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ANTITRUST AND INTELLECTUAL PROPERTY: DUTIES TO LICENSE, PARALLEL IMPORTS, AND THE QUESTION OF DIFFERENTIAL TREATMENT FOR DEVELOPING COUNTRIES

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Issues at the interface of antitrust, intellectual property and development are arising with increasing frequency and have captured the attention of the international antitrust community as well as the intellectual property and trade communities. In particular, courts, commissions, enforcers, and sometimes legislators are called upon to consider the proper role of antitrust in compelling access to essential intellectual property, the proper role of antitrust in making essential medicines available in South Africa and other developing countries, and the role of parallel imports and restraints on parallel imports in the availability of existing pharmaceuticals and development of new pharmaceuticals.

Professor Merit E. Janow, Professor in the Practice of International Economic Law and International Affairs at Columbia University's School of International and Public Affairs, and Professor Eleanor M. Fox, Walter J. Derenberg Professor of Trade Regulation at New York University's School of Law, convened a workshop to study these issues. The workshop brought together leading academics, legal practitioners, competition law officials, and judges from all over the world, including South Africa, Canada, Japan, Israel, the European Union (EU), and the United States.

The opening session, moderated by Professor Fox, focused on the interface of intellectual property and antitrust, refusals to deal, and exclusionary strategies. Initial comments were provided by Rachel Brandenburger, partner in Freshfields Bruckhaus Deringer, Brussels, and Harry First, Charles L. Denison Professor of Law, New York University School of Law. Workshop participants discussed a number of topics, including interface issues in recent monopoly and dominance cases; whether intellectual property

can ever be an essential facility; whether intellectual property should be entitled to stronger protection than other property rights; and whether certain acts are mere refusals to deal, implying antitrust rules especially deferent to the rights holder, or exclusionary practices involving intellectual property.

The second session, moderated by Professor Janow, focused on licensing and access issues in developing countries. In particular, the discussion concerned the South African HIV/AIDS problem. Norman Manoim, chief executive officer of the South African Competition Tribunal, opened the session with a description of previous antiretroviral drug litigation. Abbott Lipsky, a partner at Latham & Watkins, offered further insights in the areas of antitrust, intellectual property, and essential facilities. Participants discussed whether there is or should be a duty of pharmaceutical companies to charge a “reasonable” price for necessary drugs in developing countries, or whether they should be obliged to grant licenses to generic producers.

The closing session, moderated by Professor Fox, addressed issues surrounding restraints on parallel imports of low-priced drugs and the responses of developed countries. Ian Forrester, a partner in White & Case, Brussels, discussed the issue of parallel imports of pharmaceuticals in the EU and raised questions about the proposed U.S. legislation to facilitate imports of low-priced drugs from Canada. Participants discussed the implications of the free flow of low-priced pharmaceuticals in developed countries for consumer welfare, drug safety, and innovation. Solutions were offered to the problems in North America caused by the price gap between Canada, where new brand-ed drugs are subject to price regulation, and the United States, where companies are free to set higher prices.



Eleanor M. Fox and Merit E. Janow in foreground, left to right.

SESSION ONE

The Interface of Intellectual Property and Antitrust: Refusals to Deal and Exclusionary Strategies

Opening the first session, Rachel Brandenburger, a partner in Freshfields Bruckhaus Deringer, Brussels, discussed whether a conflict exists between intellectual property (IP) and antitrust law. Brandenburger noted the usual inquiry of whether a trade-off exists between competition and innovation. Citing John Vickers, chairman of the UK Office of Fair Trading, she proposed that there is a better inquiry: the trade-off between competition in existing products and competition to develop new and better products. While IP rights may limit competition in existing products, they also stimulate competition to innovate. Brandenburger stated that the scope of an IP right is a matter for intellectual property law while the exploitation of that right is a matter for antitrust law. An additional layer of complexity exists in Europe, where the scope of IP rights is determined by national laws, whereas antitrust law is driven at the EU level.

Having set this stage, Brandenburger asked whether IP rights should be treated differently from other property rights and whether IP rights can be essential facilities. Both the European Court of Justice and the U.S. Supreme Court have been reluctant to confirm or deny the essential facilities doctrine, she said. While some argue that the term “essential facilities” should not apply to IP, the more appropriate consideration, she suggested, is whether ownership rights in physical property infrastructure should be distinguished from rights that are granted under a registration system to protect IP. Moreover, IP rights should not necessarily be subject to greater protection despite their limited nature. Indeed, an owner of IP rights in Europe may be required to license when “exceptional circumstances” exist. The “exceptional circumstances” test was developed by the European Court of Justice in *Magill*¹ and was clarified in *IMS Health*.² It requires three elements for the finding

of abusive conduct. First, the refusal to license by a dominant firm must concern property that is necessary for the creation of a new product for which there is potential consumer demand. Second, there must be no objective justification for the refusal. Third, the refusal must be likely to exclude all competition in the secondary market. In *IMS Health*, the Court appears to have weakened the “secondary market” requirement; a potential or hypothetical secondary market may be sufficient. Uncertainty remains, also, regarding the “new product” requirement. The party requesting the license must not intend to duplicate the goods or services already offered. Beyond this clarification, the Court did not address what a new product is, whether slight improvements to a product constitute a new product, or whether the new product must be substantially different from the existing product.

