

EXPERT REPORT FMS

IN THE MATTER OF GLAXOSMITHKLINE SOUTH AFRICA ET AL.

F.M. Scherer

28 August 2003

Introduction

I have been asked by the Consumer Project on Technology (CPTech), consultants to the Competition Commission of South Africa, to prepare this statement summarizing my understanding of and opinions on the HIV drug pricing matter pending before the Competition Commission. I am not being compensated for my work in preparing the statement.

A copy of my curriculum vitae is attached as Appendix A. In brief, I am Aetna Professor emeritus in the John F. Kennedy School of Government, Harvard University. Since my retirement in 2000 I have been serving as a lecturer in the Woodrow Wilson School of Public and International Affairs, Princeton University. Between 1974 and 1976, I was director of the Bureau of Economics (i.e., chief economist) of the U.S. Federal Trade Commission. During much of my career, starting with work in 1959 as a junior consultant in the U.S. tetracycline antitrust cases, I have conducted a good deal of research and consulting on pharmaceutical industry matters. In the early 1990s I was chair of the advisory committee to the U.S. Office of Technology Assessment in the preparation of its book-length report, *Pharmaceutical R&D: Costs, Risks and Rewards* (February 1993). During the past several years I have worked with Jayashree Watal, now at the World Trade Organization, on the impact of the Uruguay Round intellectual property (TRIPS) agreements on access to pharmaceuticals by developing nations. I shall refer in this report to publications from that work.

As I understand it, the principal question before the Competition Commission is whether Glaxosmithkline and Boehringer Ingelheim and their various affiliated companies have abused dominant positions in the sale of AIDS anti-retroviral drugs (ARVs) in the South African market and, whether or not they did, what remedies might be available to make ARVs more affordable to South African citizens and health care agencies.

Compulsory Licensing Regimes

Many nations, industrialized and developing, have included in their patent laws provisions permitting compulsory licensing of patents under specified conditions.

Under U.S. law, the federal government may utilize technology patented in the United States when such utilization serves the national interest and reasonable compensation is paid.¹ During the 1950s and early 1960s, the U.S. Department of Defense exercised its right to procure patented pharmaceutical products at substantially reduced prices from sources other than the patent holder -- in most cases, from producers in nations such as Italy that provided no patent protection for pharmaceutical products.

The United States has led the world in issuing compulsory licenses to restore competition when violations of the antitrust laws have been found, or in the negotiated settlement of antitrust cases before full adjudication has occurred. By the end of the 1950s, compulsory licenses had been issued in roughly 100 antitrust cases covering an estimated 40 to 50 thousand patents, including AT&T's basic transistor concept patents, IBM's computer and tabulating card machine patents, General Electric's fluorescent and incandescent lamp patents, Du Pont's nylon patents, and Eastman Kodak's color film processing patents. Additional cases since then have led to the licensing of Xerox's plain paper copying machine patents, the tranquilizer Meproamate, synthetic steroids, the antibiotic Griseofulvin, Cytokine biopharmaceutical patents owned by Novartis and Chiron, and the 9-AC cancer drug patent rights assembled under the merger of Pharmacia AB with Upjohn.

Some of the U.S. antitrust decrees, such as those covering General Electric's incandescent lamp patents and many of the patents in AT&T's portfolio, required licensing at zero royalty rates.² Most provided for "reasonable" royalties, whose more precise meaning will be investigated subsequently.

The competition policy precedents of leading European nations and the European Community are in some respects more expansive than those of the United States. A

¹ 28 U.S.C. 1498.

² In *United States v. General Electric Co.*, 115 F. Supp. 835, 844 (1953), the court explained:

General Electric and the other defendants are mounted upon an arsenal of a huge body of patents that can easily overwhelm and defeat competition by small firms desiring to stay in or gain a foothold in the industry. These operators may well be unequipped to engage in litigation on the validity of one patent after another at what could be incalculable expense. In order to avoid it they could be required to shoulder royalties which could prove to be the very factor that would push them out of the competitive circle of the market.

