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Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach. Law: From Private to Public Good?

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THE ELEVENTH ANNUAL HONORABLE
HELEN WILSON NIES MEMORIAL
LECTURE IN INTELLECTUAL PROPERTY

RETHINKING THE ROLE OF CLINICAL
TRIAL DATA IN INTERNATIONAL
INTELLECTUAL PROPERTY LAW: THE
CASE FOR A PUBLIC GOODS APPROACH

JEROME H. REICHMAN*

INTRODUCTION	3
I. EXPORTING CLINICAL TRIAL DATA EXCLUSIVITY REGIMES FROM DEVELOPED TO DEVELOPING COUNTRIES	9
A. <i>The Egregiously High Costs and Risks of Clinical Trials</i>	9
B. <i>The Domestic Response</i>	11
C. <i>The Drive for Global Protection of Clinical Trial Data</i>	14
1. From NAFTA (1992) to TRIPS (1994)	15
a. <i>The NAFTA Provisions</i>	15
b. <i>The Softer TRIPS Provisions</i>	17
2. The Posterior Free Trade Agreements.....	22
a. <i>Expanding Protection for Clinical Trial Data in Developing Countries</i>	23
b. <i>Recent Constraints on USTR's Negotiating Mandate</i>	28
D. <i>A Missed Opportunity: The Cost-Sharing Alternative</i>	29

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2 MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW [Vol. 13:1

1. An Early U.S. Proposal Envisioned a Liability Rule	30
2. Implementing a Compensatory Liability Regime	32
II. RETHINKING THE ROLE OF CLINICAL TRIAL DATA	
REGIMES.....	36
A. <i>The Flawed Logic of Marketing Exclusivity</i>	36
1. Evaluating the Incentive Rationale.....	36
2. Why a <i>Sui Generis</i> Exclusive Property Right?.....	42
B. <i>From Private to Public Goods: The Most Logical Reform</i>	48
1. Public Disclosure: Only the First Step in a Broader Reform.....	49
2. The Case for Treating Clinical Trials as a Public Good	51
a. <i>The Drug Companies' Costs Would Decline with Government Funding of Clinical Trials</i>	52
b. <i>Lower Drug Company Costs Would Benefit Consumers in the Short Run</i>	53
c. <i>Long Run Efficiencies in Drug Discovery and Development</i>	54
(1) Stimulating More Investment in Innovative R&D with Lower Costs and Better Information	55
(2) A Secondary Market for Remedial Improvers	57
3. Implementing a Public Testing Program	58
a. <i>Awarding Clinical Tests to the Most Qualified Scientists</i>	58
b. <i>Revenue Neutral Financing with Cost Sharing and Social Funding Criteria</i>	58
c. <i>Phased Implementation</i>	60
d. <i>Globalization of the Public Good Concept</i>	61
CONCLUSION.....	65

INTRODUCTION

News about clinical trial data is constantly before our eyes lately, and little of it is good. Again and again we learn that some major drug has produced deleterious side effects.¹ Internal memos emerge showing that the pharmaceutical companies knew or should have known about negative results from the clinical data, but that they overlooked or deliberately suppressed them.² In the recent case of Zetia, for example, the manufacturers reportedly ignored test results indicating that the cholesterol-lowering drug combination of Zetia and Zocor was ineffective and potentially dangerous as well.³

On reflection, one might begin to ask why this trend seems so surprising. Clinical trials cost vast sums of money, and, as will be shown later, these costs are rising so fast that they may become unsustainable

1. See, e.g., Bruce M. Psaty & Richard A. Kronmal, *Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment: A Case Study Based on Documents From Rofecoxib Litigation*, 299(15) J. AM. MED. ASS'N 1813 (2008); Peter Benesh, *Second Guessing Continues For Merck, Schering: Vytorin Mess Won't Let Up; Experts wonder why the pharma giants can't leave well enough alone*, INVESTORS BUS. DAILY, Feb. 4, 2008, available at <http://www.investors.com>; *Rep Henry A. Waxman Holds a Hearing on FDA's Drug and Device State Lawsuit Pre-emption*, CONG. Q. TRANSCRIPTIONS (May 14, 2008); *Rep. Rick Boucher Holds a Hearing on Drug Safety*, CONG. Q. TRANSCRIPTIONS (Feb. 13, 2007) [hereinafter *Boucher Hearing*].

2. See, e.g., *Boucher Hearing*, *supra* note 1,

Within the first three years of PDUFA, seven drugs, resulting in more than 1,000 deaths, had been removed. Those seven deadly drugs, rushed for approval under PDUFA, were not needed to save lives. . . . Today we will hear . . . how Ketek was approved by the FDA, even though the FDA knew the large safety study it required was fraught with data irregularities. Ketek is prescribed for non-life-threatening illnesses, but the rush to approve has resulted in . . . approximately 10 deaths related to Ketek's use.

Id.; Psaty & Kronmal, *supra* note 1, [regarding Merck's rofecoxib]:

[I]n April 2001, the company's internal intention-to-treat analyses of pooled data from these 2 trials identified a significant increase in total mortality . . . 34 deaths among 1069 rofecoxib patients and 12 deaths among 1078 placebo patients. . . . The data submitted by the sponsor to the FDA . . . in July 2001 used on-treatment analysis methods and reported 29 deaths (2.7%) among 1067 rofecoxib patients and 17 deaths (1.6%) among 1075 placebo patients. This on-treatment approach to reporting minimized the appearance of any mortality risk.

Id. at 1813.

3. The partners in the Vytorin venture . . . went to market in 2004 with a drug that combined Schering's Zetia with Zocor, a Merck drug whose patent expired in 2006. . . . [O]n Jan. 14 [they] released the results of a two-year clinical trial that had ended in 2006. . . . [T]he trial found that while Vytorin did push down cholesterol, it did so with no health benefit to patients. Worse, it created a potentially hazardous side effect. Instead of clearing plaque from artery walls, Vytorin appears to have led to, or at least allowed, a thickening of that plaque.

Benesh, *supra* note 1.

4 MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW [Vol. 13:1

over time.⁴ A negative outcome will sink an entire research project, which, from the lab to the trial, may entail a loss of hundreds of millions of dollars.⁵ The costs of such failures must then be made up from the few products that do succeed, which, according to some estimates, means that the aggregate breakeven costs of clinical trials for any successful new chemical entity may reach one billion dollars.⁶ So one may suspect that there is a moral hazard here because if the pharmaceutical companies pay for the tests, they have a perverse incentive to paint the end results in the rosier possible light.⁷

The pharmaceutical companies have also lobbied successfully for regulatory relief from the burden of recouping the cumulative costs of clinical trial data in the form of a backdoor intellectual property right known in the United States as “marketing exclusivity”⁸ and in the European Union as “data exclusivity.”⁹ By these means, originator pharmaceutical companies obtain a period of time, ranging from three to ten years, during which would-be generic producers of existing drugs cannot themselves obtain regulatory approval for a competing drug if they rely—directly or indirectly—on the results of the originator’s own undisclosed test data, which will have been provided to governments

4. See *infra* text accompanying notes 34-43.

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

6. *Id.*

7. Jerry Avorn, *Dangerous Deception—Hiding the Evidence of Adverse Drug Effects*, 355(21) NEW ENG. J. MED. 2169, 2169-70 (2006).

