and refusals to deal in *Trinko*[30] and how you think that might apply in the broader IP setting.

DEBRA VALENTINE: We have to start with the fact that *Trinko* is a very narrow decision. It involved the rather unique context of substantial regulatory intervention under a telecommunications statute. But we did all agree that the Guidelines got it right that intellectual property is just like other property. Of course, all property has unique features and IP is easily appropriable and many people can use it simultaneously but, for antitrust law purposes it should be treated like other property. Thus, it's fair to ask, "What does *Trinko* tell us about IP licensing?" I think for IP licensors *Trinko* is very good news. It makes it clear that there are very, very few circumstances in which monopolists would ever have any duty to deal with downstream competitors. It states that monopoly pric-

[30] Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, 540 U.S. 398 (2004).

ing, at least for a short period, is an important part of the free market system. Indeed, *Trinko* specifically notes that "to safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless accompanied by . . . anticompetitive conduct." So I think *Trinko* gives substantial comfort in the context of IP licensing.

We mentioned the profit sacrifice test before, and I'll raise it again here. I don't think *Trinko* went so far as to say that the only kind of exclusionary conduct that's illegal under Section 2 is conduct that's short-term unprofitable. I think the court used that profit sacrifice inquiry as evidence of anticompetitive intent. But that's only one type of conduct that might be exclusionary or anticompetitive.

Another beneficial development for IP holders is that *Trinko* effectively sounded the death knell for the essential facilities doctrine. Since there have been some very bizarre cases that have occasionally viewed intellectual property as an essential facility, I think it's a positive step that "essential facility" is at most a moniker that's meaningless.

Trinko *effectively sounded the death knell for the essential facilities doctrine.*

—*Debra Valentine*

In addition, the court indicated that if you've never had any dealings with a supposedly excluded party, you can refuse to deal and go home and sleep perfectly comfortably at night. Now I think there's probably one drawback here and I'd be interested in others' thoughts on this. If a firm knows that if it commences and then stops dealing with another entity, and there is going to be more suspicion placed on its behavior than if it had never dealt at all, what are the incentives as a business matter? Would the firm still refuse to deal when it wanted to refuse to deal because it made business sense, and license when it made sense, or does the general principle that regulators should carefully scrutinize changed conduct warp a firm's incentives and lead to less licensing?

KENT BERNARD: Everything warps my incentives. I think you have to be a little fact-specific on this. I'll give you an example of where there's a tremendous difference. As some of you know, there's been a controversy in the scientific community over patenting what are called research tools. These are things that you use to help discover other things—to oversimplify horribly. We have a policy that we prefer that none of them were ever patented and if they are patented, we will license them nonexclusively at a fairly nominal royalty if we have it because we believe as a policy matter that's the right way to do it. That would be apart from a normal business discovery situation, and yes, honestly, we might act differently if we found something that we felt was an advantage for us and we were going to spend money on it. We don't have refusal to deal situations very often, at least in the prescription drug business, and so the question doesn't come up. But generally, our advice has traditionally been, if you don't want to deal with somebody don't deal with them. Don't start dealing with them and then decide twenty minutes later that it was a mistake, because in the normal course of events I'm sure everyone who has counseled a business has seen this. Somebody did something, and it doesn't have to be price-related. *Colgate*[31] is the classic on this. They violate your terms, you cut them off, and then they come back and say, "Gee, we made a mistake we'll never do it again," and your advice has to be you can't take them back. Otherwise you've done all the bad things that Antitrust 101 says you can't do. And for a business context that's bizarre. The idea is that you actually have to cut off your foot because somebody did some of that. So the answer that comes back is "don't start." To that extent it does change things.

[31] United States v. Colgate & Co., 250 U.S. 300 (1919).

RICH WALLIS: Tim, let's talk about compulsory licensing of IP in the United States. When does it happen? Have you seen it used in the remedy setting? What factors would drive using it in the remedy setting?

TIM MURIS: The proposed *Unocal* remedy and others like it deny potential enforcement and thus are the same as compulsory licensing in an indirect sense. A very interesting question here is in what the Department of Justice said. Let me quote its department-wide report on IP. "It is well established under United States law that an intellectual property owner's decision not to license its technology to others cannot violate the antitrust laws." With any one sentence, there can be doubt about what it means. If the statement means that the case law doesn't support antitrust liability for unilateral refusals to deal, there's obviously enormous support. Liability may be the antitrust unicorn. What the statement clearly can't mean is that there is immunity for conditional refusals. The *Colgate* analogy here is a useful one. Professor Hovenkamp has a very nice hypothetical: Chrysler has a patent on a unique windshield wiper blade and it tells the other companies it will lease it only on the condition that Chrysler can set the price for the other companies' automobiles. That is a condition on a license that an antitrust court would not and should not tolerate. The Department of Justice certainly could not have meant the sentence I read to bless conditional refusals.

