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IMPACT OF MULTINATIONAL ENTERPRISES ON MULTILATERAL RULE MAKING: THE PHARMACEUTICAL INDUSTRY AND THE TRIPS URUGUAY ROUND NEGOTIATIONS

Mohamed Omar Gad*

I. INTRODUCTION

The history of the negotiation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the context within which its initiation and progress occurred have been the subject of numerous legal and non-legal studies. In a significant number of those accounts, the discourse acknowledges that the rule making process of the TRIPS Agreement and more notably the background to this rule making process in terms of domestic, unilateral and bilateral developments in the area of intellectual property (IP) protection has been disproportionately influenced by the interests of Industrialised Countries' (ICs) corporate actors. Corporate interests with a stake in a

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high level of intellectual property safeguards encompass industries with considerable investments protected by copyright laws, trademark laws, and patent laws as well as other forms of intellectual property protection. Among the most prominent industries with investments protected by patent laws is the dynamic and research intensive pharmaceutical industry. As such, the pharmaceutical industry was and continues to be at the forefront of corporate lobbying of patent laws.

These lobbying efforts by the pharmaceutical industry and particularly those of the U.S.-based multinational pharmaceutical giants have significantly affected the course of the multilateral negotiations on intellectual property; specifically those relating to patents, during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) 1986-1994. On the other hand, Developing Countries (DCs) resisted the pressure to introduce IP rules, specifically patent rules, within the GATT framework. However, the ability of DCs to resist the pressure from the pharmaceutical multinational enterprises (MNEs), as presented through the medium of ICs' negotiating positions and unilateral and bilateral tactics, was overwhelmed. As a result, the change in the negotiating position of DCs prior to the official launch of the Uruguay Round compared to the final result of the negotiations resulting in the TRIPS Agreement is considerable. In effect, it amounted to a capitulation by DCs to the ICs' negotiating objectives, which represented pharmaceutical MNEs interests with regard to the specifics of those patent provisions of relevance to the multinational pharmaceutical industry.

The focus of analysis in this article is this anomaly in the rule making of the pharmaceutical-related patent provisions of the TRIPS Agreement. As will be argued below, the problem is in essence one of a 'top-down' exercise in the rule making of these provisions. While the interests of pharmaceutical MNEs were largely incorporated into the final text of the TRIPS Agreement, those of DCs were gradually dismissed over the course of the negotiations. Such an usurpation of a negotiating position comes not as a result of a value re-appraisal by DCs, but rather as a result of this 'top-down' pressure exerted during the rule making process. Upon reflection the flaws of such an approach are evident and complicate the implementation process, and consequently, they lead to a profusion of political and legal disputes on the relevant provisions of the Agreement as evidenced by the access to medicine dilemma on TRIPS. Therefore, the aim of this article is to identify and analyze the causes of this 'top-down' approach to rule making in the context of the pharmaceutical-related patent provisions of the TRIPS Uruguay Round negotiations, and the significant role played by the pharmaceutical MNEs therein.

4. The TRIPS Agreement refers to four more classes of intellectual property rights: geographical indication, industrial designs, layout designs (topographies) of integrated circuits, and undisclosed information.

5. On the contrary, a considerable degree of resistance to the adoption of the standards in the TRIPS pharmaceutical-related patent provisions has been exhibited by domestic stakeholders in developing countries.
It should be noted at the outset that the dangers of falling into the trap of a one-sided dogmatic treatment of the issue and ‘caricaturising’ events and positions are considerable. The background of the TRIPS negotiations and the broader process of negotiating other issues within the Uruguay Round are to date perhaps the most comprehensive and complex undertaking of international economic rule making, spanning nearly a decade of global multilateral negotiations. In such a framework, the positions of the negotiating parties of the various affected industries and of industry sub-sectors are multi-faceted. This matrix of interests is similarly anchored to a canvass of domestic, regional, and global economic and political conditions that serve only to accentuate their complexity. As a precaution against these risks, it is important to bear in mind from the outset the legitimate interests and rights of DCs in their pursuit of patent regimes and laws that stem from their developmental and public health policy priorities, as well as the interests of research-based pharmaceutical MNEs in protecting, recouping, and earning a profit on their R&D investments that amount to the “raison d’être” of the commercial nature of their activities.

This article is divided into three sections. Section II examines the position of the pharmaceutical MNEs. It will look at the interests of the pharmaceutical MNEs in terms of their concerns and justifications with the existing patent regime. It will also consider the specific problems faced by the pharmaceutical MNEs with regard to the then prevailing standards and norms of patent protection. Focusing on the United States, Section III will then examine the process through which the pharmaceutical MNEs were able to organize and lobby the main ICs to adopt their interests in their quest to address the need to overhaul the international IP regime. Section III will also examine the bilateral approach adopted by the United States (particularly the 301 processes), to engage the issue with recalcitrant DCs in parallel with the TRIPS negotiations. Finally, section IV presents the synthesis of the analysis carried out in the previous two sections, demonstrating that the TRIPS negotiations were disproportionately influenced by the pharmaceutical MNEs, and ultimately represented a ‘top-down’ approach to rule making.

II. PHARMACEUTICAL MNES PATENT REGIME PREFERENCES

The pharmaceutical industry is a broad industry that is traditionally divided horizontally into three categories according to the extent of innovation and technology in production. The first category, over the counter ("OTC") drugs, is sold directly to consumers without prescriptions and contains the least research content. Thus, the main cost outlay in their

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production is marketing costs.\(^7\) The second category is post-patent generic drugs available by prescription, which account for a high percentage of the pharmaceutical industry in key developing countries.\(^8\) Finally, the third category, in-patent drugs, involves the most outlay of R\&D costs and is almost entirely dominated by the pharmaceutical MNEs. It is the category primarily responsible for the phenomenal growth of the industry since the 1930s.\(^9\) This article focuses on the producers of this last group.

With regard to the geographic distribution of the pharmaceutical industry, especially producers of in-patent drugs, there is a wide disparity between the industry portion headquartered in ICs and those based in DCs. In a report published by the European Commission in 1985 on the eve of the launch of the Uruguay Round, the following observations on the nature of the industry were made:

The World pharmaceutical market in 1982 was worth U.S. $81,500m. Most sales were in the developed market economies. The industry is both research intensive and marketing intensive. There are substantial economies of scale and large companies have a pronounced advantage. \ldots\ A limited number of large companies dominate the world industry. Generally organised on a multinational basis, they originated in a limited number of developed countries, of which France, Germany, Japan, Switzerland, the UK and the U.S.A are the most important. Production, like consumption, is concentrated in the advanced nations.\(^10\)

This article, in its treatment of the interest, concerns and mobilization efforts of the pharmaceutical industry will focus on large pharmaceutical MNEs, \textit{i.e.} those based in ICs. This section engages in a delineation of the patent regime preferences of the pharmaceutical MNE industry, to be followed in the next section by an analysis of their mobilization efforts towards international patent law reform.

**A. Justifications, Interests, and Concerns of Pharmaceutical MNEs**

Pharmaceutical MNEs advocate that a strong patent protection regime serves not only their interests, but is also beneficial to the global economy at large, including the economies of DCs who would stand to benefit from an increase in innovation. This finds resonance in a number of accounts testifying to the economic utility of adopting a strong patent regime as

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7. For a history of the development of the OTC drug market, see \textsc{Milton Silverman \& Philip R. Lee, Pills, Profits, and Politics}, ch. 9 (1974).
8. For an account of the generic drug industry, especially as it pertains to developing countries, see \textsc{Milton Silverman, Mia Lydecker \& Philip R. Lee, Bad Medicine: The Prescription Drug Industry in the Third World}, ch. 4 (1992).
9. See \textsc{OECD, supra} note 6, at 10.
advocated by the pharmaceutical MNEs.11 Indeed, two studies published by the International Finance Corporation in 1994 and 1995 underscored the importance that the presence of a strong IP protection regime had on the inflow of FDI into a given country.12 Of the six industries examined, this was particularly true in the chemical industry, which includes pharmaceuticals.13 Furthermore, pharmaceutical MNEs argue that the discovery of new drugs is possible due to the protection afforded by patent regimes that allow the innovating firms to recoup their R&D expenditures.14