[A]nent aprotinin’s manufacturer, Bayer, had hired a private contract research organization to perform its own large observational study of postoperative complications in patients given the drug. The analysis, completed in time for the FDA meeting, reached conclusions similar to those of Mangano et al. [which were negative]. . . . [P]atients who received aprotinin had higher mortality rates and substantially more renal damage than those given other treatments. But neither Bayer nor its contractor had provided the report to the FDA or even acknowledged its existence before the meeting. . . . A few years ago, it was discovered that some companies had funded multiple clinical trials of their selective serotonin-reuptake inhibitor antidepressants but reported the results of only the favorable trials—distorting the evidence base physicians use in choosing drugs.

Id. One report found 90 percent of firm sponsored trials produced results favorable to the sponsoring firm. Stephan Heres et al., *Why Olanzapine Beats Risperidone, Risperidone Beats Quetiapine, and Quetiapine Beats Olanzapine: An Exploratory Analysis of Head-to-Head Comparison Studies of Second-Generation Antipsychotics*, 163:2 AM. J. PSYCHIATRY 185 (2006).

8. 21 C.F.R. § 314.108(b)

9. Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, 502 (2004).

under strict conditions of trade secrecy.¹⁰

Of course, the would-be competitor could not market a generic drug anyway until the originator's patent had expired, and the former would in principle remain free to conduct its own clinical trials. But the cost-benefit ratio makes the latter option illusory in practice, because—apart from the loss of time—the generic competitor, who by definition lacks a patent, could not readily charge consumers enough to recoup the enormous costs of such trials.¹¹ Moreover, repeating a pre-existing trial for such a reason raises ethical questions, because it would deny some patients access to medicines known to be effective purely for commercial purposes.¹² Because the generic competitor must rely indirectly on the originator's successful clinical test outcomes by showing that its generic product is the bioequivalent of an approved product, and therefore exempt from the need for further testing,¹³ a period of data exclusivity potentially becomes a means of keeping the generic producer off the market regardless of the status of that originator's own patent.¹⁴

In other words, even if the originator's patent had expired, or was otherwise invalidated, the data exclusivity regime may provide a de facto alternative exclusive right by blocking the competitor's entry into the market for as long as the period of such protection lasts.¹⁵ Data exclusivity regimes have thus become “increasingly dominant as an additional intellectual property layer of protection,”¹⁶ which blocks generic competition even with respect to second indications and other

10. See, e.g., Junod, *supra* note 9, at 490; Meir Perez Pugatch, *Intellectual Property Data Exclusivity, Innovation and Market Access*, in *NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES* 97-132 (Pedro Roffe et al. eds., 2006) [hereinafter Pugatch, *NEGOTIATING HEALTH*].

11. See, e.g., Karin Timmermans, *Monopolizing Clinical Trial Data: Implications and Trends*, 4 *PLoS MED.* 206 (2007).

12. *Id.* However, generic trials might also provide drugs to patients who otherwise could not afford them.

13. See, e.g., Junod, *supra* note 9, at 490 (“Marketing exclusivity precludes a second applicant from relying on the data previously provided to demonstrate the safety and efficacy of the reference drug.”); *id.* at 506 (European Union interprets reliance as in United States, namely, it “refers to reliance by the drug agency, and not to direct access and use of the data by the second applicant”). See also Timmermans, *supra* note 11, at 206 (questioning broad notion of “reliance” given that generic producers must submit their own data on quality in addition to showing chemical and biological equivalence to the original, without ever obtaining access to the originator's data).

14. See, e.g., Junod, *supra* note 9, at 480; *infra* notes 109-110 and accompanying text.

15. Timmermans, *supra* note 11, at 206, 208.

16. Pugatch, *NEGOTIATING HEALTH*, *supra* note 10, at 117.

6 MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW [Vol. 13:1

variations that are “not innovative enough to gain patent protection.”¹⁷

The lay observer might well express surprise to learn how deeply rooted these alternative *sui generis* data exclusivity regimes have become in both the United States and the European Union. After all, a consumer advocate might object, originator companies had been given a twenty-year patent monopoly for just this purpose.¹⁸ The relative strength of patents in the pharmaceutical sector is often justified by the need for consumers to cover the “risk premium,” that is, the losses accruing from failed pharmaceutical research projects, especially failed clinical trials, over and above the specific Research and Development (“R&D”) costs associated with any given successful drug.¹⁹

Later in this Article, I will critically examine the various rationales, and particularly the incentive rationale, that supporters of these regimes have put forward over time.²⁰ Suffice it to say, the pharmaceutical industry has quietly but successfully pursued this alternative intellectual property right in the results of clinical trials, independent of and cumulative with the patent rights that everyone takes for granted. Besides entrenching and expanding these regimes in the domestic laws of the United States²¹ and the European Union,²² industry

17. Junod, *supra* note 9, at 480 (quoting Greg Perry, Director General of the European Generic Medicines Assoc.).

18. Additionally, there are possible extensions for delays in approval, under 35 U.S.C.S. § 156. Suzan Kucukarslan & Jacqueline Cole, *Patent Extension Under the Drug Price Competition and Patent Term Restoration Act of 1984*, 49 FOOD & DRUG L.J. 511 (1994).

19. See, e.g., Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 602, 602 (2005) (“[P]harmaceutical companies depend upon these intellectual property protections not only to spur investment in research and development of new drugs, but also to recuperate the cost of bringing the patented drug into market, including the cost of hundreds of pro-drugs that typically die during the clinical trial phases.”). See also Henry Grabowski, *Increasing R&D Incentives for Neglected Diseases: Lessons from the Orphan Drug Act*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 457-80 (Keith E. Maskus & Jerome H. Reichman eds., 2005) [hereinafter Grabowski, *Increasing R&D Incentives*]; Michael Enzo Furrow, *Analyzing The Laws, Regulations, and Policies Affecting FDA-Regulated Products: Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 FOOD & DRUG L.J. 275 (2008) (“The recent decision by the Supreme Court in *KSR International v. Teleflex Inc.* poses a threat to the present balance, and pharmaceutical innovators in particular are at risk of losing some of the essential patent protections that allow them to recoup their drug discovery and development investment.”).

20. See, e.g., G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT’L L. & BUS 1 (2003); *infra* text accompanying notes 157-88.

21. Drug Price Competition and Patent Term Restoration Act of 1984, 98 P.L. 417

representatives have mounted a campaign to establish similar regimes at the multilateral, regional, and bilateral levels.²³ After a regional success in the North American Free Trade Agreement (“NAFTA”), this drive scored only a more modest victory in the Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994 (“TRIPS”).²⁴ When efforts to improve on the TRIPS compromise failed, the U.S. Trade Representative (“USTR”) began pressing other governments with demands for more far-reaching codified enactments of this form of protection for clinical trial results in the course of regional and bilateral Free Trade Agreements (“FTAs”).²⁵

Restrictions on the use of clinical data under FTAs can effectively empower originator pharmaceutical companies to negate a foreign state’s ability to authorize marketing approval of equivalent generic drugs for a period of five to fifteen years, even when these companies could not invoke patents to prevent the use of the drugs as such.²⁶ If developing countries reject clauses seeking to establish these alternative forms of protection for clinical trial results, they may forfeit advantageous trade concessions, especially in negotiations with the United States and possibly in trade negotiations with the European Union. Few governments have been willing to run this risk.

On the contrary, with each new success,²⁷ the pharmaceutical

(Sept. 24, 1984); 21 U.S.C.A. §§ 355(c)(3)(D), 355 (j)(5), *reprinted in* 21 C.F.R. § 314.108 (1993).

