Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement

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I. Introduction

Among the many trade conflicts that divide the postindustrial economies of Europe, the United States, Japan, and the Commonwealth from the less information-driven economies of the rest of the world, one of the most consequential is the debate over how to balance access to medicines with the intellectual property protection demanded by their developers. Among the many facets of this debate is the question of whether pharmaceuticals, vaccines, biologics, and other therapeutic or preventative health consumables (to which this article will refer collectively as “drugs”)1 should be patentable in developing countries. This debate was partly resolved by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement), which allows signatories to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”2 yet requires the patenting of pharmaceuticals after a transition period.3 Nonetheless, disagreement about access to medicines has plagued subsequent negotiations.4 The economically developed states, led by the United States, have demanded that WTO members cease liberal compulsory licensing practices and adopt patent protection regimes equivalent

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1. Many of the issues discussed in this Article apply to medical devices as well as drugs. In light of the relative economic dominance of drugs in the medical products industry, however, the focus of this Article will remain on them.


3. Id. arts. 27, 70.8.

in most significant respects to those of the United States and Europe. Developing countries have required these demands with insistence on better access to affordable drugs and medical technology originating in the economically developed states. The debate over patentability and compulsory licensing hinges partly on disagreement over whether patent protection in developing countries is a necessary incentive for optimal drug development and distribution. It is generally contended that the TRIPS Agreement has a significant effect in either promoting or retarding innovation necessary for pharmaceutical companies to invent and register drugs that prevent or treat diseases prevalent in developing countries. The WTO General Council has temporarily quieted this debate with its September 2, 2003, decision on paragraph 6 of the Doha Declaration, which sanctions compulsory licensing by the least-developed countries pursuant to notification requirements and other limitations. The Doha Round negotiations have not yet resolved, however, a second, equally contentious debate that focuses on whether similar incentives are needed to stimulate drug developers to seek marketing approval in developing countries.

Notwithstanding the media attention given to the compulsory licensing debate, it is something of a red herring. In fact, patents and international patent protection obligations are not the main obstacle to an adequate supply and distribution of necessary drugs in the developing world.


8. Compare Sykes, supra note 7, at 62 (arguing that economic incentives to do research on tropical diseases “will depend critically on the ability of pharmaceutical companies to earn rents on sales in the developing world” and that patent protection under the TRIPS Agreement provides such protection) with Ellen ’t Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha, 3 CHI. J. INT’L L. 27, 29 (2002) (noting that relatively few drugs now developed cure tropical diseases but arguing that patents increase prices and that “poor countries often do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry”).


10. Patents may prevent the populations of developing countries from obtaining some recently developed drugs, but the chronic unavailability of many inexpensive and off-patent drugs demonstrates that neither the elimination of patent rights nor compulsory licensing would contribute substantially to a solution to the most serious problems of obtaining access to drugs in developing countries. See Michael Kremer, Pharmaceuticals and the Developing World, J. ECON. PERSP., Fall 2002, at 67, 68. In fact, most drugs used to treat the most prevalent serious diseases in developing countries are no longer patented. As
the adoption of international trade rules that may further impede such access is hardly welcome. Even so, economically developed countries have consistently pushed for an interpretation of the TRIPs Agreement that would confer on large pharmaceutical companies price-inflating monopolies over drugs that are neither patented nor patentable, through guarantees of exclusive rights to clinical testing data necessary to obtain marketing approval. An analysis of and a resolution to the debate over control of this drug test data—at the levels of positive international law and international drug policy—are sorely needed.

The international debate over drug marketing approval data relates primarily to regulations in effect in WTO members concerning drug efficacy, safety, and quality. Quite apart from the investment of time and funds necessary for the discovery of a new drug, for which a patent is the usual reward, drug developers must undertake the laborious and time-consuming task of obtaining marketing approval from the government agencies charged with protecting public health. In the United States, those agencies include the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). In Europe, this function is now performed by the European Medicines Evaluation Agency (EMEA). In Canada, it is Health Canada, and in Japan, the Ministry of Health, Labor and Welfare (MHLW). These regulatory agencies typically require drug manufacturers to adhere to published manufacturing and facility safety standards and require drug develop-


11. One such obstacle is that “drug procurement and distribution is [often] inefficient or corrupt.” Kremer, supra note 10, at 72.

12. The EMEA issues certificates for products that have been authorized via the European centralized procedure. The certificates signify that marketing authorization has been given in all EU members. See http://www.emea.eu.int/hrms/aboutus/emeainfo/index.htm#certificates (last visited Apr. 10, 2004).
ers to perform a series of tests and experiments to ensure the efficacy, safety, and quality of new drugs before marketing them.13

Drug developers seeking approval to market new drugs in developing countries argue that they should be guaranteed secrecy for the data they submit to the developing countries’ regulatory authorities and that the regulatory authorities should not allow competing drug companies to rely upon data to gain market access for generic versions14 of the drug.15 Such data should be treated, in other words, as a trade secret proprietary to the submitter. Trade secret status, like a patent, would shelter the drugs from competition and, in some cases, grant a monopoly on subsequently discovered medical uses of the drug. Data exclusivity has become one of the principal methods drug developers use to gain protection from competition for off-patent or unpatentable drugs and new indications.

Almost all WTO members have regulatory agencies like the FDA and EMEA charged with approving the efficacy, safety, and quality of new drugs. In addition, all WTO members are required to maintain the confidentiality of clinical drug test data submitted in order to gain marketing approval (“marketing approval data”) under certain conditions defined in Article 39.3 of the TRIPs Agreement. In the United States, Canada, and Europe, drug manufacturers seeking to market an identical drug in competition with the initial registrant may not rely on an initial registrant’s marketing approval until five or ten years after the initial approval.16 In the United States, this has been the practice since 1984, when U.S. law first forbade the FDA to allow drug manufacturers to rely on marketing approval data submitted by their

13. Usually, these tests and experiments are arranged into four phases, culminating in testing the pharmaceutical on human volunteers. In addition, a change to the composition of a molecule or the marketing of the molecule for a previously undisclosed therapeutic purpose generally requires a new marketing approval. The U.S. FDA’s procedures for approval of a new drug are set forth in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–97 (2000) and the Public Health Service Act, 42 U.S.C. § 262 (2000). An application for approval of a new drug in the United States typically requires a full report of investigations of the drug’s safety and effectiveness; a full list of components of the drug and statement of the drug’s composition; a full description of the methods used in and facilities and controls used for the manufacture and packaging of the drug; samples of the drug and its components; and specimens of its proposed labeling. See 21 U.S.C. § 355(b)(1) (2000).

14. By “generic versions” of a new drug, this Article refers to drugs bioequivalent to a new drug marketed by persons other than the drug’s initial registrant for marketing approval.


16. See infra notes 17–20 and accompanying text.
competitors. During the first five years after it grants initial marketing approval to a drug, the FDA will not even accept an application for marketing approval without the permission of the initial registrant. Health Canada has adopted the same policy. Similarly, since 1987, European Community (EC) members have been required to grant between six and ten years of data exclusivity for drugs they approve for marketing. These countries have what is sometimes called a “data exclusivity” system for protecting marketing approval data from unauthorized use by others. After the data exclusivity period has expired, generic drug manufacturers may generally begin marketing competing drugs (assuming the absence of any blocking patent) without the full complement of clinical testing.

The purpose of data exclusivity is to ensure that the initial registrant of a new drug can recover the considerable costs of testing the drug for efficacy and safety. This purpose is achieved by requiring potential competitors to replicate the initial registrant’s clinical studies to obtain marketing approval or by not accepting applications to market generic versions of the approved drug. Without data exclusivity, drug developers contend that they cannot afford to bring drugs to market because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free ride on the initial registrant’s approval and sell the same or similar drug at a lower price. Such price undercutting is impossible in a data exclusivity system.

In contrast to the practices of the economically developed states, many developing countries allow any company seeking to register the same drug


for marketing to rely on the data submitted by the drug’s initial registrant, thereby enabling the initial registrant’s competitors to obtain marketing approval without replicating its clinical studies. Allowing later registrants to free ride on the initial registration prevents wasteful repetition of testing that has already been performed and facilitates rapid development of competition in drug markets. Moreover, when subsequent registrants may not rely on the drug developer’s marketing approval data, drug prices remain too high in the very countries where the populations need them most and can afford them least.

The battle lines over data exclusivity are predictably drawn between net exporters and net importers of intellectual property. Many developing countries see little point in granting exclusive marketing privileges to wealthy foreign drug companies so that they may sell much-needed drugs at a premium price to an impecunious population. Intellectual property exporting countries counter that they have little incentive to market such drugs in developing countries without adequate recompense in the form of data exclusivity. Not only do drug developers face competition from local generic drug manufacturers who did not have to invest in obtaining the initial marketing approval, but competing multinational drug manufacturers might free ride on the initial registration as well. The longstanding debate over which side international trade law should favor remains far from resolved and presents a major stumbling block to future WTO negotiations.

The purpose of this Article is to analyze the contentions of both sides of the debate and to propose a resolution that strikes the right balance between maximizing drug developers’ incentives to obtain new drug marketing approvals in developing countries and fostering free and fair competition in drug markets. As U.S. pressure on developing countries to yield to a data exclusivity model of drug marketing approval continues to mount, the time has come to propose an alternative approach that is consistent with the requirements of the TRIPs Agreement and satisfies the reasonable policy needs of both the pharmaceutical industry and developing countries.

One of the key points of contention in the drug access debate has been the question of whether the TRIPs Agreement requires all WTO members to adopt a data exclusivity standard or whether alternative standards would satisfy the requirements of the TRIPs Agreement. Part II of this Article addresses this question while examining the related issues of defining the scope of the intellectual property protection in Article 39.3 of the TRIPs Agree-

25. See Carlos María Correa, South Centre, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPs Agreement 6–7 (2002) [hereinafter South Centre].
26. Id.
ment and determining whether there are relevant exceptions to the data protection standards set forth therein. With the positive international law explained, Part III analyzes the policy considerations that led to the adoption of the specific wording of Article 39.3.

Part IV discusses three potential solutions to the current morass. The first is the model consistently advocated by the United States and pushed upon its trading partners: the five-year data exclusivity rule that is incorporated into the North American Free Trade Agreement (NAFTA). The second model is based on U.S. legislation that provides for a kind of compulsory licensing through a combination of negotiation and arbitration. The third model is a simple cost-sharing model that spreads the risk and the cost of obtaining marketing approval over all drug manufacturers equally.

Finally, Part V develops a model based on the concept of continuously, but prospectively, readjustable royalties under a license, which is consistent with both the positive law and the policies the WTO members advanced in Article 39.3 of the TRIPs Agreement. Part V.A proposes a mathematical model that would reconcile the competing interests of drug developers and developing countries. Part V.B adjusts the model to factor in the time value of money to ensure economic completeness, and Part V.C discusses some of the more difficult problems in determining the cost basis for the calculation of royalties. Part V.D concludes by summarizing the proposed model as fully developed and clarifying some of the finer points that might otherwise inspire objections to the model.

II. Unfair Commercial Use and Marketing Approval Data Under International Trade Law

All WTO members, which comprise approximately three quarters of the states in the world,27 are bound by the TRIPs Agreement. Consequently, the TRIPs Agreement has been the main battleground where intellectual property exporting states have wrestled with developing countries over what duties the latter should assume with respect to protecting drug companies’ interests in marketing approval data. This Part discusses the positive law of the TRIPs Agreement and evaluates the validity of the contentions of both developing countries and the intellectual property exporting states with respect to the interpretation of ambiguities in Article 39 of the TRIPs Agreement.

A. Article 39 of the TRIPs Agreement

The TRIPs Agreement sets forth the fundamental international consuetudes of intellectual property protection. Article 39.3 of the TRIPs Agreement,

effective as of January 1, 2000, with respect to all WTO members except the least economically developed countries, is tailored to provide an international standard of protection for drug and agrochemical test data submitted to gain marketing approval in WTO members. Article 39.3 provides:

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.28

This provision imposes two distinct obligations on WTO members that gather “undisclosed” test or other data when the production of such data required “considerable effort.” First, members must protect the data against “unfair commercial use.” Second, members must protect the data against any disclosure unless such disclosure is “necessary” to protect the public or unless steps are taken to ensure that the disclosure does not result in an “unfair commercial use.” Article 39.3 offers no guidance on the standard of necessity, and its reference to “unfair commercial use” creates several interpretive problems exacerbated by language elsewhere in Article 39.

1. Disclosures Necessary To Protect the Public

The exception to the nondisclosure obligation relating to public protection measures calls for a discretionary judgment by the members as to what constitutes necessity, but still is intended to raise a significant barrier to disclosure. Weaker alternative formulations of the disclosure standard could have included measures “tending to protect the public,” “helpful to protecting the public,” or “intended to protect the public.” The Uruguay Round negotiators presumably adopted the necessity standard to clarify that disclosures having the effect of protecting the public, but not “necessary” to protect the public, would violate Article 39.3. The ordinary meaning of the word “necessary” is:

I. 1. a. Indispensable, requisite, essential, needful; that cannot be done without . . . .

28. TRIPs Agreement art. 39.3. After the Doha Declaration, least-developed countries need not implement patent protection for pharmaceuticals until 2016. Such “least developed countries” account for only thirty of the WTO’s members and only 10% of the world’s population. The delay is intended to increase access to pharmaceuticals in the countries least able to afford them (and often most in need of them) by avoiding the monopolistic pricing typically associated with drug patents. See ’t Hoen, supra note 8, at 41.
II. 5. a. Inevitably determined or fixed by predestination or the operation of natural laws; happening or existing by an inherent necessity . . . .

b. Of mental concepts or processes: Inevitably resulting from the constitution of things or the mind itself . . . .

c. Inevitably determined or produced by a previous condition of things . . . .

7. Of agents: a. Impelled by the natural force of circumstances upon the will; having no independent volition.29

Each of these definitions incorporates the same essential element: inevitability. General Agreement on Tariffs and Trade (GATT) and WTO dispute settlement panels have usually interpreted the term “necessary” accordingly. In United States—Restrictions on Imports of Tuna, for example, the panel interpreted the term “necessary,” referring to measures “necessary to protect human, animal or plant life or health” in Article XX(b) of GATT to mean “that no alternative [to the measure] existed.”30 Both in this context and in that of Article XX(d), which deals with measures “necessary to secure compliance with laws or regulations which are not inconsistent with the provisions” of the GATT, other panels have interpreted this term to mean that there was no alternative measure that the GATT signatory “could reasonably be expected to employ.”31

The panels that have imported the concept of reasonableness into the definition of “necessary” offer an interpretation more likely to be consonant with the intent of the negotiators of the WTO agreements. Absent compelling contrary evidence, states should always be presumed to commit themselves to undertaking no more than reasonable obligations—Article 39.3 is best interpreted, then, to prohibit disclosure of marketing approval data unless such disclosure is the only reasonably possible means of protecting the public. The negotiators of the TRIPs Agreement evidently chose the strict necessity standard in the belief that the government should respect marketing approval data as if it is a particularly sensitive trade secret.32 Only the rare measure is “necessary” to achieve a public policy goal. Disclosure may be the most effective, convenient, or efficient way to protect the public without being “necessary” for that purpose. To satisfy Article 39.3, the disclosing WTO member must bear the heavy burden of showing that the failure to disclose would inevitably threaten the public and that no reasonable alternative ex-

32. See discussion infra Part II.B.2.
ists. There is, however, a different, less constrictive means set forth in Article 39.3 that allows states to disclose such data.

2. Disclosures Protected Against Unfair Commercial Use

The second circumstance under which a WTO member may disclose drug marketing approval data is where steps have been taken to protect the data against “unfair commercial use.” Article 39.1 of the TRIPs Agreement may offer interpretive aid for the term “unfair commercial use” in Article 39.3. Article 39.1 provides, in relevant part:

In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect . . . data submitted to governments or governmental agencies in accordance with paragraph 3.33

Under this reading, Article 39.3 is intended as an elaboration of the requirement in the Paris Convention for the Protection of Industrial Property (“Paris Convention”)34 to protect against unfair competition.

Unfortunately, the Paris Convention provides little help in interpreting the specific obligations of TRIPs Article 39.3. Article 10bis of the Paris Convention provides:

(1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

(2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.