Therefore, the pharmaceutical MNEs justified their position by emphasizing the value of protecting IP as an important contribution to innovation and to the economic progress of all countries including DCs. Moreover, it was the U.S. pharmaceutical MNEs' success in projecting their image as a highly productive industry at the forefront of America's international competitiveness that gained firm support for their cause.15 The pharmaceutical industry was awarded a highest ranking in terms of its competitiveness in a survey of thirteen U.S. manufacturing industries examined in 1992.16 In the most important IC market, this characterization of the pharmaceutical industry proved a strong argument to justify the protection of IP rights internationally. This was a U.S. industry, globally competitive at a time when the U.S. economy was under severe economic strains during the mid-1980s and facing considerable balance of payment burdens. Henceforth, the U.S. multinational pharmaceutical industry's emphasis on securing backing of its preferences for a strong international IP regime rested more on brandishing its domestic flagship industry status as opposed to other industries similarly interested in IP


13. Mansfield, supra note 12, at 2-3 (Table 1 and 2).


protection. As Ryan argued, "... the pharmaceutical interests, unlike the copyright interests, did not advocate stronger intellectual property laws based on claims of huge piracy losses in developing countries. Instead they urged U.S. action based on their opportunities and potential for future foreign investment and sales." In a report prepared for the U.S. Senate by the U.S. International Trade Commission in 1991, the protection of IP rights figured as a component of the major factors and determinants in the global competitiveness of the U.S. and other IC pharmaceutical industries.

The pharmaceutical MNEs' interest in a strong IP protection regime lies in their quest to protect their R&D, thus maintaining their ability to innovate and provide new drugs to the market. In terms of time expended in the development of a new drug, the typical R&D outlay is claimed to be between ten and twelve years, costing onwards of U.S. $350 million. The pharmaceutical MNE industry's R&D expenditures are among the highest of industry groups. Therefore, a high standards patent protection regime is a high priority for the industry. Table 1 below depicts the amount of R&D expenditure on drugs and medicines from 1976 to 1995. Undoubtedly, the numbers represent a considerable resource allocation on the part of the pharmaceutical industry in OECD countries. While we cannot accurately estimate the amount specifically contributed by the major pharmaceutical MNEs, they are responsible for a bulk of the outlay on R&D expenditures in the industry. Indeed, Ryan claims that ninety-three percent of new drug therapies are introduced by private enterprises. Table 1 also indicates that almost consistently, the United States spends the most on R&D, closely followed by the EU, with Japan lagging behind.

TABLE 1

<table>
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<tr>
<td>U.S.</td>
<td>1091.0</td>
<td>1777.0</td>
<td>3484.5</td>
<td>6287.4</td>
<td>10215.0</td>
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<tr>
<td>EU²⁴</td>
<td>1047.3</td>
<td>1808.0</td>
<td>3166.7</td>
<td>6131.8</td>
<td>7758.1</td>
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<tr>
<td>Japan</td>
<td>377.7</td>
<td>741.6</td>
<td>1568.3</td>
<td>2646.7</td>
<td>3799.9</td>
</tr>
<tr>
<td>UK</td>
<td>252.4</td>
<td>495.6</td>
<td>851.7</td>
<td>2003.3</td>
<td>2763.7</td>
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<tr>
<td>France</td>
<td>176.5</td>
<td>322.3</td>
<td>657.7</td>
<td>1062.9</td>
<td>1417.4</td>
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<tr>
<td>Germany</td>
<td>331.0</td>
<td>528.4</td>
<td>687.9</td>
<td>1263.1</td>
<td>1210.4</td>
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<tr>
<td>Italy</td>
<td>142.8</td>
<td>237.2</td>
<td>486.7</td>
<td>879.7</td>
<td>831.1</td>
</tr>
<tr>
<td>Canada</td>
<td>19.2</td>
<td>33.9</td>
<td>63.3</td>
<td>196.6</td>
<td>387.8</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3437.9</td>
<td>5044.0</td>
<td>10966.8</td>
<td>20471.5</td>
<td>28383.4</td>
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Given this considerable expenditure on R&D and the importance of new product development to the multinational pharmaceutical industry, the protection of IP rights is a major concern for pharmaceutical MNEs. Numerous studies reported the losses sustained by the major industries, particularly U.S. industries, due to the lack of effective protection and/or enforcement of IP rights abroad, especially in the major DCs.²⁶ These losses were due not only to the unauthorized exploitation of the fruits of the MNEs' R&D outlays, but also were due to the market losses suffered by the pharmaceutical MNEs. In 1985, the U.S.-based Pharmaceutical Manufacturers Association estimated that in only five countries (Mexico, Brazil, Argentina, South Korea and Taiwan) its member companies lost market shares of between thirty and seventy percent on products that should have been protected but were not.²⁷ Had a patent protection regime similar to those prevalent in ICs and containing the standards advocated by the pharmaceutical MNEs been in place, those member

²⁴. EU figures represents the total for the fifteen countries currently members of the EU.
²⁵. Figures for Germany refer to West Germany until 1990 and starting from 1991 the figure refers to the unified Germany.
companies would have enjoyed market exclusivity for their patented products for the duration of the patent term. This problem was compounded by the fact that by the early 1990s forty percent of total sales of the U.S. pharmaceutical MNEs were international sales. Finally, the vulnerability of the pharmaceutical industry to piracy was underlined by the fact that the duplication of chemical compounds is a relatively straightforward task, as opposed to researching and developing it, which entailed considerable expenses.

B. IDENTIFYING THE PROBLEM ISSUES IN INTERNATIONAL PATENT PROTECTION

From the perspective of ICs' business interests, particularly from that of the pharmaceutical multinational enterprises, the problem issues in IP protection were those of regime deficiencies and general enforcement inadequacies in the protection of intellectual property. This was true both at the domestic (DC) and international (WIPO) levels. While MNEs were generally well coordinated and had similar concerns about the deficiencies in the IP regimes of DCs as well as those in the international regime, there were some important differences. Such differences mainly concerned the importance attached to any particular type of intellectual property, whether pertaining to copyright, trademarks, or patents. Notwithstanding these differences, certain classes of problems such as enforcement and dispute settlement were crosscutting issues of interest affecting the entire industry spectrum. This facilitated the emergence of common stances on the IP issue in addition to the important specific concerns carried forth by specialized industry lobbying groups within the IP industry lobbying armada.

Before addressing the problem issues, another vital factor to bear in mind in characterising the IP problem, as argued by MNEs, ICs, and particularly the United States, has been its strategic redefinition as a 'trade'

31. For the perspectives of the electronics, pharmaceutical, recording, communications and chemical industries respectively on the international protection of intellectual property rights, see Intellectual Property Rights and Capital Formation in the Next Decade 119-159 (Charles E. Walker & Mark A. Bloomfield eds., 1988).
32. Two particularly powerful groups were the International Intellectual Property Alliance (IIPA), leading the efforts focusing on copyright, and the Pharmaceutical Manufacturers Association (PMA) leading the efforts focusing on patents as they affected the pharmaceutical industry. These groups were both U.S.-based. A larger industry-wide group was the Intellectual Property Committee (IPC), also U.S.-based and led, which played a major role in organising non-U.S. based industry in lobbying the GATT intellectual property negotiations.
problem in the first instance. As their preferred strategy opted for a transfer of the IP agenda from WIPO to the trade-based GATT regime, MNEs sought to dress the problem in the “trade gown.” In a landmark document in international business’ (including the pharmaceutical MNEs) lobbying campaign of the TRIPS negotiations that was issued tri-laterally by the Intellectual Property Committee of the United States, Keidanren of Japan, and the European UNICE in the summer of 1988, the problem was defined as follows: “[i]nadequate and ineffective protection of intellectual property against infringements of intellectual property rights has substantially distorted international trade. If adequately and effectively protected, intellectual property promotes the expansion of international trade, investment and transfers of technology.”

