

**Undisclosed Clinical Trial Data
Under the TRIPS Agreement and Its Progeny:
A Broader Perspective**

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**UNDISCLOSED CLINICAL TRIAL DATA
UNDER THE TRIPS AGREEMENT AND ITS PROGENY:
A BROADER PERSPECTIVE***

I. INTRODUCTION

The United States and the European Union are seeking to obtain universal norms protecting the results of clinical trial data pertaining to new pharmaceutical products through bilateral and multilateral trade negotiations. These efforts, if successful, would confer a *de facto* exclusive right on clinical trial results as such, independent of other, existing intellectual property rights in the underlying products, especially patents. If developing countries agree to this new form of intellectual property protection, their rights to promote the production of generic drugs and low-priced medicines generally, as recently clarified in the Doha Ministerial Declaration on TRIPS and Public Health and a related implementing Decision, could become compromised by the new, exclusive rights in clinical testing data, which are not covered by those arrangements.¹

Restrictions on the use of such data could effectively empower rights holders to negate a state's ability to authorize marketing approval of equivalent drugs, for a period of from five to ten years, even when these rights holders could not invoke patents or other formal intellectual property rights to prevent use of the drugs as such. If developing countries reject clauses seeking to establish these new forms of protection for clinical trial results, they may not obtain advantageous trade concessions, especially in pending negotiations with the United States, and possibly in trade negotiations with the European Union.

In approaching this problem, it is important to understand the economic logic that underlies the drive to protect clinical trial results, even if one deplores the abusive means and ends to which it has been put in international trade negotiations. Recent studies show that the cost of clinical trials in the United States accounts for a disproportionately large share of the overall costs of bringing new drugs to market, which may cap out at some \$800,000 million to one million per approved drug.² While the accuracy of this figure may be disputed at the margins, it necessarily includes the cumulatively high costs of clinical trials incurred for the many drugs that fail to be approved.

Undisputed is the fact that, year after year the costs of conducting clinical trials outstrip the medical component of the consumer price index.³ Similarly, other studies show that, between 1977 and 1995, the burden of data production increased by 43 per cent in mean number of pages per new drug application (NDA), by 37 per cent in mean number of patients per NDA, and by 44

* Section IV of this paper ("Treating Clinical Trials as a Public Good: The Most Logical Reform") was written by Tracy Lewis, J.H. Reichman and Anthony So. Reproduced by permission of authors. All rights reserved.

¹ I understand that Professor Correa's paper will cover these issues in detail, so I omit further discussion here. See also Francisco Rossi, *Recent Bilateral and Regional Trade Agreements and TRIPS-Plus Provisions*, paper presented to the WHO-UNDP Expert Consultation on Compulsory Licenses after Doha, New York, N.Y., September 16-17, 2004.

² See Joseph A DiMasi et al, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECONOMICS 151-85 (2003).

³ *Id.*

per cent in mean number of clinical trials per NDA.⁴ In other words, the demand for global protection of clinical testing results rests on underlying concerns about free-riding uses of private sector R&D investments that must be taken into account when evaluating the social costs to developing countries of the various proposals adopted to address those concerns.

My thesis is that the drive to protect clinical trial data internationally is but the latest and most far-reaching consequence of the deep structural problems that flow from the failure to treat clinical trials as a national and international public good. So long as this market-distorting anomaly persists, clinical data as a guarantor of public safety will be under-supplied; the scientific benefits of such trials will be impeded; and the drive to keep secret the very data that logically require the highest degree of transparency will produce the rippling legislative distortions and high social costs that now take the form of pseudo-IPRs.

The long-term solution to this problem is to rationalize the pharmaceutical supply chain by treating clinical trials as a global public good under a system that apportions costs to all participants and guarantees open access to the resulting data. Short of that solution, the developing countries must necessarily grasp at makeweight legal and political maneuvers to counter the high-handed measures taken to protect clinical data in TRIPS-plus trade agreements. Above all, they must strive to preserve the integrity of the Doha Settlement and to minimize the social costs of any data protection regime they agree to adopt.

In Part II of this informal paper, I will discuss the meaning and limits of article 39.3 of the TRIPS Agreement, with reference to its legislative history and its collocation within article 10*bis* of the Paris Convention. This discussion will show that article 39.3 in itself imposes a relatively weak burden on developing countries.

In Part III, I will briefly discuss the possibility of counter-proposals to the de facto exclusive rights approach (currently on the table in free trade negotiations) that sound in a cost-sharing or liability rule approach. This compromise proposal would enable developing countries to address the free-rider problem identified above with fewer constraints on their public health programs than would arise under existing proposals.

In Part IV, I reproduce the latest draft of a new (and as yet unpublished) proposal by Lewis, Reichman and So for treating clinical trials as a public good.⁵ This longer run solution to a deep structural problem in national and international drug supply chains aims to rationalize the treatment of clinical trials from a political economic perspective and to eliminate both the risk of free riding on private sector R&D and the need for secrecy or de facto intellectual property protection of the resulting data.

⁴ Pierre Azoulay, *The Changing Economics of Clinical Development*, paper presented to the Earth Institute Conference, Columbia University, New York, NY, May 20, 2004.

⁵ Tracy Lewis, J. H. Reichman, Anthony So, *Treating Clinical Trials as a Public Good: The Most Logical Reform*, Draft paper dated 19 November 2004. Because this is an unpublished draft article, we make it available for discussion, but ask you not to post it on the net or otherwise disseminate it without permission of the authors. Cf. also Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 JOURNAL OF INTERNATIONAL ECONOMIC LAW (JIEL) 279-320 (2004).

II. THE MEANING AND LIMITS OF TRIPS ARTICLE 39.3

The protection of undisclosed information first entered regional international law in Article 1711 of the North American Free Trade Agreement of 1992 (NAFTA),⁶ and it was subsequently incorporated into the worldwide minimum standards of intellectual property law by Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement).⁷ Besides dealing with trade secrets in general,⁸ the relevant provisions of both NAFTA and TRIPS contain clauses that deal specifically with data submitted to governments for regulatory purposes.⁹ However, the differences between the approaches of these two treaties to regulatory data submissions is of capital importance in ascertaining both the meaning and the limits of TRIPS article 39.3, as will be more fully explained below.