(3) The following in particular shall be prohibited:

1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;

2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.35

33. TRIPS Agreement art. 39.1.
35. Id. art. 10bis.
The relevance of Article 10bis of the Paris Convention to Article 39.3 of the TRIPs Agreement is obscure. To understand why, it is helpful to review briefly its history and purpose. The original 1883 Paris Convention had no provision respecting unfair competition; Article 10bis was first added in the 1900 Revision Conference of Brussels and allowed for national treatment in protection against unfair competition without prescribing any specific protections that must be afforded under that modality. Article 10bis was progressively elaborated upon in subsequent conferences, most critically in the 1925 Hague Revision Conference, which introduced the definition of “unfair competition” as an “act of competition contrary to honest practices” and included the first two nonexhaustive examples listed in Article 10bis(3). As required by the Paris Convention, the laws of most industrialized countries implement some form of unfair competition law by protecting trade secrets from unauthorized use. But the precise parameters of the “acts of unfair competition” to be protected against were left to the discretion of the members of the International Union for the Protection of Industrial Property (“Paris Union”), subject to the understanding that the specific examples provided in Article 10bis(3) must be included within the definition.

The applicability of Article 10bis of the Paris Convention to Article 39.3 of the TRIPs Agreement is distinctly limited. Carlos Correa has concluded that the unfair commercial use standard is inherently subjective, and, consequently, Article 39.3 must be interpreted to grant discretion to WTO members to define unfair commercial practices. If Correa is correct, then Article 39.3 has little legal import beyond defining the confidentiality obligation. If the “unfair commercial use” of Article 39.3 is intended to carry the same meaning as the “unfair competition” of Article 10bis, then the reference to Article 10bis gives cold comfort to states claiming that Article 39.3 of the TRIPs Agreement requires data exclusivity. It is unlikely that either the disclosure of marketing approval data by a governmental public health agency, or the use of such data to allow competition in the market for drugs, could contravene Article 10bis of the Paris Convention. Neither practice could reasonably be considered dishonest or likely to lead to confusion about the source of the data. Nor does the drug regulatory authority, by allowing other companies to rely on this data to obtain marketing approval for similar

37 See PARIS CONVENTION art. 10bis; Bodenhausen, supra note 36, at 142–43. The third example was introduced during the 1958 Revision Conference of Lisbon. Id. at 143.
38 See generally WORLDWIDE TRADE SECRETS LAW (Terrence F. MacLaren ed., 2003).
39 See Bodenhausen, supra note 36, at 144.
40 Article 10bis of the Paris Convention is, however, relevant in its entirety to Article 39.2 of the TRIPs Agreement. Article 39.2 defines what constitutes a protectable trade secret for purposes of Article 39 and provides that private owners of trade secrets must have the right to prevent the disclosure of their trade secrets “in a manner contrary to honest commercial practices.” TRIPs AGREEMENT art. 39.2.
or identical drugs, violate standards of honesty or mislead anyone.\textsuperscript{42} It appears, then, that the obligation imposed in Article 39.1 of the TRIPs Agreement with respect to Article 10\textit{bis} of the Paris Convention is separate and distinct from the obligation under Article 39.3 to protect marketing approval data against “unfair commercial use.” This interpretation is supported by the choice of terminology in Article 39.3, which differs from the terminology of the Paris Convention and that of Article 39.1. It is further supported by the architecture of Article 39, which locates the duty to provide drug marketing approval data with “effective protection against unfair competition” in a paragraph different from that imposing a duty to “protect such data against unfair commercial use.”

\textbf{B. The Meaning of “Unfair Commercial Use”}

If Article 39.3 of the TRIPs Agreement imposes an obligation to protect against “unfair commercial use” that transcends the duty to ensure that the intellectual property of WTO members is protected against “unfair competition” under the Paris Convention, then states claiming that Article 39.3 imposes an exclusivity obligation must seek it either in the negotiating history of the TRIPs Agreement or in the context of the Agreement and its underlying policy of treating marketing approval data as protected information. This Part will explore each option.

\textbf{1. Negotiating History of the TRIPs Agreement}

During the 1988 TRIPs Agreement negotiations, the United States and the EC urged other GATT signatories to adopt explicit language that would oblige members to guarantee data secrecy and exclusivity for “a reasonable period,” except upon compensating the initial registrant for the “reasonable value” of any use that offered a “commercial or competitive benefit” to any other person, including the government.\textsuperscript{43} This proposal found some acceptance when the exclusivity obligation was limited to five years, but failed to garner anything approaching a consensus.\textsuperscript{44} In the following year, the United States reformulated and resubmitted its proposal to provide for ten years of data exclusivity and payment of “full compensation” for use or disclosure, but this proposal was ultimately rejected.\textsuperscript{45} The reasons for this rejection are not clear from the written records of the negotiations. More detailed documentation of the TRIPs Agreement negotiations is unfortunately lacking,

\textsuperscript{42} At most, Article 10\textit{bis} of the Paris Convention would prevent the drug regulatory authority from allowing a company to rely for marketing approval on the submission of data that it had appropriated unlawfully.


\textsuperscript{45} \textit{Cook, supra} note 23, at 11.
but the rejection of the U.S. and EC proposals proves that negotiators did not agree upon an unalloyed obligation to ensure data exclusivity under any of the proposed terms. The travaux préparatoires of the TRIPs Agreement simply do not support a reading to the effect that Article 39.3 requires data exclusivity per se.\(^{46}\)

Notwithstanding the clear intent of the TRIPs Agreement negotiators to eschew the data exclusivity obligations proposed by the United States, the United States and the EC consistently have interpreted Article 39.3 to require data exclusivity since the signing of the WTO Agreements.\(^{47}\) In a 1995 public statement, the U.S. Trade Representative (USTR) General Counsel opined that Article 39.3 requires that marketing approval data “not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with logic and with the negotiating history of the provision.”\(^{48}\)

Since then, the USTR has made a habit of including a five-year data exclusivity requirement in bilateral trade agreements and has had considerable success in persuading U.S. trading partners to accept such a provision.\(^{49}\) A five-year data exclusivity provision was included in NAFTA\(^{50}\) and in U.S. trade agreements with Sri Lanka,\(^{51}\) Ecuador,\(^{52}\) Laos,\(^{53}\) Cambodia,\(^{54}\) Vietnam,\(^{55}\) Singapore,\(^{56}\) and Chile.\(^{57}\) The United States will undoubtedly attempt

\(^{46}\) Drug developers often claim that the negotiating history of Article 39.3 illustrates that WTO members intended to require data exclusivity but typically cite no evidence from the TRIPs Agreement’s negotiating history to validate this claim. See, e.g., EFPIA 2000, supra note 15, at 3.

\(^{47}\) See SOUTH CENTRE, supra note 25, at 32.


\(^{49}\) Cf. Pharmaceutical Patent Issues: Interpreting GATT: Hearings before the Senate Comm. on the Judiciary, 104th Cong. 35 (1997) (statement of U.S. Trade Rep. Michael Kantor) (“We have also pressed our trading partners in [sic] a bilateral basis to include 13 more agreements, increasing the level of intellectual property protection even higher [beyond NAFTA and the TRIPs Agreement].”).


\(^{54}\) AGREEMENT ON TRADE RELATIONS AND INTELLECTUAL PROPERTY RIGHTS PROTECTION, U.S.-Cambodia, art. 19(5)(B), Oct. 4, 1996, Hein’s No. KAV 5171.

\(^{55}\) AGREEMENT ON TRADE RELATIONS, U.S.-Vietnam, ch. II, art. 9(6), July 13, 2000, DOS No. 02-9, CONSOLIDATED TREATIES AND INT’L AGREEMENTS, 2002-I, at 61, 129.


to include the same provision in the many free trade agreements (FTAs) that it is now in the process of negotiating with Morocco, the South African Customs Union, the Central American republics, Bahrain and the rest of the Middle East, Australia, Thailand, Peru, Ecuador, Bolivia, and others, including the draft agreement for the Free Trade Area of the Americas. The USTR’s victories in these agreements result in benefits to the EC, Japan, Switzerland, and other drug-exporting countries as well, because the TRIPs Agreement, unlike the GATT, does not grant an exemption from most-favored-nation treatment for signatories to bilateral or regional trade agreements. Consequently, any intellectual property related trade concession granted to the United States or to any other WTO member is automatically granted to all WTO members. Using a “divide and conquer” strategy of isolating developing countries and including data exclusivity provisions in their bilateral trade agreements, the United States effectively has begun homogenizing data exclusivity, not to mention other intellectual property laws, on terms favorable to intellectual property exporting WTO members. The United States could not achieve such a result in WTO negotiations, where developing countries confederate and resist U.S. and EC pressure.

Nevertheless, not content with its success in bilateral and regional arrangements, the United States has used more coercive measures to enforce its interpretation of Article 39.3 as well. In 1996, the USTR initiated a Special 301 investigation against Australia, claiming that Australia’s drug marketing approval regime provided inadequate protection to drug approval data.63

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58. The current draft of the U.S.-Morocco FTA provides for a five-year period of data exclusivity for new pharmaceutical chemical products, regardless of whether the bound signatory requires local testing or permits reliance on a foreign marketing approval. Notwithstanding this proposed exclusivity, the draft FTA also provides for nondisclosure of the data. Draft Free Trade Agreement, U.S.-Morocco, art. 15.10, Mar. 31, 2004, at http://www.ustr.gov/new/FTA/Morocco/text/index.htm (last visited Apr. 14, 2004).


60. The current draft of the U.S.-Australia FTA also contains data exclusivity and nondisclosure provisions similar in all substantial respects to the ones in both the U.S.-Morocco FTA and the Central American FTA. Draft Free Trade Agreement, U.S.- Australia, art. 17.10(1), Mar. 1, 2004, at http://www.ustr.gov/new/fta/Australia/text/text17.pdf (last visited Apr. 18, 2004).

61. The USTR has, in fact, included such a provision in the third draft of the Free Trade Area of the Americas. Draft Free Trade Area of the Americas, Ch. XX, § B(2)(j)(1.2), Nov. 21, 2005, at http://www.ftaa-alca.org/FTAADraft03/ChapterXX_e.asp (last visited Apr. 18, 2004).


63. U.S. Trade Representative, Fact Sheet: “Special 301” on Intellectual Property Rights, at http://www.ustr.gov/reports/special/factsheets.html (last visited Apr. 18, 2004). The “Special 301” provisions of the Trade Act of 1974 require the USTR to determine whether the acts, policies, and practices of foreign countries deny adequate and effective protection of intellectual property rights or fair and equitable market access for U.S. persons that rely on intellectual property protection. Following a Special 301 investigation, the USTR must determine whether to impose trade sanctions on the foreign country in retaliation for its allegedly deficient intellectual property protection practices. Trade Act of
Australia did not grant data exclusivity; it allowed subsequent registrants to rely on a prior marketing approval by showing bioequivalence. After two years of U.S. pressure, Australia finally adopted a five-year data exclusivity standard in 1998. The USTR similarly has sanctioned other countries that do not share its view of Article 39.3. In 1997, for example, the Clinton administration withdrew Argentina's preferential tariff rates granted under the Generalized System of Preferences, reducing Argentinean imports into the United States by an estimated $260 million. The primary reason for the withdrawal of benefits was that, although Argentina observed the drug data nondisclosure requirement under Article 39.3, it allowed subsequent applicants to rely upon an initial registrant's marketing approval. Thailand, which also does not guarantee data exclusivity, has been similarly exposed to U.S. pressure. Taiwan has also been pressured by the United States, which complains that Taiwanese legislation on data exclusivity does not meet the requirements imposed on WTO members.

1974, Pub. L. No. 93-618, 88 Stat. 2041 (codified as amended at 19 U.S.C. § 2411 (2000)). Special 301 was amended in the Uruguay Round Agreements Act to clarify that a country can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPs Agreement. Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4940 (1994).

64. Under the U.S. Hatch-Waxman Act, a generic drug manufacturer can obtain marketing approval using an abbreviated new drug application after the five-year data exclusivity period has expired by demonstrating bioequivalence. See 21 U.S.C. § 355(c)(3)(E)(ii), 355(j) (2000). In Australia, a showing of bioequivalence could result in immediate marketing approval. See THERAPEUTIC GOODS ADMINISTRATION, AUSTRALIAN REGULATORY GUIDELINES FOR OTC MEDICINES A.5 (2003), available at http://www.tga.gov.au/docs/pdf/argom_6.pdf (last visited Apr. 18, 2004). "Bioequivalence" means clinical interchangeability. Two drugs are bioequivalent if they are pharmacologically identical and if the rate and extent of availability after administration in the same molar dose is nearly identical. Videau, supra note 10, at 79; see also 21 U.S.C. §§ 355(j)(8)(B)(i) (2000). A "molar dose" merely means a specific amount of the therapeutic ingredient as measured in standard chemical units (moles). One method of demonstrating bioequivalence is comparative bioavailability studies in humans by titration of the active ingredient (or one or more of its metabolites) in an accessible biological liquid, such as blood or urine. Comparative pharmacodynamic studies in humans and comparative clinical trials are also often used. Videau, supra note 10, at 79.

65. Therapeutic Goods Legislation Amendment Act, 1998, No. 34 (Austl.). PhRMA, which represents and lobbies for the powerful U.S. pharmaceuticals industry, claims that exclusivity should be granted for no fewer than ten years. PhRMA 1999, supra note 15. Through its submissions to the USTR and its lobbying efforts, PhRMA pressured Congress and the administration to negotiate with and impose trade measures against Australia in order to protect its members' marketing approval data from unfair competition.


The EC has echoed the U.S. position that Article 39.3 requires data exclusivity for a period of time left to the discretion of the WTO members.\footnote{EC members, as mentioned above, grant six to ten years of data exclusivity. See EFPIA 2000, supra note 15, at 4. But see Perry, supra note 20 (noting pressure by European drug developers to extend the protection beyond ten years).} In a bizarre \textit{volte-face}, the EC has contended that the negotiating history of the TRIPs Agreement makes "clear" that the negotiators intended exclusivity, while also admitting, in the same document, that the EC and United States did not successfully convince the developing countries to incorporate data exclusivity into Article 39.3.\footnote{European Commission, Questions on TRIPs and Data Exclusivity: An EU Contribution, Spring 2001, quoted in PhRMA 2003, supra note 15, at A-4.} The EC also has argued that the obligation to protect data against unfair commercial use is "different from protecting them from disclosure, since the latter is a separate and distinct obligation under Article 39.3."\footnote{See South Centre, supra note 25, at 29.} The EC has acknowledged that "the lack of affordable pharmaceuticals is a serious problem for developing countries and especially for the poorest people," but it also claims that "the most effective method" of protecting test data from unfair commercial use is data exclusivity "for a reasonable period of time," regardless of whether the drug is patented.\footnote{Communication from the European Communities and Their Member States to the Council on Trade-Related Aspects of Intellectual Property Rights ¶¶ 6, 15 IP/C/W/280 (June 12, 2001).} Consequently, many countries have agreed to adopt data exclusivity in their domestic laws (although without acknowledging that such a duty exists under Article 39.3),\footnote{Some, however, have made such a claim. The government of New Zealand, for example, has asserted that Article 39.3 requires a period of data exclusivity to prevent unfair commercial use. See EFPIA 2000, supra note 15, at 3–4.} but the United States and the EC have not succeeded in persuading the majority of WTO members that Article 39.3 imposes data exclusivity as an obligation.

Canada has not always followed the United States and the EC in granting data exclusivity, but the rationale it relied upon was not particularly convincing. In the wake of the TRIPs Agreement, the Canadian Ministry of Health allowed drug manufacturers that could show bioequivalence to rely upon another company’s prior drug marketing approval without disclosing the initial registrant’s marketing approval data. Soon after the conclusion of the TRIPs Agreement, drug developers challenged the Ministry’s practice in Canadian courts. In 1999, the Canadian Court of Federal Appeals determined that, so long as a subsequent registrant demonstrates nothing more than bioequivalence to the registered drug when seeking marketing approval, the Ministry of Health does not “examine or rely upon confidential information” submitted in the earlier marketing approval application.\footnote{Bayer, Inc. v. Canada (Attorney Gen.), [1999] 243 N.R. 170, 173 (Fed. Ct.) (Can.).} The court further held this interpretation consistent with Article 1711 of NAFTA on the theory that the purpose of that section is the protection of trade secrets and that
reliance on the initial registration does not disclose any trade secret.\textsuperscript{76} Notwithstanding this case, the regulations now disallow all unauthorized subsequent applications during the exclusivity period.\textsuperscript{77}

The problem with the appellate court’s reasoning is that the Ministry of Health does indeed “rely upon” the initial registrant’s confidential information whenever it grants marketing approval to subsequent applicants; if not for the initial registrant’s studies and subsequent disclosure of information, there would be no basis for concluding that bioequivalent generic drugs would satisfy the law’s efficacy and safety requirements. Only by relying upon the initial registrant’s trade secrets can the drug regulatory authority trust that bioequivalent generic drugs are effective and safe to market. While this decision was not an authoritative interpretation of Article 39.3 of the TRIPs Agreement, it does illustrate the dearth of convincing arguments that allowing drug companies to rely on the marketing approval data of their competitors is not a kind of unfair commercial use.