Furthermore, in lobbying the U.S. Congress before the Uruguay Round negotiations and throughout the course of the negotiations, business interests and especially the Pharmaceutical Manufacturers’ Association sought to define and frame their testimonies during congressional hearings on trade-related issues. Moreover, business interests lobbied for the introduction of IP infringement in the USTR’s annual report to Congress entitled “National Trade Estimate Report on Foreign Trade Barriers.” The characterization of the issue as a trade problem has therefore shifted the focus from that of DCs choosing their own IP protection regime according to their public policy priorities, to an issue of trade distortion and export losses. Commenting on the problem in DCs, the president of the Pharmaceutical Manufacturers’ Association stated: “[a]ll have significant deficiencies in intellectual property protection for pharmaceuticals, the correction of which would substantially improve the market share for U.S. pharmaceutical companies.”

33. In 1987, the Vice President of IBM argued “that intellectual property has become a trade problem is not surprising, because the source of the problem is the same as that of other trade issues. That is, nations often put domestic priorities first and only later understand that national actions favoring them can seriously erode their own international trade interests.” Kenneth W. Dam, The Growing Importance of International Protection of Intellectual Property, 21 INT’L L. 627, 630 (1987).

34. See Possible New Round of Trade Negotiations: Hearings Before the Senate Comm. on Finance, 99th Cong. 144, 149-152 (1986) (statement of Kenneth W. Dam, Vice President, Law and External Relations, IBM Corp., on behalf of the Intellectual Property Committee) [hereinafter Dam 1986 Senate Statement].


36. Id. at 11.


38. This annual report was first presented to the Senate Finance Committee and the House Committee on Ways and Means in 1985. Its statutory basis lies in section 303 of the Trade and Tariff Act of 1984.

testimony to Congress the Intellectual Property Committee argued that:

First, intellectual property is important to international competitiveness. And second, inadequate international protection of intellectual property has become a major cause of distortions in the international trading system. Under these circumstances, the IPC believes that it is both appropriate and necessary for intellectual property issues to be dealt with under international trade rules as a supplement to existing international intellectual property conventions and agreements.40

Three major problem areas have been pinpointed by MNEs: (1) problems of deficiency in DCs intellectual property regimes pertaining to standards and norms of protection; (2) problems associated with a lack of or ineffectiveness in enforcement, and the lack of a credible dispute resolution mechanism; and (3) problems of deficiencies in the standards codified in international intellectual property protection regimes, most importantly the Paris Convention.41 The focus here will be on the inadequacy pertaining to standards and norms of patent protection.

In a survey of U.S. companies conducted by the United States International Trade Commission,42 eight specific problems were identified in the patent regimes of 54 countries comprising:

- no patent protection
- patentability precluded by statute
- term too short
- early lapse
- compulsory licensing
- Paris Convention nonadherence
- patent claims are narrowed too much
- unrealistic working requirements

Not surprisingly, the patent laws of the major DCs suffered from most, if not all, of the eight inadequacies reported by U.S. firms.43 It is important here to briefly refer to the main problems perceived by the pharmaceutical MNEs.44 Pharmaceutical MNEs focused their complaints on five almost identical problems to the eight identified above.45 First was the problem associated with the absence of any patent regime in certain countries. This, however, was a problem affecting a limited number of countries.46 Second, there was the more widespread practice of excluding

40. Dam 1986 Senate Statement, supra note 34, at 146.
43. By far the worst offenders under these criteria, as identified by the firms surveyed, were Brazil and India each figuring in seven out of eight of the individual complaints; See also U.S. ITC 1988 REPORT, supra note 26, at Table 3-1.
45. As outlined in Peter C. Richardson, The Need for Adequate and Effective Protection of Intellectual Property: Perspectives of the Private Sector – Patents, 19 GA. J. INT'L & COMP. L. 352, 353-54 (1989); Peter C. Richardson was then Assistant General Counsel, and General Patent Counsel of Pfizer Inc.
46. In 1989 Indonesia and Turkey were perhaps the only major examples. Id. at 353.
certain classes of subject matter from patentability with pharmaceuticals figuring prominently in such statutory exclusions. For example, Brazil excluded pharmaceutical products and processes from patentability, warranting its “anti-pharmaceutical patent policy” as described by the Pharmaceutical Manufacturers’ Association to be “the most egregious.” Third and more widespread still, was the practice of affording pharmaceutical process protection while excluding the final products from patentability. Argentina, Egypt and India are examples of this practice. The fourth complaint of the pharmaceutical MNEs was what they perceived as inadequacy in the term of protection. This was particularly a problem given the pharmaceutical MNEs claim that bringing a new product to the market can take upwards of twelve years, and hence if the term of protection falls short of that there is effectively no protection.

Finally, the fifth complaint concerning DCs’ compulsory licensing and related lapse provisions pertains primarily to the working requirements on patent holders. Pharmaceutical MNEs have two main contentions with these provisions. The limited period of time within which working of the patent should occur (three years as authorised by the Paris Convention) is incongruent with the much lengthier period of time required by the MNEs to bring their products to the market, estimated at ten years from patent grant. The second argument was that economic realities militate against having production facilities in every single jurisdiction where patent protection is sought. Thus, it would be far more economically efficient for some markets to be supplied through imports. Once the problem issues had been identified, the pharmaceutical MNEs had the considerable task of resolving them in favor of their interests.

III. MOBILISING FOR INTERNATIONAL PATENT LAW REFORM

Multinational Enterprises, including U.S. MNEs that maintain a significant stake in intellectual property protection, sought to overhaul the international IP regime to protect their interests globally, and particularly in key DCs, after having identified specific problem issues. A main avenue to accomplish this goal was through procuring the assistance of the key players in the global economy, particularly the United States, to en-
gage bilaterally the major DCs accused of violating their intellectual property rights. Second, the MNEs sought to initiate a multilateral undertaking on the subject that would guarantee them a single governing global standard for all countries.

A. THE BILATERAL APPROACH: LOBBYING THE KEY PLAYERS

We hope the imposition of this sanction, which is modest in comparison to the revenue losses sustained by our industry in Brazil, will impress upon Brazil the seriousness with which the United States views the unauthorized appropriation of its citizens' intellectual property. Pharmaceutical Manufacturers' Association

In pursuit of their aims for international patent law reform, pharmaceutical MNEs, as well as MNEs in general, realized early on in the quest for a strong patent regime that the involvement of the U.S. administration and Congress as allies was essential to their efforts. Not only was the United States a strategic market for the vast majority of its trading partners and one they could not afford to forego, but equally, the United States was also a leader in international economic diplomacy whose domestic economic legislation had a worldwide impact. A logical first step for the concerned business sectors was to fine-tune the U.S. legislative and policy process to conform to their objectives and then to deploy this arsenal of laws "as instruments of commercial warfare." Below, an overview of the most relevant U.S. legislation in this regard is presented, followed by an analysis of how the U.S. pharmaceutical lobby and specifically the Pharmaceutical Manufacturers Association, potently deployed this arsenal against two key DCs, Brazil and Argentina. Finally, while the United States' bilateral approach on IP matters was by far the most significant during and throughout the Uruguay Round negotiations, a brief analysis EC's role is also discussed below.

Through a series of amendments particularly in 1988, U.S. trade legislation integrated the protection of IP rights. Perceived unjustified acts by foreign trading partners constituted violations, which required the U.S. Trade Representative to intervene to protect the intellectual property of its citizenry. The most famous of these legislative instruments were Section 337, Section 301, "Special 301" and "Super 301." While the first instrument was designed to protect U.S. IP owners from violations in import trade, the three latter instruments were designed to induce change

53. Ryan, supra note 17, at 67.
in the IP regimes of America's trading partners using access to the highly coveted U.S. market as leverage.