A. Relation of TRIPS Article 39.3 to the Paris Convention

While the relevant NAFTA provisions begin by simply requiring the signatory states – Canada, Mexico, and the United States – to “provide the legal means for any person to prevent trade secrets from being disclosed.... in a manner contrary to honest commercial practices,”¹⁰ the drafters of TRIPS article 39 decided to locate this subject matter of protection within the broader framework of international norms prohibiting unfair competition, as set out in Article 10*bis* (1967) of the Paris Convention for the Protection of Industrial Property of 1883.¹¹ It follows that any specific obligations concerning pharmaceutical trial data that are set out in article 39.3 of the TRIPS Agreement must initially be interpreted in light of the duty to “ensure...effective protection against unfair competition” under article 10*bis*(1) of the Paris Convention.

The international minimum standards embodied in article 10*bis* of the Paris Convention have evolved slowly and with great difficulty owing to disparities in the treatment of unfair competition in the domestic laws of member states and to the lack of consensus about all but the most basic prescriptions implementing the “confusion” and “deception” rationales of general unfair competition law.¹² As Ladas observed in 1975, “the law of unfair competition, in contrast

⁶ See Article 1711 (“Trade Secrets”), North American Free Trade Agreement, 32 I.L.M. 298 (1993) and 32 I.L.M. 605 (1993).

⁷ Marrakech Agreement Establishing the World Trade Organization (“WTO Agreement”), Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”), 33 ILM 81 (1994), article 39.3.

⁸ Compare art. 39.1, 39.2 of TRIPS, *supra* note 7, with arts. 1711.1-17.4 of NAFTA, *supra* note 6.

⁹ Compare art 39.3 of TRIPS, *supra* note 7, with arts.1711.5-1711.7 of NAFTA, *supra* note 6.

¹⁰ Art. 1711.1, NAFTA, *supra* note 6.

¹¹ Paris Convention of 1883, as last revised at Paris 1967, article 10*bis*. This collocation apparently derives from an early Swiss position paper. See 2 THE GATT URUGUAY ROUND—A NEGOTIATING HISTORY (1986-1992) at 2307, 2307 nn. 429-430 (citing authorities) (T.P. Stewart, ed. 1993)[hereinafter STEWART]. It is mandated by the following language in Article 39.1 of the TRIPS Agreement: “In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention, Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.” TRIPS Agreement, *supra* note 7, art. 39.1.

¹² See generally 3 S. LADAS, Patents, Trademarks and Related Rights: National and International Protection 1675-79 (1975); see most recently Anselm Kamperman Sanders, Unfair Competition Law 6-77, 121-54 (advocating “new action of malign competition.” Restatement (Third) of Unfair Competition

to the patent, design, or trademark law, which because of their technical character, are more or less certain and have reached a stage of maturity, has been progressing slowly, and is still full of uncertainties. Neither its basis nor its boundaries are yet settled.”¹³ He added that the reluctance of states “to interfere with lawful competition made protection more difficult, the borderline between it and unfair competition being not always easy to trace.”¹⁴

Historically, these difficulties gave rise to the vague and general language of article 10*bis*(1), which entered the Paris Convention in the Brussels Act of 1900¹⁵ and provides “that countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.”¹⁶ While the dictionary meanings of “effective” are themselves vague and range from “having an effect; powerful in effect” to “actual, existing; actually usable,”¹⁷ one must invoke even these laconic definitions with extreme care owing to the historical uncertainty that has always attended this broad, general admonition. In this connection, later observers stressed “the extremely vague and general character of the undertaking ... and the entire lack of any detailed indications of the precise character of the frauds at which this is aimed...,”¹⁸ and the fact that there has been no subsequent consensus on the scope of this general obligation.¹⁹

A further effort at clarification was finally achieved at the Hague Conference in 1921, when a second general prescription was added to article 10*bis*, along with the first set of more detailed minimum standards.²⁰ The general prescription added in 1921, which appears in its present form as article 10*bis*(2), now states that “Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.”²¹ The circularity of this prescription was understood from the start because it begs the question of what acts are contrary to honest practices.²²

However, more detailed and specific obligations sounding in the confusion and deception rationales of general unfair competition law were also codified in article 10*bis*(3) at that time,²³ and these provisions were subsequently expanded to their present form in 1958, *viz.*:

(3) The following in particular shall be prohibited:

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;
false allegations in the course of trade of such a nature as to
discredit the establishment, the goods, or the industrial or

Law §§1, 38 (1995) (stressing “freedom to compete” and rejecting exclusive rights in intangible trade values).

¹³ 3 S. LADAS, *supra* note 12, at 1676.

¹⁴ *Id.*

¹⁵ *Id.* at 1678.

¹⁶ Paris Convention, *supra* note 11, art. 10*bis*(1).

¹⁷ The CONCISE OXFORD DICTIONARY (6th ed. 1976), 330.

¹⁸ See 3 LADAS, *supra* note 12, at 1680 (citing authorities).

¹⁹ *Id.*, at 1678-79.

²⁰ See 3 LADAS, *supra* note 12, at 1682.

²¹ Paris Convention, *supra* note 11, art. 10*bis*(2).

²² See 3 LADAS, *supra* note 12, at 1682-83.

²³ See *id.*, at 1682

commercial activities, of a competitor;
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.²⁴

The adoption and gradual evolution of these provisions made the function of article 10*bis*(2) clear. Basically, it ensured that any consensual norms rendered actionable by article 10*bis*(3) did not exhaust the potential field of action under article 10*bis*(2).²⁵ It also came to ensure that acts “contrary to honest practices” were understood to refer to “honest practices in international trade,” and not just to practices as viewed in local law.²⁶ Beyond these acquired understandings, however, the effective meaning of article 10*bis*(2) has been relegated to the specific implementing provisions of article 10*bis*(3). While these provisions are sufficiently detailed to be self-executing in countries where this option is constitutionally feasible,²⁷ they had never evolved beyond the version adopted in 1958, when the present version of Article 10*bis*(3) was added.