Brandenburger then turned to the Commission’s *Microsoft* decision³ and asked whether Microsoft’s refusal to provide seamless interface information to work group server rivals was an exclusionary strategy or a simple refusal to deal. She noted that the Commission appeared to have moved away from the “exceptional circumstances” test by examining all the circumstances surrounding Microsoft’s refusal to supply rather than relying on an exhaustive checklist of exceptional circumstances. The decision did not specifically address what the rival must do to constitute creation of a new product. The Commission did, however, conclude that Microsoft’s refusal to supply the seamless interface information had resulted, and would result, in blocking new functions in operating systems or in work group servers. Brandenburger speculated that if, on appeal, the Commission could demonstrate that competitors had been prevented from developing better products than those offered by Microsoft, and that those would-be improvements were sufficient to constitute a new product, the Court could possibly uphold the Commission’s decision as a refusal to deal. Further, the Commission could attempt on



Joseph Stiglitz, Merit E. Janow, and Eleanor M. Fox, left to right

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Peter M. A. L. Plompen and Joseph Stiglitz, left to right

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David Lewis

appeal to characterize the remedy as merely the disclosure of an industry standard, in which case a lower threshold than that provided by the *IMS Health* test would seem appropriate. She invited workshop participants to consider how much inventive effort is actually required to create protocols and specifications that allow work group servers to interconnect with Windows.

Did Microsoft engage in an exclusionary strategy? Microsoft had ceased to provide information to competitors that it had previously made available to some. The Commission argued that Microsoft changed from a competitive course of action when Microsoft did not have its own work group server, to a noncompetitive one after Microsoft developed a competitive work group server. If the Commission’s decision relies on a theory of exclusionary strategy, rather than a simple refusal to deal, Brandenburger said, the ramification may be that a potentially dominant supplier would be safer never to make information available in the first place.

Brandenburger then addressed the defensive leveraging issue. Leveraging occurs when a dominant firm in one market uses its leverage to prevent the development of a complementary product in a secondary market. The Commission’s analysis rested on whether Microsoft’s dominance in the PC operating systems market increased its incentive to prevent others from entering the work group server market, whether denying access to the seamless interface information lowered the quality of competing work group servers, and whether this both increased demand for Microsoft’s work group servers and protected Microsoft’s dominance in PC operating systems. Underlying the Commission’s decision was the view that the effects of leveraging may be particularly strong in industries with network effects.

Harry First, Charles L. Denison Professor of Law, New York University School of Law, was the second inter-venor and brought the discussion back to how we regard intellectual property. The traditional approach to IP rights was to view them as legal monopolies.

Consequently, due to concerns about monopolistic exploitation, they were often narrowly defined. The approach has changed. Intellectual property is now seen as essentially similar to tangible property. However, the inherent “public goods” aspect of intellectual property makes it more prone to free riding and, consequently, rights holders typically argue that stronger protection is necessary to achieve adequate returns and optimal levels of innovation. Indeed, the Supreme Court in *Trinko*⁴ accepts the idea that owners of monopolies should be given strong protection so as to promote innovation and allow maximum returns, because the opportunity to charge monopoly prices, at least in the short term, is what attracts business acumen in the first place.

First then examined the issues of liability and remedies in the U.S. *Microsoft* case.⁵ The Justice Department originally proposed a remedy requiring Microsoft to include competing browsers in Windows for three years, and to allow original equipment manufacturers to remove Microsoft’s browser from Windows altogether. The nineteen states and the District of Columbia proposed an order requiring Microsoft to provide seamless interface information in order to permit competing browsers to function effectively with Windows. Both sets of proposed remedies, said First, related to critical aspects of the bundling and interoperability issues in the European Commission’s case. In the U.S. case, however, only the bundling issue, and not interoperability, arose as part of the liability case (rather than only at the remedies stage). A duty to facilitate interoperability, said First, would have presented additional complexities in the IP context.

In the decision of the D.C. Circuit, the issue of IP protection appeared most prominently in relation to Microsoft’s license agreements with original equipment manufacturers (OEMs). First explained that the agreements prohibited OEMs from altering Windows’ boot-up sequence or its initial appearance (including desktop icons), fearing that such modifications

could be done in ways that would facilitate greater competition from rival browsers. However, whether such modifications violated Microsoft's IP rights was not discussed in the decision. Microsoft argued that its lawfully acquired IP rights in the software allowed Microsoft to impose whatever contractual terms it wanted without giving rise to antitrust liability. The court rejected this argument, stating that it was "no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability."⁶

In the discussion that followed, one participant argued that Microsoft's licensing agreements with OEMs should have been found to be reasonable because, since Windows is a copyrighted work, the creation of derivative works is one of Microsoft's enumerated statutory rights. The participant then turned back to the European Commission's *Microsoft* decision and argued that what the Commission required Microsoft to disclose was valuable proprietary technology and was in fact unnecessary for interoperability. Moreover, the technology would be costly for Microsoft to disclose and would give competitors the ability to offer identical products at a much lower cost. The participant also noted that, unlike previous dominance cases in Europe, the European Commission's *Microsoft* decision did not actually conclude that a competitor was foreclosed from the work group server market, but rather that there was a tendency toward foreclosure.