Under EU law, it is possible, under so-called "exceptional circumstances," that it is an abuse of a dominant position for a dominant enterprise to refuse to license its intellectual property.

—Peter Plompen

CARL SHAPIRO: *Trinko* is certainly not friendly to imposing a duty to deal, even on monopolists. I think *Trinko* is about unilateral unconditional refusals to license; imposing conditions is a whole different matter. And remedy is a different realm as well, since one is fixing the problem caused by other violations. If somebody has violated the law, you want to restore competitive conditions, whether it's Microsoft having to license certain copyrights or Unocal with the patents, or a merger where you have a licensing remedy. All of those involve mandatory licensing. But it is a whole different issue as to how we fix harm to competition caused by other conduct. I hope we can get even more clarity than *Trinko* that there's no duty to license patents even for a monopolist.

RICH WALLIS: We have been talking about how the U.S. agencies treat compulsory licensing. There appears to be a difference in Europe.

PETER PLOMPEN: As to the use of compulsory licenses in the framework of remedying merger situations or remedying abuse situations, I don't think there is a difference between Europe and the U.S. But of course everybody knows there is a difference with respect to the possibility that refusal to license in certain situations may be deemed to be an abuse of a dominant position. That's exactly the issue that has come before the European courts in the *IMS*[32] case and also more recently to the President of the Court of First Instance in Europe, in the *Microsoft* case.[33] Under EU law, it is possible, under so-called "exceptional circumstances," that it is an abuse of a dominant position for a dominant enterprise to refuse to license its intellectual property. The criteria until now have been that the refusal to license must prevent the emergence of a new product, a not essen-

[32] Case C-418/01, IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG, [2004] E.C.R. I-05039 (Apr. 29, 2004), *available at* http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:62001J0418:EN:HTML.

[33] Case T-201/04R, Microsoft v. Comm'n, Order of the President of the Court of First Instance (1), 22 Dec. 2004 (proceedings for interim relief under Article 82 EC).

tially duplicative product; that the license be indispensable to carry on business in the particular market, which means that alternative solutions, even if less advantageous, do not exist or cannot be created by an equally efficient party due to economic obstacles, legal reasons, or whatever; and there must also not be an objective justification for the refusal, and the only thing that we know since *Microsoft* is that probably the very fact that you have intellectual property is not an objective justification under European law.

What is, however, interesting in the decision of the President of the Court of First Instance in the *Microsoft* case is that the President agreed that Microsoft had made a serious point when it said that there is a difference between the situations in earlier judgments in *Magill*[34] and *IMS* on the one hand, and *Microsoft* on the other hand, in that Microsoft apparently had invested in creating its technology, while the information protected by copyright in *Magill* and in *IMS* was more or less publicly available information. That was a relevant difference.

The other relevant issue according to the President in the *Microsoft* proceedings, was the fact that the old case law criteria for an abusive refusal should not be deemed to require the existence of two different product markets: the product market where you have a dominant position and the market for the product incorporating the input that you need. It is sufficient if you need an input, whether or not it is marketed as a separate product on the market, and it is sufficient that you need a certain input to be able to enter a market with a new non-essentially duplicative product. If there is no objective justification for the refusal, and if indeed the license is indispensable in the way just stated, then a refusal to license such intellectual property may be deemed to be an abuse of a dominant position.

This is very much being debated, not only in the U.S. but also in Europe, also within the framework of a far broader discussion about the application of the rules on abuse of a dominant position generally. The issue should be seen against the background of European competition law. European competition law is something that grew out of the ordo-liberal economic approach, which has its basis in Germany in and after the second world war. And it is really based on two pillars. The first is that every restriction in the commercial freedom of another party in itself is anti-competitive unless it is somehow justifiable. The second is that you should not make use of the dependency of somebody else.

You see this basic discussion coming back again nowadays. It has been reflected in the new modernization regulation of last year where there's an explicit exception to the rule (which I described earlier) that European law has pre-eminence over national law for situations that are covered by Article 82. Indeed, the law says that when a national court or a national authority is applying Article 82, it should also take the same approach with respect to national law. But national enforcers are allowed to be stricter than European law would require. And the second important exception is that laws which predominantly have a goal other than competition in the pure sense can also still be applied by national authorities and by national courts. That includes, specifically, unfair competition rules.