Gaining a further consensus on any additional specific stipulations thus proved “extremely difficult if not impossible.”²⁸ Ladas ascribes this lack of consensus to the different legal traditions in which unfair competition principles are rooted; to the different moral standards that apply in different countries, and the lack of any objective standard of “unfair competition;” to the different levels of competition (or degrees of competitive intensity) that actually prevail in different countries;²⁹ and perhaps above all, to the lack of any agreed standards for determining “where ... lawful competition end[s] and unlawful competition begin[s].”³⁰

It follows that any positive duty to avoid acts of competition that are contrary to honest usage³¹ are effectively circumscribed by the more detailed provisions of Paris Convention Article 10*bis*(3). In this light, the consensus that produced articles 39.2 and 39.3 of the TRIPS Agreement in 1994 may properly be viewed as having added two more mandatory prescriptions to the list already set out in article 10*bis*(3) of the Paris Convention (1967).

By the same token, there is no authority or legal basis for enlarging the specific prescriptions and obligations embodied in articles 39.2 and 39.3 of the TRIPS Agreement by referencing them to Articles 10*bis*(1) and 10*bis*(2) of the Paris Convention. In other words, the historical and legal logic of the Paris Convention mandates that the degree of “effectiveness” ascribable to the TRIPS provisions in article 39 depends entirely on the specific meaning of, and limits on, articles 39.2 and 39.3 themselves, and not on any residual authority, power, or meaning inherent in or emanating from articles 10*bis*(1) and 10*bis*(2) of the Paris Convention.

²⁴ Paris Convention, *supra* note 11, art 10*bis*(3) (1967 text). Article 10*bis*(2) was expanded at the London Conference of 1934, and the important provisions of art. 10*bis*(3) were expanded in 1958. *See* 3 LADAS, *supra* note 11, at 1683-85.

²⁵ *See* 3 LADAS, *supra* note 12, at 1682-83.

²⁶ *See* G.H.C. Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property As Revised at Stockholm in 1967, at 144.

²⁷ *See* BODENHAUSEN, *supra* note 26, at 143.

²⁸ *See* 3 LADAS, *supra* note 12, at 1685.

²⁹ *Id.* at 1688.

³⁰ *Id.* at 1688-89.

³¹ *Id.* at 1688.

B. Evolution of TRIPS Article 39.3

While doctrines forbidding the misappropriation of trade secrets, or related doctrines protecting confidential information, were well known in many different countries, there was no consensus on either the theory or the mode of protecting this subject matter at the international level before the advent of TRIPS article 39.3.³² The decision to incorporate the protection of undisclosed information into article 39.2 of the TRIPS Agreement thus broke the pre-existing stalemate, which had prevented further elaboration of Paris Convention article 10*bis*(3) after 1958. The mode of implementing this new consensus closely tracked the model law adopted in most state jurisdictions in the United States, *viz*, the Uniform Trade Secrets Act,³³ which lessened the immediate need for that country to enact a federal trade secrets law.³⁴ The TRIPS formulation also tracked some of the provisions on trade secrets that had been adopted in NAFTA, notably the provisions set out in article 1711(1).

Even here, however, the TRIPS Agreement did not simply incorporate the NAFTA provisions on trade secrets as a whole.³⁵ This selectivity shows that despite the widespread protection of undisclosed information in the domestic laws, which finally made a new consensus possible within the framework of Paris Convention article 10*bis* in 1994, the drafters of the TRIPS Agreement did not simply use the NAFTA Agreement as their model. *A fortiori*, a similar refusal to adopt the NAFTA provisions on regulatory data submitted to governments under article 39.3³⁶ carries even greater interpretative weight, given that test data as a topic at the international level is of comparatively recent vintage, and that it is necessarily one on which no international consensus had yet been formed.

There is no mention of undisclosed regulatory data in Ladas' discussion of comparative and international unfair competition law, which was published in 1975.³⁷ Concerns about preserving

³² Cf. 3 LADAS, *supra* note 12, at 1616-19 (discussing international protection of know-how). One should recall, moreover, that no consensus on any general doctrines of "misappropriation," "slavish imitation," or "parasitical copying" (as distinct from "passing off") had been formed at the international level, and for that reason, one cannot read such doctrines into article 10*bis* of the Paris Convention. Had it been otherwise, indeed, article 10*bis* of the Paris Conventions as it stood in the 1980s might already have provided "effective protection" against wholesale copying of the products of investment in high-tech goods, in which case the multilateral negotiations of the Uruguay Round that produced the TRIPS Agreement might have been superfluous. See generally J.H.Reichman, *Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection*, 22 VAND. J. TRANSNAT'L L. 747, 769-95 (1989).

³³ See 2 STEWART, *supra* note 11; J. H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE—THE TRIPS AGREEMENT, 21, 64-66 (C.M. Correa & A.A. Yusuf eds., 1998).

³⁴ *Id.*

³⁵ On the contrary, TRIPS article 39.2 makes no reference to three additional NAFTA provisions beyond article 1711(1) that 1) require protectable trade secrets to be evidenced in a physical support (article 1711.2); 2) prohibit limits on the duration of trade secret protection (1711.3); and that 3) discourage the voluntary licensing of trade secrets "by imposing excessive or discriminatory conditions" (article 1711.4). Compare TRIPS Agreement, *supra* note 7, art 39.2 with NAFTA, *supra* note 6, arts 1711.2-1711.4.

³⁶ Compare TRIPS Agreement, *supra*, note 7, art. 39.3 with NAFTA, *supra* note 6, arts., 1711.5 and 1711.6.