In the circumstances such as these it would appear that royalty free licensing of patents on lamps and lamp parts is an essential remedy as a preventive against a continuance of monopoly in this industry. It would appear to be no more objectionable as confiscatory than where compulsory licensing is ordered. In the latter case the owner admittedly is permitted to receive a royalty but he nevertheless loses a monopoly inherent in his ownership of the patent, and the royalty he is forced to accept at times is not one that he fixes. Royalty free licensing and dedication are but an extension of the same principle, not to be directed indiscriminately, of course, but well within the therapeutic measures to be administered under circumstances such as were made to appear in this case.

company that controlled patented processes used to produce a key chemical intermediate for a drug effective against tuberculosis was found under Article 86 of the European Community treaty to be abusing its monopoly power when, after entering into production of the drug through its own subsidiary, it subsequently refused to sell or license the intermediate to an independent pharmaceutical manufacturer.³

Reacting to the "stagflation" tendencies of the 1970s, the German Federal Cartel Office instituted a series of actions asserting that enterprises with dominant market positions, based in some cases on patent rights, had abused their monopoly power by effecting unjustified price increases.

The United Kingdom and Canada provide the leading examples of compulsory licensing of drug patents without a finding that the anti-monopoly laws have been violated. In the United Kingdom, Section 41 of the Patents Act of 1949 distinguished foods, medicines, and surgical devices from other patent-protected products by articulating a rebuttable presumption in favor of compulsory licensing to ensure that the products are "available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights." Between 1953 and 1971, a total of 20 compulsory licenses were granted in response to 54 applications, covering inter alia such important products as Chloromycetin, Librium, and Valium.

The U.K. laws on compulsory licensing were recently amended. Compulsory licensing of WTO-member nationals' patents can be ordered under Section 48 of the current Patents Act when the U.K. demand for a patented invention is not being met "on reasonable terms," or when the patent owner has refused to grant a license "on reasonable terms," or (under Section 51) when a monopoly found by the U.K. competition policy authorities to be operating against the public interest has refused to make patent licenses available "on reasonable terms."⁴

Canada's experience has been more far-reaching. Since 1923 Canada had a law providing for compulsory licensing of the right to manufacture within Canada drugs (and also food products) protected by patents (usually process patents, since product patents were not available at the time). Recognizing that importation of bulk ingredients was virtually essential if Canadian consumers were to receive the intended benefit of medicines "available ... at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention," the Canadian Parliament amended the law in 1969 to permit compulsory licenses for importation.

Between 1969 and 1977, 227 licenses were issued. Although some license recipients did not follow through by actually supplying the drug in Canada, in many cases, and

³ *Commercial Solvents v. Commission of the E.C.* [1974] E.C.R. 223.

⁴ See www.patent.gov.uk

especially for the drugs with substantial sales volume, competition was secured in the generic provision of drugs that would otherwise have been monopolized by the patent owner.

On average, generic drugs supplied under compulsory license captured roughly 19 percent of the total sales of the product lines in which they competed, with penetration rates varying widely across Canadian provinces, depending upon the extent to which provincial drug reimbursement rules encouraged or discouraged generic substitution. A study of 29 drugs subjected to compulsory licensing in Canada but patented in the United States revealed that the Canadian prices were on average 47 percent lower than their U.S. counterparts in 1982. For Valium, one of the world's best-selling drugs during the 1970s and the licensed drug sales leader in Canada, the price to hospitals fell from \$42 per 1,000 units before licensing to \$4.10 by the end of the 1970s.⁵

Compensation Determination Experience

For U.S. government use of Enrico Fermi's patent governing plutonium production, a payment of \$300,000 was made -- one percent of the government World War II investment in the Hanford plutonium extraction facilities. The heirs of Robert S. Goddard were paid \$1 million for the government's use of Goddard's rocket engine patents -- about 0.01 percent of the value of the liquid-propelled rockets produced by the U.S. government during the life of the patents.