The fact remains, however, that data exclusivity per se is not required by the plain terms of Article 39.3, as many developing countries maintain. In deference to the sovereignty of states, the principle of \textit{in dubio mitius} discourages the interpretation of a treaty to impose an onerous obligation where the language and intent of a treaty provision are ambiguous.\textsuperscript{78} The United Nations Conference on Trade and Development\textsuperscript{79} and the World Health Organization (WHO)\textsuperscript{80} have adopted consonant interpretations of Article 39.3 as well. Of course, the refusal of WTO members to adopt the U.S. proposal does not prove that the TRIPs Agreement negotiators disfavored data exclusivity entirely, but it certainly does call the U.S. and EC interpretation into question. It is also telling that many WTO members (developing countries in particular) disagree with this interpretation and have not adopted a data exclusivity approach in their internal laws.\textsuperscript{81} In particular, the African Group, India, and several Southeast Asian, Caribbean, and South American countries submitted a group paper to the TRIPs Council in June 2001 stating their position that not only does Article 39.3 not require data exclusivity, but it confers no property rights whatsoever in marketing approval data:

\begin{quote}
39. Protection of Test Data (TRIPS Article 39.3): Article 39.3 of the TRIPS Agreement leaves considerable room for Member countries to implement the obligation to protect test data against unfair competi-
\end{quote}

\textsuperscript{76} Id. at 175.
\textsuperscript{77} Canadian Food & Drugs Act, supra note 19.
\textsuperscript{81} See \textit{South Centre}, supra note 25, at 52 n.35; PhRMA 2003, supra note 15, at A-1.
tion practices. The Agreement provides that “undisclosed information” is regulated under the discipline of unfair competition, as contained in article 10bis of the Paris Convention. With this provision, the Agreement clearly avoids the treatment of undisclosed information as a “property” and does not require granting “exclusive” rights to the owner of the data.

40. . . The protection is to be granted against “unfair commercial use” of confidential data. This means that a third party could be prevented from using the results of the test undertaken by another company as background for an independent submission for marketing approval, if the data had been acquired through dishonest commercial practices. However, Article 39.3 does permit a national competent authority to rely on data in its possession to assess a second and further applications, relating to the same drug, since this would not imply any “unfair commercial use.”

In summary, the weight of the evidence indicates that, notwithstanding the arguments of the United States and the EC, the “unfair commercial use” language of Article 39 of the TRIPs Agreement does not encompass a data exclusivity obligation per se as a matter of positive law, particularly not when disclosure of marketing approval data is “necessary to protect the public.” Nonetheless, the terms of Article 39.3 plainly indicate that some form of protection against naked exploitation of the marketing approval data is required, even if the TRIPs Agreement does not mandate the protection of such data through an unconditional grant of exclusive rights. Correa’s conclusion that Article 39.3 imposes no international requirement common to all WTO members cannot be the correct interpretation of Article 39.3. States must be presumed never to assume or impose on others meaningless obligations when a reasonable alternative interpretation is possible. Unfortunately, an adequate alternative interpretation cannot rest soundly on either the ambiguous travaux préparatoires or the balkanized subsequent practices of states.

2. Marketing Approval Data: Trade Secret or Public Information?

If WTO members did not clearly intend to require data exclusivity, the precise parameters of “unfair commercial use” remain in doubt. In such a case,
normal principles of treaty interpretation should govern the meaning of the term. Under Article 31 of the United Nations Convention on the Law of Treaties ("Vienna Convention"), a treaty must be "interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." Subsequent state practice should be taken into account in interpreting unclear treaty language. However, the discussion above makes clear that, although states have increasingly submitted to data exclusivity obligations pursuant to various bilateral and regional trade agreements, there is no consistent state practice under the TRIPs Agreement. The Vienna Convention also provides that the drafting history of the treaty should be used as a "supplementary means of interpretation" when the interpretation under Article 31 leaves the meaning of the treaty ambiguous or obscure. But again, as discussed above, the travaux préparatoires merely indicate that the signatories declined to adopt the specific data exclusivity obligation proposed during the TRIPs Agreement negotiations.

The ordinary meaning of "commercial use" in this context is the use of marketing approval data as part of an exchange of consideration between two or more parties on terms set by the market. The ordinary meaning of "unfair" is "[n]ot fair or equitable" or "unjust"—specifically in "(business) competition." Determining the ordinary meaning of the language is always the first step in treaty interpretation, but the WTO Appellate Body has correctly noted that "dictionary meanings leave many interpretive questions open." The meanings of "inequitable" and "injustice" are no less disputable than that of "unfair." All of these terms seem to relate to the concept of one’s getting something other (specifically, less of something desirable or more of something undesirable) than that to which one is entitled. What can be discerned, then, is that to satisfy the requirements of Article 39.3 of the TRIPs Agreement, a WTO member may not disclose marketing approval data unless it has taken steps to ensure that the data is not used commercially without the data’s creator getting that to which it is entitled. The question, then, is what the initial registrant deserves—not as a matter of ethics, but as a matter of international law.

85. Id. art. 31.1.
86. Id. art. 31.3(b).
87. Id. art. 32. Of course, even when the meaning of the language seems clear, resort may be had to the travaux to confirm the validity of the interpretation. See Maria Frankowska, The Vienna Convention on the Law of Treaties Before United States Courts, 28 Va. J. Int’t L. 281, 334–35 (1988).
88. General dictionaries may give a more limited but less economically and legally accurate definition of "commerce," such as the "[e]xchange between men of the products of nature or art . . . [or] of merchandise, especially as conducted on a large scale between different countries or districts." 3 The Oxford English Dictionary, supra note 29, at 552.
89. 19 id. at 13.
To answer this question, it is helpful to put the obligations imposed by Article 39.3 into context. If the release of marketing approval data to the drug regulatory authority constitutes public disclosure by the drug developer, there is no trade secret. Consequently, reliance on the data by competitors in that country cannot be an unfair commercial use. One obligation that is clear from Article 39 is the general duty of confidentiality by the WTO member’s drug regulatory authority. A duty of confidentiality is inconsistent with the notion that the submission of marketing approval data ipso facto constitutes a public disclosure of the data. Although exceptions to the confidentiality obligation exist for the protection of public health, the very fact that the state’s ability to disclose the data in such circumstances is an exception indicates that the negotiators did not intend for marketing approval data to be treated as publicly disclosed in normal circumstances. In other words, submission to a drug regulatory authority of data meeting the requirements of paragraph 3 does not alter the status of the data under Article 39.3.

Most marketing approval data begin as a trade secret of the drug developer under Article 39.2 because the developer will virtually never wholly reveal the data to the public except in the course of applying for a patent. The confidentiality obligation with respect to the marketing approval data is consistent with treatment of the data as a trade secret of the developer. It is not surprising, then, that Article 39 comprises Section 7 of Part II of the TRIPs Agreement, which is concerned with trade secrets (or “Undisclosed Information”) generally, of which drug marketing approval data is a subset provided for in paragraph 3. Article 1.2 of the TRIPs Agreement, which labels the subject matter protected by Section 7 as a category of “intellectual property,” also supports the classification of marketing approval data as a protected trade secret.

The law of trade secret protects information that is valuable by virtue of not being publicly known. Public knowledge of the trade secret unaccompanied by the exclusive right to its use diminishes or destroys whatever monopoly power the trade secret confers. Unlike copyrights, trademarks, and patents, however, trade secrets are protected by principles of contract law and privacy law rather than by publicly recorded, state-conferred grants of exclusionary rights. By virtue of their official registration, patented inventions, copyrighted works, and trademarked names or devices become known to the public automatically and in full. A trade secret, once publicly revealed,
becomes public property because it loses an essential trait. Its claim to protection rests upon the reasonable efforts of the owner to keep it secret by, inter alia, refusing to divulge the secret to any party not under an obligation of confidentiality to the owner. Contractual privity is, therefore, a prerequisite to trade secret protection, except where the secret has been misappropriated. The privacy law connection comes into play when a person (typically a competitor) thwarts the owner's efforts at protecting the confidentiality of a trade secret by duplicity or by cunning. A competitor that obtains access to the trade secret through tortious industrial espionage, breach of contract, inducement of an employee or other person to breach a confidentiality obligation, or similar means has engaged in one type of unfair commercial use by misappropriating the trade secret. In contrast, a competitor who gains such access through reverse engineering or through other legitimate means has committed no violation of the law forbidding unfair commercial use.

Drug regulatory approval authorities of WTO members are obligated by Article 39.3 of the TRIPs Agreement to protect marketing approval data from treatment inconsistent with its trade secret status. In other words, if the data was a trade secret prior to disclosure to the state, and the state is bound by Article 39.3 to continue to treat the data as secret, then the TRIPs Agreement negotiators must have intended to forbid the use of the data by the state in a manner inconsistent with its characterization as a trade secret. A fundamental characteristic of proprietary information is that a person may only use such information if, and to the extent, permitted by its owner. Consequently, when considered in light of trade secret principles, the prohibition on unfair commercial use is best interpreted as a requirement for data exclusivity, unless one of the exceptions in Article 39.3 applies.

As discussed above, the public health language of Article 39.3, as an exception to the general rule of data confidentiality, should not be read to authorize the disclosure of marketing approval data under all circumstances. The most plausible explanation for this exception is that the state should not be hobbled by trade secret rights while exercising its sovereign obligation to protect public health in an emergency. The public-health exception demonstrates that the negotiators of the TRIPs Agreement agreed that the state's

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9, 1886, 828 U.N.T.S. 221, S. Treaty Doc. No. 99-27. Trademarks need not be registered to receive protection in common law countries. However, such registration facilitates protection and, in any case, public use is a primary precondition to protection of trademarks under the common law, which protection is geographically coextensive with the mark’s use. See generally J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition (4th ed. 2000).
95. Consequently, WTO members must enjoin the revelation of a trade secret to protect its value to the owner. See TRIPs Agreement art. 39.2.
96. See, e.g., DVD Copy Control Ass’n v. Bunner, 75 P.3d 1, 26 (Cal. 2003); Unif. Trade Secrets Act §§ 1(2), 2(a).
97. See, e.g., Bunner, 75 P.3d at 9; Unif. Trade Secrets Act § 1.
98. See, e.g., Bunner, 75 P.3d at 9.
99. Data may be disclosed (1) when necessary to protect public health or (2) when sufficient protections have been implemented to ensure that the disclosure of the data did not result in unfair commercial use. TRIPs Agreement art. 39.3.
duty to protect public health cannot be subservient to private intellectual property rights. To the extent that the state can reasonably perform its function of protecting public health without compromising the initial registrant’s trade secret rights, disclosure of the marketing approval data is justified.\textsuperscript{100} Such disclosure may be justified to allow a third party, such as a public interest organization, a university, a hospital, or another noncompetitor of the drug developer to review and verify the accuracy, reliability, and completeness of the data. However, disclosure of the information to a competitor would hardly be necessary to protect public health unless the competitor had the only available facilities for testing the drug. Even then, granting the competitor a license to use the data \textit{commercially} would be unnecessary. Such disclosure would, therefore, occur on condition of confidentiality by the person or entity to whom the data is disclosed. The public-health exception cannot justify abrogating the obligation of data exclusivity by either the state or the verifier of the data under circumstances short of a public emergency.\textsuperscript{101}

The second exception, allowing disclosure where sufficient protections have been implemented to avoid unfair commercial use, has more profound implications for the duty to maintain data exclusivity. If “fairness” is intended in an economic sense, commercial use of a trade secret is only “unfair” when the trade secret owner is not adequately compensated for the market value of the secret. Obviously, a blanket refusal by a drug regulatory authority to disclose or to allow reliance on the trade secret would prevent unfair commercial use. But there are other means for protecting against unfair use that do not require providing a monopoly on the marketing approval data. The purpose of the duties of confidentiality and of data exclusivity may be satisfied even when the data has been released to a competitor of the initial registrant, or a competitor has been permitted to rely on the data, or both. In these instances, the drug regulatory authority must ensure that adequate compensation renders the disclosure and use of the data economically “fair.” Ironically, this result is similar to the proposal advanced by the United States and rejected by the TRIPs Agreement negotiators, creating a quandary. It appears that the TRIPs Agreement negotiators papered over their differences on data exclusivity. On one hand, they declined to incorporate an explicit data exclusivity obligation into Article 39.3, even one that allowed use of the data with the payment of “fair” compensation. On the other hand, the resulting text is drafted in such a manner that the best reading imposes precisely the obligations that a large number of negotiators refused to countenance. In any case, it is clear that, although Article 39.3 imposes a basic obligation to treat marketing approval data as a trade secret proprietary to the submitter, WTO members retain discretion to define the circum-

\textsuperscript{100} See supra discussion in Part II.A.1.
\textsuperscript{101} A public emergency might arise if the initial registrant is unable to supply the approving state’s market for some necessary drug. Reliance on the marketing approval data by competitors would be justified to ensure that an adequate supply of the drug is available to prevent a public health crisis.
stances under which disclosure of and reliance on the marketing approval data is economically “fair” to the owner. Notably, nothing in the TRIPs Agreement forbids WTO members from granting compulsory licenses to use private trade secrets in that state if adequate compensation is provided.102 What kind of compensation might render such a use “fair” is a question taken up in Parts III, IV, and V of this Article.

C. The Meaning of “New Chemical Entities”

Another ambiguous element of Article 39.3 is the range of subject matter protected from unfair commercial use, namely drugs or agrochemicals that “utilize new chemical entities.” Whether the chemical entities must be “new” in the sense of “previously undiscovered” or merely “new” in the sense of having never before received marketing approval in the country at issue is not clear from the text. Many developing countries, and some commentators as well, have interpreted the term “new” as having been deliberately left undefined so that each WTO member would have discretion to define the term in its own jurisdiction.103 It has also been argued that, because a previously approved chemical entity may have second indications that require additional marketing approvals, data submitted to obtain such approval need not be protected from disclosure. Such chemical entities are not “new,” although the indication may be new.104 According to this argument, WTO members have discretion to reveal publicly any data submitted for a drug previously approved for marketing in another country.105

The narrow interpretation of “new chemical entities,” while true to the text of Article 39.3, relies on a formalistic reading that seems dissonant with the policy purpose that Article 39.3 serves. Although WTO panels and the Appellate Body typically resort to such formalistic readings of trade agreements, such readings do not accord with the norms of treaty interpretation required by customary international law. Customary international law, as reflected and codified in the Vienna Convention, provides that an international treaty must be interpreted “in good faith in accordance with the ordinary
meaning to be given to the terms of the treaty *in their context and in the light of its object and purpose.*” 106 Whenever treaty language is vague and more than one interpretation of a legal text is possible, it is appropriate to consider how each interpretation accords with the policy purposes that the text was intended to promote.

The explicit purpose of Article 39 of the TRIPs Agreement is the protection of commercially valuable data from disclosure and from “unfair commercial use.” The data that Article 39.3 seeks to protect is a valuable trade secret, which is to say, it satisfies the following definition: (1) it required “considerable effort” to produce; (2) it is commercially valuable; and (3) it is not currently publicly available. 107 When a state regulatory authority requires the submission of data that was not required by other states where previous marketing approvals have been obtained, the value of such data is significant. Even when this data is the same as that on which the registrant relied in obtaining prior marketing approvals in other WTO members, its value is undiminished insofar as the foreign regulatory authorities have maintained its confidentiality, as generally required by Article 39.3. Thus, the value of that data does not depend on whether the first marketing approval worldwide occurred in the WTO member at issue; it depends on whether the data is publicly available in that WTO member. The best reading of Article 39.3, then, is that “new chemical entities” should refer to chemical entities not previously registered in the specific WTO member where marketing approval is being sought, rather than to chemical entities that are new worldwide.

Similarly, the fact that the discovery of a second indication of a known chemical entity does not constitute the discovery of a “new chemical entity” does not affect the value of the marketing approval data. In both cases, the rationale for protecting the data from unfair commercial use remains undiminished. The data would have remained a trade secret in the country at issue if the developer had not been required to disclose it to the drug regulatory authority of that country. By requiring the disclosure of the data in each case, the WTO member allows the initial registrant’s competitors to benefit from research for which they never paid. The purposes of Article 39.3, then, are best served when “new chemical entities” also includes second indications of previously approved chemical entities. Nonetheless, the clear language of Article 39.3, requiring that the chemical entities themselves be “new,” does not support this reading. The rule of treaty interpretation limiting the obligations of states to those voluntarily undertaken further favors a reading of “new chemical entity” that is limited to the plain language of the term. Consequently, the soundest interpretation of this term as a matter of positive international law is that only new drugs themselves, and not

106. *Vienna Convention*, supra note 84, art. 31(1) (emphasis added).
107. *TRIPS Agreement* art. 39.2(b).
new indications, must be protected from disclosure and unfair commercial use. While this reading does not accord with the structure and purpose of Article 39 as harmoniously as one that also provides protection for second indications, the terms chosen by the negotiators leave little doubt that they intended to impose no obligation to protect marketing approval data relating to second indications for chemical entities not considered “new.”