³⁷ See generally 3 S. LADAS, *supra* note 12, 1675-1744.

the confidentiality of regulatory data have surfaced only in the last twenty-five years.³⁸ Since 1982, the United States has adopted provisions to protect regulatory data submitted to federal agencies in connection with pesticides.³⁹ Since 1984, the United States also adopted regulatory exclusivity provisions for clinical trial data, which reportedly “provide a *de facto* measure of regulatory data protection and which now provide five years [of] such protection for new chemical entities and three years for data filed in support of... chemical entities which have already been approved for use in medicines but [for] which fresh authorizations are [to be] based on new clinical investigations.”⁴⁰

Since 1987, the European Community members have provided protection for data filed in support of marketing authorizations for pharmaceuticals, which can last from six to ten years, and this form of protection has subsequently been extended to other product areas at the European level.⁴¹ Analogous forms of protection have been enacted in Australia and New Zealand since the TRIPS Agreement entered into force.⁴²

United States practice reportedly underlies the three provisions set out in Article 1711 of NAFTA, which deal explicitly with regulatory data, *viz*, articles 1711.5, 1711.6 and 1711.7.⁴³ These provisions are set out below:

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

³⁸ See, e.g., Trevor M. Cook, *The Protection of Regulatory Data in Pharmaceutical and Other Sectors*, at Preface (2000).

³⁹ See TREVOR COOK, *supra* note 38, at 7, 4-01 *et seq.*; Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) 7 U.S.C. §§136-136(y).

⁴⁰ See TREVOR COOK, *supra* note 38, at 4-01 *et seq.*

⁴¹ *Id.* at 7; see generally *id.* at 3-01 *et seq.*

⁴² *Id.* at 6; see generally *id.* at 5-01 *et seq.* See further Carlos M. Correa (South Center monograph).

⁴³ See TREVOR COOK, *supra* note 38, at 7.

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.

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.⁴⁴

Logically, the United States sought to include analogous provisions into the TRIPS Agreement. Position papers submitted by both the United States and Switzerland in the late 1980s advocated the imposition of express limiting conditions on the release of proprietary information submitted to governments for regulatory purposes.⁴⁵ In particular, the U.S. draft proposed the following language:

Contracting parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right-holder except with the right-holders consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given the right-holder.⁴⁶

In contrast, the European Commission “favored less limiting conditions” and did not specifically address governmental functions.⁴⁷

These proposals, however, met with strenuous resistance from the outset, and this conflict appeared in the Brussels Draft TRIPS Agreement of 1990.⁴⁸ While Article 1A of this version essentially anticipates article 39.1 as adopted in 1994, Article 4A contains a bracketed provision that marks off the U.S. (and E.U.) positions from that of other countries opposed to this new form of protection for regulatory data. This proposed provision is reproduced below:

4A. PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In

⁴⁴ NAFTA, *supra* note 6, 1711.5-1711.7.

⁴⁵ See 2 STEWART, *supra* note 11, at 2307-08; *id.* at 2307 nn. 432-433 (citing Switzerland and U.S. Draft Texts in late 1980s).

⁴⁶ See 2 STEWART, *supra* note 11, 2307, *quoting* U.S. Draft Text, art. 33 (late 1980s).

⁴⁷ See *id.*, at 2307 (citing EC Draft Text, art. 28(b) (late 1980s)).

⁴⁸ Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Brussels, Belgium, 26 November 1990 [hereinafter Brussels Draft TRIPS Agreement 1990], art 42[A], reproduced in 2 STEWART, *supra* note 11, at 260, 278-79.

addition, PARTIES shall] protect such data against disclosure,
except where necessary to protect the public.⁴⁹

This proposal applied the regulatory data provision to cover approval of “new pharmaceutical products or of a new agricultural chemical product.” In addition, the bracketed provision essentially required “protection against unfair commercial use and disclosure, as well as nonuse of the information for the approval of competing products, for no less than five years, unless the person submitting the information agrees.”⁵⁰

One year later, article 39.3 of the Chairman’s Draft Final Act of 20 December 1991, known as the “Dunkel Draft of 1991,” which became the influential compromise draft largely adopted in the end, had discarded the bracketed text altogether.⁵¹ This draft version is reproduced below:

3. PARTIES, 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, PARTIES 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.⁵²

As one can easily verify for oneself, article 39.3 of the Dunkel Draft 1991 tracks the final version of article 39.3 as adopted in 1994 word for word. The sole exception is that the term “Parties” used in 1991 was changed to “Members” in 1994.⁵³

It follows that, whatever else article 39.3 means in its expurgated or decapitated final form, it cannot possibly mean what it would have meant had the bracketed obligations of the Brussels Draft of 1990 been carried over into either the Dunkel Draft or the Final Act of 1994. To ignore the clear evolution of the text in favor of quasi-exclusive rights in regulatory data, in a form that was proposed but ultimately excised from the Final Act, would in effect amount to imposing unbargained-for trade concessions under a discredited “TRIPS plus approach” that has no legal foundation whatsoever. It would thus place so-called “legitimate expectations about the conditions of competition” as derived from powerful countries’ negotiating positions above the “rule of law” embodied in the text.

Such an interpretation would violate both article 31 of the Vienna Convention on the Law of Treaties⁵⁴ and the clear teaching of the Appellate Body in the *India Mail Box Case*.⁵⁵ In reversing

⁴⁹ Id.

⁵⁰ See 2 STEWART, *supra* note 11, at 2308.

⁵¹ Id.

⁵² Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 20 December 1991 [hereinafter “Dunkel Draft”], art 39.3, reproduced in 2 STEWART, *supra* note 11, at 869.

⁵³ Compare Dunkel Draft 1991, *supra* note 52, art 39.3 with Brussels Draft 1990, *supra* note 48, art 42[A]. See also, 3 STEWART, *supra* note 11, at (noting only small number of changes to Dunkel Draft in Final Act).