22. Council Directive 2001/83, 2001 O.J. (L 311) 67 (EC), *replacing* Council Directive 87/21, 1987 O.J. (L 015) 36 (EC).

23. *See, e.g.*, Susan Scafidi, *The “Good Old Days” of TRIPS: The U.S. Trade Agenda and the Extension of Pharmaceutical Test Data Protection*, 4 YALE J. HEALTH POL’Y L. & ETHICS 341 (2004); Jerome H. Reichman, *The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Good?*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 135-39 (Pedro Roffe et al. eds., 2006); Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 81-96 (Pedro Roffe et al. eds., 2006) [hereinafter Correa, NEGOTIATING HEALTH].

24. *See infra* text accompanying notes 66-84.

25. *See infra* text accompanying notes 96-120.

26. *See infra* notes 108-13.

27. For a review of the main IP-related elements of FTAs with Vietnam, Jordan, Singapore, Chile, Morocco, Australia, DR-CAFTA, and Bahrain with a focus on how they exceed TRIPS, see Carsten Fink & Patrick Reichenmiller, *Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements*, The World Bank Group, Trade Note 20, Feb. 7, 2005, available at <http://worldbank.org/trade>. For Latin America, see David Vivas-Eugui, *Regional and bilateral agreements and a TRIPS-plus world: The Free Trade Area of the Americas (FTAA)* (QUNO, Geneva, QIAP, Ottawa, ICTSD, Geneva 2003).

8 MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW [Vol. 13:1

companies' demands have become more audacious, to the point where some of the pending FTAs with Latin American countries—for example, Colombia and Peru—seemed so to exceed limits of reasonableness, that they elicited some restraining intervention from Congress.²⁸ Meanwhile, the proliferation of data exclusivity provisions in FTAs, with their Most Favored Nation (“MFN”) repercussions under Article 4 of the TRIPS Agreement,²⁹ establishes facts on the ground that have growing implications for the future.³⁰ If nothing intervenes, this powerful new intellectual property regime will become an ever more likely candidate for permanent recognition at the multilateral level.³¹

This Article will track these developments and critically examine their deeper implications. Part I surveys the soaring costs of clinical trials in developed countries, a phenomenon that must be kept in mind when assessing the protectionist pressures brought to bear at the international level. Following a brief summary of the domestic responses to this and related problems in the United States and European Union, this part will describe and analyze the specific efforts that have been made to establish data exclusivity in multilateral, regional, and bilateral agreements.

Part II evaluates this trend as a whole. It first asks what legal and economic logic justifies this form of intellectual property protection. To the extent that an incentive rationale can be mustered to justify a *sui generis* regime of clinical data exclusivity at all, it questions the validity of adopting a patent-like regime to support mere investment as such,

28. *Recent Agreement ‘Big Setback’ for Rx Companies*, American Health Line, May 18, 2007.

A recent agreement between the Bush administration and Congress on a new policy for trade agreements with Columbia, Panama and Peru includes provisions that would increase the use of generic medications in those nations and “marks the first big setback for the pharmaceutical industry since Democrats claimed Capitol Hill,” the Wall Street Journal reports. The new policy would eliminate “linkage,” which requires trade partners to ensure generic medications do not violate any patents before they allow such treatments to reach the market.

Id. See *infra* text accompanying notes 121-25.

29. See Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 4, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments— Results of the Uruguay Round, 33 I.L.M. 1125, 1197 (1994) [hereinafter TRIPS Agreement].

30. See, e.g., Timmermans, *supra* note 11; Antony Taubman, *Unfair Competition and the Financing of Public Knowledge Goods: The Problem of Test Data Protection*, 3 J. INTEL. PROP. & PRACTICE 591, 603 (2008).

31. See TRIPS Agreement, *supra* note 29, art. 71.1 (“[T]he [TRIPS] Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.”).

without obtaining any given level of creative achievement in return.

The final segment of Part II will contend that the technical debate surrounding the treatment of clinical data as a subcategory of intellectual property law masks a much deeper problem. Here, I argue that the real conceptual flaw at the core of this anomalous regime is the uncritical practice of treating clinical trials as a private rather than a public good. I then re-elaborate the case for government oversight and government funding of clinical trials³² and attempt to show the advantages that would arise from treating clinical trials of new pharmaceutical products as a global public good. The Conclusion summarizes the enquiry and sets out core findings and recommendations.

I. EXPORTING CLINICAL TRIAL DATA EXCLUSIVITY REGIMES FROM DEVELOPED TO DEVELOPING COUNTRIES

We will see in Part II that different justifications for *sui generis* protection of clinical test data have been put forward at different times with varying degrees of persuasiveness.³³ What remains constant behind the changing rhetoric is the fact that the costs of clinical trials are high, growing higher, and have lately become potentially unsustainable.

A. *The Egregiously High Costs and Risks of Clinical Trials*

Recent studies claim that the cost of clinical trials in the United States accounts for a disproportionately large share of the overall cost of bringing new drugs to market and now reaches \$800 million to \$1 billion per approved drug.³⁴ While the accuracy of this figure may be disputed at the margins,³⁵ it necessarily includes the cumulatively high costs of

32. Tracy R. Lewis, Jerome H. Reichman, & Anthony D. So, *The Case for Public Funding and Public Oversight of Clinical Trials*, ECONOMISTS' VOICE (Jan. 2007), available at <http://www.bepress.com/ev> [hereinafter Lewis et al., *The Case for Public Funding*].

33. See *infra* Part II.

34. DiMasi et al., *supra* note 5, at 166. The cost of clinical trials is only 70% of the total figure of \$802 million that they estimate. Cost-of-capital inflates the cost of pre-clinical research significantly. *Id.* at 164.

35. Christopher P. Adams & Van V. Brantner, *Estimating The Cost Of New Drug Development: Is It Really \$ 802 Million?*, 25 HEALTH AFF. 420, 427 (2006) (“[F]or one large pharmaceutical firm, the expected cost of developing a drug is \$521 million, while for another large firm, it is \$2,119 million.”). Moreover, the figures for the nonprofit sector appear to be much lower. See, e.g., WORLD HEALTH ORGANIZATION, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 75-76 (2006) (“[T]he estimates for public-private partnership products tend to be much lower. . . . [T]he final cost of clinical trials is estimated at between US\$ 76 and US\$ 115 million . . . [with] a total per-drug R&D

10 MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW [Vol. 13:1

clinical trials incurred for the many drugs that fail to win approval.³⁶

Year after year, the costs of conducting clinical trials reportedly outstrip the medical component of the consumer price index.³⁷ Similarly, between 1977 and 1995, the burden of data production increased by 43% in mean number of pages per new drug application (“NDA”),³⁸ by 37% in mean number of patients per NDA, and by 44% in mean number of clinical trials per NDA.³⁹

Other things being equal, there has been an increase of more than

cost of between US\$ 115 and US\$ 240 million.”).