The workshop moderator invited participants to consider competing arguments regarding the interoperability issue in *Microsoft* in the face of different facts. First, what if the intellectual property to be disclosed is not the product of much creativity and is not costly to disclose? On the other hand, what if the intellectual property is very complex, valuable, and costly to disclose? Do—and should—these different facts make a legal difference?

One participant stated that in 1994 Microsoft licensed certain networking technology to AT&T, and products

made pursuant to that agreement remain on the market today. The contract ended in about 2001, after the alleged refusal to supply Sun Microsystems with different material. The European Commission ordered Microsoft to deliver yet a different set of material. According to the participant, declining to assume a perpetual duty to license technology to the world is not, in such circumstances, a disruption of supply. Whether or not society would be better off if Microsoft behaved differently, said the participant, it is problematic to characterize Microsoft's conduct as abusive when it simply refused a competitor's request for a large amount of valuable intellectual property. What the European Commission was seeking in *Microsoft* was a result-oriented remedy: interoperability in the work group server market. Using the behavioral approach under Article 82 of the EC Treaty of Rome, he said, was not the appropriate tool to achieve the Commission's desired result. While formulating a new set of special rules for companies like Microsoft may be appropriate, he added, the Commission's analysis in the decision, on the basis of current law, seems unpersuasive and result oriented rather than behavior oriented.

Another participant noted a striking difference between the European Commission's approach to interoperability in *Microsoft* and the U.S. Supreme Court's approach in *Trinko*.⁷ While the European Commission demonstrated a willingness to determine whether forced dealing in a specific case is appropriate, the U.S. Supreme Court in *Trinko* expressed a fundamental fear that such case-by-case balancing is likely to chill *ex ante* incentives to innovate and invest. Further, in *Trinko*, the Court distinguished the *Aspen*⁸ case on the grounds that, in *Aspen*, the dominant firm's refusal to deal made no business sense but for an anticompetitive purpose. According to the participant, the European Commission did not examine similar considerations in *Microsoft*. The participant added that another important point in *Trinko* is the importance

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Margaret Bloom, Molly S. Boast, and Paul Crampton, left to right





Calvin S. Goldman

To determine the optimum scope of an IP right, the goals of static and dynamic efficiency should be balanced in a way that maximizes social welfare.

of looking at the availability of remedies other than antitrust remedies. For example, where there is a contractual remedy, an antitrust remedy may not be required.

Turning back to the “new product” requirement in the *IMS Health* test, another participant suggested that the dynamic nature of technology adds complexity to the issue of what constitutes a “new product.” Unlike traditional goods markets, where identifying separate products is generally obvious, software and technology can be more ambiguous. To illustrate this point, the participant used the example of a car, which is naturally considered a single product even though it consists of separate goods such as a frame and an engine. In contrast, software is rapidly changing and, according to the participant, “last year’s complementary product may be a competing product this year.”

On the issue of whether IP can be an “essential facility,” one participant suggested that this question is too narrow. He proposed, instead, that the relevant issue is whether certain IP should be identified as “infrastructure.” Because the distinguishing feature of such technological infrastructure is that it generates massive downstream positive externalities, ensuring open access is necessary to achieve maximum benefits. Another participant argued that IP should never be considered an essential facility because, unlike static infrastructure networks, technology changes rapidly. If IP were designated as an essential facility, antitrust authorities would be required to define the terms under which parties deal, even as the market constantly changes. Thus, argued the participant, antitrust authorities would be placed in a position similar to regulators, and it would be practically impossible for the authorities to constantly catch up.

The participant then suggested that IP owners should be required to share their IP only when a “plus factor” exists; in particular, egregious conduct in highly exceptional circumstances. Another participant added that an important plus factor to consider is fair-

ness. Specifically, decision makers should consider whether the dominant firm built its market power on the efforts of its competitors.

The fundamental premise underlying IP protection, said another participant, is that although exclusive rights tend to lessen short-term static efficiency, granting some degree of exclusivity to IP creators establishes long-term incentives for innovation. To determine the optimal scope of an IP right, the goals of static and dynamic efficiency should be balanced in a way that maximizes social welfare. The participant noted that, historically, one of the advantages of patents versus trade secrets was that patents require disclosure, thus allowing the public to use the disclosed information to advance the state of technology. In contrast, the participant continued, the issue of secrecy in the *Microsoft* case demonstrates a change in the notion of intellectual property.

Participants debated whether optimal legal solutions would be most effectively achieved by *per se* rules or by a rule of reason approach. It was argued that, because compulsory licensing cases require a determination of the optimal scope of IP protection in order to achieve proper incentives for innovation, a rule of reason approach is currently more suitable. As jurisprudence becomes more developed in this area, *per se* rules could be established.