Section 337 was designed to protect U.S. producers from:

\ldots unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States. \ldots \textsuperscript{60}

"Unfair methods of competition and unfair acts," included violation of U.S.-owned IP rights.\textsuperscript{61} While a previous amendment to Section 337 served to depoliticize the process by transferring the authority to issue orders excluding the importation of foreign goods violating U.S. IP rights from the President to the International Trade Commission\textsuperscript{62} and thus shielding U.S. business from the 'whims' of the diplomatic prerogatives of the President. The MNE lobby, however, was not entirely satisfied with the process. Primarily, complainants had to show that the "unfair method of competition" or the "unfair acts" had the effect of destroying or substantially injuring the industry.\textsuperscript{63} They also had to prove that they were an "efficiently and economically operated" industry "in the United States."\textsuperscript{64} Due to these burdensome conditions, U.S. IP owners seeking to exclude imports of goods infringing their IP rights lobbied for an amendment. The amendment to Section 337 occurred as part of the 1988 Omnibus Trade and Competitiveness Act.\textsuperscript{65} The amended Section 337 eliminated the injury requirement in those investigations related to statutory IP rights (\textit{i.e.}, patents, copyrights, trademark, and mask works) where it declared "unlawful" "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) infringe a valid and enforceable United States patent. \ldots \textsuperscript{66}"  

Hence, this facilitated complainant's argument limiting it to a showing of statutory IP infringement only. The 1988 amendment deleted the re-

\textsuperscript{59} However, the initial impetus for integrating intellectual property concerns into legislation primarily dealing with trade, was initially apparent in the Caribbean Basin Economic Recovery Act and in the Generalized System of Preferences Renewal Act; See Mossinghoff 1985 House Statement, supra note 27, at 194.
\textsuperscript{61} Between the years 1974 and 1986 more than ninety percent of Section 337 investigations initiated by the ITC were IP related. See GAO study quoted in, A.S. Newman, The Amendments to Section 337: Increased Protection for Intellectual Property Rights, 20 LAW & POL'Y INT'L BUS. 571, n. 9 (1989).
\textsuperscript{62} 1975 amendment in subsection (a), Pub. L. No. 93-618 substituted "Commission" for "President." See Sell, supra note 3, at 166.
\textsuperscript{64} Id.
quirement that the industry be "efficiently and economically" operated, and it simplified the other requirement that it be a domestic industry (reference to the old text of an industry "in the United States"). In the latter case, the amendment refers to the Commission as granting relief "only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work or design concerned, exists or is in the process of being established." In the following paragraph, an "industry in the United States" shall be considered to exist if there is: (A) significant investment in plant and equipment; (B) significant employment of labour or capital; or (C) substantial investment in its exploitation [of the IP protected article], including engineering, research and development, or licensing.

While U.S. MNEs were able to protect their domestic market from import competition quite effectively after the amendments to Section 337, the lack of what they deemed adequate IP protection in overseas markets continued to create major problems for them. A different set of trade legislation was required to combat 'lax' IP protection in foreign markets. This need was fulfilled through Section 301 of the Trade Act of 1974 as amended. This instrument was designed to protect the United States from certain "unfair trade practices" by its trading partners. It did so initially by requiring the Trade Representative to "take all other appropriate and feasible action within the power of the President" to enforce the right of the United States under any trade agreement, or to respond to any act, policy or practice of a foreign country that "is inconsistent with, the provisions of, or otherwise denies benefits to the United States under, any trade agreement" or "is unjustifiable AND burdens or restricts United States commerce." In this regard, "unjustifiable" was defined to include, inter alia, "any act, policy, or practice. . .which denies. . .protection of intellectual property rights." Furthermore, "unreasonable" was also defined to include, inter alia, any act, policy, or practice that denies the "provision of adequate and effective protection of intellectual property rights. . . ." The "appropriate and feasible action" within the power of the President, to take in case of a violation under section 301, included the suspension or withdrawal of concessions in a trade agreement with the country in violation under section 301, or the imposition of duties and other such restrictions, or fees and restrictions on the imports or services of such a country respectively.

It was not until the 1988 amendments to section 301, however, that the USTR was obligated to take action with regard to a 301 complaint, thus

no longer retaining discretion in deciding whether to initiate action. New powers were also introduced in the Omnibus Trade and Competitiveness Act of 1988, where under "special 301", the USTR was required to identify countries which deny "adequate and effective" protection of IP rights to American firms and to investigate their practices.\(^75\) Furthermore, according to the new "super 301," the USTR was required to identify "priority foreign countries" and to self-initiate section 301 investigations of the practices of these so-designated countries.\(^76\) Such identification was based on the USTR's annual National Trade Estimate Report on Foreign Trade Barriers.\(^77\)

Mainly through the Pharmaceutical Manufacturers' Association Section 301 was put to effective use by the U.S. Pharmaceutical MNEs as part of their strategy to induce and coerce change in the patent regimes of certain strategic markets in DCs.\(^78\) Indeed, as Ryan argues, "[s]pecial 301 intellectual property policy has similarly been used for the benefit of some of the most globally competitive American industry sectors – pharmaceuticals and fine chemicals, films and music recordings, computer software – and these industry groups have shaped the USTR’s diplomacy agenda for protecting intellectual property."\(^79\)

Section 301 investigations cover a number of very interesting landmark cases relating to the U.S. bilateral approach to international IP protection.\(^80\) Nonetheless, the most interesting and relevant from the perspective of pharmaceutical MNEs were two cases initiated by the USTR in

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77. This Report, required by statute under Section 303 of the Trade and Tariff Act of 1984, identifies and analyzes acts, policies or practices that constitute significant barriers to or distortions of U.S. exports of goods and services, property protected by trademarks, patents and copyrights exported or licensed by U.S. citizens, and U.S. direct investment overseas.
In all eight cases [301 IP cases], the targeted governments agreed to improve intellectual property protection along the lines desired by the United States. Furthermore, the timing of the changes demonstrates the strong link between this exercise of U.S. leverage and the changes in targeted states. In short, both the substance and the timing of these policies can be explained as a product of coercion. 
Id. at 323.
79. RYAN, supra note 17, at 85.
response to petitions filed by PMA against Brazil in 1987\textsuperscript{81} and against Argentina in 1988.\textsuperscript{82}

In its petition against Brazil, PMA specifically targeted the denial of patent protection for pharmaceutical products and the processes for preparing those products.\textsuperscript{83} The result of this denial, PMA argued, adversely affected its member companies in four ways: injury to their patent rights, injury to their investments in Brazil, injury to their exports from the United States and other nations to Brazil, and lost opportunities that would otherwise exist for further investment and trade with Brazil.\textsuperscript{84}

PMA estimated the losses of its member companies at U.S. $160 million between 1979 and 1986 and projected losses under the status quo until the year 2000 amounting to U.S. $280 million.\textsuperscript{85} Counsel for PMA argued that such action from Brazil burdened and restricted U.S. commerce. An accompanying legal memorandum stated that “the 1984 amendments to the Trade Act enable the Petitioner to satisfy the unreasonable requirement of Section 301 of the Trade Act, as amended, by showing that the Brazilian system unfairly denies adequate and effective protection of intellectual property rights with respect to pharmaceutical products.”\textsuperscript{86} On the importance of the petition from the U.S. industry perspective, PMA argued:

\begin{quote}
[t]his Petition deals directly with the capacity of United States industry to compete on a fair basis in an important market for American products. The issues raised by this Petition cannot be answered by referring to the needs of governments to develop their economy or meet the material needs of their people. Thoughtful leaders and scholars in developing nations recognize that these nations will benefit more from respect for the intellectual property rights of others than from contributing to the weakening of those rights.\textsuperscript{87}
\end{quote}

On the other hand, while Argentina provided patent protection for pharmaceutical processes, it did not provide protection to pharmaceutical products.\textsuperscript{88} As such, PMA’s petition against Argentina was primarily