⁵⁴ See Vienna Convention on the Law of Treaties, arts. 31-32.

the panel's reliance on just such a test in that case, and in vindicating a strict textual construction of the TRIPS Agreement consistent with Vienna Convention article 31, the Appellate Body stressed the importance of both article 19 of the Understanding on the Settlement of Disputes (DSU) and article 1.1 of the TRIPS Agreement.⁵⁶ The former provides that a WTO Panel "cannot add to or subtract from the covered obligations,"⁵⁷ while the latter provision states that "members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."⁵⁸

C. Meaning and Limits of Article 39.3

With the deletion of the bracketed version of the Brussels Final Draft of 1990 from both the Dunkel Draft of 1991 and the Final Act of 1994, there is no room for any interpretation that would graft a *de facto* exclusive property right onto the scheme of protection for regulatory data that article 39.3 actually mandates in its final form. Instead, WTO Members, when requiring the submission of undisclosed tests or other data as a condition of approving the marketing of pharmaceutical or agrochemical products that utilize new chemical entities, must take positive action to protect such data against "unfair commercial use." There is also an independent obligation to protect such data against "disclosure, except where necessary to protect the public;" but the text goes on to recognize that the steps taken to prevent "unfair commercial use" would normally encompass and discharge the duty to protect such data against "disclosure."⁵⁹

In ascertaining the meaning of this provision, the first observation is that members are under no duty to "require...the submission of undisclosed test or other data." If a state foregoes such a requirement, as by relying upon the health and safety decisions of other jurisdictions, or on the published medical literature, or a combination of both, it arguably incurs no liability whatsoever under article 39.3.

When a state does require the relevant submission of undisclosed data, it remains free to make noncommercial uses of the data and to make any other uses of them that are "fair," even if such uses produce a commercial impact. A legitimate noncommercial use would presumably encompass use by various government departments to avoid any health or safety risks revealed by the data in the local environment. Similarly, the promotion of research and science in the public interest would presumably allow some uses of the data that would be both noncommercial and fair, consistent with any research exemption embodied in the domestic patent laws.

The relevant dictionary meaning of "fair" as "just, unbiased, equitable, legitimate, [or] in accordance with rules,"⁶⁰ clarifies little in the context of article 39.3. On its face, the provision requiring fairness is clear only at the extremes. At one pole, "disclosure" is clearly included within the concept of measures to prevent unfair commercial use. Hence, states requiring the submission of clinical trial data must take steps not to disclose the contents of these submissions

⁵⁵ India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, WTO Appellate Body, WT/D550/AB/R, December 19, 1997 (97-5539), reversing in part and affirming in part WTO Panel Report.

⁵⁶ India-Patent Protection, above n. 55 at 13; *see also* Jerome H. Reichman, *Securing Compliance with the TRIPS Agreement After U.S. v. India*, __ JIEL 585, 592-97 (1998).

⁵⁷ DSU, [cite], art. 19.

⁵⁸ TRIPS Agreement, *supra* note 7, art. 1.1; *India-Patent Protection*, *supra* note 55, at 16.

⁵⁹ TRIPS Agreement, *supra* note 7, art. 39.3.

⁶⁰ The Concise Oxford Dictionary (6th ed. 1976), at 372.

to unauthorized third parties. At the opposite pole, however, the duty to prevent “unfair commercial use” imposes a conduct based liability rule, but not an exclusive property right requiring non-use of the data or of the health and safety conclusions to which they lead. Otherwise the deletion of the proposals embodied in the Brussels Draft TRIPS Agreement of 1990 would be ignored.

Between these two extremes, the meaning of “unfair commercial use” will depend on the kind of practices that domestic and foreign trade secret laws have traditionally regarded as unfair. This follows from the fact that the drafters of article 39.3 expressly linked it to article 10*bis* of the Paris Convention and thus to the duty it imposes to avoid any “act of competition contrary to honest practices in industrial or commercial matters.”⁶¹

Many possible scenarios can be envisioned in this context.⁶² For example, a government agency could not disclose the data to a competing local firm, so as to give them commercially advantageous know-how, without violating both the express anti-disclosure provision and the rule against unfair use. Nor could a government agency facilitate a third party’s ability to access or otherwise make use of the data by means that fell short of outright disclosure. By the same token, a government agency could not itself exploit the commercial advantages that knowledge of the confidential test data conferred in order to become a commercial rival of the submitting firm.⁶³ Similarly, if government employees having access to the data submitted were subsequently to make use of the commercially valuable know-how it conveyed, that use would presumably be unfair. These examples merely illustrate types of unfair use that a comparative analysis of trade secret laws would reveal.

At the same time, governments that merely cross-reference the conclusions reached on the basis of data submitted elsewhere, or that allow competitive production of bioequivalent products for local consumption once marketing approval has been granted, will arguably not have committed any actionable “unfair commercial use” of regulatory data submitted by any firm, domestic or foreign, within the purview of article 39.3. In such cases, it is not the confidential data themselves that are being unfairly used, even if a first comer is compelled to submit them in order to meet health and safety requirements. It is the health and safety outcome to which the data lead that is being used, i.e., a matter of public record,⁶⁴ and it is the need to promote and ensure competition in the local marketplace that makes such use both “fair” and obligatory.⁶⁵

The proposition that it is not an unfair use of regulatory data to allow others to compete by means of equivalent products (once the local authorities become satisfied that such products satisfy applicable health and safety requirements) was upheld by two important tribunals operating, respectively, under the domestic laws of the United States and Canada. In 1984, the United States Supreme Court observed that the filing of confidential data prior to Congressional decisions to confer special protection upon such data could not be construed as conferring any assurance against internal agency use during the consideration of the application of a subsequent firm for registration.⁶⁶ The reluctance of the U.S. Supreme Court in this case to impose an

⁶¹ Paris Convention, *supra* note 11, art. 10*bis*(2).

⁶² For more details, see Carlos Correa [South Center Publication].

⁶³ See, e.g., Christopher Arup, *The New World Trade Organization* 199 (2000).

⁶⁴ See, e.g., *Bayer, Inc. v. Canada (Attorney General)*, 1999 F.C.A.D.J. 142.

⁶⁵ Cf. e.g., *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1019-20 (1984). See further Carlos Correa [South Center], above n. 62.