While most participants agreed that a common analytical framework would be helpful, they recognized that formulating such a framework is challenging. Each case so far has been unique. If it is true that without significant protection of the freedom of action of even the dominant firm, incentives to innovate are effectively destroyed, then the Supreme Court’s concerns in *Trinko* seem plausible. Additionally, the prospect of treble damages for prevailing private plaintiffs in the United States presents another difficulty in finding a common framework. The question is whether, as a practical matter, requiring disclosure even only in exceptional cases chills overall innovation.

The moderator closed the discussion with questions for further thought. First,

is there an important value in open architecture, and should we “trust antitrust”? Or do we achieve better results by trusting the individual business players, even dominant firms in network markets? The answer must take into account how the incentives fall on each side.

SESSION TWO

Licensing and Access Issues in Developing Countries: The South African Antiretroviral Drug Case

HIV/AIDS is a severe epidemic in South Africa, and millions of affected individuals have no access to drugs that may alleviate the disease. Such drugs are produced principally by GlaxoSmithKline and Boehringer Ingelheim and, according to activists, are overpriced. The crisis has produced, among other things, an attempt to use South African competition law to compel price reduction or licensing to generic companies. This episode tests the reach of antitrust, as well as the possible limits of intellectual property protection.

Opening this session, Norman Manoim, chief executive officer of the Competition Tribunal in South Africa, provided factual background on previous South African antiretroviral drug litigation. In 2002 a nongovernmental organization called the Treatment Action Campaign (TAC) had, together with other individuals, brought a complaint to South Africa’s Competition Commission, alleging that GlaxoSmithKline and Boehringer Ingelheim were charging excessive prices for antiretroviral drugs in contravention of South Africa’s Competition Act.⁹ The TAC complaint also claimed that a significant amount of innovation in the field of antiretroviral drugs was the result of publicly funded research. When determining the rewards for innovation, TAC argued, this should be taken into account. The Competition Commission referred the complaint to the Competition Tribunal, indicating that it had determined that a prohibited practice had been established. Shortly thereafter, a public announcement stated

that the pharmaceutical companies, the Competition Commission, and TAC had entered into a settlement. Pursuant to the settlement, GlaxoSmithKline and Boehringer Ingelheim would grant nonexclusive licenses to several other firms for antiretroviral drugs in exchange for the withdrawal of the complaint.

At about the same time as the TAC complaint was filed, another nongovernmental organization, the Natal Group (NG), also filed a complaint. NG was not included in the TAC settlement. Despite the fact that the Commission, TAC, and the pharmaceutical companies thought that the TAC settlement had ended the matter, NG referred its complaint to the South African Competition Tribunal. Manoim stated that NG is now solely concerned with obtaining a judicial declaration that GlaxoSmithKline and Boehringer Ingelheim contravened the Competition Act. Under South African law, explained Manoim, such a declaration is required in order to enable a suit for damages. Several procedural hurdles, however, may prevent the case from being heard.

The relevant South African competition law prohibits excessive pricing by firms in a dominant position.¹⁰ In order to establish dominance, one must first define the market. Thus, one must consider whether each antiretroviral drug or cocktail is in a market of its own. Under South African law, a firm is deemed to be dominant if its market share is above 45 percent.¹¹ While South African law states that it is unlawful for a dominant firm to charge excessive prices, the law does not define what is an excessive price, and there is no South African case law on this issue. The TAC complaint compared the prices of patented antiretroviral drugs in South Africa with generic prices available elsewhere in the world, and alleged that the prices of patented drugs were far in excess of the generic prices, even with an allowance for research and development, higher profits, licensing fees, and the incentive to develop new drugs.¹²

While the public sector could require compulsory licensing, it had not chosen to do so.¹³ Thus, TAC alleged that it could not rely on the public sector



Dennis Davis

The relevant South African competition law prohibits excessive pricing by firms in a dominant position.

Mary E. Bartkus, Norman Manoim, and Harold S. H. Edgar, left to right





Margaret Bloom, Molly S. Boast, Paul Crampton, and Spencer Waller, left to right

Using antitrust law in areas where it is institutionally inappropriate is like “trying to program a computer with a baseball bat.”

because of the lack of government belief in providing drugs. There was no other alternative to provide a remedy, TAC argued, but antitrust law.

The second intervener was Abbott Lipsky, a partner at Latham & Watkins, who examined whether antitrust is the appropriate tool to ensure access in cases such as the South African antiretroviral drug case. First he argued that protection of intellectual property rights is not the only way to promote innovation. To illustrate this point, he raised an example in which mandatory sharing and patent pools have resulted in dramatic innovation. In the early days of the American aircraft industry, he explained, the Wright brothers had patents on one aspect of aircraft construction while Glenn Curtiss had patents on another. From about 1903 to the end of World War I, no one would make aircraft because they feared being sued under either the Wright patents or the Curtiss patents. When Congress perceived a potential military need for aircraft, it threatened to confiscate both sets of patents unless the parties reached a solution. Consequently, said Lipsky, the Curtiss-Wright Corporation was created and an aircraft patent pool was formed. The company was governed by a committee of representatives consisting of all of the component manufacturers, and the committee jointly decided whether proposed innovations should be pursued. In this way, antitrust intervention was avoided while innovation flourished.