\textsuperscript{82.} Initiation of Section 301 Investigation; Argentina’s Failure To Provide Adequate and Effective Intellectual Property Protection for Pharmaceuticals, 53 Fed. Reg. 37,668 (Sept. 27, 1988).
\textsuperscript{83.} Petition filed by P. Trooboff, Covington & Burling, on behalf of the Pharmaceutical Manufacturers’ Association, in Brazil – Pharmaceutical Patents, USTR Public Docket No. 301-61, \textit{hereinafter PMA Brazil Petition}. The specific object of the complaint is article 9(c) of the Brazilian Patent Law, which excludes, \textit{inter alia}, pharmaceutical products and the processes for their production from patentability.
\textsuperscript{84.} PMA Brazil Petition, \textit{supra} note 83, at 2.
\textsuperscript{85.} \textit{Id.} at Appendix E “Lost Sales by U.S. Pharmaceutical Industry Resulting from Brazilian Failure to Provide Patent Protection.”
\textsuperscript{86.} \textit{Id.} at 12.
based on the absence of product protection – an absence it notes was sufficient for a section 301 determination of unfairness in the earlier Brazil case.\footnote{89} Moreover, PMA advanced four additional causes of complaint inherent in the Argentine patent law. Primarily, PMA’s petition noted that patent protection for pharmaceutical processes under Argentine law was inadequate and ineffective and therefore a totally unsatisfactory substitute for product protection.\footnote{90} This result was due largely to the ineffectiveness of process protection in the pharmaceutical industry, because the end product could be developed with easily changeable processes. Second, ‘innovators’ bore the burden of proving that the defendant infringed their pharmaceutical process patent as opposed to the defendant proving he did not. Thirdly, the enforcement of patent rights suffers from weaknesses in the remedial provisions and enforcement of the patent law because there is no injunctive relief, and a financial penalty estimated when the law was enacted in 1864 has become severely devalued.\footnote{91} Finally, article 47 of the patent law provides for the lapse of all patents if they are not worked in Argentina within two years from the year of grant, which is a provision in violation of article 5 of the Paris Convention that mandates the passage of a minimum period of three years.\footnote{92}

Compared to the Brazil case, the estimated economic losses suffered by PMA member companies seemed to be much more severe—with sales losses of up to U.S. $526 million between 1980 and 1987, and estimated losses reaching over U.S. $1 billion from 1987 to 2000.\footnote{93} Given these losses, PMA sought four main remedies: the introduction of product patent protection for pharmaceutical products, the protection of trade secrets, amendment of the lapse provision of article 47 of the Argentine patent law, and most interestingly, market exclusivity rights for “pipeline” products that are currently subject to patent protection in countries other than Argentina.\footnote{94} This latter remedy was a precursor for the discussion of exclusive marketing rights during the negotiations on TRIPS.

While reflecting bilateral concerns of the U.S. pharmaceutical industry in important markets such as Brazil and Argentina, the Brazil and Argentina petitions were filed with a broader purpose in mind. As an engagement of leading DCs (particularly of Brazil) antagonistic to the regulatory position of the pharmaceutical MNEs for stronger patent protection worldwide, these two cases served to underscore the resolve of the pharmaceutical MNEs. In the words of PMA President Gerald Mossinghoff:

\footnote{89} PMA Argentina Petition, \textit{supra} note 83, at 16-17.
\footnote{90} PMA Argentina Petition, \textit{supra} note 83, at 20.
\footnote{92} \textit{Id.} at 434; \textit{Multilateral Protection of Industrial Property}, art. 5, 21 U.S.T. 1583, 1592 (July 14, 1967).
\footnote{93} PMA Argentina Petition, \textit{supra} note 87, at Appendix G “Lost Sales by U.S. Pharmaceutical Industry Resulting from Argentine Failure to Provide Patent Protection.”
\footnote{94} \textit{Id.} at 32.
Brazil is a leader of the so-called G-77 countries' effort to reduce the already minimum standards for patent protection in the Paris Convention. It has also opposed efforts to include intellectual property protection within the purview of the GATT as a trade-related issue. As a newly industrialised nation, it is time for Brazil, the eighth largest economy in the west, to start playing by the rules of the international trading system.95

The pressure created by PMA in launching the Brazil section 301 case, however, went beyond any of the other IP-related section 301 cases because it led to the first imposition of retaliatory measures. On July 21, 1988, the U.S. President determined that "Brazil's failure to provide process and product patent protection for pharmaceutical products is unreasonable and burdens or restricts U.S. commerce," and directed the USTR to hold hearings on imposing "increased duties or other import restrictions" on some Brazilian products from a list of products accounting for U.S. $200 million in trade.96 On October 20, 1988, the U.S. President issued proclamation 5885, which increased U.S. import duties by 100 percent ad valorem on articles imported and produced in Brazil to the value of U.S. $40 million.97 This action was terminated on July 2, 1990 pursuant to the Brazilian government's announcement of its decision to seek legislation to provide patent protection for pharmaceutical products and processes.98 By contrast, the Argentine investigation was terminated upon the withdrawal by PMA of its petition on September 23, 1989 that cited progress in bilateral consultations between the governments of the United States and Argentina.99

The United States clearly had a powerful statutory arsenal to tackle the issue of international IP protection. Put to effective use by the U.S. international business sector, this arsenal was notoriously unilateralist, coercive, and in certain aspects, GATT-illegal. The European Communities submitted a GATT complaint against Section 337. Subsequently, the GATT panel found it to be inconsistent with article III(4), where it accorded procedural treatment less favorable to imported products allegedly infringing U.S. intellectual property as compared to products of U.S. origin.100 Furthermore, Brazil also lodged a GATT complaint against U.S. section 301, but withdrew the complaint following a mutual under-

96. Determination Under Section 301 of the Trade Act, 53 Fed. Reg. 28,177 (July 27, 1988). Transcripts of the hearings, which took place on September 8, 1988, over two sessions, are available with the author and can be accessed from USTR Public Docket No. 301-61.
98. Determination to Terminate Increased Duties on Certain Articles from Brazil, 55 Fed. Reg. 27,324 (July 2, 1990).
standing. As a leading commentator argued in the late 1980s on the state of 301 action:

No doubt exists, however, that this program meets with a high degree of foreign resistance, risks significant damage to United States foreign policy interests, and is terribly inefficient. Moreover, gains achieved by United States negotiators are passed on at no cost to its major trade competitors in the European Communities and Japan, thus strengthening the argument for a multilateral approach.101

In contrast to the United States, the European Community and its member states lagged behind in terms of the priority they accorded to the protection of IP rights. This was particularly the case with patents, as the EC was a net importer of patents vis-à-vis trademarks and copyrights of which it was a net exporter.102 The EC was reluctant to link the IP issue to trade and introduce it as an issue in the forthcoming round of GATT negotiations, where initially, the EC adopted an approach very close to the DCs' position. Only gradually did the EC warm to the U.S. approach of the inclusion of an agreement on IP.103 In the EC's policy document for the new round of negotiations, the Council of Minister's "Overall Approach," the EC not only separated the treatment of counterfeit goods from that on IP, but more importantly, presented a weak statement on its objectives, stating:

International trade increasingly depends upon an appropriate protection of intellectual property rights. . .Such protection should guarantee an adequate return on investment devoted to developing new goods and services. . .while at the same time avoiding unreasonable barriers to trade. The New Round could contribute to the definition of a better balance between these often conflicting objectives, having due regard to ongoing work in other organisations such as WIPO. As a first step, a review of those GATT provisions that already deal with intellectual property, including in particular Articles XX and IX, should be undertaken.104

The EC had no forceful agenda for international IP protection, seeking neither at the bilateral nor at the multilateral level. In addition, the degree of business influence on EC policymaking was more limited compared to that enjoyed by business over the U.S. policymaking process.105

This leads us to the importance attached by the MNEs to a multilateral approach to IP protection where they sought an international lobbying campaign in favor of introducing high standards on patent protection into the new GATT round of negotiations.