In what was initially described as the largest patent compensation case in history, Hughes Aircraft claimed a 15 percent royalty, or \$3.3 billion in total, on the value of 81 government satellites using Hughes' geostationary orbit technology. The U.S. government argued for, and received, a 1 percent royalty in the U.S. Court of Claims.⁶

According to a 1991 survey, the highest royalty rate paid by the U.S. government in compensation for the use of a portfolio of pioneering private patents was 10 percent.⁷ Rates of 6 percent were said to be applied "as a general rule" in the absence of contrary evidence.

Some important U.S. antitrust judgments, as noted earlier, have required that patent portfolios be licensed at zero royalty rates. In the more typical cases, royalty rates have been modest. For example, licensees were required to pay 0.5 percent ad valorem for the first Xerox plain paper copying machine patent they used, an additional 0.5 percent for the second patent, and then an additional 0.5 percent (implying a maximum royalty of 1.5 percent) for the remainder of Xerox's vast patent portfolio. At the time, Xerox was devoting 5.6 percent of its sales revenue to research and development. In an action later reversed on unrelated

⁵ Despite opposition from consumer advocates and Canadian generic drug providers, the Canadian compulsory licensing law was weakened in 1987, with the imposition of a seven to ten year exclusivity period for drug patent holders, and eliminated altogether in 1992. The principal impetus was lobbying by U.S. and European pharmaceutical manufacturers anticipating the debate over the proposed free trade treaties between Canada, the United States, and (later) Mexico. As a quid pro quo, the multinational drug manufacturers agreed to locate in Canada drug research and development activities roughly proportional to Canada's share of their world sales and to accept a new regime of "reasonable price" controls by the Canadian Patented Medicines Review Board.

⁶ See *Hughes Aircraft v. United States*, 86 F3d 1566 (Fed. Cir. 1996).

⁷ McGrath (1991).

procedural grounds, the Federal Trade Commission ordered that the patent covering the antibiotic tetracycline be licensed at an ad valorem royalty rate of 2.5 percent. Before generic competition began, tetracycline was sold at wholesale for a price of \$30.60 per 100 capsules. Production costs were on the order of \$3.00, so a "profits lost" royalty rate would have been on the order of 90 percent.

In most compulsory licensing cases, royalties were left to be settled through negotiations by the parties, so no public record exists. But in the minority of cases requiring the courts to step in and settle disputes, royalties of from 0.2 to 3.0 percent have been reported. The merger of Ciba-Geigy with Sandoz was approved in 1997 by the U.S. Federal Trade Commission under an order requiring inter alia that Cytokine patents be licensed at royalty rates not exceeding 3.0 percent and gene therapy patents at a flat payment of \$10,000 plus a royalty rate exceeding by not more than 1.0 percent the royalty the merged firm was required to pay to the U.S. National Institutes of Health, which had made important contributions to the technology.

The United Kingdom Comptroller of Patents pursued an essentially cost- and profit-based approach to setting royalties for compulsory licenses to drugs under section 41 of the U.K. Patents Act. To research, development, and testing costs averaged over the licensing firm's pharmaceutical operations, a fairly generous profit margin was added to arrive at the royalty per kilogram. This approach led to a fixed royalty per kilogram of the tranquilizer Librium that approximated 18 percent of the average price received by Hoffmann LaRoche on its U.K. sales, but a higher percentage rate on the lower sales price attainable by generic producers. On Librium's more potent sister drug Valium, the per-kilogram royalty was set at roughly 22 percent of the selling price received by Hoffmann-LaRoche.

These royalties, although lower than the marginal profit rates realized by the patent-holding drug manufacturers, were sufficiently high to have impaired significantly the market inroads of compulsory-licensed substitute drugs.

During the 1970s and much of the 1980s, Canada had the world's most far-reaching compulsory drug licensing program, at least in part because of the royalty determination approach adopted. Section 41(1) of the Canadian Patent Act as amended in 1969 declared:

[I]n ... fixing the amount of royalty or other consideration available, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention.