D. Conclusions

At the 2001 WTO Ministerial Conference in Doha, the Africa Group and other developing countries convinced WTO members to issue a ministerial declaration stating that the need to incentivize drug testing must be balanced with the need to protect public health in developing countries.109 The members also affirmed that the TRIPs Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”110 Members have not, however, proven quick to agree on how unfair commercial use plays into the balance between market incentives and drug access.

As discussed above, a naked right of data exclusivity, as opposed to some other approach consistent with the international protection of trade secrets, is not necessary to satisfy the policies of Article 39.3 of the TRIPs Agreement. However, it is clear from the general structure of the Agreement (putting marketing approval data under the heading dealing with trade secrets) and the terms of Article 39.3 (requiring trade secret-type protections for the data) that WTO members must treat certain data submitted to state authorities for drug marketing approval as protected intellectual property. Yet, although the interpretation of Article 39.3 offered in this Part may best accord with the policy purposes of the TRIPs Agreement, it is not clear what kind of trade secret protection would best fulfill those policy purposes. Part III of this Article analyzes the strength of the arguments for and against an unalloyed right to nondisclosure and exclusivity of marketing data, and evaluates how these arguments might best be used to formulate a resolution of each side’s concerns within the four corners of the proper interpretation of Article 39.3.


110. Doha Declaration, supra note 109, ¶ 4. Any agreements subsequent to the TRIPs Agreement, including ministerial declarations such as the Doha Declaration, are not binding in the dispute resolution process, but may be used as an interpretive aid if the declaration relates to vague or ambiguous legal texts. See Vienna Convention art. 31.5(a).
III. Secrecy, Monopoly, and Access to Medicines

Preclinical testing for drug marketing approval typically encompasses feeding a drug to, injecting the drug into, or otherwise testing the drug on non-human mammals.\(^{111}\) Following evaluation of the toxicity, pharmacokinetics, and pharmacodynamics of the drug on animals, the agencies usually demand testing on human subjects in varying conditions and over varying periods of time. In the last stages of testing before approval, several hundred human test subjects may be required. These studies tend to last several years and require the expenditure of millions of dollars before the conditions for marketing approval are satisfied.\(^{112}\) In the United States, the most recent statistics suggest that the cost of obtaining marketing approval averages $403 million out of pocket and $802 million fully capitalized (i.e., accounting for the time value of money).\(^{113}\) Although these figures are probably greatly exaggerated because they fail to account for significant cost offsets and overstate the costs of studies conducted by private drug developers,\(^{114}\) it is beyond doubt that the marketing approval process is risky, laborious, and expensive.

The arguments in favor of data exclusivity advanced by large drug developers and the WTO members that represent their interests are based on both economic and equitable considerations.\(^{115}\) The economic argument arises from the claim that, without such exclusivity, drug developers will have insufficient incentive to conduct the costly clinical research and trials necessary to obtain marketing approval.\(^{116}\) The equitable argument is based on the view that, because generic drug manufacturers and other subsequent registrants


\(^{113}\) See DiMasi et al., supra note 112, at 166.


\(^{115}\) Economic incentives and ethics form the two bases of trade secret law in the United States as well. One court has observed that “the primary[ ] purpose of ... trade secret law ... is to promote and reward innovation and technological development and maintain commercial ethics.” Bunner, 75 P.3d at 12 (citing San Francisco Arts & Athletics, Inc. v. United States Olympic Comm., 483 U.S. 522, 536 (1987)). See also Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 493 (1974) (“Trade secret law promotes the sharing of knowledge, and the efficient operation of industry; it permits the individual inventor to reap the rewards of his labor . . . .”).

\(^{116}\) See, e.g., Cook, supra note 25 at 9–10 (quoting Statement of Views of the European, Japanese and United States Business Communities (June 1988), reproduced in Annex III in “GATT or WIPO?—New Ways in the International Protection of Intellectual Property,” ed. Beier & Schricker, VCH 1989. (“Without [data exclusivity] the disclosing party cannot afford the risk of disclosing the information and foregoes the possibility for the local manufacture or sales . . . . The original registrant cannot recover its investment under such circumstances.”).
do not produce the test and clinical data upon which they rely, they are unfairly benefiting from the "sweat of the brow" of the initial registrant.

The same reasons justify claims that drug regulatory authorities should be forbidden from disclosing the data to third parties, regardless of whether generic drug manufacturers are permitted to rely on the data. These arguments usually focus on data exclusivity because it grants greater protection than nondisclosure. A drug regulatory authority could permit a generic drug manufacturer to rely on the data without ever revealing that data to the manufacturer (as Canada formerly did), and the drug developer would thereby lose the benefit of exclusive use of the data. On the other hand, disclosing the data to a generic drug manufacturer does not necessarily relieve the manufacturer of the duty to create such data for its own version of the drug. The nondisclosure obligation thus loses most of its relevance if exclusivity is granted. Nonetheless, drug developers and the governments that represent them have consistently claimed the right to both benefits.

A. Economic Incentives for Marketing Approval

The assertion that data exclusivity is a necessary incentive to seeking marketing approval, while often advanced,117 is an unproven empirical claim. In at least some circumstances, it is possible that the benefit of being the first registrant will outweigh the cost of obtaining marketing approval, especially if drug developers achieve brand-name recognition for their products early, such that competing generic drugs either are unknown to consumers or seem like inadequate or inferior substitutes.118 However, as noted above, the cost

117. See, e.g., EFPIA 2000, supra note 15, at 2; PhRMA 2003, supra note 15, at A-3 ("Data exclusivity provides an administrative mechanism to protect clinical data, which, in turn, encourages the growth of pharmaceutical research and development in the country.").

118. It has been argued that the first-mover advantage is not particularly prevalent in the pharmaceutical industry. Kremer, supra note 10, at 73–74. However, survey evidence indicates that, in the United States, physicians favor brand-name drugs based on a perception of superior quality and reliability. See John Hudson, Generic Take-Up in the Pharmaceutical Market Following Patent Expiry: A Multi-Country Study, 20 INST. REV. L. & Econ. 205, 207 (2000). In Europe and Japan, physicians’ financial incentives may lead them to favor prescribing brand-name drugs. Id. at 210. Nonetheless, empirical studies show that elasticity is high enough to result in significant lost sales following the entry of generics into the marketplace. Id. at 215, 219–20. At least for the consumer drugs, brand recognition is apparently sufficiently important to motivate generics manufacturers to emulate brand-name packaging, and to motivate drug developers to counter by lobbying against generics’ use of similar packaging. See generally Stephen Barlas, FDA Flashes Red Light to Packaging Stays, PACKAGING WORLD MAG., July 2003, at 86, available at http://www.packworld.com/articles/Departments/16535.html (last visited May 2, 2004); Greg Erikson, Private-Label Packaging: To Copy or To Create, That Is the Question, PHARMACEUTICAL & MED. PACKAGING NEWS, Sept. 1998, at 25, available at http://www.devicelink.com/pmpn/archive/98/09/004.html (last visited May 2, 2004). See also Aidan Hollis, “Pseudo-Generic” Strategy in the Canadian Pharmaceutical Market, BUSINESS BRIEFING: PHARMAGENERICS, Sept. 2002, at 99 ("[I]n most drug markets, there are some consumers and some doctors who believe that the brand-name drug is somehow more reliable and more efficacious than any generic version."); Hudson, supra, at 219 ("[I]n the over-the-counter market . . . brand image is a more important factor than in the prescription market."). Although empirical evidence is lacking, the first-mover advantage is undoubtedly reduced in developing countries, where private health insurance is rare, disposable income is much lower, and most drugs are provided through a cost-conscious government.
of obtaining marketing approval is quite high, while the marginal cost of manufacturing pharmaceuticals is usually low.\(^{119}\) Thus, the first-mover advantage for registering a drug would need to be significant to overcome the negative price effects of competition from drug manufacturers that free ride on the initial registrant’s marketing approval. Accordingly, it is argued that, without a temporary monopoly, the developers of new drugs will have no incentive to incur regulatory approval costs.\(^{120}\)

It is also possible that drugs not requiring the grant of a monopoly to motivate marketing approval represent a very small minority of cases. However, given the unusually high growth in sales and returns on equity\(^{121}\) of large drug developers, skepticism of this position appears justified. As of July 2003, the median return on equity (net of research expenses) of the nine pharmaceutical companies listed in the top 300 of the Fortune 500 was over four times that of the remaining 277\(^{122}\) companies.\(^{123}\) Average return on equity for the drug developers was even greater in proportion to that of other companies of comparable size (52% versus 11%\(^{,124}\)).

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<th>Relative Economic Performance of Large Pharmaceutical Companies (July 2003)</th>
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<td><strong>Pharmaceutical developers in the Fortune 300</strong></td>
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<td><strong>All Fortune 300 companies</strong></td>
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More generally, the value of the U.S. pharmaceutical industry’s worldwide sales has grown by a factor of more than thirty-two since 1970.\(^{125}\) Since 1990,

\(^{119}\) See Kremer, supra note 10, at 73.

\(^{120}\) See Sykes, supra note 7, at 60, 62.

\(^{121}\) Return on equity may not be an ideal measure of the profitability of the large companies in one industry relative to large companies in other industries. It does, however, reflect three of the most important variables of a company’s economic performance: profitability, asset management, and financial leverage. Return on equity is calculated by dividing one year of earnings by the average shareholder’s equity for that year. The ratio of earnings to sales is the profit margin; the ratio of sales to assets is the asset turnover; and the ratio of assets to equity is the amount of leverage that the company has.

\(^{122}\) Only the returns on equity of publicly traded companies were used; these constitute all but 14 of the largest 300 companies.

\(^{123}\) The top 300 companies were chosen to maintain comparability; all pharmaceutical companies in the Fortune 500 are ranked above 300. The information that forms the basis for these calculations was taken from the Fortune magazine website (http://www.fortune.com) and the Charles Schwab website (http://www.schwab.com) (on file with the Harvard International Law Journal).

\(^{124}\) See supra note 123 and accompanying text.

the industry has grown twice as fast as the U.S. economy. This is hardly the picture of a suffering industry.

Although many countries do not grant data exclusivity, large drug developers do benefit from five or more years of data exclusivity (plus whatever market power their patent rights may confer) in their largest markets—the United States, Canada, Europe, and Japan. The United States offers a five-year period of data exclusivity to new drug registrants, and the European Union offers between six and ten years of exclusivity. (Nearly half of all EC members grant ten years of exclusivity by default.) In each jurisdiction, not only does the initial registrant have exclusive access to the data submitted, but the regulatory authority may not rely on the data to approve subsequent applications to market the same drugs. The returns on equity that form the basis of the calculations above undoubtedly reflect, at least to some degree, the market power conferred by data exclusivity. Whether drug developers would be as profitable without such exclusivity is an open question. Until better empirical evidence is available, the safest route may be to assume that some, but certainly not all, foreign marketing approvals would not be sought without adequate compensation for the costs of obtaining such approval.

The fact that remuneration for the costs of obtaining an initial drug marketing approval might encourage more applicants to seek marketing approval does not, however, necessarily favor data exclusivity. Data exclusivity raises problems of economic efficiency that transcend the simple equation of more or fewer drug marketing approvals. First, it forces potential competitors to undergo the same time-consuming and expensive drug testing that the initial registrant performed. During the time that such duplicative testing takes place, the initial registrant benefits from a monopoly on the drug at issue. A monopoly creates a loss of what in economic terms is called "consumer surplus," some of which is retained by the monopolist in the form of profits, and the remainder of which constitutes a deadweight loss. In other words, a monopoly restricts the supply of the drug so that some who could pay for

130. See Dodds-Smith, supra note 20, at 113.
131. Council Directive 65/65, supra note 129, art. 8, as amended by Council Directive 87/21, supra note 129, art. 1. Of course, drug regulatory authorities usually impose some requirements on subsequent registrants, such as generics manufacturers, even after the exclusivity period, but these are usually limited to the much simpler processes of showing bioequivalence. See supra note 64 and sources cited therein. The uncertainty associated with developing and testing a new drug is not imposed on subsequent applicants because subsequent registrants need merely replicate the initial registrant’s approved molecule.
the drug in a competitive market will not receive it, while those who do obtain the drug must pay higher prices than under a competitive market. Second, duplicative testing adds more costs to the drug market and drives up the price of generic drugs. Such externalities argue against data exclusivity where a reasonable alternative is available.

The “solution” to the problem of duplicative testing that has been adopted in the United States, Europe, and several other developed countries is to preclude competition in a drug altogether for five to ten years after an initial registration, even in the absence of a patent. This kind of cure may be worse than the disease since it does not allow competitors the option of undergoing the duplicative testing, even when such testing is economically efficient (i.e., when it results in lower-priced drugs). Considering that many drugs are not discretionary purchases, but correlate highly with the quality and even preservation of human life, an unnecessary monopoly such as that conferred by unqualified data exclusivity should be eschewed.

**B. Equitable Considerations**

The debate about the equity of allowing subsequent applicants to free ride on the drug testing data of the initial registrant has relevance only with respect to drugs upon which the patent has expired, or to those that are unpatentable, such as certain kinds of therapeutic biologics. Registrants of patented drugs generally need not concern themselves with competition because subsequent registrants are precluded from competing in the relevant market for the term of the patent (usually twenty years after the filing date). Unpatented drugs, such as drugs invented under conditions precluding patentability, can benefit, at best, from trade secret protection under the TRIPs agreement.

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132. While it could be argued that subsidization should be encouraged to the extent that it promotes foreign drug marketing efforts, this contention proves too much. Even granting that the TRIPs Agreement was intended to force developing countries to contribute such subsidies to drug developers, there is no evident reason to prefer to shift this burden to generics manufacturers in the form of royalties or, for that matter, to developing country populations in the form of exclusive marketing rights. Both of these approaches distort the market, as opposed to an open payment of a subsidy by the developing country government that creates fewer market-distorting externalities. The political unpalatability of these more straightforward options argues a fortiori against options that make less economic sense but achieve the same result.

133. See supra text accompanying notes 18–20. As noted above, there is a movement in the EC to extend the data exclusivity period to eleven years. See supra note 20 and sources cited therein.


135. Article 35 of the TRIPs Agreement requires patent protection to last no less than twenty years after the filing date. TRIPs AGREEMENT art. 35.

136. For example, a drug might be insufficiently inventive, or might have been sold commercially too long before the inventor applied for a patent. See, e.g., 35 U.S.C. §§ 101, 103(a) (2000) (granting patents only for "new and useful" inventions that would not be obvious to a person of ordinary skill in the rele-
Agreement. This lack of patent protection becomes especially problematic where a slow patenting process significantly eats into the period of patent protection, which generally runs from the date of filing and not from the date the patent is granted. Economically developed countries have already begun solving the delay problem by negotiating a “patent credit” in bilateral and multilateral FTAs for delay in marketing approval. Several years ago, the United States began requiring its FTA partners to extend the period of patent protection to compensate for the delay in obtaining marketing approval. Assuming the delay problem is adequately addressed, proponents of data exclusivity observe that, where patent protection is lacking, there is no significant barrier to the subsequent registration of generic drugs based on the initial marketing approval. A patent blocks unlicensed manufacturers from manufacturing or testing the drug for commercial purposes, forcing would-be competitors to forego competition entirely or to undertake the expensive, lengthy, and risky process of inventing around the patented drug. In the absence of a patent, then, there is little to prevent generic drug manufacturers from free riding on the initial registrant’s marketing approval. The initial registrant is forced to disclose its otherwise protected trade secret in order to obtain marketing approval; by disclosing this secret to competitors or allowing them to rely on the data, the WTO member is, in effect, expropriating the registrant’s trade secret. Subsequent registrants can maintain prices lower than the initial registrant because they benefit from the trade secret without having to recoup the costs of performing extensive testing to obtain marketing approval. To prevent such purportedly inequitable use of the data, drug developers argue that both data confidentiality and data exclusivity should be maintained. Clearly, if the concept of unfair use of a trade secret covers anything beyond fraud or deception, it should cover free riding by competitors.