B. THE MULTILATERAL APPROACH: PHARMACEUTICAL MNEs AND THE TRIPS PATENT NEGOTIATIONS

What is new in this case is that industry identified a trade problem, devised a solution, and reduced it to a concrete proposal that it then advanced to governments. These private sector actors succeeded in getting most of what they wanted from an IP agreement, which now has the status of public international law.106

The pharmaceutical MNEs, as other international business interests, eventually realized that reliance on the bilateral approach was an unsustainable strategy. Not only were certain bilateral tactics GATT-illegal, but they were also subject to the political priorities of the government deploying them and thus unreliable in the long term. More importantly, reliance on an international regulatory framework requiring signatory parties to adhere to the standards enshrined therein guaranteed IP owners a durable and legitimate, if indirect, mechanism of protection. This was even more highly coveted if this framework comprised standards conforming to their preferences with an effective enforcement and dispute settlement mechanism. Therefore, a multilateral approach was preferred, and GATT as a venue was ideal in this regard. However, this did not entail forfeiture of the bilateral approach, which was still advocated by a leading MNE executive as necessary to secure agreement within GATT. Therefore, bilateral pressure was a tactic to achieve the multilateral GATT strategy.107

U.S. MNEs began a campaign to launch multilateral trade negotiations within the GATT ambit on IP, aiming to produce a multilateral code that included the “adoption and implementation of adequate and effective rules for the protection of intellectual property.”108 Two U.S. business mobilization efforts were crucial in this regard—the Advisory Committee for Trade Negotiations (ACTN) and the Intellectual Property Committee (IPC). Established by statute in 1974 to provide the U.S. President with advice on trade negotiations, the ACTN was a committee of leading executive officers from major U.S. corporations with a stake in U.S. and international trade policy.109 On the issue of IP protection and the quest of the U.S. business community to include the issue within the GATT ambit by including it in the upcoming new round of multilateral trade negotiations, the ACTN issued in October 1985 an outline of a multilateral IP agreement to be concluded within GATT and supplied it to the U.S. ad-
ministration. This was followed by a report issued by the ACTN Task Force on Intellectual Property, which ultimately influenced the administration's statement on the protection of U.S. IP abroad.

In addition to the ACTN effort, one of the leading U.S. corporate officers, Pfizer's CEO Edmund Pratt (who also served as Chair of ACTN) together with the CEO of IBM, decided in March 1986 to establish the IPC as a coalition of senior executive officers from twelve major U.S. corporations in diverse areas of activity with a common interest in IP protection. The objectives of the IPC were:

- the inclusion and successful negotiation of a satisfactory arrangement for IP (patents, copyrights, trade secrets and trademarks) in the new round of GATT trade negotiations.
- the development of a coherent international strategy, including bilateral negotiations, in support of IP protection.
- cooperation between the U.S. private sector and the international business community in support of improved international IP protection.
- changes in various U.S. trade laws to improve IP protection.

Therefore, in its quest for the successful negotiation of a GATT-based IP protection regime, the IPC sought to secure an international consensus between business interests not only in the United States but also in Europe via UNICE and Japan via Keidanren. In this regard, the IPC had a number of MNEs in the pharmaceutical and chemical industries with a high stake in ensuring a strong patent protection regime for future multilateral negotiations on the issue, including Bristol-Meyers, Merck, Pfizer, Du Pont and Monsanto. Pfizer took the lead in this group—particularly in lobbying the U.S. Congress. Similarly, Pfizer engaged the TRIPS negotiators on the ground in Geneva where it hired a number of Geneva-

111. U.S. TRADE REPRESENTATIVE, ADVISORY COMMITTEE FOR TRADE NEGOTIATIONS TASK FORCE ON INTELLECTUAL PROPERTY RIGHTS, SUMMARY OF PHASE II: RECOMMENDATIONS OF THE TASK FORCE (1986).
113. See Dam 1986 Senate Statement, supra note 34, at 146. See also Carol Bilzi, Towards an Intellectual Property Agreement in the GATT: View of the Private Sector, 19 GA. J. INT'L & COMP. L. 343, 343-45 (1989); Sell, supra note 3, at 183-86.
114. Dam 1986 Senate Statement, supra note 34, at 149.
115. The fruits of this cooperation was the issuance of the Trilateral Report, referred to earlier, and arguably the single most important contribution of international business to the Uruguay Round negotiations.
based lobbyists for that purpose.\textsuperscript{116}

Despite Pfizer's active role within the IPC, the Pharmaceutical Manufacturers Association (PMA) and its associated lobbying of the U.S. administration and Congress was the spearhead of the pharmaceutical MNEs' mobilization campaign to defining, fine-tuning, and pursuing their goals of international protection of IP rights.\textsuperscript{117} As examined above, PMA was also active in petitioning for the initiation of 301 investigations. Resulting in a considerable advantage in its access to policy-makers and expertise in the IP area, PMA was presided over by none other than Gerald J. Mossinghoff, a former U.S. Assistant Secretary of Commerce and Commissioner of Patents. Obviously, PMA realized that the involvement of the U.S. administration and Congress in its' endeavour was crucial to the success of its efforts. Apart from the exertions of ACTN on the administration and its direct impact on the U.S. position on international IP protection as well as the work of the IPC in lobbying the administration and in framing the U.S. negotiating objectives through Congress,\textsuperscript{118} PMA was undoubtedly the principal mobilization vehicle of U.S. pharmaceutical MNEs in lobbying the U.S. Congress. A direct method for performing this task was through testimony concerning the negotiations, U.S. national interests in the new round of multilateral trade negotiations, and its follow-up during Congressional hearings that ran during the TRIPS negotiations.\textsuperscript{119} This effort maintained pressure on the U.S. legislature and the presidential administration through constantly voicing MNEs concerns on IP. Pressure was also maintained through PMA's evaluation of the final TRIPS Agreement itself during congressional hearings on the results of the Uruguay Round.\textsuperscript{120}

\begin{itemize}
  \item \textsuperscript{116} Interview with Gerald J. Mossinghoff, former President, Pharmaceutical Manufacturers Association, in Washington, D.C. (Aug. 29, 2002).
  \item \textsuperscript{117} During the period from 1985 and until the end of the Uruguay Round and beyond, PMA representatives regularly appeared before Congress as witnesses for hearings on issues related to IP protection.
  \item \textsuperscript{118} Dam 1986 Senate Statement, \textit{supra} note 34. See also \textit{GATT: The Impact on American Industries: Hearing and Mark-up on H.R. 362 Before the Subcomm. on Econ. Policy, Trade and Env't of the House Comm. on Foreign Affairs, 103rd Cong. 44-79} (1994) (statement of Jacques Gorlin, Intellectual Property Committee).
  \item \textsuperscript{120} See Trade Agreements Resulting from the Uruguay Round of Multilateral Trade Negotiations: Hearings Before the House Comm. on Ways and Means and its Subcomm. on Trade, 103rd Cong. 559-568 (1994) (statement of Gerald Mossinghoff, President, Pharmaceutical Manufacturers Association). See also \textit{Trade Agreements Resulting from the Uruguay Round of Multilateral Trade Negotiations: Hearings Before the House Comm. on Ways and Means and its Subcomm. on Trade, 103rd Cong. 134-149} (1994) (statement of Timothy Hackman, Intellectual Property Com-
As referred to earlier, the IPC played a prominent and active role in engaging international business interests headquartered outside the United States, focusing its efforts mainly in Europe and Japan. Furthermore, in July 1986 the International Chamber of Commerce endorsed a similar approach favored by U.S. MNEs on IP protection for the Uruguay Round.\(^{121}\) As to the specifics of the pharmaceutical MNEs’ forward international deployment, an important role was performed by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).\(^{122}\) IFPMA was important to the pharmaceutical MNEs’ lobbying strategy at the international level for two main reasons. Primarily, it was a venue where discussion and ‘agreement’ on specific courses of action could swiftly be dispensed across the world given its international membership, coupled with the fact that IFPMA was largely influenced by the U.S. PMA. In the words of Gerald Mossinghoff: “PMA had a lot to do with IFPMA policies.”\(^{123}\) Second, and most conveniently, IFPMA was headquartered in Geneva and only a stone’s throw from where the TRIPS negotiations were being held in GATT. Thus, it was able to follow up on developments and provide feedback as well as engage the negotiators personally. IFPMA’s then Executive Vice-President, Richard Arnold, was praised by PMA President as having proved a consistent and resourceful lobbyist and a great help for the pharmaceutical industry.\(^{124}\) Finally, mention should also be made of the work undertaken by the International Association for the Protection of Industrial Property (IAPIP).\(^{125}\) A private association aiming towards the protection of industrial property. IAPIP was the oldest of the organizations reviewed possessing a tradition stretching as far back as the 1890s.\(^{126}\) Among the key questions IAPIP members reviewed and issued resolutions on were those on “GATT/WTO” and on “Enforcement of Intellectual Property Rights.”\(^{127}\)