⁶⁶ *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1019-20 (1984).

unqualified restriction on the use of data filed with regulatory authorities⁶⁷ was expressly conditioned on the need to sustain competition in unpatented products.⁶⁸

A similar decision was reached in the case of *Bayer Inc. v. Canada*, in which the Canadian Federal Court of Appeal construed Canadian law in light of article 1711 of NAFTA, to determine if Canada was barred from approving a competitor's generic drug without at least five years of protection from competition when that competitor based his application for marketing approval on a comparison with the innovator's own product.⁶⁹ The court held that the safety and effectiveness of the generic product could be demonstrated by showing that the competitor's product was the pharmaceutical and bio-equivalent of the innovator's product, which was being publicly marketed. Because the Minister need not rely on the confidential information as such in that event, the minimum five-year market protection otherwise available under domestic regulations did not apply.⁷⁰

By the same token, the Court held that articles 1711.5 and 1711.6 of NAFTA did not require a different outcome so long as the generic manufacturer was able "to establish the safety and effectiveness of its product on the basis of bio-equivalence or bio-availability studies without the Minister having to examine and rely on confidential data filed by the innovator."⁷¹ Such a demonstration was not an "unfair commercial use" within the purview of either the Canadian regulation or article 1711, which "do not provide or require that the innovator be protected from competition."⁷²

The decision of the Canadian Court of Appeal is all the more compelling in that it was taken in the face of the NAFTA regime, which, as previously observed, is much stronger than the regime ultimately adopted in article 39.3 of the TRIPS Agreement. The latter regime, which reflected a decision to delete provisions analogous to those in articles 1711.5 and 1711.6 of NAFTA, would mandate a similar conclusion, even if the Canadian court were to have misconstrued the NAFTA provisions applicable in that case.

D. Conclusions and Recommendations

1. Any obligations that TRIPS Article 39.3 add to Paris Convention article 10*bis*(3) constitute a further specification of the general obligations set out in articles 10*bis*(1) and 10*bis*(2). However, the latter articles do not enlarge the boundaries of the specific obligations codified in article 39.3 of the TRIPS Agreement.
2. Although it was logical for the United States to seek provisions based on NAFTA during the TRIPS negotiations, which would have conferred a *de facto* exclusive right on certain regulatory data, these provisions were excised from the Dunkel Draft in 1991 and never restored to the Final Act of 1994. Among the proposed provisions thus excised was a requirement of "nonuse of the information for the approval of competing products," which appeared in the Brussels Draft Final Act of 1990 but was deleted from the Dunkel

⁶⁷ See TREVOR COOK, *supra* note 38, at 5.

⁶⁸ See *Ruckelshaus v. Monsanto Co.*, 467 U.S. at ____.

⁶⁹ *Bayer, Inc. v. Canada (Attorney General)*, 1999 F.C.A.D.J. 142 (FCA, 1999).

⁷⁰ *Bayer v. Canada*, at 8-10.

⁷¹ *Id.* at 15.

⁷² *Id.* at 16.

- Draft of 1991. WTO panels lack any authority to restore the deleted provisions by interpretation, because that would violate articles 31-32 of the Vienna Convention on the Law of Treaties, article 19 of the DSU, and article 1.1 of the TRIPS Agreement.
3. The meaning of “unfair commercial use” will depend on the kind of practices that domestic and foreign trade secret laws have traditionally regarded as unfair. For example, governments should not set themselves up as commercial rivals who benefit from the submission of regulatory data; they must impede state employees from doing the same; and they must impede citizens from gaining access to confidential regulatory data by devious means.
 4. However, article 39.3 of the TRIPS Agreement does not prevent governments from relying on decisions to allow the production of relevant products in other jurisdictions nor does it prevent members from authorizing the manufacture of bioequivalent products on the basis of positive regulatory decisions by local authorities. Legislative history, competition policy, and sound principles of treaty interpretation support this conclusion, as do important decisions in two domestic courts.

III. A COMPENSATORY LIABILITY OPTION

It was predictable that the United States would seek to obtain the principles it had failed to embody in the Dunkel Draft of the TRIPS Agreement, as well as those embodied in the NAFTA text, in the course of posterior multilateral and bilateral free trade agreements that it has lately been negotiating with developing countries.⁷³ The logical starting point was the Brussels Draft of 1990. It would have imposed a *de facto* exclusive right to clinical trial data for five years; and it sought to prohibit governments or third parties from *relying* upon such data “for the approval of competing products.”⁷⁴ Also logical was a provision comparable to article 17.7 of NAFTA, which re-emphasized “the period of exclusive use.”⁷⁵

As Professor Correa’s paper will undoubtedly show, U.S.T.R.’s position on this issue has hardened over time. Language in the free trade agreements thus tends to undermine concessions that developing countries obtained under the Doha Ministerial Declaration on TRIPS and Public Health and the Supplementary Implementing Decision of August 30, 2003. I will not delve into these issues in this paper.

A. Reevaluating an Early U.S. Position

Largely overlooked in ongoing free trade negotiations, however, was the somewhat softer position on regulatory test data that the U.S. had put forward in the later 1980s. That version required non-use of trade secrets “submitted to carry out governmental functions” or for

⁷³ See, e.g., Francisco Rossi, *Recent Bilateral and Regional Trade Agreements and TRIPS-Plus Provisions*, Draft Paper presented to the WTO-UNDP Expert Consultation Meeting, New York, N.Y., 16-17 September 2004.

⁷⁴ See *supra* notes 45-46 and accompanying text (quoting U.S. Draft Text, art. 35).

⁷⁵ See *supra* notes 44, 49 and accompanying text.

“commercial or competitive benefit” of either the government or third parties “except with the right-holders consent, *on payment of the reasonable value of use*” or if a reasonable period of exclusive use is given the right holder.⁷⁶ While this language seems deliberately ambiguous, it suggests that payment of compensation could become a trigger for consent unless a period of exclusivity was expressly provided. In other words, the initial U.S. position appeared willing to consider a cost-sharing or “liability rule” approach, based on compensation, as an alternative to the exclusive property right approach embodied in NAFTA, which would have been consistent with some pre-existing American practice, as explained below.