Opponents of data exclusivity reply that an unpatentable drug is ipso facto unworthy of protection by the government. The U.S. strategy of per-

140. Cf. id. (“If it were not for the obligation to provide test data to governments to gain marketing approval, data generated at considerable cost, time, and risk would be considered a trade secret.”).
141. See id.
142. Cf. EFPIA 2000, supra note 15, at 2 (“If [generic drug manufacturers] immediately or almost immediately rely on the innovator’s data, they benefit from an unfair commercial advantage.”).
143. See, e.g., Perry, supra note 20, at 17–18; EUR. GENERIC MDS. ASS’N, supra note 21, at §§ 3–4.
suading or coercing its trading partners into granting data exclusivity is, in
this view, a “backdoor attempt[ ] to convey private monopoly power for drugs
that do not qualify for patent protection.” 144 Such drugs are either not new
or not inventive,145 and drug developers may not seek patent-like protection
over such drugs by the indirect means of monopolizing their testing data.
The cost of obtaining marketing approval, in this view, is the forfeiture of
trade secret rights in the data, or at least of the exclusive right to benefit
from the data. It is certainly the case that having exclusive rights to a drug on
one hand, and being required to demonstrate the drug’s safety, efficacy, and
quality on the other, are conceptually unrelated.

The foregoing objection to data exclusivity does not deny that drug de-
velopers have an equitable basis for seeking economic incentives to share
drug marketing approval data. It simply denies that data exclusivity is the
most equitable solution. It was noted above that the duplicative testing that
may be occasioned by a rule of data exclusivity is economically wasteful. How-
ever, duplicative testing is worse than wasteful—it is unethical. Animal testing
of drugs causes the suffering and death of many millions of animals every
year.146 Duplicative research caused by lack of access to confidential marketing
approval data increases the number of animals unnecessarily subjected to test-
ing. It may also subject humans to suffering in the form of side effects or
prolonged unameliorated symptoms where some indications of the drug,
though known to the drug regulatory authority by virtue of a prior registra-
tion for the drug, remain unknown to the subsequent applicant.

However, the solution adopted by those WTO members that refuse to
register competing drugs at all during the exclusivity period is open to the
same moral criticism. It is no more ethical to allow persons in need of drugs
to pay higher costs during the exclusivity period147 than it is for the state to
expropriate a drug company’s marketing approval data. Higher costs mean
that at least some people in need of drugs will go without them, resulting in
unnecessary suffering and death.148

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144. See Letter from Ralph Nader, James Love, and Robert Weissman to President Clinton
Regarding Trade Sanctions Against Argentina for Policies on Health Registration Data and Political Activity (Feb.
Nader Letter to Clinton].

145. This argument oversimplifies the reasons why a drug may not benefit from patent protection.
Patent claim drafting is a tricky art, and a patent may be denied on highly technical grounds, such as
failure to disclose adequately the best means for practicing the invention. See, e.g., 35 U.S.C. § 112 (2000) (writ-
ten enablement requirement).

146. In the United States alone, some 14 million animals are reportedly used each year for drug test-
ing. ANIMAL PROTECTION INSTITUTE, FACT SHEET: ANIMAL TESTING AND ALTERNATIVES, at http://
www.api4animals.org/88.htm (last revised Apr. 17, 2000).

147. See Nader Letter to Clinton, supra note 144.

148. Estimates of the number of human deaths caused by disease in the developing world vary widely,
partly depending on the kind of diseases under consideration. The EFPIA claims that six million people
in the developing world die each year from disease epidemics, particularly AIDS, tuberculosis, and ma-
laria. See Ager, supra note 10, at 16. The U.S. pharmaceutical industry, on the other hand, claims that
about three million people in the developing world died of AIDS-related diseases last year, plus some
nine million who died from infectious diseases other than AIDS in 2002. See PhRMA, HEALTH CARE IN
will undoubtedly occur if the drug developers lack adequate financial incentive to obtain marketing approval, a balance must be struck between providing incentives for drug marketing and preventing monopolistic behavior. As noted above, WTO members recognized in the Doha Declaration on the TRIPS Agreement and Public Health that these goals must be balanced. In the context of international trade negotiations, the balance is often thought to weigh more heavily toward access. Companies that stand to profit from data exclusivity tend to pay their dividends to the world’s richest populations, while the consumers who pay the higher prices to finance these dividends often come from the world’s poorest countries. The WHO has accordingly contended that "poorer populations in developing countries should not be expected to pay the same price as do the wealthy for newer essential drugs." In any case, if it is possible to avoid unfair use of the initial registrant’s data by competitors while avoiding imposing monopoly prices on consumers, such a policy should be preferred strongly to unqualified data exclusivity.

C. Public Health and Transparency Considerations

Finally, there is the question of whether disclosure and nonexclusivity practices endanger public health. Disclosure of marketing approval data honors the public's interest in being informed about the safety and effectiveness of an approved drug and allows independent observers, such as academics and public interest groups, to conduct further testing and to verify or dispute the accuracy and impartiality of the data submitted by the registrant. It is sometimes observed that drug developers have an incentive to suppress unfavorable results from their drug testing or to exaggerate their efficacy findings. The lack of access to testing data seriously impedes third parties from uncovering bias, inaccurate or incomplete results, and false claims.

149. Doha Declaration, supra note 109, ¶ 3.
151. See Eeva Ollila & E. Hemminki, Secrecy in Drug Regulation, 9 INT’L J. OF RISK & SAFETY IN MED. 169 (1996), and sources cited therein.
152. Id. at 168. Of course, the threat of lawsuits and negative publicity may deter exaggeration or suppression of information in some instances. See M. N. Graham Dukes, Drug Regulation and the Tradition of Secrecy, 9 INT’L J. OF RISK & SAFETY IN MED. 147–48 (1996). However, such drug liability cases are notoriously difficult to prove and, in many countries, punitive damages and criminal prosecutions are highly unlikely under any circumstances. As for negative publicity, it works best at punishing deceptive drug claims when substitutes for the products offered by the stigmatized company are available, which is not always the case in developing countries.
based on that data.\textsuperscript{153} The public may thereby be defrauded and public health exposed to unnecessary danger. By refusing to disclose drug testing information, the drug regulatory authority may prevent the discovery of undetected side effects, dangers, counterindications, or even the inefficacy of an approved drug. Whether such independent assessment is “necessary to protect the public”\textsuperscript{154} may be arguable in any given instance, but disclosure is certainly more helpful to that end than nondisclosure. As one commentator observed, nondisclosure “facilitates the circulation and use of substandard drugs.”\textsuperscript{155}

Part II.A.1 described how Article 39.3 of the TRIPs Agreement implicitly recognizes that public health considerations may necessitate disclosure of marketing approval data, but requires WTO members to protect against unfair commercial use of the data. The public disclosure of such data is perfectly compatible with protection against unfair commercial use under a rule of data exclusivity that disallows competing registrations during the exclusivity period. It is also, however, compatible with other models for preventing unfair commercial use. The public disclosure of data is independent of granting drug marketing approval; it can be done regardless of whether marketing approval has been granted or denied. As Parts IV and V will demonstrate, it is possible to craft a regime in which drug manufacturers must fulfill requirements in addition to showing that their drugs are safe and effective in order to obtain marketing approval. These requirements can be tailored to address the economic and equity concerns advanced by drug developers.

D. Conclusions

The considerations discussed above lead to the conclusion that nondisclosure and data exclusivity are undesirable, but that some arrangement is necessary to provide economic incentives for drug companies to seek marketing approval and to prevent unfair commercial use of the data by their competitors. A simple Lockean model of equity would require that drug developers not bear the entire cost of marketing approval when they will not alone benefit from the approval, or when other approvals will be used to their economic detriment.\textsuperscript{156} Yet, the need to verify the accuracy and completeness of testing data and the necessity of avoiding artificial monopolies and duplicative research argue forcefully for nonexclusivity. The problem with the exclusivity model is that it treats data as the exclusive property of the drug developer when the public also has a clear interest in the data by virtue of the very same marketing approval. The ethical and public-health implications of trade secrets in drug marketing approval data argue against both

\textsuperscript{153} See Ollila & Hemminki, supra note 151, at 167–69.
\textsuperscript{154} See TRIPS Agreement art. 39.3.
\textsuperscript{155} South Centre, supra note 25, at 24.
data exclusivity and nondisclosure. A better solution than secrecy and monopoly must be invented. The drug regulatory authority, rather than treating the data as fortuitously in its possession and subject to its total discretion, might be considered a trustee of the initial registrant's trade secret. What alternatives such trusteeship implicates is the subject of the next two Parts of this Article.

IV. POTENTIAL SOLUTIONS

In practice, there are several ways to compensate the initial registrant for the costs of generating marketing approval data without requiring nondisclosure or conferring a monopoly. This Part will explore a few possible methods of compensation and will explain why each method falls short of the ideal balance between providing incentives to drug developers and promoting the public interest in access to safe drugs. The first method is found in Article 1711 of NAFTA. NAFTA imposes a five-year minimum data exclusivity requirement without forbidding the signatories to consider marketing approval applications generated independently. The second method originates in a particular U.S. environmental law designed to regulate pesticides and related registrations using a market-oriented approach. The third is based on a simple licensing model in which the costs of generating the data are shared among all registrants without any minimum exclusivity period or need for negotiation. Each approach is compatible with Article 39.3 of the TRIPs Agreement in protecting the data from unfair commercial use, and each has unique advantages and disadvantages.

A. The NAFTA Model

The signatories to NAFTA agreed to a temporary data exclusivity standard in drug marketing approval applications. Article 1711 binds the signatories to protect against the disclosure of marketing approval data on terms similar to those in the TRIPs Agreement. Unlike TRIPs, however, NAFTA

157. Article 1711 provides, in relevant part:

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter’s permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person’s efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.
specifically adds a minimum five-year period of exclusivity during which the drug approval authorities may not allow competitors to rely on the initial registrant’s data. NAFTA makes clear, then, that signatories are expected to treat the data as a protected trade secret of the registrant for at least five years regardless of the lack of patent protection. Moreover, Article 1711 does not allow parties to disclose data upon payment of “fair” compensation to the initial registrant, as proposed by the United States during the TRIPs Agreement negotiations. The NAFTA approach was emulated in the following year by the Comunidad Andina (Andean Group) and is advocated by the United States in its negotiations of bilateral FTAs with developing countries.

The United States and the EC, as explained in Part II.B.1, have sought to convince their trading partners to adopt a similar approach by claiming that data exclusivity is required by Article 39.3 of the TRIPs Agreement and, failing that, by negotiating bilateral and regional FTAs that incorporate a data exclusivity obligation. NAFTA is an example of one such treaty. Notwithstanding the vehemence of the support in wealthy countries for the NAFTA approach, though, it suffers from several of the drawbacks identified in Part III of this Article. First, the guarantee of nondisclosure, like that in the TRIPs Agreement, may be interpreted to mean that third parties and the public in general may not test the validity and completeness of the data upon which the marketing approval authorities relied. There is no reasonable justification for subjecting drug consumers to unnecessary risks by precluding independent review so long as the incentive to create the marketing approval data is preserved. Second, duplicative research may occur during the five-year period, leading to wasteful, unethical, and possibly dangerous repercussions. Third, the five-year period creates an automatic monopoly that may increase the price of drugs for at least five years, harming medical insurers and uninsured consumers who may not be able to afford the drugs. A final problem, not discussed in Part III, is that the five-year period is entirely arbitrary. Five years of data exclusivity may not be enough to compensate the drug developer adequately for products requiring the most complex and extensive testing (which is why most European states grant ten years of exclusivity), while five years may be excessive for the straightforward testing

7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

NAFTA art. 1711.

158. Id.
159. See supra note 45 and accompanying text.
160. See SOUTH CENTRE, supra note 25, at 10.
161. The impact of this duplication may be limited to some degree, however, by the abbreviated approval procedures allowed for products based on bioequivalence and bioavailability studies. See NAFTA art. 1711(6). As discussed above, however, the United States and Canada do not take advantage of that provision during the exclusivity period, because both countries preclude all applications for registered drugs for five years after the initial registration. See supra text accompanying notes 18–19.
associated with the most profitable drugs (which means that the harm caused
by the European standard is doubly egregious in those situations). A prede-
termined, uniform monopoly period is a very blunt policy instrument be-
cause it treats all drug marketing approval efforts alike when, in fact, they
may vary significantly.

B. The FIFRA Model

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was en-
acted by the U.S. Congress in 1980 to protect the natural environment against
harmful agricultural and related chemicals.162 FIFRA requires any company
producing certain regulated chemicals in the United States to register with
the Environmental Protection Agency (EPA) and to seek approval for new
chemicals (or preexisting chemicals with newly discovered uses) prior to
marketing in the United States.163 Like the TRIPs Agreement, FIFRA for-
bids the disclosure of chemical testing data submitted to the EPA and, un-
like the TRIPs Agreement, even provides for criminal penalties against gov-
ernment employees who knowingly disclose such data to the public or to third
parties.164

In FIFRA, Congress attempted to preempt data exclusivity problems by
providing for ten years of data exclusivity with mandatory licensing of data
submitted to the EPA.165 Any person seeking to use marketing approval
data submitted pursuant to FIFRA first must attempt to negotiate a volun-
tary license from the registrant, generally in exchange for a license fee or
some other compensation, such as a cross-license. If, after ninety days, the
initial registrant and subsequent applicant cannot reach an agreement, either
party may elect to initiate arbitration. The arbitrator will issue a final and
binding determination of the license fee payable to the registrant, thereby
resolving the issue.166 The duty to pay compensation lasts for up to fifteen
years after the data is submitted167 and is as mandatory for the registrant to
accept as it is for the applicant to pay. The U.S. Supreme Court has confirmed
that FIFRA permits the EPA to use the data submitted by an initial regis-
trant in considering a subsequent application for marketing approval, so
long as the EPA requires the applicant to pay "reasonable compensation" to
the initial registrant.168

The FIFRA scheme has three prominent strengths. First, it avoids grant-
ing the initial registrant a dilatory monopoly to the detriment of competi-
tion in the market. Second, it gives the parties an opportunity to settle the

167. Id.
matter voluntarily, which in some circumstances may be preferable to a coercive approach.\textsuperscript{169} Both parties, knowing that an unpredictable and possibly time-consuming arbitration may lie ahead, have sound reasons to negotiate in good faith and to arrive at a mutually acceptable settlement. In contrast, both the NAFTA approach and codified systems of fixed compensation impose a predetermined solution that may be unacceptable to one or both parties. Although arbitration may also result in such an undesirable solution, the parties have an opportunity and an incentive to arrive at a reasonable solution voluntarily. The third strength is that the FIFRA scheme is inexpensive to administer because settlements involve no government participation and the arbitration costs are paid by the parties. This feature is likely to be attractive in developing countries, where governments are generally overburdened and cash poor.

The disadvantages of the FIFRA scheme, however, may make it unpalatable to negotiators. First, the computation of the licensing fee is standardless and, therefore, unpredictable. Two parties seeking access to the data may pay widely differing amounts over widely differing periods of time. The arbitrator is unlikely to have any privileged insight as to what amount is commensurate with the market value of the data. Even if the arbitrator did have such insight, it is not clear that the payment of the market value of the data by a subsequent applicant would result in the optimal balance between providing incentives to generate the marketing approval data and encouraging competition in the drug market. There is, moreover, no mechanism to prevent the initial registrant from recovering an amount in excess of its costs to develop the data. Overcompensation to the registrant could hinder competition and raise the price of drugs.

Second, while the FIFRA model is virtually costless to the government, it may be costly to the parties to negotiate an agreement and to arbitrate should negotiations fail. In addition, unless a settlement can be negotiated quickly, the process can be very time consuming. It is in the interests of the initial registrant to draw out negotiations (which may last up to ninety days under FIFRA\textsuperscript{170}), during which time it maintains a monopoly on the drug. Arbitration may take months on top of the initial negotiation period. Following the arbitration, one of the parties may appeal on specified grounds, resulting in delays that can exceed a year before the data is made available. In short, under the FIFRA scheme, there are numerous ways for the initial registrant to maintain a monopoly, thereby preserving high drug prices and a limited supply.

The FIFRA model has significant advantages over the NAFTA model, but it suffers from shortcomings that render it unacceptable as an option for in-

\textsuperscript{169} Voluntary settlement is preferable insofar as it reduces transaction costs and allows the market to work its invisible hand. Where there is a large disparity, however, in both bargaining power and the expectations of the parties, the advantages of voluntary settlement are severely proscribed.

ternational negotiators seeking to guarantee competition in the drug market while ensuring that incentives are maintained for obtaining initial marketing approvals. Such competition is particularly important in developing countries, where high costs for some drugs may result in widespread suffering and death.

C. The Simple Division Royalties Model

An alternative to the FIFRA model would be to adopt a fixed cost-sharing approach among all registrants of the drug. Under such a system, subsequent registrants would not have to repeat the initial registrant’s testing so long as they paid an equal portion of the costs of these tests to all other registrants (whatever the number). At the time of applying for marketing approval, the initial registrant would be required to prove the costs of obtaining such approval. \(^{171}\) The simplest model for cost sharing would be to divide the number of registrants in any given year by the total costs associated with gaining marketing approval and to have each subsequent registrant reimburse the initial registrant with a proportionate amount. For example, if three generic drug manufacturers seek to capitalize on the marketing approval of an initial registrant (Company A), each generic drug manufacturer will pay one-quarter of Company A’s costs, so that all registrants share equally in the costs.