In an early test case, the Commissioner of Patents rejected a fixed per-kilogram royalty proposal by Valium patent holder Hoffmann- LaRoche, which would have amounted to 30 percent of HLR's selling price and a substantially higher percentage of a generic substitute's price. Instead, an ad valorem rate (against the licensee's price, not the licensor's)

of 4.0 percent was set. On appeal, the Exchequer Court affirmed the Commissioner's 4.0 percent rate, among other things rejecting the suggestion that royalties on licensed sales should reimburse a pro-rated share of the patent holder's research and development program outlays.⁸

The 4.0 percent royalty rate was applied almost uniformly in subsequent compulsory licensing orders, among other things avoiding a detailed inquiry into unique cost factors by the Commissioner of Patents and the reviewing courts and hence facilitating procedures that expedited the entry of generic substitute drugs into the Canadian market.

To sum up, there is wide variation in the way responsible government agencies and courts have set the amount of compensation awarded to patent holders when patents have been subjected to compulsory licensing. The United Kingdom has provided the most generous compensation in its drug patent licensing decisions; the United States the least generous compensation in key antitrust case orders. None of the royalty determinations on which information is available have established rates approaching those that would emerge under a "lost profits" criterion.

⁸ *Hoffman-LaRoche v. Frank W. Horner*, 61 C.P.R. 243 (1969), 64 C.P.R. 93 (1970); affirmed by [1972] S.C.R. vi (note); 5 C.P.R. (2d) 3 (note).

Pricing to maximize global welfare

In our most complete published analysis, Watal and I conclude that when the prices of drugs are set across a diversity of nations, some relatively rich and some relatively poor, and assuming that the demand curves for rich nations are located higher relative to costs than the demand curves for poor nations, the most desirable structure of prices is one in which there is significant price discrimination, with consumers in rich nations paying relatively high prices and consumers in poor nations paying relatively low but above-marginal-cost prices.⁹ This scheme of discriminatory pricing, sometimes called Ramsey pricing and sometimes equity pricing or tiered pricing, ensures that consumers in rich nations make larger contributions to the recoupment of research and development costs than those in poor nations, but all make some contribution. Specifically, we conclude (p. 928):

It can be shown that the most efficient solution is one in which prices are elevated above the marginal costs of production more, the less elastic demand is in any given market. 'Most efficient' in this sense means that the fixed costs are recovered and the sum of producer's surplus (e.g. contributions to fixed costs and profits) plus consumers' surplus (i.e., the amount consumers are able and willing to pay, less what they actually pay) is maximized [footnote not included here]. Discriminatory pricing along Ramsey lines approaches as closely as one can reasonably hope to an ideal price-setting method in an intrinsically imperfect world.

Market segmentation strategies

In a parallel article published in Brigitte Granville, ed., *The Economics of Essential Medicines* (London: Royal Institute of International Affairs, 2002), pp. 42-48, Watal and I discuss a market segmentation case, which, we speculate, might approximate conditions in South Africa, with its particularly unequal distribution of income. One hypothetical demand segment pertains to the affluent minority with substantial per-capita income and comprehensive health insurance; the other is the less well-off and poorly-insured majority. In this case there are two equilibria. If both consumer groups are served, we estimated a uniform profit-maximizing price of \$24 per Rx, with 240,000 prescriptions filled monthly. But higher profits can be realized by catering only to the affluent minority at a price of \$59 per Rx, with 102,500 prescriptions filled per month.

Such a market segmentation strategy might have received a "distinction" grade in my marketing course at the Harvard Business School (to be sure, 45 years ago, before AIDS was known). But when the lives of thousands of persons are at stake, it is repugnant morally, and in my parallel "Business Responsibilities and Society" course, it might have received a "low pass" grade ("fail" grades being administered only rarely). Since competition policy was then (and apparently still is) the province of the "Business Responsibilities" course, it would

⁹ Scherer and Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Nations," *Journal of International Economic Law*, vol. 5 (December 2002), pp. 925-928.

not be inappropriate for a national competition policy authority to find evidence of such market segmentation strategies supporting a conclusion that a dominant market position has been abused.