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123. Interview with Gerald J. Mossinghoff, supra note 116.
124. Id.
126. Id.
So far, we have examined the mechanism of action that the MNEs and particularly the pharmaceutical MNEs undertook to push for their international IP protection objectives at the multilateral level. These mechanisms were naturally used to push for the norms they wished to incorporate into a new regime for IP protection. With regard to the form within which these norms were to be incorporated, the IPC sought their inclusion within the GATT. The argument they presented was that IP was, after all, not a new issue to the GATT being that its articles XX(d), IX, XII, XVIII, and III, are of relevance to patents, trademarks, or copyrights.128 Furthermore, given that the root cause of the problem being dealt with was the "trade-related" aspects of IP rights, it was clearly within the scope of GATT. The IPC advocated a dual pronged approach within GATT: primarily, finalising negotiations over the anti-counterfeiting code for trademarks, and second, introducing IP provisions that would focus on patent and copyright infringement and "could seek to develop and enforce substantive norms and standards...and...agreed rules of behaviour, . . .dispute settlement procedures and authority to impose trade restriction on countries that tolerate violation of intellectual property rights."129 Two years later however, with the GATT mandate on IP firmly in place and negotiations underway, the IPC changed its preferred approach and opted for a GATT "agreement" rather than an anti-counterfeiting code and amendment of GATT articles.130

The Trilateral Report issued by the IPC, Keidanren, and UNICE detailed the standards and norms championed by MNEs for adoption into an agreement. In the words of Pfizer’s Vice President and General Counsel, it was the "standard reference" for the GATT IP negotiations regarding the views of the private sector.131 The provisions advocated by the Trilateral Report on the standards for patent protection are presented in Table 2 below, where they are compared to the submissions of the EC,132 the United States,133 and Japan.134 Most importantly, those standards advocated the patentability of both products and processes without discrimination as to subject matter and a patent term of twenty years from

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128. Dam 1986 Senate Statement, supra note 34, at 152, 165.
129. Id. at 153.
130. Trilateral Report, supra note 35, at 18-19. Interestingly, this was also the approach advocated by the U.S. delegation in the first meeting of the negotiating group on intellectual property (Negotiating Group 11).
133. GATT, Suggestion by the United States for Achieving the Negotiating Objective – Revision, MTN.GNG/NG11/W/14/Rev.1 (Oct. 17, 1988) [hereinafter Revised U.S. Submission].
On the issue of working and compulsory licensing, the Report required that there be no revocation on grounds of non-working and that a compulsory license awarded for non-working shall be granted only to permit local manufacture. Where impractical, importation authorized by the patentee shall be deemed to satisfy the requirements for working. Finally, neither exclusive nor sole compulsory licenses shall be granted, nor shall compulsory licensing provisions discriminate against particular classes of subject matter—an important requirement for the pharmaceutical industry. In the case of a compulsory license being granted, full compensation should be due to the patentee.  

### TABLE 2


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<td>Exclude others from the right to exclude others from the manufacture, use or sale of the patented invention and, in the case of a patented process, the ability to exclude others from the use or sale of the direct product thereof.</td>
<td>Prevent third parties not having the proprietor’s consent from making, offering, putting on the market or using, ...or importing or stocking the product for these purposes. For processes, the right to prevent others not having proprietor’s consent from using, offering, putting on the market, using, or importing or stocking for these purposes the product obtained directly by that process.</td>
<td>Prevent third parties not having owner’s consent from: In case of a product – manufacturing, using, assigning, leasing or importing the product, and acts of displaying, for the purpose of assignment or lease, the product; in case of a process – acts of using the process; in case of a process for the manufacture of a product – using the process, using, assigning, leasing or importing the product directly. manufactured by the process, displaying, for the purpose of assignment or lease, the product directly manufactured by the process.</td>
<td>Exclude others from the manufacture, use or sale. In the case of a process, the right to exclude others from importation, use or sale of at least the direct product thereof.</td>
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136. *Id.* at 32-33.
140. Revised U.S. Submission, *supra* note 133.
The congruence between the provisions advocated by the business community and those advanced by the main IC delegations during the negotiations on TRIPS was indicative of the influence MNEs had on forging the IC positions. Regardless, towards the latter stages of the negotiations the pharmaceutical MNEs began to voice discontent with certain

141. The U.S. paper notes that the terms “useful” and “unobvious” encompass or are synonymous with the terms “capable of industrial application” and “inventive step.” Revised U.S. Submission, supra note 133 at 3.

142. This was the first reference to the ordre public exception of the eventual TRIPS Article 27(2).
aspects of the unfolding instrument. This mainly centered on what they considered to be overly long transition provisions for DCs and the lack of 'pipeline' protection. Nonetheless, the multilateral strategy of the MNEs was by all counts successful in launching the TRIPS negotiations towards the realization of their interests.

IV. TRIPS PATENT NEGOTIATIONS: AN EXERCISE IN TOP-DOWN RULE MAKING?

The evidence presented thus far in this article reveals that the TRIPS negotiations, specifically as they pertained to patent standards, were the product of a process that was disproportionately influenced by the interests of pharmaceutical MNEs at the expense of DC interests, resulting in a 'top-down' model of rule making. This section will first deal with the factors that led to this format in the TRIPS rule making process. Second, the section will briefly highlight this case with insights on the process of international regulation, particularly with regard to the role of non-state actors therein. Finally, this article will end with brief comments on the implications of the TRIPS negotiation phase to the main argument of the volume on the issue of fairness in GATT/WTO rule making.

A. PHARMACEUTICAL MNEs AND THE TRIPS PATENT NEGOTIATIONS OUTCOME

The role of the pharmaceutical lobby, particularly the U.S. pharmaceutical lobby represented by the Pharmaceutical Manufacturers Association and more generally by the IPC, has undoubtedly been a major catalyst, if not the raison d'être, for the drive towards the relevant standards on patent protection in the TRIPS Agreement. The reason for this success by the pharmaceutical MNEs in this rule making exercise was due to four key factors.

The first two factors relate respectively to the cohesion and organizational prowess of the pharmaceutical MNE lobby. Arguably, the nature of the 'piracy' problem faced by the pharmaceutical giants was peculiar in eliciting a high level of cohesion within their rank, as it posed a common problem faced by most of them especially in the larger DC markets. This facilitated the emergence of a strong cohesive stance revealed in the formation of the IPC, which involved a number of pharmaceutical MNE members, as well as a clear stance by the PMA on the issue. It was further reinforced by international solidarity primarily through the IPC-UNICE-Keidanren unified position, and second, through the efforts of

143. Hearings on Fast Track: Intellectual Property: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Senate Comm. on the Judiciary, 102nd Cong. 172 (1991) (statement of C.L. Clemente, Vice President and General Counsel, Pfizer Inc.). In addition, Susan Sell notes complaints by the U.S. pharmaceutical industry with regard to the compulsory licensing provisions. See Sell, supra note 3, at 185.
144. This led to the publication of the Trilateral Report.
the international federation, IFPMA. Related to the factor of cohesion in the success of the pharmaceutical MNE efforts is their organizational prowess. Not only were these MNEs financially well resourced, but they were equally successful in having exceptional human resources to bear on the issue. The experience and networks of such key figures as Edmund Pratt, Gerald Mossinghoff, and Richard Arnold, among others, were major contributing factors in this regard. Furthermore, the coordination of work by the pharmaceutical lobby in ‘working’ Capitol Hill and the Administration, and in information gathering and direct lobbying of delegates in Geneva, as largely conducted by IFPMA, was also an organizational ability, unmatched by the majority of DC delegations.

Also related to the MNEs organizational abilities, the third factor was their success in defining the problem, in devising a solution, and ultimately in supplying it in a legal format. Earlier, the ‘genius’ of framing the IP problem in a trade context was discussed. Furthermore, the utility of providing a proposed draft document very close to treaty language in the form of the Trilateral Report at the early stages of the negotiations proved an effective tool in gaining momentum. Finally, the fourth factor relates to the ability of the MNEs to effectively lobby the dominant state actor(s) during the Uruguay Round negotiations and particularly on the TRIPS patent standards provisions. This will be further alluded to below as an important element of influence by non-state actors in international rule making.

B. NON-STATE ACTORS IN INTERNATIONAL RULE MAKING

The involvement of transnational corporations and producer associations, and their interaction with governments in making of the TRIPS Agreement, demonstrates that an elite of powerful actors has joined the nation state in the management of the global economy.