The simple division cost-sharing model has several advantages over both the NAFTA and the FIFRA models. Unlike the NAFTA model, there is no prescribed monopoly period. Consumers could benefit from competition in the drug market immediately after competing drug manufacturers proved bioequivalence to the initial registrant’s molecule. Duplicative testing would be unnecessary as well. Unlike the FIFRA model, the simple division model does not implicate an unpredictable arbitral procedure or give the initial registrant the opportunity to delay the market entry of competitors.

There are, however, several problems with this model. First, not every registrant will be able to pay a large fraction of Company A’s costs up front. These costs tend to run into the tens or hundreds of millions of dollars, \(^{172}\) and small pharmaceutical manufacturers in developing countries rarely will be able to bear such a burden. Equally important, the simple division model does not account for changes over time in the number of registrants, and thereby creates a potentially messy administrative procedure. Not all registrants will enter the market at once. If Company B enters the market one year after Company A, it will pay 50% of the latter’s costs. If Company C then enters the market and pays 33.3% of Company A’s costs, Company A will have to refund 16.6% of its costs to Company B. The differences in timing of entry will create an unwieldy cost distribution as new market entrants seek to register for marketing approval. Finally, for various reasons,

\(^{171}\) See discussion infra Part V.C.2.

\(^{172}\) See supra text accompanying note 112.
some registrants may never enter the market after obtaining marketing approval. It may be inconsistent with the idea of correlating the benefits of market access with the costs of obtaining approval if access is never used. A company may bear up to 50% of the burden of obtaining marketing approval without reaping any benefits if it never enters the market or if it must exit the market promptly. Ideally, there should be some way of reducing the burden on such companies to avoid giving a systemic advantage to large, well-capitalized drug manufacturers over the smaller manufacturers characteristic of developing countries.

V. The Readjustable Royalties Model

After the discussion above, it is helpful to refocus attention on the initial U.S. proposal during the TRIPs Agreement negotiations, which would have required data exclusivity except upon the payment of fair compensation to the registrant. The U.S. proposal, though rejected, is not precluded by the current wording of Article 39.3 of the TRIPs Agreement. If properly implemented and elaborated, it could resolve many of the problems with the potential resolutions discussed in Part IV. The solution proposed in this Part is to require generic drug manufacturers to partially compensate the first registrant of the drug for the costs of obtaining marketing approval in WTO members. The ideal readjustable royalties system would require cost sharing, as in the simple division model described above, but more precisely in proportion to the benefit derived from the initial registrant’s research. Such a system should correlate the benefits of market access with the costs of obtaining such access. The benefits of access are, as is usually the case, correlated with the degree of market concentration and the shape of the demand curve. The latter variable is independent, but market concentration is a direct function of the number of marketing approvals issued. Therefore, the smaller the number of registrants that rely upon a prior marketing approval, the greater the share that each subsequent registrant should pay of the initial registrant’s marketing approval costs.

173. For example, the market for a drug may radically diminish soon after a subsequent registrant’s entry, resulting in the loss of its potential market share to the competing manufacturers (particularly the initial registrant) that already benefit from brand-name recognition. The diminution of the market may not significantly harm the initial registrant, but the subsequent registrant may derive little benefit from its registration. In an alternative scenario, the subsequent registrant, being a local (developing country) company smaller than the initial registrant, might find that sharing one half or one third of the marketing approval costs diminishes its capital to the point where it cannot afford to market the drug on the same scale as its competitors, resulting in unprofitability or even insolvency.

174. See supra note 43 and accompanying text.

175. In other words, low market concentration tends to decrease the market power of each market player.
A. General Statement of the Readjustable Royalties Model

There are many ways to structure a system to share the costs of obtaining marketing approval among the initial registrant and its competitors. A satisfactory model must provide an appropriate allocation of costs over the appropriate period of time, be based on a fair assessment of the initial registrant's costs, account for the time value of money, and be simple and efficient to administer. This Part attempts to address these challenges by proposing a new model—the Readjustable Royalties Model—for the calculation of royalty payments to the initial registrant by subsequent registrants. The Readjustable Royalties Model avoids the weaknesses of the models discussed in Part IV while capitalizing on the strengths of each to the extent feasible. Equally important, the model is consistent with the obligations set forth in Article 39.3 of the TRIPs Agreement, as it prevents unfair commercial use of the data.

The model begins from the premise, upon which the simple division cost-sharing model was based, that the initial registrant must prove the cost of the drug testing necessary to obtain marketing approval at the time of applying for the approval. At that time, the drug regulatory authority would become the trustee of the data and would be required to treat it as a trade secret of the registrant to the extent of not allowing generic drug manufacturers to use the data commercially or to rely upon it for the purpose of seeking approval to market a competing drug. The state authority would not, however, be obligated to grant unqualified data exclusivity to the initial registrant. Instead, subsequent companies wishing to use or to rely on the initial registrant's prior marketing approval would be required to pay a royalty to the registrant for a predetermined number of years after the marketing approval had been granted.

The royalty could be calculated as a percentage of the initial registrant's cost ranging from 50% to a small fraction, depending on how many competitors share in the usage of the data. There are several possible mathematical models that would lead to an equitable and efficient arrangement. An elegant model would require each of the first few companies seeking subsequent marketing approval to pay a fixed percentage of the total cost for every year during a fixed number of years following the initial registrant's approval. For example, the royalty formula could require the first four generic drug manufacturers that rely on the initial registrant's data each to pay 2% of the cost of the initial registrant's mandatory drug testing for the first ten years after the marketing approval has been obtained. The initial registrant would recover between 20% and 80% of its costs, depending on how much competition it faces.

Alternatively, and perhaps more equitably, the costs could be front-loaded onto the first few subsequent registrants, since these competitors would obtain the greatest benefit from their use of the initial registrant's data. Under this alternative, additional subsequent registrants would pay reduced royalties corresponding to the diminished benefit of marketing approval after several
competitors preceded them in entering the market. A formula for each subsequent registrant’s annual payment might read:

\[
\frac{\alpha + 0.01(\beta - 1)}{\beta} = \gamma \quad \text{[a]}
\]

where \(\alpha\) is the fixed base annual percentage to be paid by the first subsequent registrant, \(\beta\) is the total number of subsequent registrants marketing the pharmaceutical, and \(\gamma\) is the annual percentage of the initial registrant’s costs paid by each generic-drug manufacturer. The formula expressing the initial registrant’s total recovery would accordingly read:

\[
(\gamma)(\beta) = \frac{\theta}{\eta} \quad \text{[b]}
\]

or equivalently:

\[
(\beta)(\gamma)(\eta) = \theta \quad \text{[c]}
\]

where \(\eta\) is the maximum number of years following the initial marketing approval during which the royalties must be paid and \(\theta\) is the total percentage of the initial applicant’s costs that will be paid over \(\eta\) years.

Formulas [a] and [b] have several useful features. Assume that the drug approval authority in Country X—a WTO member—were to grant Company A marketing approval following testing of Company A’s pharmaceutical, Hypotheticin. Further assume that Hypotheticin is itself an unpatentable natural product, but was created using a patented process. A generic alternative created by a noninfringing process is ready for registration in a matter of months, and the inventor of the process, Company B, seeks to sell its bioequivalent version of Hypotheticin in Country X based on Company A’s marketing approval. Under the model proposed here, the regulator would allow Company B to rely on Company A’s prior marketing approval on the condition that Company B pays a royalty of \(\alpha\) percent of Company A’s costs. Assume that \(\alpha = 0.05\) (i.e., 5%) of the costs per year, and \(\eta = 10\) years. Formula [a] yields:

\[
\frac{0.05 + 0.01(1-1)}{1} = \gamma = 0.05
\]

176. For an explanation of the impact of generic entry on drug prices over time, see generally Hudson, supra note 118, at 216–19.  
177. Consequently: \(\alpha = \frac{\theta}{\frac{\eta}{a}} - a \cdot a \cdot a\)  
178. Of course, Company B also must meet the other marketing approval requirements of Country X,
Thus, Company B would be required to pay 5% of Company A’s cost per annum for ten years, ultimately resulting in an even split between Company A and Company B of the costs of obtaining marketing approval under Formula (b):

\[(1)(0.05)(10) = \theta = 0.50\]

or 50% total to be paid by Company B to Company A.¹⁷⁹

Formula (a) further provides that the next generic drug manufacturer (Company C) to seek marketing approval must pay royalties to Company A in the amount of:

\[\frac{0.05 + 0.01(2-1)}{2} = \gamma = 0.03\]

or 3% per year. Beginning in the year that Company C enters the market, Company B would reduce its royalties from 5% per year to 3% per year, yielding a total gain to Company A of 6% per year, or, under Formula (b):

\[(2)(0.03)(10) = \theta = 0.60\]

over the ten-year period.

As the model is presented, manufacturers entering the market after the fourth generic drug manufacturer (i.e., those following Company E) do not pay royalties to Company A, on the theories that (1) Company A should not recover more than 80% of its costs, and (2) the benefit to the fifth subsequent registrant is attenuated.¹⁸⁰ The upshot is that, as long as the initial registrant has competitors for ten years after approval, it will receive at least one half of its investment, and up to 80% depending on how many competitors enter the market. The higher the number of competitors that benefit from its marketing approval, the more its costs are shared.

This formula could, however, be altered in several ways to reflect local market conditions or the preferences of WTO members. The length of time during which royalties are payable (η), for example, is a variable that could be lengthened or reduced. Similarly, the maximum number of market entrants who must pay royalties (β) could be increased or decreased, assuming always that the formula is not altered to allow the initial registrant to re-

¹⁷⁹ Technically, the split in costs in the model would not actually be fifty-fifty under the simplified model discussed here. Because Company A’s royalties would be received over a ten-year period after its outlay for the drug approval testing, it would lose the time value of its money. This problem is addressed infra in Part V.B.

¹⁸⁰ Where the second condition does not hold true, the model can be adjusted by increasing the maximum number of generics manufacturers (i.e., subsequent registrants) required to pay royalties (β) and decreasing the α term.
cover more than 100% of its real costs. The flexibility of the model is one of its key strengths, as it allows room for negotiation and experimentation by WTO members to find the optimal balance between incentives to seek marketing approval and competition in the drug market.

For example, suppose that WTO members in the Doha Round of negotiations agree that up to nine subsequent registrants should share in the costs of the first applicant’s marketing approval, but they do not want any subsequent registrant to pay more than 30% of the total cost of Company A’s approval, because generic drug manufacturers in developing countries generally have limited capital. Moreover, assume the negotiators want to limit the duty to pay royalties to eight years. Expressing these sums mathematically:

\[ \alpha = \frac{\theta}{\eta} = \frac{0.3}{8} = 0.0375 \]

while \( \beta \leq 9 \) and \( \eta = 8 \). Under this arrangement, the first subsequent registrant (again, Company B) would pay 30% of Company A’s costs over eight years, equaling 3.75% of Company A’s total costs per year for each of the eight years as expressed above (assuming, as usual, that Company A continues to market the pharmaceutical all eight years).公司 C, the second competitor of Company A to enter the market, alters the outcome so that both Company B and Company C now each pay:

\[ \frac{0.0375 + 0.01(2-1)}{2} = \gamma = 0.02375 \]

or 2.375% of Company A’s total costs per annum, yielding a total of 4.75% paid to Company A each year by both competitors. Company A’s total recovery, if two generic drug manufacturers market the drug over the entire eight-year period, is 38%:

\[ (2)(0.02375)(8) = \gamma = 0.38 \]

By the time the ninth competitor (Company J) enters the market,182 Formula (a) yields:

\[ \frac{0.0375 + 0.01(9-1)}{9} = \gamma = 0.01305 \]

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181. If Company A withdraws from the market before \( \eta \) years have elapsed, there is no reason why subsequent registrants should discontinue paying royalties to Company A or its assignees.

182. Again, this argument assumes for the sake of simplicity that all nine competitors enter the same year as Company A and continue to market the pharmaceutical for \( \eta \) years. Whether this holds true will, of course, affect \( \theta \), but the decreased royalties that Company A receives should be amply compensated by the reduced competition from the generics manufacturers whose products leave the market, assuming
or 1.305% of Company A’s total costs per annum from each entrant. Although this amount may seem small, when nine entrants are each paying that amount, Company A nets 11.75% of its costs per annum; Formula \(b\) yields a total of:

\[
\theta \times (0.01305)^8 = 0.94
\]

or 94% of its total costs over eight years. The available data on the effect of generic entry into the brand-name market tends to show that the greater the number of generic competitors that enter the market, the lower the profitability to the initial registrant. In short, under the proposed model, Company A’s rationale for bemoaning its lost data exclusivity is undermined in direct proportion to the increase in competition from generic-drug manufacturers. Applied properly, the Readjustable Royalties Model accomplishes the twin goals of not imposing the full financial burden of marketing approval research on the drug developer and fostering increased competition in the drug market.

**B. Factoring in the Time Value of Money**

The model proposed in Formulas \(a\) and \(b\) does not explain how the initial registrant of a drug can recover the time value of the funds it expended to obtain marketing approval. The time value of money can be substantial given the high costs of obtaining marketing approval; if the initial registrant is reimbursed 80% of its costs over ten years, it loses interest on a significant portion of those costs. The most direct way to address this concern is to add a compounded market rate of interest (at \(\kappa\) nominal interest) to each later market entrant’s royalties. Adding interest yields the following formula with respect to any given subsequent market entrant:

\[
\left(\frac{\alpha + 0.01(\beta - 1)}{\beta}\right)(1 + \kappa)^{\eta} = \gamma
\]

where \(\eta\) equals the number of years that have elapsed (beginning with “1”) since the subsequent registrant entered the market. Interest on each market participant’s total payment is now factored into the amount that it must pay annually, yielding Formula \(d\) as the expression of the finished Readjustable

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Royalties Model. The value of $k$ should ideally be set at the simple market interest rate in the country at issue, but could alternatively be based on a fixed real interest rate set by agreement of the WTO members either in a separate agreement or in the Doha Round negotiations.184

C. Determining the Cost Basis

An important but thus far unanswered question is how to determine the value upon which $\theta$ is based. There are two main facets to this valuation issue. First, the method of correlating the geographic scope of marketing approval costs to royalties will influence significantly how the model balances the incentives to drug developers to seek marketing approval with the ability of generic drug manufacturers to meet the cost of royalties and thereby compete with the initial registrant. Second, the method of calculating the cost of obtaining marketing approval must be examined more closely. This Part will consider each question in turn.

1. Geographic Scope

There are several possible geographic scopes that could provide the cost basis for drug marketing approval under the TRIPs Agreement. The most favorable to large drug developers would be a model with an international cost basis. An alternative, less ambitious option would be to multiply the initial registrant’s international costs by the fraction of the world market share for that drug which the approving country at issue maintains. A third option would be for competitors in any given country to share the costs of the initial marketing approval where the drug is first marketed, as well as any costs of local marketing approval. Finally, it might be argued by less economically developed countries that the geographic basis should be maximally limited so that generic drug manufacturers share only in the costs of the registration in the approving WTO member at issue. Each option will be examined below.

The first option, basing royalties on worldwide costs, is likely to provoke two objections. First, a system based on worldwide costs would be difficult to administer and would create unpredictable results in many cases, because there may be a lag of several years between the initial marketing approval and subsequent approvals in other countries. Subsequent registrants in the first country may find themselves sharing costs of the initial registrant’s marketing approvals many years later. Generic drug manufacturers would thereby be exposed to unforeseeable risks that would discourage them from entering

184. The market interest rate in the country at issue is preferable insofar as it reflects the cost of borrowing money in that country and is, therefore, a less market-distorting measure of the time value of money than a fixed universal interest rate. In other words, money tied up in obtaining marketing approval in Country X is equivalent to an investment in Country X. The compounded market interest rate payable in Country X is, consequently, the appropriate measure of the time value of money for marketing approval in Country X.
the drug market. Second, because generic drug manufacturers in Country X might obtain no advantage from the initial registrant’s subsequent registrations in Country Y, it would be inequitable to require such subsequent registrants to share in the initial registrant’s costs of obtaining marketing approval in Country Y. There is no evident policy justification for generic drug manufacturers in one country to subsidize the initial registrant’s foreign marketing efforts.

The second option is a variant of the first that involves multiplying the total cost of obtaining marketing approval worldwide by the percentage of the world market occupied by the developing country. This approach eliminates the overpayment problem, but adds to the administrative burden of the system. The developing country’s world market share is likely to fluctuate during the payment period (especially if subsequent marketing approvals are obtained for generic drugs intended for export), and accurate data on this point is unlikely to be available in a timely manner.