Lipsky then turned to the essential facility doctrine. The essential facilities doctrine under European and American law, he said, assumes that an industrial structure that cannot be practically duplicated is essential to competition in a particular sector. This, argued Lipsky, is a classic case for public utility regulation and is exactly the point at which antitrust law should not apply. Indeed, for the reasons articulated by the U.S. Supreme Court in *Trinko*,¹⁴ he said, courts are particularly unsuited for the kinds of mandatory sharing judgments that must be made following a finding of an essential facility. Lipsky warned that using antitrust law in areas where it

is institutionally inappropriate is like “trying to program a computer with a baseball bat.”

Mandatory sharing, said Lipsky, is not the problem. Rather, the problem is decreeing a mandatory sharing regime after firms have made investments, formed expectations, and established commercial relationships. When mandatory sharing is imposed *ex post*, incentives to innovate are destroyed.¹⁵ A preferable approach, he suggested, would be to use *ex ante* methods, which would not distort incentives for innovation. For example, direct public funding can be used in areas of particular importance, such as the control of a disease like AIDS.

In discussing the South African HIV/AIDS problem, one participant identified two very different bases of the problem. First, until several years ago, South African President Thabo Mbeki had opposed the use of antiretroviral drugs, insisting that they did not work and actually might poison the population. Second, South Africa’s health care infrastructure, while relatively advanced compared to most of Africa, is relatively primitive compared to health care in the first world. Consequently, there is a strong advantage in combining three antiretroviral drugs in a “triple cocktail” pill taken once a day. The difficulty is that GlaxoSmithKline controls patents on some antiretroviral drugs while Boehringer Ingelheim has patents on others. These various drugs are essential components of any combined therapy. Because the pharmaceutical firms refused to cross-license their patents, an effective triple cocktail could not be created. According to the participant, this could be characterized as an essential facility problem. The cause for intervention may have been this lack of cooperation.

It was reported that the South African antiretroviral drug issue first arose in 2002 when generic pharmaceutical companies filed a complaint with the Competition Commission. At that time, the Commission decided not to refer the complaint to the Tribunal. It took into account the pro-competitive functions of high prices, namely to induce entry and

innovation and to reward higher quality or convenience. Further, it recognized that the granting of patents encouraged research and development.¹⁶

In contrast, when the TAC complaint was filed, the Competition Commission stated that its duty was to ensure that cheaper drugs were made available to the public. The Competition Commission looked to foreign jurisdictions in which refusing to grant access to an essential facility is a recognized form of abuse, and an IP right may be an essential facility. One practicing lawyer argued that, given this context, developed nations have a particular responsibility to establish clear and carefully considered competition laws because developing countries are likely to adopt similar laws.

Would requiring reasonable pricing for critical pharmaceutical products have a significant effect on overall incentives for innovation? According to one participant, it would only have a minuscule effect because, at high prices, sales in developing countries are relatively low.

It was suggested that the South African case introduces a global issue: is there a right for developing countries to benefit from the research conducted in other countries? Antiretroviral drugs are a global public good; the research holds benefit for individuals all over the world. The real question, it was suggested, is who should bear the costs for such global public goods. A participant argued that it makes sense for the United States and Western Europe to pay. This would be the most effective form of assistance those countries could provide to developing nations.

Pharmaceutical firms were criticized for moving substantial amounts of profit offshore. In fact, said a professor, the Internal Revenue Service is currently pursuing pharmaceutical firms for the movement of billions of dollars offshore, and in proper perspective this dwarfs any profits that might be made in South Africa.

The group debated whether antitrust law is an appropriate tool to use in the South African antiretroviral drug case. One intervener argued that competition law should be used only as a last resort and only when it would be more effec-

tive than other measures. Another added that the case has little to do with antitrust and much more to do with a larger important set of social issues. Others disagreed, believing that antitrust law could be an appropriate instrument to regulate excessive prices. For example, a professor noted that in the United States, musical performing rights organizations (ASCAP and BMI) have been subject to an antitrust decree since 1941, requiring them to license performing rights at reasonable rates. The courts have successfully intervened when the parties have had difficulty determining reasonable rates. Turning back to the South African antiretroviral drug case, the participant suggested that South Africa could implement a creative antitrust solution and that the first world could ultimately learn something from such a solution. Competition in competition policy, he said, could be beneficial.

A South African judge explained the important role of the South African Constitution, adding a dimension not present in the law of most other nations. Section 27 of the South African Constitution grants a right to health. The constitutional right to health may give added weight to the argument that individuals have a statutory right to affordable drugs. Another South African participant added that while the South African Constitutional Court has already determined that South Africans have a right to health in the AIDS context, the Court has not yet determined who pays for it.¹⁷ Implicit in an excessive pricing claim is that, rightly or wrongly, under South Africa's Competition Act, the costs can be borne by the drug companies. Another participant suggested that the real issue is whether the companies or the countries should pay for innovation in critical pharmaceutical products.

A member of the group drew the conversation to a close by noting that malaria and other forms of infectious disease, rather than AIDS, are the leading cause of death in South Africa. Therefore, he argued, before concepts like excessive pricing are introduced into law, there must be a sense of "where you want to draw the line."

Would requiring reasonable pricing for critical pharmaceutical products have a significant effect on overall incentives for innovation?