This is the basic difficulty we are having at present in Europe. In applying Article 82, our enforcers do more than just act against exclusionary conduct. They also act against exploitative abuses. Furthermore, enforcement is characterized by "type-casting." Certain types of behavior, if done by a company having a dominant position, are per se prohibited without having to look at

[34] Joined cases C-241/91 P and C-242/91 P, Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v. Comm'n, [1995] E.C.R. I-00743 (Eur. Ct. Justice Apr. 6, 1995).

actual economic effects. That is of course creating problems particularly in dynamic economic environments. How can you compete in a dynamic environment if certain generally acceptable business models are not acceptable if practiced by a dominant enterprise? Should companies change their business models once they reach a certain level of market power, or even when they reach a certain market share? That is what the debate is about. You can see some of it already in the TTG; that the TTG contain a recognition of the fact that competition laws should take the dynamics of the market into account. On the other hand, the economic approach with respect to Article 82 is still not there; and there was a clear discrepancy among major competition officials of different countries within Europe at a conference in Brussels only a few weeks ago.

DEBRA VALENTINE: You have Member States that can go beyond Article 82. We have states that have all sorts of unfair competition laws, too. So it's sauce for the goose and sauce for the gander. I think Peter is correct that *Microsoft* is going to be very revealing in indicating how close the U.S. and Europe are coming in this area. Thus far, the cases that we Americans are aware of in the EU—whether *Magill* or *IMS*—do not involve any novel, original, or creative intellectual property. For example, in *IMS Health*, the pharmaceutical industry provided the zip codes where firms were selling their products to an entity that packaged these zip codes and manipulated them to provide marketing data for the pharmaceuticals. In essence, Member States were giving IP protection to products that would likely never be granted protection here. So EU-wide competition law was used to overrule unduly protective Member State copyright or patent law.

PETER PLOMPEN: I would like to make a remark about what I think is a positive development in the *IMS* judgment which I have not noticed in comments that I've heard up to now. And that relates to the question whether or not a certain input is indispensable. It is very clear that the court is not allowing an argument that something is indispensable if you need it but getting the input in another way is a little bit more expensive or a little bit more difficult. The Court of Justice explicitly refers to the situation that an alternative would not be available to someone acting on a similar scale. So it's not just a question of something that has developed in the market, and now would require new investments to get a similar structure, and that is impossible in view of the big lead that the other already has in the market. The comparison that the Court says should be made with respect to indispensability, as I read it, is that the party that requests the license for the input should be required to show that even if it were operating at the same level, at the same scale as the incumbent, it would not be economically feasible for it to develop or to create an alternative to the existing one. I think this is a very big limitation on the applicability of what we all call the *IMS* doctrine.

RICH WALLIS: Debra, how do you reconcile U.S. and EU law at this point, particularly when you are advising clients? There are very few licensing situations that stay in one country; they are all worldwide. How do you give advice just looking at the U.S. and EU, and how does the fact that another 90 countries have antitrust regimes complicate matters?

DEBRA VALENTINE: The truth is that you can't say that the EU should not have looked at *Microsoft*, because it did affect their markets, or that the U.S. shouldn't have looked at *Ciba Geigy-Sandoz* (now Novartis). The ideal would be to have, particularly in IP with its worldwide markets, the regulator with the primary interest making the decisions. A system of comity. The trouble with that scenario is that it entails the U.S. making the decision about Microsoft's behavior and the EU making the decision about Airbus' conduct. I fear that this could foster national champions. So for now

there is no solution. In the very area where we should have the greatest convergence, since IP markets tend to be worldwide and technology is easily exported, there is extraordinary diversity. As you say, we have not only 90 countries with different competition laws; we still have many countries without IP laws and with no respect for IP whatsoever. We also have countries that grant patents for processes but not for actual products. Unfortunately, you've got to play by all the rules. So while you want to counsel to the highest, most rational law that enables you to pursue legitimate business purposes, there are constant obstacles, like EU pricing laws for dominant firms, that get in the way of sensible behavior.

In the very area where we should have the greatest convergence, since IP markets tend to be worldwide and technology is easily exported, there is extraordinary diversity. As you say, we have not only 90 countries with different competition laws; we still have many countries without IP laws and with no respect for IP whatsoever.