An Analysis of AIDS Drug Prices

Watal and I go on from that theoretical perspective to inquire whether the prices of AIDS anti-retroviral drugs were in fact substantially higher in rich nations than in poor nations, as the so-called Ramsey pricing strategy advises. To explore the question we obtained from IMS, probably the leading international pharmaceutical data collection firm, detailed information on sales revenues and quantities sold for 15 AIDS anti-retroviral drugs in 18 nations or national groups, all with low or intermediate income per capita, over the years 1995 through 1999 -- before generic offers from Cipla of India and then other companies created competition for the prominent multinational companies. The nations or national groupings included Argentina, Brazil, Central Africa, Chile, Columbia, the Dominican Republic, Ecuador, French West Africa, India, Indonesia, Malaysia, Mexico, Peru, the Philippines, South Africa, and Thailand. Computed from the data were average price realizations for standardized dosage forms, expressed as a ratio of published Red Book wholesale list prices for the same products at the same time in the United States. Because most actual transactions in the United States occurred at a discount from Red Book prices, these so-called price relatives were considered to be at parity with U.S. price levels at a value of approximately 0.80. Data were available for 461 individual product-nation-company-year observations associated with companies recognized as research-oriented multinationals. What one sees is a wide scatter of price relatives, ranging from 4.95 (nearly five times published U.S. prices) down to 0.02 (with a total of 10 observations below 0.30). The simple average price relative was 0.85, suggesting if anything prices slightly above U.S. norms. The Pearsonian correlation between the price relatives and GDP per capita (computed at purchasing power parity rates) was +0.127. Pricing did conform in a crude way on average to the Ramsey norm, but with a great deal of variation about central tendencies.

Among the 461 observations for multinational companies, affiliates of Glaxosmithkline, with their especially strong position in AZT, accounted for 209, or 45 percent. Of these, 19 were for sales in South Africa. For South Africa there were 46 observations in total for all companies. By my calculations, Glaxosmithkline accounted for 56.4 percent of the AIDS drugs doses sold in South Africa during the five years covered by our sample.

Glaxosmithkline's price relatives for South Africa were on average 0.68, with a standard deviation of 0.18. Thus, they were on average about 15 percent less than the assumed U.S. norm (estimated to be sure with uncertainty) -- a small deviation, considering that gross domestic product per capita in South Africa is only about \$3,000 and it has one of most unequal distributions of income (the bottom 80% of income earners collect about \$1,400 a year) and the one of the highest HIV infection rates in the world.¹⁰

¹⁰ See United Nations Development Programme, Human Development Report: 2000, pp. 158-159; South Africa Survey 1999/2000 p. 398; United Nations Human Development Report 2003 (reporting that richest 20% of population in South Africa collects 66.5% of all income).

Controlling through multiple regression analysis for variations in sales coverage, average income, type of drug, year, and prevalence of HIV, Glaxosmithkline's average non-hospital prices for South Africa over the period were in rough parity with those in the United States.

I leave to the Competition Commission the value judgment as to whether prices in South Africa that differed little from those in the much wealthier United States, after other relevant influences are controlled, should be considered "excessive" under South African law. My own opinion is one of dismay for the absence of substantially lower prices in South Africa and in other low- and medium-income nations, with many millions of citizens suffering from a debilitating and potentially fatal disease whose worst effects could have been averted if the afflicted persons were able to afford already developed anti-retroviral therapies.

The Triple Therapy Problem

I am aware that clinical studies have shown that a three-drug "cocktail" is much more effective than single drugs in curbing the progression of HIV without the emergence of harmful mutations. Especially when medical services are difficult to access, the probability that an appropriate dosing regimen will be followed is appreciably higher if three drugs are combined in a single pill than when the drugs must be taken individually.