36. DiMasi et al., *supra* note 5; Adams & Brantner, *supra* note 35.

37. See Lori Shields, *Spotlight on Research Fees: Trends in Cost-per-Subject Pricing*, 3 J. CLINICAL RESEARCH BEST PRACS. 3 (March 2007) (“From 2000 to 2005, the price that sponsors pay U.S. research sites per subject for Phase II and III trials increased by 42% . . . [and] the complexity of these clinical studies, as measured by the total number of procedures performed, increased by 49%. . . . [T]he rest of the world . . . saw costs increase by 43% and complexity by 60%.”); Bruce Booth & Rodney Zimmel, *Prospect for Productivity*, 3 NATURE REVS. DRUG DISCOVERY 451, 454 (May 2004) (showing a five-fold increase in clinical trial costs from 1991 to 2000, and claiming “the industry trend towards more tests per patient and more patients per trial has led to significant increases in the direct costs of clinical trials”). *But see* Eric L. Eisenstein et al., *Sensible Approaches for Reducing Clinical Trial Costs*, 5 CLINICAL TRIALS 75 (2008). “Over the past decade . . . funding for phase 1–4 clinical trials . . . has increased from 37 to 64% of their biomedical research expenditures. However, Food and Drug Administration approvals of new molecular entities dropped from 35.5 to 23.3 entities per year over the same period.” *Id.* at 76. Nevertheless, “[o]ur results suggest that it is possible to reduce significantly the costs of clinical trials without adversely impacting their scientific objectives. The resulting cost savings would provide increased funding so that additional therapies could be tested and made available for patient care.” *Id.* at 83.

38. Pierre Azoulay, *The Changing Economics of Clinical Development*, Earth Inst. (May 20, 2004) (slide 7 showed 38,044 mean pages per NDA in 1977-1980 and 90,650 in 1989-1992, an increase of 138%). *See also* Hamilton Moses, III et al., *Financial Anatomy of Biomedical Research*, 294 J. AM. MED. ASS'N 1333, 1337 (2005) (Table 3 showing Phase 1-3 trial spending growing from \$3.1 billion in 1994 to \$14.2 billion in 2003).

39. THE DRUG DEVELOPMENT PROCESS: INCREASING EFFICIENCY AND COST-EFFECTIVENESS 338-39 (Peter G. Welling et al. eds., Marcel Dekker, Inc., 1996) (“According to the Boston Consulting Group, the average number of patients in clinical trials per New Drug Application has almost tripled from 1321 in 1981-1984 compared with 3567 in 1989-1992 while, over the same period, the average number of clinical studies per NDA increased from about 30 to 60 and the number of pages per NDA increased from approximately 45,000 to 90,000[.]”) (citing S. Engel & J.F. Jalkiewicz, *Mixing up a New Formula*, (12)(15) MED AD. NEWS 3, 1993). *See also* Jeffrey S. Handen, *Drug Discovery in the Modern Age: How We Got Here and What Does It Mean?*, in INDUSTRIALIZATION OF DRUG DISCOVERY: FROM TARGET SELECTION THROUGH LEAD OPTIMIZATION 7-8 (Jeffrey S. Handen ed., CRC Press 2005) (“The average number of studies per NDA has increased from 30 in the early 1980s to 70 in the mid-1990s. The number of pages per NDA has increased from an average of 38,000 in the late 1970s to in excess of 100,000 in the mid-1990s. The average number of patients per NDA has increased from 1321 in the early 1980s to 4327 in the mid 1990s.”) (citing ACTIVITIES OF THE INTERNATIONAL PHARMACEUTICAL INDUSTRY IN 2000, CMR INTERNATIONAL (Surrey, U.K.)).

11% per year in clinical trial costs.⁴⁰ Moreover, “[t]he most obvious risk in drug development is that, despite a long and costly development process, most new drug candidates will not reach the market. Failure can result from toxicity, carcinogenicity, manufacturing difficulties, inconvenient dosing characteristics, inadequate efficacy, economic and competitive factors, and various other problems.”⁴¹

Reportedly, about 20% of all compounds entering trials survive to FDA approval.⁴² If one combines the actual costs of clinical trials that succeed with the overall costs of those that fail, one arrives at the often quoted price tag for each successful drug of \$800,000 to \$1 billion, which includes the “risk premium” to recoup the costs of failed drug profits and failed clinical tests.⁴³

It bears noting at the outset that while the private sector must absorb these burdensome costs, the federal government has been spending some thirty billion dollars annually to cover the even riskier costs of upstream basic medical research conducted at universities.⁴⁴ Nevertheless, the soaring costs of clinical trials in developed countries are a fact of life that will not go away. The demand for global protection of clinical tests largely arises from underlying concerns about perceived free-riding on private-sector R&D investments to cover these costs. Such concerns must be taken into account when evaluating the social costs to other countries, especially developing countries, of the data protection measures based upon them.

B. The Domestic Response

While this Article is not primarily concerned with the situation in the United States, it is instructive to observe that, until recently, the impact on the public at large of measures to protect clinical test data in this country has been relatively modest. Federal law currently gives

40. DiMasi et al., *supra* note 5, at 168 (Table 4 showing clinical trial costs growing at a rate of 11.8% when capitalized cost is not considered and at 12.2% when capitalized cost is considered).

41. Grabowski, *Increasing R&D Incentives*, *supra* note 19, at 459.

42. DiMasi et al., *supra* note 5, at 165 (finding a 21.5% success rate).

43. *Id.* at 180 (DiMasi sums up the numbers from Fig. 2 at 167. But note this is the capitalized cost of developing a new drug, including preclinical costs. Clinical costs as such were estimated at \$467 million per approved drug. Also note that these estimates are in year-2000 dollars.).

44. Arti K. Rai, Jerome H. Reichman, Paul F. Uhler & Colin Crosswell, *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 *YALE J. HEALTH POL'Y L. & ETHICS* 1 (2008) [hereinafter Rai et al., *Pathways Across the Valley of Death*].

12 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1]

originator companies a five-year period of exclusive marketing rights in clinical trial data, which starts from the date the compound is approved by the Federal Drug Administration.⁴⁵ Since 1987, the European Community Members have provided protection for data filed in support of marketing authorizations for pharmaceuticals, which can now last from eight to eleven years, and this form of protection has subsequently been extended to other product areas in Europe.⁴⁶ Analogous forms of protection have been enacted in many other countries since the TRIPS Agreement entered into force.⁴⁷

The basic five-year period established in U.S. law is independent of the originator's patent rights, which last for a period of twenty years.⁴⁸ Because the patent granting process and the regulatory approval process, including clinical trials, are long, the effective patent life is considerably shorter than the statutory period of twenty years. In theory, the period of market exclusivity could extend the effective period of patent exclusivity by denying generic producers the right to rely on the originator's existing clinical trial results for another five years. In practice, however, with regard to traditional small-molecule compounds, there is little or no impact on consumers because the five-

45. Concerns about preserving the confidentiality of regulatory data have surfaced only in the last 25 years. TREVOR M. COOK, SPECIAL REPORT: THE PROTECTION OF REGULATORY DATA IN PHARMACEUTICAL AND OTHER SECTORS (Sweet & Maxwell 2000). Since 1982, the United States has adopted provisions to protect regulatory data submitted to federal agencies in connection with pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). *Id.* at 7; 7 U.S.C. § 136 et seq. In 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.

COOK, *supra* note 45, at 7. See Drug Price Competition and Patent Term Restoration Act of 1984, 98 P.L. 417 (Sep. 24, 1984); 21 U.S.C.A. §§ 355(c)(3)(D), 355(j)(5) (reprinted in 21 C.F.R. § 314.108) (1993). The five-year period of exclusivity extends from the approval of the original drug to the approval of a generic version based on bioequivalence. Pugatch, NEGOTIATING HEALTH, *supra* note 10, at 103.

46. Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, 05 EC, 30 April, L136/34; Pugatch, NEGOTIATING HEALTH, *supra* note 10, at 105. See also Junod, *supra* note 9; Carlos M. Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69 (2002) [hereinafter Correa, *Unfair Competition Under the TRIPS Agreement*]; Correa, NEGOTIATING HEALTH, *supra* note 23.

47. See generally Taubman, *supra* note 30.

48. 35 U.S.C. § 154 (1994).

year period of data exclusivity runs concurrently with the period of patent protection and is usually absorbed into its duration with little overlap.⁴⁹

There is, however, a gray area where clinical data are used to justify new indications of chemical entities that have already been approved, which can yield another three-year term of exclusivity in the United States. This three-year term “for making product changes that require clinical trials to gain approval” starts with the approval of the supplemental application.⁵⁰ In such cases, uncertainty in the rules could reportedly lead to delays in the entry of generic producers beyond the life of the patent itself.⁵¹

Pending legislative proposals, if enacted, could confer twelve to fourteen years of market exclusivity on data pertaining to approved biological medicines, that is, the large molecule medicines that are currently attracting considerable attention.⁵² Here there are questions about the FDA’s ability to approve so-called bio-similar generics, which are not chemical compounds and which depend on materials that are deemed bioequivalent or sufficiently bio-similar as to justify reliance on the originator’s test data without need to conduct new tests on the

49. Professor Rebecca Eisenberg states, “The five-year period of data exclusivity for a new chemical entity begins with first market approval and therefore often runs concurrently with patent protection, although in some cases it may last longer.” Rebecca Eisenberg, *The Role Of The FDA In Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 360 (2007). Footnote nine in Eisenberg’s article notes an exception: Paxil gained marketing exclusivity via this mechanism after the patents on it had expired. *Id.* at 348.

50. Eisenberg, *supra* note 49, at 360; Junod, *supra* note 9.

51. Junod, *supra* note 9. *But see* Eisenberg, *supra* note 49, at 360 (“The data exclusivity thereby gained is limited to the terms of the new approval, and will not prevent a competitor from using an ANDA to sell the product as previously approved, or for previously approved indications. This has proven to be a very significant limitation on the use of a supplemental NDA to gain approval to market a drug for a new indication.”).

52. PATHWAY FOR BIOSIMILARS ACT, H.R. 5629, 110th Cong. (2008). The *Pathway for Biosimilars Act* provides in § 101(k)(7) for twelve years of exclusivity for the “reference product,” but it does not consider evergreening applications relevant. *Id.* Exclusivity is extended up to fourteen years from initial approval if a significant new indication is approved as a supplement within eight years of the original approval. *Id.* An additional six months to the twelve or fourteen year exclusivity term can be awarded for discovery of beneficial pediatric use. *Id.* *Biologics Price Competition and Innovation Act of 2007* had the same twelve year term but not the fourteen year term or pediatric extension. BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2007, S. 1695, 110th Cong. § 2(k)(7) (2007). A biological product is defined as “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.” Public Health Services Act, 42 U.S.C. § 262(i) (2002). *See* Marc A. Goshko, U.S. Legislative Considerations for Generic Biologics, 10th Annual IGPA Conference (Nov. 29, 2007).

generic product.⁵³ Because the methods of scientific assessment are different for biologics than for small-molecule compounds, there are unanswered legal, economic, and administrative questions in this area. For example, one economist knowledgeable about the industry estimates that the breakeven point for producers of biologics is much higher than that for small molecules, largely because of higher risk of failure in Phase III clinical trials.⁵⁴

The pending legislation would enable the FDA to recognize biosimilarity for purposes of generic entry in exchange for a marketing exclusivity period (derived from the costs of data) for twelve to fourteen years. If enacted, this provision could extend beyond the effective life of the patent, which would otherwise be shortened by the years needed—sometimes as much as ten years—to obtain regulatory approval in the first instance.⁵⁵

C. *The Drive for Global Protection of Clinical Trial Data*

The United States and the European Union have been seeking universal norms to protect the results of clinical trial data on new pharmaceutical products through bilateral and multilateral trade negotiations.⁵⁶ When developing countries agree to this new form of

53. Two U.S. statutes apply to the regulation of biological products. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 30.1 et seq. (FFDCA); Public Health Services Act, 42 U.S.C. § 262 (PHSA). See also Goshko, *supra* note 52.

54. Henry Grabowski, Data Exclusivity for New Biological Entities (June 2007) (working paper, on file with Duke Univ. Dept. Econ.) [hereinafter Grabowski, Data Exclusivity], *available at* <http://www.econ.duke.edu/Papger/PDF/DataExclusivityWorkingPapers.pdf>. Professor Grabowski's elegant analysis makes no mention of the role that government funding might play with regard to biologics, and no independent verification of his figures has so far been found. *Id.*

55. However, there are other existing measures that may partly compensate patentees for this loss of effective patent life. See Hatch-Waxman Act, 21 U.S.C. § 355, 35 U.S.C. § 271(e) (1994).

56. See U.S. TRADE REPRESENTATIVES, 2008 SPECIAL 301 REPORT (2008), *available at* http://www.ustr.gov/Document_Library/Reports_Publications/2008/2008_Special_301_Report/Section_Index.html; PRESIDENT'S 2007 TRADE POLICY AGENDA AND 2006 ANNUAL REPORT, *available at* http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Trade_Policy_Agenda/asset_upload_file278_10622.pdf (mentions test data protection as an issue multiple times). *But see* PRESIDENT'S 2008 TRADE POLICY AGENDA AND 2007 ANNUAL REPORT, *available at* http://www.ustr.gov/assets/Document_Library/Reports_Publications/2008_Trade_Policy_Agenda/asset_upload_file490_14556.pdf (While the report does not mention test data protection, this omission was not a change in policy, just in public emphasis). Is this a change in policy or just in public emphasis? Data exclusivity has now

intellectual property protection, their rights to promote the production of generic drugs and low-priced medicines generally, as clarified in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health⁵⁷ and in related implementing decisions,⁵⁸ can become compromised by the new, exclusive rights in clinical test data, which are not directly covered by those arrangements.⁵⁹

1. From NAFTA (1992) to TRIPS (1994)

NAFTA was a kind of blueprint for the TRIPS Agreement of 1994. It set out, and largely obtained, many of the IP objectives that USTR hoped to later codify during the Uruguay Round of Multilateral Trade Negotiations.

a. The NAFTA Provisions

The NAFTA provisions on intellectual property established two important principles with regard to clinical test data. One was that clinical data submissions to governments for regulatory approval of new chemical entities must be protected against non-disclosure, or at least “unfair commercial use.”⁶⁰ The other was that a generic producer could not rely on pre-existing test data for regulatory approval based on “bioequivalence and bioavailability studies” for a period of at least five

also surfaced in confidential negotiations between the European Union and developing countries on European Economic Partnership Agreements.

57. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, Ministerial Declaration of 20 November 2001, WT/MIN(01)/DEC/2, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.doc.

58. General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003), available at <http://docsonline.wto.org/DDFDocuments/t/WT/L/540.doc>; General Council, *Amendment of the TRIPS Agreement*, WT/L/641, (Dec. 8, 2005), with attachment, *Protocol Amending the TRIPS Agreement* (Annex setting out pending Article 31bis).

59. See Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 962-65 (2007).

60. North American Free Trade Agreement, Can.-U.S.-Mex., art. 1711.5, Dec. 17, 1992, 32 I.L.M. 605, 675 (1993) [hereinafter NAFTA] provides as follows:

If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural 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 the data is protected against unfair commercial use.