As many participants in this Conference know, a cost-sharing approach is also consistent with my published proposals for a “compensatory liability regime” as a possible alternative to over-extending the patent system and multiplying hybrid regimes of exclusive intellectual property rights. Built around “take and pay” liability rules for value-adding uses of innovation, this approach could enable developing countries to stimulate local innovation at lower social costs than under existing intellectual property regimes, and to address particularly hard problems in the field of intellectual property rights, such as the legal protection of traditional knowledge and databases.⁷⁷

If this approach were applied to clinical trials, it would at the very least allow governments and third parties to rely on both test data and positive regulatory outcomes for purposes of authorizing the marketing of equivalent or competing products otherwise permitted under international intellectual property law, provided that the second comers paid a reasonable royalty to the data originators to help defray their costs of R&D. The same principles could also be used to create a secondary market for products that failed the clinical testing process, with a view to allowing improvers to overcome the resulting investigational obstacles and find new uses for such products in return for payment of compensatory royalties to originators.⁷⁸

In either case, use of “compensatory liability” principles would overcome any residual free-rider problem, mentioned in the Introduction, that arises from the enormous costs of conducting clinical trials for new pharmaceutical products under existing FDA standards. At the same time, such an approach would not create barriers to entry or other anticompetitive effects flowing from the inability of local governments to implement flexibilities available under the TRIPS Agreement owing to TRIPS-plus exclusive rights in regulatory data.

B. Implementing a Cost-Sharing Approach

I have heard reports that Jamie Love had found U.S.T.R. open to suggestions to explore a cost-sharing approach, which would be consistent with their previous position. Moreover, U.S. law already establishes a version of the cost-sharing approach for agricultural chemical registration,

⁷⁶ See *supra* note 46 and accompanying text (emphasis supplied).

⁷⁷ See, e.g., J. H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VANDERBILT L. REV. 1743 (2000); J. H. Reichman & Tracy Lewis, *Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (K. E. Maskus & J. H. Reichman eds, Cambridge Univ. Press, forthcoming 2005). See generally J. H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUMB. L. REV. 2432 (1994).

⁷⁸ See Tracy Lewis, J. H. Reichman, and Anthony So, *Treating Clinical Trials as a Public Good: The Most Logical Reform* (Draft article reproduced in Part IV of this paper).

under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).⁷⁹ Under this regime, “[a]fter the expiration of an exclusivity period, generic entrants have an automatic right to use registration data. Disputes over compensation will not delay generic entrance, and are resolved while generic firms are on the market.”⁸⁰

Consistent with these premises, Robert Weissman has recently drafted language to implement the “cost-sharing approach.” Its provisions are intended to give “generic firms an automatic right to use originators’ data, but requires them to pay a share of the documented costs of generating the data, proportionate to the size of the markets in which they are selling their product.”⁸¹ His proposals deny compensation for use of data pertaining to products covered by patents; and they impose an upper limit on the multiple of actual costs that originators may recoup.⁸² Weissman also acknowledges that U.S. arbitrators are willing to consider a “risk premium” to reflect the cost of testing that results in unapproved products.⁸³

However, no cost-sharing proposals appear in the draft Free Trade Agreements that I have seen, nor is there evidence that developing countries have put such proposals forward. On the contrary, there is strong resistance to any such compromise accommodation, as Prof. Correa has explained in other forums. For one thing, acceptance of a cost-sharing approach would diminish the victory achieved in obtaining the so-called “misappropriation approach” embodied in article 39.3 of the TRIPS Agreement as it stands, which my foregoing analysis suggests lacks teeth. Other objections are that brand name companies already obtain enough compensation from the patent system generally and that, in developing countries, “the consumer interest in low-priced medicines outweighs the brand-name company claim to compensation for generating data.”⁸⁴

In my view, these arguments are unpersuasive for at least two reasons. First, resistance to the exclusive rights approach has so far failed completely, and central governments that are eager to sign Free Trade Agreements thus find themselves saddled with ever harsher exclusive rights clauses without even attempting to fall back on counter proposals sounding in compensatory liability principles. Second, developing country negotiators may underestimate the aggregate weight that clinical trial costs actually have on the pharmaceutical supply chain in the United States, and they tend to ignore the huge “risk premium” built into the pricing of medicines in that country owing to the high costs of trials that result in denials of market approval.

In other words, the United States drug supply system irrationally saddles pharmaceutical companies with the costs of providing a pure public good in the form of clinical trials.⁸⁵ As a result, that public good will be inherently undersupplied; while foreign firms and governments

⁷⁹ See 7 U.S.C. §§136-136(y), at §136a(c)(2)(B), which states: “[T]he [EPA] administrator, without the permission of the original data submitter, [may] consider any such item of data [cited] in support of an application by another person ... if the applicant has made an offer to compensate the original data submitter ... the terms and amount of compensation may be fixed by an agreement between the original data submitter and the applicant or, failing such an agreement, binding arbitration.”

⁸⁰ Robert Weissman, *Data Protection: Options for Implementation*, paper presented to the WHO-UNDP Expert Consultation, New York, N.Y. 16-17 September 2004, at p. 10

⁸¹ *Id.* at ____.

⁸² *Id.* at 14.

⁸³ *Id.* at 13. See *infra* Part IV, stressing the crucial role of “risk premiums” in current pharmaceutical pricing practices.

⁸⁴ Robert Weissman, above n. 80, at 15.

⁸⁵ See Lewis, Reichman & So, above n. 78 (reproduced *infra*, Part IV).

that rely on these artificially scarce and costly test results without contributing to their costs will be stigmatized as “free riders” on American consumers (who already pay for huge investments in basic research through taxes as well as defraying the risk premiums inherent in clinical trials).