In order to offer a three-drug cocktail, the patent rights of at least two companies -- e.g., Glaxosmithkline with its AZT and 3TC and Boehringer Ingelheim with Nevapirine -- must be combined. My understanding of the facts is that the two companies have not pooled their patent rights to offer a three-drug cocktail, nor have they licensed other firms to do so. This, I find, is ethically irresponsible, and might be found an abuse of the patent privilege.¹¹

Appropriateness of a Compulsory License Remedy

Assuming *arguendo* a conclusion that Glaxosmithkline and Boehringer Ingelheim have abused their dominant positions, remedies must be imposed. My experience in three decades of competition policy research, enforcement, and consulting is that a finding of guilt without effective remedies is futile. Although I recognize that other possible remedies might be applied, I focus here on the one to which I have paid special attention -- that is,

¹¹ On the importance of combining patents to offer the best therapies and mechanisms (including mandatory licensing with arbitration) for ensuring that it happens, see F. M. Scherer, "The Economics of Human Gene Patents", *Academic Medicine*, vol. 77 (December 2002 Part 2), pp. 1361-1364.

compulsory patent licensing.¹² I believe a licensing remedy is feasible, and it would be particularly efficacious in the present case.

TRIPS Agreement

Under Article 40 of TRIPS, compulsory patent licensing is one of the measures that can be implemented when administrative proceedings have identified conditions that are "an abuse of intellectual property rights having an adverse effect on competition in the relevant market."¹³ Article 31(k) states that the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration paid to the patent holder in Article 40 cases, i.e., that payments might be less than in other compulsory licensing cases.¹⁴

Compulsory licensing ordered to correct an abuse of intellectual property rights is particularly important to address a particular issue in Article 31 of the TRIPS. Article 31(f) provides a general rule that any compulsory license be "predominantly for the supply of the authorizing nation." However, for licenses issued as remedy to anticompetitive practices, Article 31(k) waives this restriction. Thus, a compulsory license to remedy an Article 40 competition abuse, unlike others, could be granted predominantly or even solely for export. This can be particularly important when cross-border supply is essential either to obtain sufficient economies of scale for low cost production, or when it is desirable to supply other countries with low cost medicine -- for example other African countries suffering from the AIDS crisis.

Royalties

Under the U.S. antitrust precedents reviewed by Watal and myself, ad valorem royalty rates in the range of zero to 3.0 percent have been reported. Absent such a finding, a wider range of royalty rates has been observed. In some U.S. government use cases, which are analogous compulsory licensing without evidence of abuse, the range of royalties has run from less than 1 percent to 10 percent. The highest known royalties under special national drug licensing laws were in the United Kingdom, where royalties commonly ranged between 18%-22% ad valorem -- and those rates, apparently, were so high that generic supply was significantly inhibited. In Canada the standard royalty rate for the licensing of patented drugs was 4.0 percent ad valorem.

¹² See e.g. Scherer et al., *Patents and the Corporation* (Boston, 1958, 1959); and Scherer, *The Economic Effects of Compulsory Patent Licensing* (New York University Graduate School of Business Administration: 1977); and especially the survey in Scherer and Watal, *Journal of International Economic Law*, pp. 914-925.

¹³ Article 40's language appears to track in a general way the "abuse" doctrine of U.S. patent antitrust law, although the article as a whole can be reconciled with European legal traditions holding that failure to supply or license a patented product at all, or supplying the product at unreasonably high prices, might be deemed abusive.

¹⁴ This language may have been influenced by experience in the General Electric case discussed earlier in which a federal court declared that compulsory license recipients need pay no royalties at all because General Electric's dominant position in electric lamp bulbs rested upon "an arsenal of a huge body of patents."

It seems clear that the royalties set in compulsory licensing cases have been well below those that would have been negotiated at arms length and that agencies making royalty determinations in such cases enjoy a considerable range of discretion.