Id.

16 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1

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.”⁶¹

This innocuous sounding provision could have produced new barriers to generic producers because it seemed to open a five-year window of market exclusivity in Canada and Mexico for drugs that were not otherwise patented there for one reason or another, or for drugs whose period of patent protection in those countries was about to expire. However, these effects were tempered by the ambiguous language in a third provision, which seemed to allow a regulatory authority room to approve a drug by expressly “relying” on the date of first approval in the originator country,⁶² say, the United States. In that case, the five year period would probably run contemporaneously with the U.S. patent and not necessarily add any appreciable time of independent exclusivity in Canada or Mexico.⁶³

Despite the ambiguity inherent in these provisions, the Bayer pharmaceutical company contended that Canada had violated the treaty when it gave regulatory approval to a generic drug based on a showing of bioequivalence. The crux of the argument was that this approval violated the requirement that clinical test data must be protected

61. Article 1711.6 of NAFTA provides as follows:

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.

NAFTA, *supra* note 60, art. 1711.6.

62. Article 1711.7 of NAFTA provides as follows, “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, *supra* note 60, art. 1711.7.

63. This conclusion disregards the ambiguities that might arise from data showing new indications for an existing chemical entity. See *supra* notes 50-51 and accompanying text. For the view that United States practice underlies the three provisions set out in Article 1711 of NAFTA, which deal explicitly with regulatory data through Articles 1711.5, 1711.6, and 1711.7, see COOK, *supra* note 45, at 7.

“against unfair commercial use.”⁶⁴ In 1999, however, a Canadian court held that Canada was not barred from approving a competitor’s generic drug without at least five years of protection from competition when that competitor had based his application for marketing approval on a comparison with the innovator’s own product.⁶⁵

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 bioequivalent of the innovator’s product, which was being publicly marketed. Because the minister need not rely upon the confidential information as such in that event, the minimum five-year market protection otherwise available under domestic regulations did not apply.

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 bioequivalence or bio-availability studies without the minister having to examine and rely on confidential data filed by the innovator.” 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.”⁶⁶

b. The Softer TRIPS Provisions

Logically, the United States sought to build upon, and strengthen, its NAFTA blueprint during the Uruguay Round of Multilateral Trade Negotiations, which lasted from 1986 to 1994. These proposals, which met with strong resistance from the outset, survived into the Brussels Draft of the TRIPS Agreement in 1990.⁶⁷ Here, however, they appeared in a bracketed provision that marked off the United States’ (and

64. *Bayer Inc. v. Canada* (Attorney Gen.) (Trial Division), [1998] 1 F.C. 553, T-1154-97 (Can.), *affirmed by* [1999] 243 N.R. 170 (Fed. Ct. App.) (Can.), *appeal denied* [2000] 259 N.R. 200 (Can.); Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 135-39. *See also* *Bristol-Myers Squibb Co. v. Canada* (Attorney Gen.), [2005] 1 SCR 533, 2005 SCC 26.

65. *Bayer Inc. v. Canada* (Attorney Gen.), [1999] 243 N.R. 170 (Fed. Ct. App.) (Can.), *appeal denied* [2000] N.R. 200 (Can.).

66. Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 143.

67. Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Brussels, Belgium, Nov. 26, 1990, art. 42 [hereinafter *Brussels Draft TRIPS Agreement 1990*], *compiled in* STEWART, *THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY* (1986-1992) 260 (Terence P. Stewart ed., 1993).

18 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1

European Union's) position from those of other countries opposed to recognizing any period or principle of exclusive marketing rights attributable to the submission of clinical test data as such. This bracketed provision would, in effect, have required nonuse of the information for the approval of competing products for no less than five years, unless the originator who submitted the data otherwise agreed.⁶⁸ One year later, in an effort to reach a final agreement, the Chairman's Draft Final Act (the so-called Dunkel Draft of 1991) discarded the bracketed U.S.-EU proposal altogether.⁶⁹ The Dunkel Draft, with only minor technical changes, was then adopted as Article 39.3 of the TRIPS Agreement in 1996.⁷⁰

Article 39, as a whole, constituted an historic achievement in that it brought trade secret protection within the ambit of the Paris Convention's existing provisions mandating worldwide measures against unfair competition.⁷¹ However, as I explained in a previous article, the

68. Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 135-39. Article 4A contained a bracketed provision that marks off the United States (and European Union) positions from those of other countries opposed to this new form of protection for regulatory data. This proposed provision is reproduced as follows: "PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of agricultural chemical products, . . . the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use." Brussels Draft TRIPS Agreement of 1990, *supra* note 67, art. 4A, at 2308. 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 addition, PARTIES shall protect such data against disclosure, except where necessary to protect the public." *Id.* This proposal applied the regulatory data provision to cover approval of "new pharmaceutical products or of a new agricultural chemical product." STEWART, *THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY* (1986-1992) 2308. In addition, the bracketed provision essentially required "protection against unfair commercial use and disclosure, *as well as non-use of the information for the approval of competing products*, for no less than five years, unless the person submitting the information agrees." *Id.* (italics supplied).

69. Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 20 December 1991, art. 39.3 [hereinafter Dunkel Draft], *compiled in* STEWART, *THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY* (1986-1992) 869 (Terence P. Stewart ed., 1993).

70. 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 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.

Dunkel Draft, *supra* note 69.

71. See Paris Convention for the Protection of Industrial Property, art. 10*bis*, Mar. 20,

collocation of clinical test data within the provisions regulating unfair competition negated any inference that the TRIPS drafters had imposed an exclusive intellectual property right on this subject matter and indirectly confirmed the implications to be drawn from the deletion of the U.S.-EU bracketed proposal between 1990 and 1991.⁷²

As adopted, Article 39.3 of TRIPS merely obliged

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, to 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.’⁷³

WTO Members have no duty to “require . . . the submission of undisclosed test or other data” and they may rely upon the health and safety decisions of other jurisdictions, or on the published medical literature, or a combination of both, without incurring liability 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 other uses of them that are “fair,” even if such uses produce a commercial impact. For example, governmental use to avoid health or safety risks revealed by the data in the local environment are fair by definition. 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.”⁷⁴

In principle, the meaning of ‘unfair commercial use’ will

1883, as rev. at Stockholm, July 14, 1967, 21 U.S.T. 1583 [hereinafter Paris Convention]; G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY AS REVISED AT STOCKHOLM IN 1967 (BIRPI 1968). See generally STEPHEN P. LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION (Harvard Univ. Press 1975).

72. See generally Reichman, NEGOTIATING HEALTH, *supra* note 23, at 135-39.

73. *Id.* at 141-42.

74. *Id.* Cf. TRIPS Agreement, *supra* note 29, art. 27.2 (exception to patentability for *ordre public*).

20 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1]

depend upon the kind of practices that domestic and foreign trade secret laws have traditionally regarded as unfair, together with any new case law dealing specifically with the protection of clinical test data as a distinct category of unfair competition law. 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’ ([A]rticle 10*bis*(2)).⁷⁵

Many different scenarios may be imagined,⁷⁶ including the possibility that any given state might include “unjust enrichment” within the purview of its domestic unfair competition law.⁷⁷ In such a state, courts could consider the extent to which allowing regulatory approval on the basis of bioequivalence, without more, destroyed any incentive to generate the data needed to bring the product to market,⁷⁸ as well as the extent to which that incentive had been amply sustained in the country of origin (or other relevant countries). But none of these scenarios necessarily justifies the five-year exclusive marketing right that the Dunkel Draft definitively deleted in 1991.