—Debra Valentine

RICH WALLIS: Tim, you wrote an article, and I'll paraphrase your point, but you talked about "lowest common denominator." When you have so many countries, whether it's fly-specking a merger or looking at a licensing arrangement, how do you counsel clients in a way that makes sense when there's not only the U.S. but also other countries that have some connection to the deal?

TIM MURIS: This is an extraordinarily difficult problem in intellectual property, much more so than in mergers, although I think the focus on international antitrust convergence has been correctly on mergers. Mergers are divisible and, for the most part, countries can take different views and still approve the merger. Divestitures can occur, and the facts can be different between Europe and the U.S., for example. Intellectual property, however, usually involves a worldwide market. There is thus going to be a pressing need for close cooperation. There were very extensive discussions between the U.S. and Brussels about the Technology Transfer Block Exemption. Some of the original proposals would have been by far the most profound divergence. Because of very good work by Commissioner Monti, Philip Lowe, and others, divergence didn't occur. Because of the least common denominator phenomenon, it would be a real problem. In antitrust discussions of convergence, our focus has been on mergers because of the filings in so many countries, but I think our focus will move over time more to intellectual property.

RICH WALLIS: Kent, there is considerable talk about convergence in the antitrust arena. We've got organizations like the ICN and the OECD, that are working on convergence, perhaps first in cartels, perhaps simultaneously in the merger arena. These areas have a head start, but IP is far behind in that discussion. And of course there is not a great deal of discussion or movement towards convergence of IP laws at the moment. How do you navigate these conflicts in a way that does not completely eviscerate IP rights?

KENT BERNARD: It's complicated, but I think if I were to give you a one word or a hyphenated word answer it would be "carve-out." Nowhere is it written that license terms have to be the same in every country in the world. It's a simpler agreement if they are, but if you do business in all the countries in the world, you quickly discover that there are a lot of things that are different among countries. And in many things that you're doing, you are making exceptions or having local agreements for how are you going to handle something in a specific country. With IP what we have tried to do generally is, obviously, there will be something for the U.S.—you already know the rules. There will be something for the EU where there really is a structure you can deal with. And then you're going to take a deep breath and pick which countries you feel you need to carve out or not carve out, for example, and it's not done by legal analysis as much as factual analysis. If you're going to have a major investment in a manufacturing plant in a particular country and it needs the IP license to be valid to do that, then you're going to make sure that you're okay under whatever

rules, screwy or not, that country has in place. What the big wild card in this is, and I'd like to open this up for discussion, are countries where there is no IP rule. Or, what is almost worse, where there is an IP rule, but there's no enforcement mechanism. We're shortly going to be dealing with some of the countries that are going to be the largest producers of products in the world. You're looking at China; you're looking at India. It's not a matter of how you're going to structure your license, it's a matter of protecting what you have and figuring out how you'll ever enforce it. On that one I think we're all in the same boat of just trying to figure out what the rules can be, and anybody who has got any advice I'd be happy to write it down.

PETER PLOMPEN: I agree with most of what has been said, although I must make one small remark as to the lowest common denominator. I think in making the decision of how to phrase your license agreements it is also very important to do that on the basis of information about where the license agreement is going to have its major effect, because if the market or the product involved is, for instance, to a large extent produced in the U.S., that will be quite important for deciding how to structure your license agreement. On the other hand, even if many of your licensees are producing in the Far East, as nowadays often is the case at least in my industry, then it's also very important that those licensees, when exporting to Europe or exporting to the U.S., have to live by the rules over there. This may provide an extra argument in any debate with them—how to apply intellectual property/antitrust in their own countries because you can clearly show where there is a difference as to the way they benefit from the rules in Europe and the U.S. and the way other parties importing in the licensees' home countries are being treated. But this is of course another area, e.g., that of the TRIPS Agreement of the WTO.

DEBRA VALENTINE: And that's where I wanted to add something which was almost missed. We competition lawyers all love each other and love talking about competition law and principles. But I think with intellectual property, we've got to start dealing with the trade people. The reason that India is enacting an IP law, the reason that China is instituting IP law, is they want to get into the WTO. And it is going to be the WTO and TRIPS and the regimes that grow up around those principles that are going to be the source of your protection or my protection for our IP. This dialogue with trade officials is something we're not great at yet but it's something we're going to have to do.

RICH WALLIS: I hope everyone has enjoyed this discussion as much as I have. Please join me in thanking our panel. ●