In the specific case of AZT, it is well known that much of the underlying research was conducted in government-financed laboratories as distinguished from laboratories of the drug's patent holder, Burroughs-Wellcome (later acquired by Glaxosmithkline). During the early 1990s the U.S. government's contribution along with the importance of having affordable anti-AIDS therapies were widely cited as reasons why Burroughs-Wellcome should reduce its AZT prices, although there was no allegation that the U.S. antitrust laws had been violated, and the government lacked alternative formal institutions for compelling more favorable pricing

I believe that South Africa should draw important lessons from the comparative experience on setting royalties. High royalty rates, as in the British drug licensing experience, could undermine the objective of making drugs widely available to low-income consumers on competitive terms; low royalty rates, as in the Canadian experience, could provide the basis, assuming that other conditions are satisfied, for competitive drug supplies while compensating patent holders to at least some extent for their research and development contributions. The choices made in industrialized nations provide ample precedent for royalty-setting on the modest side of the range of possibilities.

Need for Clear Standards

The longer the issuance of compulsory licenses is delayed after patented drugs enter the marketplace, the less time licensees have to recover their startup costs and the more difficult it is to achieve effective competition among multiple generic substitute suppliers. Thus, if compulsory licensing is to be successful, expeditious licensing procedures are a necessity. Toward this goal, it will be essential for South African authorities to establish clear and transparent precedents in early cases, as was done in Canada, so that they can perform subsequent reviews efficiently.

REFERENCES

- European Commission (1974): "Refusal by a Dominant Firm To Sell Raw Materials," *Antitrust Bulletin*, vol. 19, Fall , pp. 605-618.
- Eastman, H.C. (1985): *Report of the Commission of Inquiry on the Pharmaceutical Industry*, Canadian Government Publishing Centre, Ottawa.
- Fox, Eleanor M. (1986): "Monopolization and Dominance in the United States and the European Community," *Notre Dame Law Review*, vol. 61 pp. 981-1020.
- Gorecki, Paul K. (1981): *Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programs*, Technical Report No. 8, Economic Council of Canada, Ottawa: May.
- Hollabaugh, Marcus A. and Robert Wright (1960): *Compulsory Licensing under Antitrust Judgments*, Staff Report, Subcommittee on Patents, Trademarks, and Copyrights, U.S. Senate Committee on the Judiciary, Washington.
- Kaufer, Erich (1980): "The Control of the Abuse of Market Power by Market-Dominant Firms under the German Law against Restraints of Competition," *Zeitschrift fuer die gesamte Staatswissenschaft*, Band 137, September, pp. 510-532.
- McGrath, Richard J. (1991): "The Unauthorized Use of Patents by the United States Government or its Contractors," 18 *American Intellectual Property Law Association Quarterly Journal* 349, 359.
- McRae, James J. and Francis Tapon (1985): "Some Empirical Evidence on Post-Patent Barriers to Entry in the Canadian Pharmaceutical Industry," *Journal of Health Economics*, vol. 4 (March), pp. 43-61.

Neumeyer, Fredrik, (1959): *Compulsory Licensing of Patents under Some Non-American Systems*, Study No. 19 of the Subcommittee on Patents, Trademarks, and Copyrights, U.S. Senate Committee on the Judiciary, Washington.

Scherer, F. M. (1977): *The Economic Effects of Compulsory Patent Licensing*, New York University Monograph Series in Finance and Economics, New York.

Scherer, F. M. (1980). *Industrial Market Structure and Economic Performance*. Boston: Houghton-Mifflin.

Scherer, F. M., and Jayashree Watal (2002). "Post-TRIPS Options for Access to Patented Medicines in Developing Nations." *Journal of International Economic Law*, vol. 5, pp. 913-939.

Schmidt, Ingo (1983): "Different Approaches and Problems in Dealing with Control of Market Power: A Comparison of German, European, and U.S. Policy Towards Market-Dominant Enterprises," *Antitrust Bulletin*, vol. 28 (Summer), pp. 417-469.

U. S. Department of Health, Education, and Welfare (1968). Task Force on Prescription Drugs, Background Paper, *Current American and Foreign Programs* (Washington).