The third option, limiting the cost sharing to the country of initial marketing approval and the country of the generic drug manufacturers at issue, 185 resolves administrative difficulties and eliminates unpredictability. It also responds to the objection to excessive subsidization, to a degree, because regardless of how many foreign registrations the initial registrant obtains, generic drug manufacturers need only pay royalties based on the cost of, at most, two registrations. Under this approach, a drug developer that obtains marketing approval in Country X, then subsequently obtains the first such marketing approval in Country Y, could recover a portion of its costs for both Country X and Country Y from generic drug manufacturers in Country Y. The scheme gives the initial registrant a greater incentive to obtain marketing approval in other countries after its initial domestic registration.

There is an additional argument in favor of the third option. The first marketing approval tends to be the costliest, regardless of where it is sought, because there is some overlap in research requirements among most countries, and some countries allow drug developers to rely wholly or partly upon prior FDA or EMEA approval. Assume that Company A first seeks approval in Country X—where marketing approval is expensive—and then seeks a less-expensive approval in Country Y. Compensation for costs incurred in Country Y alone would be insufficient since they represent only a fraction of the total registration costs.

There are, however, several reasons to reject the third option’s binational cost basis. First, most drug developers do not seek marketing approval for drugs based on the sales potential in less economically developed countries. Instead, they seek such marketing approvals because they expect to obtain

185. These may, of course, be the same country. For example, a Swiss registrant may obtain initial marketing approval in Switzerland, in which case subsequent Swiss registrants would share in the costs of the initial registrant’s marketing approval in Switzerland only. The objections to this option do not apply to these registrants.
adequate returns in the country of initial registration—often their domestic market—and in other wealthy countries. In such cases, the expense of seeking initial marketing approval may be a sunk cost that the drug developer will not consider in determining whether to register the drug in a foreign market. 186 Developing countries, which account for more than three-quarters of the world’s population, account for only 10% of the world’s pharmaceutical market. 187 While royalties based on this initial registration may create an additional incentive to market the drug in such countries, royalties will not deter unfair commercial use. They amount, in effect, to subsidies, encouraging foreign marketing approval applications that may or may not be necessary and that, in any case, distort markets and impede access to pharmaceuticals in the developing world. 188

The third option is susceptible to the additional objection, however, that it is not necessarily equitable to generic drug manufacturers in subsequent countries. Unlike the initial registrant, generic drug manufacturers in Country Y derive no benefit from the initial registrant’s marketing approval in Country X unless they, too, market in Country X and are granted a license to rely on the data in Country X. With only a few exceptions, drug manufacturers in developing countries rarely have the capacity to qualify to sell drugs in developed-country markets and to enter such markets on competitive terms. 189 In fact, the compulsory licensing debate’s virulence derives from the drug-exporting countries’ fear of competition in lucrative foreign markets and even their home markets by generic drugs manufactured in developing countries under compulsory licenses (such competition being forbidden by Article 31(f) of the

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186. Wealthy foreign markets may, of course, be very profitable, and drug developers may count on foreign sales in such markets to justify research investments, but the same cannot be said for most developing countries, where access to drugs is a pressing issue. Drug developers undoubtedly account for expected returns on such markets when making research investment decisions, but these markets have similar trade secret protection regimes for marketing approval data. In any case, most wealthy countries participate in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals (“ICH”), established in 1990 by Japan, the EC, and the United States, which is intended to eliminate the wasteful duplication of work and procedures caused by different regulatory requirements among drug approval authorities in participating countries. See http://www.ich.org (last visited May 2, 2004). Thus, the TRIPs Agreement does not aim so much at harmonizing data protection standards among wealthy countries as at narrowing the disparity in protection of trade-related intellectual property between economically developed countries and developing countries. For a general discussion of early efforts at drug testing standardization efforts, see Rosemarie Kanusky, Pharmaceutical Harmonization: Standardizing Regulations among the United States, the European Economic Community, and Japan, 16 HOUS. J. INT’L L. 665 (1994).

187. See World Health Assembly, infra note 148, at 1. Perhaps more disturbing is the fact that the entire African continent accounts for less than 1% of the world’s consumption of pharmaceuticals. Oxfam et al., Beyond Philanthropy: The Pharmaceutical Industry, Corporate Social Responsibility and the Developing World 8 (2002); Daniel Pruzin & Gary Yerkey, Developing Countries Prepared to Use New WTO Accord to Import Cheap Medicines, DAILY REP. FOR EXECUTIVES (BNA), Sept. 3, 2003, at A-3 (on file with the Harvard International Law Journal).

188. Subsidies, by their very nature, distort markets by ushering the allocation of resources away from uses favored by market forces and toward the subsidized use. See generally Sanford Ikeda, Dynamics of the Mixed Economy: Toward a Theory of Interventionism (1997) (discussing the role and effects of subsidies in competitive markets).

189. See infra note 191.
TRIPs Agreement). Most of the least-developed countries could not even supply their own needs for generic versions of essential drugs, much less afford to export them.

If the drug developer did, in fact, invest in the cost of obtaining marketing approval in Country X with a view toward also profiting in Country Y (which accepts the drug without significantly more clinical testing than was performed in Country X), then the argument for the third option becomes stronger. When all of the costs are weighted heavily toward the country of initial registration, but profits in other countries promise to be significant, the equities weigh in favor of a binational cost basis. To prevent duplicative recovery, however, the binational basis of the third option must be hybridized with the relative benefit calculation of the second option. Instead of relying on the highly variable measure of market share, the cost basis should ideally be the combined costs in Country X and in Country Y multiplied by the ratio of the aggregate annual drug spending in Country Y to that in Countries X and Y combined. If an accurate comparison of drug spending is infeasible due to a lack of reliable data, gross domestic product (GDP) may be used. GDP is at best a crude measure of the relative incentive to obtain drug marketing approval in any given country, because per capita drug spending varies among countries. Nonetheless, it is a reliable and fair proxy for purposes of determining a cost basis, which need not be microscopically precise because, regardless of actual per capita spending on drugs in any given country, consumers in impoverished countries (i.e., countries with relatively low per capita GDPS) will also have low drug spending because they have less funds to purchase drugs.

In algebraic terms, the cost basis for WTO members that rely upon the prior approval of a drug regulatory authority of another WTO member in which the initial registrant has already obtained approval is as follows:

190. TRIPs Agreement, art. 31(f).
191. See General Council, supra note 9, pmbl. & Annex. See also Piero L. Olliaro et al., Drug Studies in Developing Countries, 79 Bull. World Health Org. 894 (2001) (“One of the common features of ‘developing countries’ in terms of pharmaceuticals is the lack of ability to generate independently the drugs that they need.”); Pruzin & Yerkey, supra note 187, at A-3 (describing intent of “major African countries” to use compulsory licensing under the August 30 TRIPs Council Decision to import necessary drugs due to lack of manufacturing know-how and capacity). On the other hand, some developing countries, such as Brazil, Egypt, and India, have relatively mature drug-exporting industries. Egypt, for example, could boast in 1999 of having 32 drug manufacturers, 12 of which were multinational companies. See Moustapha El-Hadary (sic), Remarks at the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals: Implementation and Implications (Apr. 25–29, 1999), at http://www.who.int/medicines/library/qsm/icdra99/icdra99_ich_impl.shtml (last updated Mar. 16, 2004).
192. Although many developing countries accept marketing approvals from drug regulatory authorities in other countries, there are reasons why local clinical testing may be advisable. Regional genetic, metabolic, morphological, and environmental variations among populations—including diet, physical activities, altitude, and climate—may affect the efficacy, safety, contraindications, and side effects of drugs. See Angela Scheuerle, Limits of the Genetic Revolution, 155 Archives Pediatric & Adolescent Med. 1204 (2001). See, e.g., William C. Cushman et al., Regional and Racial Differences in Response to Antihypertensive Medication Use in a Randomized Controlled Trial of Men With Hypertension in the United States, 160 Archives Internal Med. 825 (2000).
where $\chi_{rel}^\text{c}$ is the cost basis in WTO members that rely upon drug marketing approval from the drug regulatory authority of another WTO member in which the initial registrant has already obtained such approval, $\sigma$ is the drug expenditures (or GDP) of the WTO member of subsequent approval, $\nu$ is cost to the initial registrant of obtaining marketing approval in the initial WTO member, $\rho$ is the additional cost to the initial registrant of obtaining marketing authorization in the WTO member of subsequent approval, and $\mu$ is the drug expenditures (or GDP) of the WTO member that granted the initial marketing approval.

The fourth option addresses these concerns by limiting the royalty basis to the costs incurred in the country in which the subsequent registrants will market the drug. The initial registrant in Country $Y$ would pay only a portion of the cost of obtaining marketing approval in Country $Y$ under this model. Each country of registration would be treated as an isolated market giving rise to royalty obligations only when generic drug manufacturers entered that market. This option has the advantage of not requiring generic drug manufacturers to share in the cost of a prior foreign marketing approval from which they derive no direct benefit, thereby limiting their costs to the proportional benefit they derive.

Nonetheless, this option provokes the objection that, although generic drug manufacturers may not market in the country of initial marketing approval (Country $X$), they still benefit from the greater costs expended by the initial registrant in that country, especially if the registration in Country $Y$ costs very little relative to the initial approval. Under the fourth option, generic drug manufacturers would free ride on this benefit, and the initial registrant would be left to its own devices under the law of Country $X$ to obtain compensation from generic drug manufacturers in Country $X$ for the costs of marketing approval in that country.

There are two replies to this objection. First, Article 39.3 of the TRIPs Agreement is not designed to create a monopoly over any and all benefit from a drug developer’s worldwide generation of drug marketing data. The purpose of Article 39.3 is to prevent unfair commercial use in each WTO member’s territory. Regardless of what costs a drug developer incurs to market its drug in Country $X$, when it seeks marketing approval in Country $Y$, Country $Y$ need only concern itself with the trade secrets to be protected in its territory. The value of trade secrets in its territory is independent of their value in Country $X$, which is a separate market for the trade secret. Consequently,

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193. As Piero Olliaro and his colleagues have observed, "[e]veral regulatory authorities in developing countries do not have a system to deal with new chemical entities, as only products that have been developed, reviewed and registered elsewhere are considered." Olliaro et al., supra note 191, at 894.
the royalties should be based on the value of the trade secrets where the royalties are paid, not in some other country. Because the drug regulatory authority in Country Y may only grant marketing approval within the territory of Country Y, the value of the trade secret in Country Y presents the most rational cost basis for the royalty.

The second reply is that no further royalties will be needed as an incentive to obtain marketing approval in Country Y. As noted above, the initial registrant often may rely on the data submitted in Country X for subsequent marketing approvals, thereby reducing the cost of obtaining approval in Country Y. Thus, the costs of the first drug marketing approval are generally the highest. This is the very fact that provoked the objection to the fourth option. Remember, however, that with respect to developing countries, the outlays for obtaining marketing approval in Country X may be sunk costs.194 Sunk costs have no effect on the drug developer's decision of whether to seek marketing approval in Country Y whenever the decision to market in Country Y was made after the expenditures were made. To the extent that the drug developer lacks financial incentive to market its new drug in Country Y, it can license its trade secret to one or more regional drug manufacturers, in Country Y or elsewhere, which then can benefit from the protections afforded to the initial registrant in Country Y under the Readjustable Royalties Model. Granting compensation to the drug developer for the costs of marketing approval in Country X might give the drug developer a greater incentive to seek marketing approval in Country Y, but not because the drug developer would be suffering from unfair commercial use in the absence of such an incentive. The incentive would merely represent a subsidy paid by generic drug manufacturers to the initial registrant.195

Such a subsidy is likely to be more unfair to the subsequent registrants than its absence would be to the initial registrant. This raises an additional consideration that may weigh in favor of limiting the basis for royalties to each country in which marketing approval is sought. The United Nations Development Program (UNDP) estimates that 80% of the patents granted in developing countries are owned by residents of “industrial countries.”196 Most new drugs receive marketing approval and are marketed in wealthy coun-

194. For orphan drugs developed specifically for primary marketing in developing countries, the argument for a binational cost basis is the most convincing. An orphan drug treats a disease that either is very rare or affects people living in poverty, so that marketing of the drug becomes unprofitable and drug manufacturing and marketing is abandoned. In the United States, Congress addressed this problem in the 1982 Orphan Drug Act, Pub. L. No. 94–414, § 526(a)(2), 96 Stat. 2049 (1982) (codified as amended at 21 U.S.C. § 360bb (2000)). The Orphan Drug Act focuses exclusively on the domestic drug market, however. See 21 U.S.C. § 360bb(a)(2) (2000) (defining the applicability of the Act to diseases or conditions affecting certain numbers of people “in the United States”). A creative solution to the problem of the pharmaceutical industry’s emphasis on treatments for diseases common in wealthy societies is the Institute for OneWorld Health, a nonprofit pharmaceutical company, whose mission is to develop and disseminate affordable medicines for the diseases that disproportionately affect developing countries. See http://www.oneworldhealth.org (last visited May 2, 2004).

195. See discussion supra note 188 and accompanying text.

tries (where per capita consumer spending on drugs is highest) before marketing is expanded to less-wealthy countries. Drug manufacturers in less-wealthy countries, on average, have considerably less financial resources and liquidity than manufacturers in wealthier countries. Therefore, if subsequent registrants in Country Y must pay royalties to the initial registrant for the latter's costs of obtaining marketing approval in Country X, it will result in a transfer of wealth from smaller drug manufacturers (often in developing countries) to larger manufacturers (almost always in wealthy countries).

Where the drug regulatory authority of a WTO member declines to rely on a prior marketing approval in another WTO member, the arguments in favor of a cost basis exclusive to the WTO member at issue are decisive. In such cases, Formula (e) offers an inappropriate cost basis, because it accounts for costs not relevant to generic drug manufacturers in the WTO member at issue. A cost basis more appropriate for such countries is given by the simple formula:

$$\chi_{\text{ind}} = \rho$$  \[f\]

where $\chi_{\text{ind}}$ is the cost basis in WTO members of subsequent approval and $\rho$ is the cost to the initial registrant of obtaining marketing authorization in the WTO member of subsequent approval.

In summary, where a WTO member relies upon a prior marketing approval in another WTO member to grant marketing authorization in its own territory, a binational cost basis, apportioned by the relative income of the two countries, prevents free riding and avoids creating a disincentive to the initial registrant to seek marketing approval, without permitting any significant overcompensation to that registrant. In such circumstances, Formula (e) is the most appropriate geographical basis for cost calculations. In contrast, where a WTO member does not rely on a prior marketing approval, but requires independent clinical testing in its own territory, taking the drug marketing approval costs specifically incurred in each country individually as the cost basis for the royalties payable by generic drug manufacturers in that country is the option that best fulfills the goals of the TRIPs Agreement.197 It ensures that drug developers seeking marketing approval in foreign countries do not incur prohibitive costs in obtaining such approval, it prevents unfair commercial use, it avoids overcompensating the initial registrant of a drug, and it tends to prevent unnecessary transfers of wealth from developing WTO members to wealthy WTO members. In such circumstances, Formula (f) is most appropriate.

197. But see discussion supra note 194.
2. Valuation Methodology

Once the geographic scope of the basis for royalty payments has been determined, the salient question becomes how one can know the cost of obtaining marketing approval for any given drug. Presumably, generally accepted accounting principles (GAAP) should suffice to show the cost basis for the drug marketing approval. The question of which costs are properly included in the GAAP analysis fortunately exceeds the scope of this Article, but two important points should be noted.

First, to the extent that cost sharing promotes efforts to obtain marketing approval for new drugs, it is crucial to define the extent to which the costs of failed efforts to bring a drug molecule to market (as opposed to the costs of successful testing alone) should be included in the basis for the cost of successfully bringing a modified version of the failed molecule to market. One of the most important functions of the marketing approval process is to encourage drug developers to improve molecules; clinical trials revealing problems with a molecule perform a valuable and integral function in the drug approval process. The Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) report that, for every 5,000 drugs tested, an average of only five make it to clinical trials, and only one of those is ultimately approved for patient use. Because the failed tests are an integral part of the approval process, the appropriate solution is to include the costs of such failed tests in the basis upon which royalties are calculated. Excluding the cost of clinical testing of failed molecules would arbitrarily relieve subsequent registrants of the duty to pay for the “benefit” of the failed tests and would limit the incentives for drug developers to seek marketing approval.

The difficult question is not whether to include costs of failed registration efforts, but which costs to include. Some molecules may be so dissimilar to the molecule ultimately approved that they might reasonably be considered as part of an entirely separate drug-registration effort. The degree of similarity is necessarily a question of fact to be resolved by the drug regulatory authority, but international standards defining “compensably similar” molecules would impart uniformity and predictability.