William J. Kolasky, Donald I. Baker, and Charles Stark, left to right

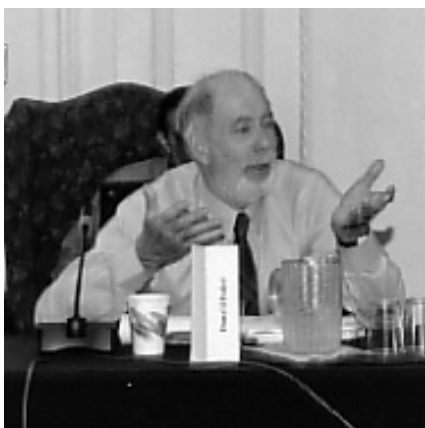




F. M. Scherer and Ilene Knable Gotts, left to right

In the United States, the law currently bans parallel imports in branded prescription drugs, whereas in the EU internal market IP holders may not block parallel imports.

Donald I. Baker



SESSION THREE

Restraints on Parallel Imports of Low-Priced Drugs and Responses of Developed Countries

Session three addressed the responses of developed countries to parallel imports of low-priced drugs, with particular focus on the EU and North America (United States–Canada). In the United States, the law currently bans parallel imports in branded prescription drugs, whereas in the EU internal market (as opposed to trade into the EU), IP holders may not block parallel imports. The use of intellectual property or contractual restraints to keep all parallel imports out of a member state is an antitrust offense on the theory that the restraints isolate markets and thus harm trade and competition.¹⁸ In the United States a pending bill would require pharmaceutical companies to allow and even facilitate parallel imports of low-priced drugs into the United States. The session focused on whether government facilitation of parallel imports is wise policy.

Participants raised a number of concerns of developed countries regarding the implications of the free flow of low-priced pharmaceuticals for consumer welfare, drug safety, and innovation. They also proposed ways to solve the problems in North America caused by the price gap between Canada, where new branded drugs tend to be much lower priced because of price regulation, and the United States, where companies are free to set their own prices.

The first commentator, Ian Forrester, a partner in White & Case, Brussels, discussed the special situation of parallel imports of pharmaceuticals within the EU and raised some questions about the North American situation and U.S. legislation.

In Europe, to pursue the goal of market integration, derogations have been made from the normal rules governing packaging, labeling, and trademarks. Consequently, wholesalers are allowed to repackage medicines delivered in Greece, Italy, or Spain to

make them more attractive to patients in northern Europe. These derogations are unique and in practice apply only to pharmaceuticals. There have been a number of episodes (imperfect packaging, language omitted from the patient leaflets, batch numbers omitted), which, according to the pharmaceutical industry, indicate that wholesalers are not reliable and trade is risky. However, Forrester is not aware of any patient who has ever suffered harm from such episodes. The topic, he said, is underresearched, and those who comment are thought to be impartial.

The message he offered for North America was that there may be some parallels: dangers in Canada due to allegedly careless pharmacy practices, yet a lack of specifically documented harms. Does this mean drugs are overregulated in Europe and North America and that losing some precautions does not matter? Or does it mean that we accept some diminution in public health protection in order to achieve other goals, such as market integration and cheaper drugs for the elderly? This topic, Forrester argued, requires more research.

F. M. Scherer, Aetna Professor Emeritus, Harvard, was the second commentator. He analyzed the reasons that lead to parallel trade and explained why reimportation of drugs from Canada would not solve the problem of high-priced pharmaceuticals in the United States.

He stated that compulsory licensing, and therefore a lower level of profits for pharmaceutical companies, would harm innovation. There is strong evidence that when profits in pharmaceuticals rise, research and development (R&D) expenditures rise and vice versa; therefore prices of pharmaceuticals should be set to encourage R&D.

But how do we set prices?

In a wealthy country like the United States, the demand curve is high relative to the zero axis. In poor countries, the demand curve is low relative to the zero axis. According to the Ramsey pricing rule in economics, to maximize the profit contribution to repayment of

R&D outlays, one of the best pricing policies is to set high prices in the wealthy countries (low price-elasticity markets) and low prices in the poor countries (high price-elasticity markets). This pricing scheme results in price differences of pharmaceuticals between rich and poor countries.

Price differences, however, cause parallel trade of low-priced drugs from poor to rich countries. The parallel trade undermines the high prices in rich countries and discourages pharmaceutical companies from setting low prices in poor countries. Price differences are similarly caused by price controls. In order to have an optimal pricing scheme, export of low-priced pharmaceuticals from poor to rich countries should be inhibited.

With respect to the U.S.-Canada issue concerning parallel trade, Scherer made two initial remarks. First, Canadians are per capita as rich as U.S. citizens. Second, Canada has systematic reference price controls in pharmaceuticals. As a result, branded drugs have lower prices in Canada than in the United States, where companies set the highest price the market will bear. The price differences lead to parallel imports of pharmaceuticals from Canada to the United States. The drugs imported from Canada undermine the profitability of pharmaceutical sales in the United States and raise concerns for the pharmaceutical companies regarding recovering of investments and making profits. Safety issues, it was argued, are not really a part of these concerns.