I and my co-authors, Tracy Lewis and Anthony So, contend that the long-term solution to this problem resides in treating clinical trials of new pharmaceutical products as a global public good (GPG),⁸⁶ rather than as a private sector obligation whose results and outcomes must necessarily be rendered artificially scarce in order to appropriate returns from investment. Our views are reproduced verbatim, for purposes of discussion, in Part IV of this paper. Note, however, that if we are right, and clinical trials were properly viewed and treated as a GPG, it would still be necessary for governments around the world who participated in such a scheme to contribute a fair share to the aggregate costs of clinical trials, adjusted for relative capacities to pay and for per capita GDP. Otherwise, the free-rider problem would simply shift from the private to the public sector without additional relief for U.S. consumers.

In the meanwhile, I submit that a continued failure to embrace the compensatory liability approach will result in the uniform imposition of the exclusive rights approach currently endorsed by the United States and the European Union, with irrevocable harm to local strategies seeking access to essential medicines by means available under the Doha settlement. As Weissman argues, developing countries “are finding that the misappropriation approach is not a viable negotiating posture” despite its solid grounding in the TRIPS text and legislative history. “By contrast, the cost-sharing approach can give developing countries something to offer that may undercut demands for data exclusivity by addressing the underlying basis for any claims to reward to brand name companies for conducting clinical tests.”⁸⁷

Finally, developing country negotiators must give more thought to the impact of data protection provisions on other flexibilities in the TRIPS Agreement, especially under the exclusive rights approach, and they should build countervailing safeguards into the relevant Free Trade Agreements. While I defer these considerations to Prof. Correa, it does seem to me that any government that feels it must accept the pseudo exclusive rights approach should at least insist on a pseudo-compulsory license or waiver to deal with emergencies and hardship situations. Consider, for example, the following language:

If either of the Parties deems that earlier delivery of a generic product has become important for the public interest, including reasons of public health, it may authorize a waiver of the five-year waiting period on condition that reasonable compensation be paid as a form of cost-sharing for early reliance on the clinical trial data in question, assuming that such use falls within the purview of all the provisions governing unfair use in this Part of the Agreement. Such reasonable compensation, to be paid only for the period waived, and no longer than five years, may be based on a reasonable royalty in favor of the firm or entity that originated the data in question. In case of dispute, the quantum of reasonable royalties shall be decided by resort to internationally recognized arbitral procedures.

C. Conclusions and Recommendations

Developing countries negotiating Free Trade Agreements with the United States (and the

⁸⁶ *Id.* Cf. also Maskus & Reichman, *Privatization of GPG*, above n. 5.

⁸⁷ Robert Weissman, above n. 80, at 15-16.

European Union) are unlikely to avoid pressures for TRIPS-plus protection of clinical trial data pertaining to new pharmaceutical products. The soaring costs of clinical trials in the U.S., and the high risk premium deriving from the aggregate costs of both successful and unsuccessful trials, elicit irresistible pressure on U.S.T.R. by the pharmaceutical industry and subject non-protecting countries to charges of free-riding rather than fair following. Governments eager to sign trade agreements are unlikely to resist these demands, and each treaty that affords protection makes it harder for other countries, even those not involved directly in FTAs, to resist similar pressures.

However, developing countries could and should resist the imposition of exclusive rights in clinical trial data by the back door, which gives the pharmaceutical companies another monopolistic and socially costly remedy—over and above patents—that is altogether disproportionate to the underlying economic problems at issue. Rather, developing countries should unite behind proposals for a cost-sharing solution, built on liability rules, that would address the free-rider problem without creating barriers to entry or otherwise interfering with public health programs undertaken within the framework of the Doha Ministerial Declaration on TRIPS and Public Health.

A compensatory model would be consistent with both earlier U.S. proposals and U.S. practice with regard to agricultural chemical products. If developing countries endorsed this counter proposal and refused to adopt the exclusive rights approach on grounds that it was inconsistent with TRIPS and contrary to their rights under the Doha Ministerial Declaration on TRIPS and Public Health, they would find themselves in a very strong legal position. If pressures for exclusive rights did not abate in response, these countries should be prepared to bring the matter before the Council for TRIPS and even to initiate dispute settlement action, and they should refuse to cooperate further on trade initiatives of interest to developed countries until the demand for exclusive rights was withdrawn.

Developing countries should give careful consideration to proposals for treating clinical trials as a global public good, to be discussed in part IV. These proposals would alleviate the free-rider problem and help to rationalize the pharmaceutical supply chain within the broader context of an incipient transnational system of innovation.

IV. CONCLUSIONS AND RECOMMENDATIONS

1. If developing countries favorably considered proposals to treat clinical trials of pharmaceuticals as a global public good, their willingness to publicly support the costs of such trials wherever they took place, on a capacity to pay basis, would counter the pressures for secrecy and help to make clinical trial results available worldwide for follow-on research and development. It would also lead to economies of scale and scope that should gradually reduce the costs of clinical trials worldwide; and it could exert a powerful downwards pressure on the prices of medicines, which currently express a high risk premium to cover the soaring costs of privately funded clinical trials in developed countries.
2. To the extent that funding for clinical trials of new pharmaceutical products became a global public sector responsibility, it would produce at least three additional benefits. First, by sharing clinical trial data under the open access norms of science,

the costs of redundant investigations will be squeezed out of the global public health system. Second, pressures to force developing countries to confer exclusive intellectual property rights in clinical trial data as such would give way to a system in which lower supply costs (and equitable contributions to the global costs of clinical testing) made patented drugs and other essential medicines universally more affordable.

3. Third, as the costs of certifying candidate drugs for market consumption became lower, the incentives to invest in research to discover new drugs should increase, and the barriers to entry should correspondingly be reduced. Any transnational lowering of entry barriers achieved by treating clinical trials as a global public good should accordingly intensify the incentive effects of existing international standards of intellectual property protection and make it more feasible for small and medium-sized firms to compete in the global market on the basis of research-driven drug initiatives.
4. Global public benefits could be further enhanced if the results of failed or negative clinical testing were made available for improvements under compensatory liability principles. Rather than just shelving products that failed clinical testing or that otherwise promised insufficient returns, reliance on such a regime could enable companies everywhere to build on cumulative and sequential innovation in the pharmaceutical sector while sharing in both the results of clinical trials and the costs of R&D.