It could be argued that, by relying on a cost basis that includes only the expense of testing failed drugs that are similar to the ultimately approved drug, drug developers unfairly bear the burden of testing other drugs. In this

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198. A detailed explanation of GAAP can be found in Patrick R. Delaney et al., Wiley GAAP 2004: Interpretation and Application of Generally Accepted Accounting Principles (2003).


200. The definition of such a standard exceeds the scope of this Article, but it would presumably be based on the molecules purporting to ameliorate or relieve the same medical condition through the same or similar biochemical pathways.
view, by using a narrower cost basis, the true cost of obtaining marketing approval for drugs is underestimated and the incentives to develop new drugs are limited. However, there are pragmatic, doctrinal, and policy reasons for rejecting this contention and adhering to the narrower cost basis. The pragmatic reason is that drug developers generally seek to obtain marketing approval in their own countries before seeking it abroad; drugs that fail to meet marketing approval standards in the most lucrative market generally are not marketed elsewhere, but are abandoned. There is no readily ascertainable method for sharing the costs of failed drugs by contributions from foreign generic drug manufacturers in countries in which the drug is never marketed. The TRIPs Agreement simply does not apply to such failed drug efforts.

The doctrinal reason for adhering to a narrower cost basis is that Article 39.3 of the TRIPs Agreement is not intended to create incentives for new drug development per se, but rather to remove impediments to drug marketing in foreign markets. It most certainly never occurred to the diplomats negotiating the TRIPs Agreement that drug manufacturers in WTO members should share in the costs of developing new drugs in foreign countries. Such a notion is "foreign" indeed to the concepts of trade secret law.

Finally, a policy reason for favoring a narrower cost basis is, paradoxically, the flip side of the purported objection. Because most drug developers conduct research, development, and initial testing in wealthy countries, the net flow of payments under the broader approach would increase in favor of wealthy countries. Expecting generic drug manufacturers in developing countries to pay their fair share of the costs of using trade secrets in their country is one thing, but requiring them to subsidize wealthy foreign drug developers is quite another.

The second point on the question of which costs should be included in the GAAP analysis is that a reasonable rule would require that the compensable costs be incurred at the expense of the registrant itself. Registrants that have conducted limited or no clinical trials, but have instead benefited from a public grant, have no legitimate claim to compensation because they never incurred the relevant costs. Competition from subsequent registrants is not "unfair" to them in the sense of Article 39.3 of the TRIPs Agreement, because (1) the initial registrant is as much a free rider on the public weal as subsequent registrants, and (2) compensation is not a necessary incentive to seek

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202. See Agrawal, supra note 6, at 28. Agrawal notes, however, that, at least in the 1980s, many initial approvals obtained by U.S. drug companies were obtained outside the United States due to relatively long marketing approval delays in the United States. See id. at 31–32.

203. It could also be argued that, as a policy matter, there should be no compensation for failed drug testing efforts, because to do so would effectively subsidize failure. This argument is unconvincing, however, if there are adequate incentives for drug developers to avoid failure in the form of lost opportunity costs that compensation cannot offset.
drug marketing approval; the initial registrant does not bear the economic risks of the testing necessary to gain that approval. To the extent that such registrants can prove that they incurred costs in purchasing the rights to marketing approval data, the rationale for cost sharing stands. But where the marketing approval data has been developed at the public expense, no incentive to conduct marketing approval research is necessary.204

D. Other Implications of the Model

The Readjustable Royalties Model, like any firm legal rule, may provoke attempts at strategic circumvention by generic drug manufacturers. Most notably, by waiting $\eta$ years before entering the market, generic drug manufacturers can avoid paying royalties entirely while still benefiting from the initial registrant’s trade secrets. If WTO members implemented Formula (d) using a low $\eta$, or if the WTO members left it open to each WTO member to choose its own $\eta$ and a given member were to implement a low $\eta$, the benefit obtained by waiting until $\eta$ years expire would increase.

The strategic circumvention point is not really an objection to Formula (d) per se, but rather a weakness in one possible implementation of it. It is important to remember that Formula (d) presents a framework for negotiating a licensing deal compatible with the TRIPS Agreement, not the negotiated solution itself. If the Readjustable Royalties Model is to offer a meaningful solution to the drug access and intellectual property protection issues raised here, the $\eta$ term must be high enough to prevent this type of strategic behavior. In fact, a long royalty payment period does not necessarily disadvantage developing countries. On the contrary, by not entering the market for $\eta$ years, generic drug manufacturers necessarily confer what may be a profitable monopoly on the initial registrant, so the initial registrant is unlikely to object to a high $\eta$ term. But because Formula (d) must be designed to prevent the initial registrant from recovering more than 100% of its costs of obtaining marketing approval in any given WTO member, lengthening $\eta$ does not necessarily result in higher compensation for the initial registrant. What a

204. Such public grants to private corporations are not uncommon, at least in the United States. The case of Taxol presents a prominent example. Taxol (Paclitaxel), a drug effective at treating metastasized breast cancer, was invented by the National Cancer Institute (NCI)—one of the U.S. government’s National Institutes of Health. After developing the drug, NCI sponsored numerous clinical trials at considerable expense, but never patented the drug. Instead, according to Ralph Nader and his associates, NCI gave exclusive rights to use the clinical data to Bristol-Myers Squibb (BMS), a Fortune 100 pharmaceutical company worth some $41 billion, for approximately $5 million worth of Taxol. Nader Letter to Clinton, supra note 144, at 3. BMS, without sponsoring a single clinical trial, soon began selling Taxol at between 19 and 24 times the cost of production, making billions of dollars in monopoly profits. As of the end of 1999, BMS was reportedly making some $1.2 billion annually in Taxol sales. See Sell, supra note 5, at 507. Meanwhile, the U.S. government pays higher prices through Medicare and Medicaid for a drug that it developed and tested in the first place. Nader Letter to Clinton, supra note 144, at 3. The grant of a monopoly on taxpayer-financed research to private companies raises objections in its own right, but the relevance of such arrangements to international trade in drugs should not be overlooked. Where the drug developer never incurred the costs of generating the marketing approval data, data exclusivity is unjustifiable. Data exclusivity cannot create an incentive to engage in clinical research that has already been conducted.
higher $\eta$ term does inevitably accomplish is to lower the annual royalty payments of each competitor, thereby reducing barriers to market entry. This is obvious from the inverted relationship of $\gamma$ to $\eta$ in Formula (b):

$$(\gamma)(\beta) = \frac{\theta}{\eta}, \text{ or } \gamma = \frac{\theta}{(\eta)(\beta)}$$

Finally, it should be noted that the model discussed in this Part addresses use of or reliance on drug marketing approval data by generic drug manufacturers; it neither requires nor prohibits the public disclosure of the data. That said, like the FIFRA model, the compensation obligation in the Readjustable Royalties Model applies to subsequent registrants alone, not to other users of the data. Noncommercial use of the data does not give rise to royalties for several reasons. First, such use does not give rise to a danger of unfair commercial use. Noncommercial uses may have many purposes, but, by definition, none of them involves marketing a product in competition with any other product. Noncommercial uses thus do not employ the data for the advantage of a competitor of the initial registrant. Second, such uses may be necessary for academic and consumer protection research that can check the possibility of biased or incomplete testing results by the health products industry and discover previously undetected dangers or problems with the drugs. This interpretation is consistent with the World Intellectual Property Organization’s Model Provisions on Protection Against Unfair Competition, which limit the definition of unfair competition in the context of marketing approval data to uses “in the course of industrial or commercial activities.” In the NAFTA model, the public disclosure of the data is pos

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205. Such data may be used to the disadvantage of the registrant, but this point is unrelated to the question of unfair commercial use. For example, if a consumer protection group discovered an undisclosed side effect of an approved drug, this discovery may well damage sales of that drug.

206. The WHO, along with numerous medical practitioners and nongovernmental organizations, has called for the free publication of clinical drug testing data to ensure accurate, complete, and unbiased information critical to promoting and protecting public health. See, e.g., Oxfam et al., supra note 187, at 22; Frank Davidoff et al., Sponsorship, Authorship and Accountability, 358 The Lancet 9285, 9285 (2001); Jonathan Quick, Maintaining the Integrity of the Clinical Evidence Base, 79 Bull. World Health Org. 1093 (2001).

207. WORLD INTELLECTUAL PROPERTY ORGANIZATION, MODEL PROVISIONS ON PROTECTION AGAINST UNFAIR COMPETITION art. 6(4) (1996). The full text of Article 6(4) reads:

(4) [Use or Disclosure of Secret Information Submitted for Procedure of Approval of Marketing] Any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in

(i) an unfair commercial use of secret test or other data, the origination of which involves considerable effort and which have been submitted to a competent authority for the purposes of obtaining approval of the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities, or

(ii) the disclosure of such data, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Id. It is interesting to note that, in July 2002, the following provision was added to Article 6 of the
sible without giving rise to a danger of unfair commercial use because commercial use of the data by companies other than the initial registrant is preempted during the exclusivity period. Under the Readjustable Royalties Model, the public disclosure of the data is possible without risking unfair commercial use because any commercial use is predicated on the payment of royalties that ipso facto make the commercial use fair. In light of the many advantages of public disclosure of the data, then, and the removal of the threat of unfair commercial use, such disclosure should accompany implementation of the Readjustable Royalties Model.

VI. Conclusions

The difficulty of reconciling the interpretation of Article 39.3 of the TRIPs Agreement mandated by an application of traditional canons of treaty interpretation with the treaty’s own negotiating history elucidates the unresolved rifts among WTO members over how far the treaty obligations should extend in requiring intellectual property protection for drug marketing approval data. Although the intent of the negotiators to require (or accept) the institution of trade secret protections is generally undoubted, it is also clear that differences remained over the extent to which WTO members would be obligated to treat drug marketing approval data as a fully protected trade secret of the submitter. In considering proposals to settle the issue, it is important to bear in mind that the primary purpose of trade secret law, international and otherwise, is to avoid creating disincentives to the creation and exploitation of valuable information and know-how. Yet, Article 39.3, like the WTO General Council decision on Implementation of Paragraph 6 of the Doha Declaration, is designed to prevent unnecessary barriers to access to necessary medicines in developing countries. An interpretation (or renegotiation) of Article 39.3 that preserves necessary trade secret protections without imposing unnecessary barriers to access to medicines should be welcomed by all WTO members, particularly if it is not administratively onerous and raises no ethical objections.

Each of the three approaches discussed in Part IV of this Article partially accomplishes these goals, but each equally has some highly undesirable characteristics. The Readjustable Royalties Model proposed in this Article suffers from none of the drawbacks of the other models and has several notable advantages. Unlike the NAFTA model and the European legislative scheme, the Readjustable Royalties Model does not confer an undesirable monopoly on registered drugs for any period of time, thereby facilitating competition in the drug market and, consequently, lowering drug prices. Such a result is especially desirable in developing-country markets, where objections to the interpretation of Article 39.3 of the TRIPs Agreement as requiring data

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exclusivity are strongest. The Readjustable Royalties Model also avoids the potential ethical objections to the NAFTA model and the European scheme, as there is no possibility of requiring competing drug manufacturers to undertake duplicative research beyond the necessary bioequivalence studies.

The Model proposed here also avoids both the uncertainty and the delay associated with the mandatory negotiation period and arbitration of the FIFRA model. Initial registrants of a drug have neither the incentive nor the capacity to engage in dilatory conduct to prevent licensing of their marketing approval data that would undermine a lucrative monopoly. Potential competitors, for their part, do not face the possibility of an arbitration that results in unpredictable or excessive licensing fees. Because the details of Formula (d) would either be fixed in an amendment or supplement to the TRIPs Agreement, or at least in the legislation of each WTO member, both the initial registrant and potential subsequent registrants have full prior knowledge of the cost of entering the market for any specific drug in any specific WTO member.

Finally, unlike the simple royalties model, the Readjustable Royalties Model does not impose high barriers to market entry or create labyrinthine administrative complications. Royalties are necessarily spread over a number of years, and new competitors can register for marketing approval without requiring retroactive adjustments in the royalties payable by each previously registered competitor. While some recalculation will be necessary each time a new drug manufacturer obtains marketing approval or leaves the market, the new royalty level always applies prospectively.

Beyond avoiding these weaknesses, the Readjustable Royalties Model offers several advantages. Most importantly, if structured and applied properly, it avoids both undercompensating and overcompensating the initial registrant. While the initial registrant begins with a de facto monopoly over the drug, the monopoly is not state-sponsored, but natural under the conditions of the market attributable to its properly protected trade secrets. Once a generic drug manufacturer develops the capacity to compete, the only impediments to its market entry are the normal conditions for drug manufacturing (e.g., approved facilities, a showing of bioequivalence to the previously registered drug, etc.). The compensation received by the initial registrant for the loss of its trade-secret-conferred monopoly is presumptively fair, because the initial registrant receives compensation that increases in direct proportion to the number of competitors it faces. Overcompensation is not possible because the Model is premised on the understanding that the total royalties paid can never exceed the real\textsuperscript{208} cost of developing the data.

A second advantage of the Readjustable Royalties Model is its flexibility. Formula (d) retains as variables: (1) the length of the royalties payment period ($\eta$); (2) the percentage of the initial registrant’s total costs payable by subsequent registrants ($\beta$, which is a function of $\eta$, $\beta$, and $\gamma$); and (3) the

\textsuperscript{208} The term “real,” as opposed to “nominal,” is used in the economic sense of accounting for the time value of money.
maximum number of subsequent registrants that must pay royalties ($\beta$). WTO members can adjust these variables to suppress unnecessary market barriers and can tailor Formula $[d]$ to their unique competitive market. For example, if wealthy Country X has a vibrant and sophisticated drug industry and a lucrative market, it might maintain a short royalty payment period (e.g., 5 years) with a high percentage for the first subsequent registrant (e.g., 10% of total costs per annum) and an unlimited number of potential registrants. Developing Country Y, on the other hand, which has a relatively poor populace and a small drug industry, might maintain a very long royalty payment period (e.g., 15 years) with a low percentage for the first subsequent registrant (e.g., 3.3% of total costs per annum) and a limited number of potential registrants (e.g., five). Such flexibility would allow wealthy WTO members to ensure that the mandatory trade secret license pays profitable but equitable returns to the initial registrant without tying up the liquid capital of small drug manufacturers in developing countries. It was the desire to retain precisely this kind of flexibility that prompted the negotiators of the TRIPs Agreement to reject a preconceived formula for avoiding unfair commercial use and to leave the language of Article 39.3 susceptible to multiple interpretations. Like Article 39.3, the Readjustable Royalties Model imposes no fixed time period for data exclusivity of any kind on WTO members unless the WTO members agree to a fixed period in a side agreement or amendment to the TRIPs Agreement. The Readjustable Royalties Model accomplishes the legitimate objectives of both economically developed and developing WTO members without disturbing that flexibility.

Finally, and not to be discounted, the model proposed in this Article is fully consistent with the terms of Article 39.3 of the TRIPs Agreement. To transform the model into an international standard, all that is required is a side agreement interpreting Article 39.3 to permit WTO members to use a version of Formula $[d]$ as a form of compulsory licensing of the initial registrant's marketing approval data. This approach accords with the requirement of treating the data as a trade secret of the initial registrant of which the state drug regulatory authority is a trustee rather than an owner. Most importantly, it also accords with the compromise worked out by the TRIPs Agreement negotiators, who sought to protect such data from unfair commercial use without conferring a naked right to data exclusivity. The Readjustable Royalties Model reflects this compromise while offering concrete guidance on an international standard for protecting against the unfair commercial use of drug marketing approval data.
Table of Terms

\( \alpha \) fixed base annual percentage to be paid by the first subsequent registrant

\( \beta \) total number of subsequent registrants marketing the drug that are required to pay royalties to the initial registrant

\( \gamma \) annual percentage of the initial registrant’s costs paid by each generic drug manufacturer

\( \kappa \) nominal interest payable on costs of developing marketing approval data

\( \eta \) maximum number of years after the initial marketing approval during which royalties must be paid

\( \eta_i \) number of years that have elapsed (beginning with “1”) since the subsequent registrant entered the market

\( \theta \) total percentage of the initial applicant’s costs that will be paid over \( \eta \) years

\( \chi_{\text{all}} \) cost basis in WTO members that rely upon drug marketing approval from the drug regulatory authority of another WTO member in which the initial registrant has already obtained such approval

\( \chi_{\text{non}} \) cost basis in WTO members that do not rely upon drug marketing approval from the drug regulatory authority of another WTO member

\( \mu \) aggregate annual drug spending (or GDP) of the WTO member of initial marketing approval

\( \nu \) cost to the initial registrant of obtaining marketing authorization in the WTO member of initial marketing approval

\( \sigma \) aggregate annual drug spending (or GDP) of the WTO member relying on a prior approval

\( \rho \) cost to the initial registrant of obtaining marketing authorization in a WTO member of subsequent approval