As a response to parallel trade of low-priced drugs from Canada, the U.S. pharmaceutical companies reduce their shipments of drugs to distributors in Canada in order to make products sufficiently scarce in Canada and decrease the likelihood of the shipping of the drugs back to the United States. The shortages in the Canadian market could cause two possible results: if prices were allowed to move freely, the insufficient supply would cause prices to rise; if prices were not allowed to move freely, the shortages would cause non-price rationing.

But how is the Canadian government expected to react?

The Canadian officials fearing shortages would probably try first to stop the flow of parallel exports to the United States. Their second resort would be to impose compulsory licensing in order to fight shortages and/or black markets. Pharmaceutical companies were already confronted with compulsory licensing in Canada during the late 1980s. Later, the drug industry accepted an offer by the Canadian government to abide by price controls in place of compulsory licensing. Parallel trade and shortages will probably induce the Canadian Government to move again toward compulsory licensing.

The efforts to cut off parallel trade have succeeded in drying up the supply of drugs from Canada to the United States. As a result, the various middlemen in the United States are turning to other countries, such as Ireland and Mexico, for drug supplies. This complicated set of flows will probably create some safety concerns. In any case, even if parallel trade were facilitated, Canada's market size cannot satisfy a significant fraction of the United States' low-priced drug needs.

Scherer concluded that importing drugs from Canada would not solve the problem of expensive drugs in the United States, for various reasons. First, there are not enough drugs in Canada to satisfy U.S. needs for low-priced drugs. In addition, pharmaceutical companies in the United States will take action to prevent parallel imports by denying supplies to distributors that export to the United States. Third, it will be in the interest of exporting countries that control their prices to prevent parallel trade.

Participants agreed that international price differences caused mainly by national price regulations trigger parallel trade. It was pointed out that different governments regulate prices in order to achieve particular objectives, for example to support their domestic drug industry. Therefore, it was argued, the regulation of prices is part of each country's industrial policy and not an

Price differences, however, cause parallel trade of low-priced drugs from poor to rich countries. The parallel trade undermines the high prices in rich countries and discourages pharmaceutical companies from setting low prices in poor countries.

John Frank and Ian Forrester, left to right





Mark Warner and Joseph Stiglitz, left to right

One participant said that pharmaceuticals would achieve a more consumer-friendly global price as a result of free parallel trade. Others countered that price discrimination is necessary to provide poor countries with essential pharmaceuticals and to save millions of lives.

antitrust issue.¹⁹ One participant queried whether countries that set low prices for pharmaceuticals fulfill their obligation to protect intellectual property rights pursuant to the TRIPs agreement.

Regarding safety concerns, one participant stated that warnings have been made to the American public that drugs sold in the United States were produced in underdeveloped countries, implying substandard products. These warnings, the intervenor said, are inaccurate. Many U.S. multinational pharmaceutical companies outsource their basic drug production to Indian companies, which ship the drugs back to the United States. India is the leading supplier of generic drugs to the United States.

A participant suggested that a solution to parallel trade could be “negotiations” between the different countries to set prices. Another suggestion was that the EU could regulate differential prices in its member states, balanced if necessary by the European budget. This solution was opposed as not feasible; social security systems remain under the aegis of national authorities.

Another participant raised the question of whether and how the resale behavior of distributors should be controlled. Reexportation of drugs often causes shortages in the domestic markets. It was therefore suggested that

drug companies should organize their production capacity and inventory management in such a way as to ensure that domestic demand is satisfied in the countries in which its subsidiaries operate. What happens if these companies are unable to control the reselling behavior of their purchasers? Those purchasers, desiring to profit, sell the product to the countries that have high-priced drugs and pocket the profits for themselves. Consequently there is not enough product left in that country, as it has almost all gone to higher-priced countries, enriching the intermediary.

The proposition that the freedom to price discriminate is good and that the unleashing of parallel imports is bad was hotly debated. One participant said that pharmaceuticals would achieve a more consumer-friendly global price as a result of free parallel trade. Parallel trade would reduce drug prices in the hospital market, making more drugs available. Others countered that price discrimination is necessary to provide poor countries with essential pharmaceuticals and to save millions of lives. The freedom to restrain parallel trade helps pharmaceutical companies fulfill their “social responsibilities,” i.e., set low prices in poor countries without the threat of parallel imports back into the developed countries.



Joseph Stiglitz, Harry First, Merit E. Janow, Eleanor M. Fox, Vanu Gopala Menon, and Mark Warner, left to right



¹ *RTE v EC Commission*, judgment 10 July 1991, upheld on appeal as Case C-241/91 P, *RTE and ITP v. Commission* (1995) E.C.R. I-743, judgment 6 April 1995.

² *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*, Case C-418/01, 29 April 2004, not yet published in ECR but available on the Court's Web site at <http://curia.eu.int> (2004 ECJ CELEX LEXIS 166).

³ Commission Decision 24.03.2004 (Case COMP/C-3/37.792 Microsoft), stay of remedies denied, appeal pending.

⁴ *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004).

⁵ *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C.Cir.), cert. denied, 534 U.S. 952 (2001).

⁶ *Id.*, at 63.