As to case law precedents, they are not favorable to a tough interpretation of the “nondisclosure” and fair use requirements of Article 39.3. In the United States, for example, a 1984 Supreme Court decision 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

75. Reichman, *supra* note 23 at 141-42. *See also* Paris Convention, *supra* note 71, art. 10*bis*(2); BODENHAUSEN, *supra* note 71.

76. Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 141.

On its face, the provision requiring fairness seems clear only at the extremes. At one pole, “disclosure” is expressly 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 to unauthorized third parties. At the opposite pole, however, the duty to prevent “unfair commercial use” arguably imposes a conduct-based liability rule, but not an exclusive property right requiring only authorized uses 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.

Id.

77. *See* Taubman, *supra* note 30, at 601.

78. *Id.* at 602.

firm for product registration.⁷⁹ The reluctance of the U.S. Supreme Court in that case to impose an unqualified restriction on the use of data filed with regulatory authorities was expressly conditioned on the need to sustain competition in unpatented products.⁸⁰

As noted above, moreover, “a similar decision was reached in the [1999] case of *Bayer Inc. v. Canada*, in which the Canadian Federal Court of Appeal construed Canadian law in light of Article 1711 of NAFTA,”⁸¹ which resembles the provision adopted in Article 39.3. The Canadian court found no grounds in this provision to bar regulatory approval of generics on the basis of a showing of bioequivalence to formulations approved under pre-existing data submissions.⁸²

In general, one may conclude that the TRIPS provisions set out in Article 39.3 did expand the worldwide obligations of WTO members to prohibit acts of unfair competition within the meaning of Article 10*bis*(3) of the Paris Convention.⁸³ But incorporation of this provision into Article 10*bis* of the Paris Convention (and by virtue of that incorporation, of article 10*bis* into the TRIPS Agreement itself)⁸⁴ in no way enlarged the boundaries of the specific obligations codified in Article 39.3.⁸⁵ If anything, they further precluded any application of Article 39.3 in a manner representing an exclusive property right, as distinct from a conduct-based liability rule.⁸⁶

The ultimate meaning of ‘unfair commercial use’ under Article 39.3 “will depend upon the kind of practices that domestic and foreign trade secret laws have traditionally regarded as unfair.”⁸⁷ These practices are

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

80. *Id.*

81. Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 143.

82. *See supra* notes 65-66 and accompanying text.

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 stronger [overall] than the regime ultimately adopted in Article 39.3 of the TRIP[s] 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.

Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 143.

83. For an analysis, see *id.*, at 137-44.

84. *See* TRIPS Agreement, *supra* note 29, art. 2.1.

85. Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 137-44.

86. *See* Correa, *Unfair Competition Under the TRIPS Agreement*, *supra* note 46, at 81-84.

87. Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 144. For example, governments should not set themselves up as commercial rivals who profit from the

22 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1

too diverse to establish any consensus-based rules of universal application.⁸⁸ However, Article 39.3 of the TRIPS Agreement

does not prevent governments from relying upon decisions to allow the [marketing] of relevant [medicines] in other jurisdictions, nor does it prevent Members from authorizing the [marketing] 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 [at least] two domestic courts.⁸⁹

2. The Posterior Free Trade Agreements

The soft provisions of the TRIPS Agreement were the most that the technology-exporting countries could obtain at the multilateral level. After 1994, the only substantive multilateral agreements were the WIPO cyberspace treaties of 1996, and these produced a negotiated middle ground in which users' and consumers' interests were relatively well balanced against those of rights holders'.⁹⁰ Since then, efforts to ratchet up patent protection at the multilateral level have been blocked by developing country resistance,⁹¹ and a coalition of those countries plus non-governmental organizations ("NGOs") has put a Development Agenda, with emphasis on "Access to Knowledge," at the forefront of WIPO's future work program.⁹²

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. *Id.*

88. Taubman, *supra* note 30, at 602.

89. Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 144.

90. WIPO Copyright Treaty of 1996, *available at* <http://www.wipo.int/treaties/en/ip/wct/> [hereinafter WCT]; WIPO Performances and Phonograms Treaty of 1996, *available at* <http://www.wipo.int/treaties/en/ip/wppt/> [hereinafter WPPT]; Jerome H. Reichman, Graeme B. Dinwoodie, & Pamela Samuelson, *A Reverse Notice and Takedown Regime to Enable Public Interest Uses of Technically Protected Copyrighted Works*, 22 *BERKELEY TECH. L.J.* 981 (2007).

91. Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 *DUKE L.J.* 85, 99-122 (2007).

92. WIPO, Committee on Development and Intellectual Property (CDIP), Second Session, July 2008, Revised Draft Report, WIPO doc. CDIP/2/4 Prov. 2 (November 21, 2008) (Annex I, Information on Activities in Respect of 19 Adopted Recommendations); Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 *YALE L.J.* 804 (2008); Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 *PLOS BIOLOGY* 0147 (2004).

As Professor Ruth Okediji and others have observed,⁹³ the response of the technology-exporting countries was to shift their negotiating efforts to regional and bilateral trade agreements, where their bargaining position was disproportionately stronger.⁹⁴ In one FTA after another, ever tighter and more unbalanced intellectual property provisions have been accepted by governments willing to pay almost any price for the trade concessions offered them in other areas.⁹⁵

a. Expanding Protection for Clinical Trial Data in Developing Countries

Why developing countries at all economic levels have succumbed to the one-sided, virtually nonnegotiable intellectual property provisions that USTR has imposed upon them in the various FTAs remains unclear.⁹⁶ Certainly, it was not for lack of technical expertise or advice. If anything, the negotiators representing the Latin American countries, for example, often evidenced more skill and ability than their USTR counterparts, who took their marching orders from a “knowledge cartel”⁹⁷ without engaging in overly subtle nuances of persuasion. In

93. Ruth Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. & TECH. J. 125 (2004); Daniel J. Gervais, *TRIPS and Development*, in *INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT* 3, 260 (D.J. Gervais ed., Oxford 2007).

94. See generally Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1 (2004).

95. Timmermans, *supra* note 11. Note the status of treaties: Establishment of a Free Trade Area, U.S. – Jordan FTA, Oct. 24, 2000; Free Trade Agreement, U.S.-Singapore FTA, May 6, 2003; Free Trade Agreement, U.S.–Chile FTA, June 6, 2003; Free Trade Agreement, U.S.–Morocco FTA, June 15, 2004; Free Trade Agreement, Dom. Rep.–Cent. America, Aug. 5, 2004; Establishment of a Free Trade Area, U.S.–Bahrain FTA, Sep. 14, 2004; Establishment of a Free Trade Area, U.S.–Oman, Nov. 15, 2004; Establishment of a Free Trade Area, U.S.–Australia FTA, May 18, 2005; Establishment of a Free Trade Area, U.S.–Peru FTA, Apr. 12, 2006. Additional FTAs have been signed with Colombia, Panama, and Korea but have not been ratified by Congress. For a complete list, with reference to clinical test data protection, see Taubman, *supra* note 30, 594 n. 24.

96. See, e.g., Fink & Reichenmiller, *supra* note 27. See also William Watson & Viet D. Do, *Economic Analysis of Regional Trade Agreements*, in *REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM* 3-22 (L. Bartels & F. Ortino eds., Oxford 2006).