The practice of rule making at the international level has been an important area in international legal study, in international relations theory, and in regulation theory. Under established international legal practice, rule making and the process of treaty making as pursued during the Uruguay Round, follows the precepts enshrined in the 1969 Vienna Convention. Article 2(1)(a) of the Convention defines a “treaty” as an international agreement concluded between States in written form and

145. Edmund Pratt is former CEO of Pfizer and convenor/founder of the IPC.
146. Gerald Mossinghoff was President of PMA during the Uruguay Round and former U.S. Under-Secretary of Commerce and Commissioner of Patents.
147. Richard Arnold was Executive Vice-President of IFPMA during the Uruguay Round.
148. Braithwaite and Drahos enumerate ‘individuals’ as important actors involved in international economic regulation. For their analysis, see JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 494-97 (2000).
governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation.\textsuperscript{151} As far as the issue of identifying the actors involved in the treaty making process, the Convention ascribes standing only to states.\textsuperscript{152}

Despite this fact of international legal discourse ascribing capacity only to 'states' in engaging in the rule making effort, the examination thus far in this study has focused on the inordinate degree of influence exerted by the pharmaceutical MNEs in these negotiations. While neither the MNEs nor their associations participated formally in the negotiations, their influence was clearly felt. Ascribing the representation of the MNE interests to the formal representation of their home-states has been established under the doctrines of 'diplomatic protection' and 'state responsibility.'\textsuperscript{153}

However, other strands of theoretical analysis have sought to account for the increasingly important role of MNE influence as of other non-state actors in international rule making. Primarily from international legal theory, these include the vision of the 'process-oriented approach,' chief among which are the writings of the New Haven School that recognizes that participants in the international legal process are defined not by their possession of the attribute of 'sovereignty,' but rather by their possession of the attribute of 'effective authority' and/or 'effective control.'\textsuperscript{154} Second, international relations theory offers a tradition of placing non-state actors and domestic influences as major contributing factors to international negotiations.\textsuperscript{155} In this regard, the work of Robert Put-

\begin{itemize}
\item \textsuperscript{151} Article 2(1)(a) of the 1986 Vienna Convention offers the same definition with the added provision of international organisations as possible parties. See Vienna Convention on the Law of Treaties Between States and International Organizations or Between International Organizations, 25 I.L.M. 543 (1986).
\item \textsuperscript{154} The process-oriented approach to law found its most forceful proponents in the New Haven School, founded by Professors Myres S. McDougal and Harold Lasswell at the Yale Law School. It must be noted, however, that a process-oriented approach to law is by no means the invention of the New Haven School. Rather it is rooted in the Sociological Movement, which found earlier expressions, most notably in Legal Realism. See Alan Hunt, \textit{The Sociological Movement in Law} (1978). For a recent review of the approach, see Rosalyn Higgins, \textit{Problems and Process: International Law and How We Use It} (1994); see also Harold D. Lasswell & Myres S. McDougal, \textit{Jurisprudence for a Free Society: Studies in Law, Science and Policy, Volume I} (1992); Myres S. McDougal, \textit{International Law, Power and Policy: A Contemporary Conception}, 82 Recueil des Cours 137 (1953).
\item \textsuperscript{155} See \textit{Transnational Relations and World Politics} (Robert O. Keohane & Joseph S. Nye, Jr. eds., 1971). See also Richard W. Mansbach et al., \textit{The Web of World Politics: Nonstate Actors in the Global System} (1976). For a more recent account and slightly altered work in this tradition, see \textit{Bringing Transnational Relations Back In: Non-State Actors, Domestic Structures and International Institutions} (Thomas Risse-Kappen ed., 1995).
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nam on negotiation as a two-level game (including the domestic level) is particularly relevant.\textsuperscript{156} Finally, regulation theory offers important insights on the ability of a regulatory activity or undertaking to be initiated and controlled by certain private interests.\textsuperscript{157} Most importantly in this regard is 'public choice' theory, which posits that regulation, rather than being initiated originally in the pursuit of public interest, in fact originates in the self-interested pursuits of business for governmental intervention on behalf of their interests.\textsuperscript{158}

C. IMPLICATIONS OF THE TRIPS PATENTS NEGOTIATIONS

As becomes evident from the examination above, DCs and the pharmaceutical MNEs approached the issue of patent protection from different perspectives. As their interests were at odds, the discourse employed by each party in the debate to justify their positions was different. While this article warned earlier of the dangers of falling into the trap of an ideologically grounded debate on the relevant merits of either party's position and their approach to the issue, it is important to note the diametrically opposed nature of some of their justifications. MNEs argued that existing international IP regimes, most notably the Paris Convention, were never intended to address trade-related distortions, and hence the existence of a problem in international economic regulation was required to be addressed in a new fashion.\textsuperscript{159} On the other hand and diametrically opposed to this contention, was the argument by DCs, as expressed by India's submission to the negotiating group on TRIPS. Their argument was that the philosophy behind regimes for the protection of IP was to encourage and promote public policy priorities, and that the trade-related problems associated with it were the quest of IP owners to distort such a goal to fulfill their narrower interests.\textsuperscript{160}

Supported by other IC delegations (particularly the EC) during the Uruguay Round negotiations, the role performed by the United States also contributed to this 'top-down' rule making process. Apart from the bilateral diplomatic pressures and unilateral sanctions applied mainly by

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\item[156.] Robert D. Putnam, \textit{Diplomacy and Domestic Politics: The Logic of Two-Level Games}, 42 INT'\textsc{l} ORG. 427 (1988).
\item[159.] See Trilateral Report, \textit{supra} note 35, at 15.
\end{enumerate}
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the United States,\textsuperscript{161} the said delegations were also engaged in manipulative negotiating tactics with DC delegations partly through their ability to offer concessions to DC delegations in other areas of the Uruguay Round negotiations such as in textiles. However, they were also able to exclude DC delegations from key decision making, notoriously in the ‘green room’ process of negotiations among the like-minded ICs with the results offered on a take it or leave it basis for DCs.

Two further factors contributed to this characterization of a ‘top-down’ rule making process. Primarily, the forum of the GATT was amenable to the interests of ICs. The GATT/WTO system and particularly its rule making process in the form of rounds of negotiations to be carried forward as a single undertaking with the end product in the form of a package, lends itself to those negotiating delegations with the most bargaining power. Particularly, the ability of the United States and EC to offer DC delegations concessions in important areas was paralleled by their ability to force a capitulation on the part of DC delegations on the issue of TRIPS. Finally, the lack of cohesion among DC delegations on the issue of TRIPS, as in other issues during the Uruguay Round, facilitated this process and made them an easier target of IC pressure.\textsuperscript{162}

The \textit{fait accompli} resulting in the adoption of the TRIPS Agreement at the end of the Uruguay Round was by no means the end of the line with regard to the pharmaceutical patent dilemma. Its implementation and the complications leading to the Doha Declaration and the subsequent negotiations on implementing paragraph 6 of that Declaration, proved beyond doubt that the debate on the relative ‘fairness’ of the TRIPS Agreement has not been settled.\textsuperscript{163} This complicates its implementation and leads to a profusion of legal and political disputes that are proving detrimental not only to TRIPS and the WTO regime, but also to the interests of all parties involved—including DCs and MNEs.

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\item \textsuperscript{161} For an attack by certain delegations during the negotiations, on the Special 301 process, as being a violation of the commitments under the Punta del Este Declaration, specifically with regard to standstill and rollback, see GATT, MTN.GNG/TRIPS/I (Jul. 25, 1991), at paras. 4-5.
\item \textsuperscript{162} On the breaking up of ‘third world unity’ during the Uruguay Round, see Chakravarthi Raghavan, \textit{Recolonization: GATT, the Uruguay Round and the Third World} 75-77 (1990).
\item \textsuperscript{163} This point is also addressed by Susan Sell. She argues that, while DCs might have changed the black letter law of their IP regimes, action on its own will not guarantee their conviction of its merits. See Susan Sell, \textit{Power and Ideas: North-South Politics of Intellectual Property and Antitrust} (1998).
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