⁷ See note 5, *supra*.

⁸ *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985).

⁹ Materials supporting the TAC complaint to the South African Competition Commission are available at <http://www.tac.org.za/Documents/DrugCompaniesCC/DrugCompaniesCC.htm>.

¹⁰ Section 8(a), South African Competition Act, 1998.

¹¹ Section 7(a), South African Competition Act, 1998.

¹² The TAC complaint stated that the

Competition Commission's approach to excessive pricing was dealt with in "Excessive Pricing, Fairness and Economic Value", appearing in a Commission publication entitled *Competition News* (September 2001), available online at www.compcom.co.za/resources/SeptNews.pdf. In this article, the Commission stated that:

It may be necessary to take a pragmatic approach to the analysis of excessive pricing. Such an approach may be as follows: in order to establish economic value, a cost-based approach should be followed, taking the manufacturing costs of the particular product into account, with an industry norm profit margin added. It may also be necessary to add premiums for special circumstance, i.e. risk, cost of innovation or intellectual property, etc. (at page 7)

¹³ The South African government initiated large-scale litigation against pharmaceutical companies in 2002 to obtain the right to require licensing in these situations and to parallel import. See footnote 18, *infra*.

¹⁴ *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko*. *Id.*, at note 4, *supra*.

¹⁵ Later in the discussion, Lipsky clarified that this may not be a problem in the South African context because excessive pricing, refusal to deal, and essential facilities provisions are already written into South African law.

¹⁶ See the 2003 Annual Review of the Competition Commission of South Africa,

available online at:

<http://www.compcom.co.za/resources/Annual%20report%202002&03%20HTML/Annual%20Review/reviewsetframe.html> or <http://www.compcom.co.za/resources/Annual%20report%202002&03%20WORD/compcomm%20ann.review.doc>.

¹⁷ See *Minister of Health v. Treatment Action Campaign*, Case CCT 8/02, July 5, 2002 (holding that, under the Constitution of the Republic of South Africa, "the government [must] devise and implement within its available resources a comprehensive and co-ordinated programme to realise progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV"); available online at <http://www.concourt.gov.za/judgments/2002/tac.pdf>.

¹⁸ In the precedential case *Consten and Grundig v. Commission*, cases 56, 58/64, [1966] ECR 299, the European Court of Justice held that it is a most serious infringement of Article 81 of the EC Treaty for a producer to parcel out distribution territories at Member State lines, to require an exclusive distributor to sell only within a state and to prohibit selling into the exclusive territories of others.

¹⁹ This is an antitrust issue in the EU (see footnote 18, *supra*).

AGENDA

Workshop, Co-sponsored by
NYU School of Law and
Columbia School of International and
Public Affairs and APEC Study Center

Saturday, October 9, 2004
9:00 a.m. to 1:45 p.m.

Post-Fordham International Competition
Policy Conference held at NYU School
of Law, 40 Washington Square South,
Greenberg Lounge

INTERNATIONAL COMPETITION POLICY: ANTITRUST AND INTELLECTUAL PROPERTY— DUTIES TO LICENSE, PARALLEL IMPORTS, AND THE QUESTION OF DIFFERENTIAL TREATMENT FOR DEVELOPING COUNTRIES

8:45–9:00 coffee

9:00–9:10 welcome, Merit E. Janow and Eleanor Fox

9:10–10:30 Session One: Antitrust and Intellectual Property—U.S. and EU

Interface issues in monopoly/dominance cases: *IMS*, *Microsoft*, implications of *Trinko*. We distinguish two kinds of cases: where the sole challenged act is refusing to license IP, and where the main challenged act is an exclusionary practice that involves IP. Is IP ever an essential facility? Is IP entitled to special status, more than other property rights? Is Microsoft's refusal to provide seamless interface information to workgroup server rivals an exclusionary strategy or a simple refusal to deal?

Moderator

Eleanor Fox

Initial commentators

Rachel Brandenburger

Harry First

10:30–10:40 coffee

10:40–12:00 Session Two: International—development issues and parallel imports

Issues raised by the South African anti-retroviral drug cases: Is there and should there be a duty of pharmaceutical companies to charge, in developing countries, no more than a reasonable price for necessary drugs or to grant a license to generic producers? What differences between a refusal-to-license case and an excessive pricing case: legally, economically, practically? Should we distinguish questions of fairness from questions of efficiency? Would arbitrage undermine special treatment for developing countries, and how could it be prevented?

Moderator

Merit E. Janow

Initial commentators

Norman Manoim

Tad Lipsky

12:00–1:30 Session Three (working lunch): Restraints on parallel imports of low-priced drugs and responses by developed countries

Is there or should there be a duty of pharmaceutical companies to allow or even facilitate parallel imports? Consider, e.g., the EU antitrust law against such vertical restraints within the European market, and the proposed U.S. legislation to facilitate imports of low-priced drugs from Canada. What are the implications of the free flow of parallel imports—for consumer welfare, for innovation?

Moderator

Eleanor Fox

Initial commentators

Ian Forrester

F. M. Scherer

1:30–1:45 Concluding remarks: Merit E. Janow, Eleanor Fox

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