97. See Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in *INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME* 3-45, 19 (Keith E. Maskus & Jerome H. Reichman eds., 2003) [hereinafter Maskus & Reichman, *The Globalization of Private Knowledge Goods*]. See generally SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (Cambridge Univ. Press 2003).

24 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1]

virtually every case, the intellectual property provisions, left to the end of the negotiations, were put forward on a take-it-or-leave-it basis. As each single state or group of states succumbed to the latest set of demands, USTR elevated past demands to a new and higher level in the next round of negotiations. As Professor Bryan Mercurio recently observed, “the current bilateralism unashamedly seeks to fragment developing country coalitions while at the same time taking advantage of unequal bargaining power in bilateral negotiations.”⁹⁸

Whether, at the end of the day, the aggregate value of the overall trade concessions obtained by the central administrations in these FTAs justifies or compensates for the losses accruing from rents and other restrictions on intellectual property is not for me to adjudicate.⁹⁹ Whatever the gains, there is reason to believe that the central administrations that sign these agreements have undervalued or ignored the social costs of these intellectual property provisions. If so, the hidden costs will likely play out in terms of hampering the delivery of essential public goods, such as public health, education, agriculture, and scientific research, which remain heavily dependent on the public sector in these countries, owing to the rising costs of knowledge goods and other inputs needed for the delivery of these same public goods.¹⁰⁰ While there remain some defensive options that states may still take, even after these treaties enter into force,¹⁰¹ there is little evidence that

98. Bryan Mercurio, *TRIPS-Plus Provisions in FTAs: Recent Trends*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM 215, 221 (Lorand Bartels & Frederico Ortino eds., 2006).

99. For the difficulties in evaluating outcomes, see, e.g., Watson & Do, *supra* note 96.

100. See Maskus & Reichman, *The Globalization of Private Knowledge Goods*, *supra* note 97. But see Gervais, *supra* note 93, for a more optimistic view.

101. For measures pertaining specifically to clinical trial data, see, e.g., Timmermans, *supra* note 11, at 207-08:

- 1) “Limiting the duration of data exclusivity, and/or specifying that it cannot extend beyond the patent term ;”
- 2) “Limiting the scope of data exclusivity” to new chemical entities;
- 3) Requiring rapid registration of new medicines;
- 4) Allow compulsory licenses of clinical trial data;
- 5) Allow waivers of data exclusivity on specified public health grounds.

Id. For defensive measures pertaining to other public goods, see, e.g., Rochelle C. Dreyfuss, *TRIPS-Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21 (2004); Ruth L. Okediji, *Sustainable Access to Copyrighted Digital Information Works in Developing Countries*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (Jerome Reichman & Keith Maskus eds., 2005) [hereinafter Okediji, INTERNATIONAL PUBLIC GOODS]; P. BERNT HUGENHOLTZ & RUTH L. OKEDIJI, OPEN SOCIETY INST., CONCEIVING AN INTERNATIONAL INSTRUMENT ON LIMITATIONS AND EXCEPTIONS TO COPYRIGHT, FINAL REPORT (2008); Abbott &

governments will actually resort to these measures (except, perhaps, in the public health area) for fear of incurring retaliatory pressure from major economic powers.¹⁰²

Meanwhile, one government after another continues to sign these FTAs, and the protectionist tide, which rises with each new agreement, then spreads around the world via the TRIPS Agreement's own MFN clause, which—unlike that of the General Agreement on Tariffs and Trade 1994 (“GATT 1994”)—is virtually unlimited in its sweep.¹⁰³ As a result, the tangle of ever-tighter FTA provisions on intellectual property become de facto candidates for multilateral recognition in the future.¹⁰⁴

Within this context, numerous TRIPS-plus provisions have been adopted that bear on regulatory approval of generics in general and the use of clinical trial data in particular.¹⁰⁵ For example, several U.S. FTAs introduce so-called linkage clauses, which can prevent the regulatory authorities from granting approval to a generic version of a drug under patent without the approval of the patent holder.¹⁰⁶ These constraints may apply even if bioequivalence has otherwise been demonstrated. In such cases, the agency responsible for safety and efficacy of drugs is suddenly charged with observing questions of patentability, infringement, and related intellectual property issues, for which it lacks competence. The patent holder can short circuit both an infringement

Reichman, *supra* note 59.

102. For evidence of both bold measures and retaliatory pressures in the public health arena, see Abbott & Reichman, *supra* note 59, at 949-57; *Brazil, Thailand Lose Trading Privileges in Wake of IP Disputes*, Food & Drug Letter, Aug. 17, 2007 (“Two countries recently accused of violating pharmaceutical intellectual property (IP) rights have now lost certain trading privileges with the U.S. The Bush administration removed Brazil and Thailand from the list of developing countries that receive duty-free treatment for certain exports, U.S. Trade Representative (USTR) Susan Schwab announced June 28.”).

103. See TRIPS Agreement, *supra* note 29, art. 4; Mercurio, *supra* note 98. See also ICTSD/UNCTAD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (Cambridge Univ. Press, 2005), available at <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm> [hereinafter ICTSD/UNCTAD RESOURCE BOOK].

104. See TRIPS Agreement, *supra* note 29, art. 71.1; Taubman, *supra* note 30, 603-04.

105. See, e.g., Correa, NEGOTIATING HEALTH, *supra* note 23, at 81-96; Pugatch, NEGOTIATING HEALTH, *supra* note 10, at 126; Frederick M. Abbott, *The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 27-40 (Pedro Roffe et al. eds., 2006) [hereinafter Abbott, NEGOTIATING HEALTH].

106. See, e.g., Chile–U.S. FTA § 17.10.2(c), June 6, 2003, available at http://www.ustr.gov/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/Section_Index.html (accessed Jan. 18, 2009); Oman–U.S. FTA §15.9.4(a), Nov. 15, 2004 (pending implementation), available at http://www.ustr.gov/Trade_Agreements/Bilateral/Oman_FTA/Final_Text/Section_Index.html (accessed Jan. 18, 2009).

26 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1]

action and the generic producer's process of marketing approval by reaching above their heads, so to speak. The ability of these linkage provisions to block regulatory approval where enforced can thus sidestep many of the important flexibilities preserving state control of public health, including compulsory licenses.¹⁰⁷

With regard to test data exclusivity as such, recent FTAs seek to specify time periods during which the national regulatory authorities cannot rely on the clinical studies and data provided by originators for purposes of approving generic drugs on the basis of bioequivalence or similar standards.¹⁰⁸ In effect, these FTAs reimpose prescribed periods of nonuse in the manner of the bracketed U.S.-EU proposal that was deleted from the draft TRIPS Agreement in 1991.¹⁰⁹ Unless the generic manufacturer undertakes its own costly and wastefully duplicative clinical trials, which could elevate the cost of the generic substitute, it must sit on the sidelines for the specified period of time, usually no less than five years, even when there is no underlying patent on the product itself, as often occurs in developing countries.¹¹⁰

In other words, the data exclusivity provision in FTAs with developing countries operates independently of any patent protection the originator may possess, and of any R&D costs it may otherwise have recouped in OECD countries. As a result, drugs that are off patent or otherwise denied retroactive patent protection under TRIPS¹¹¹ may nonetheless remain off limits to would be generic producers in developing countries for the specified period of marketing exclusivity. Under a growing number of these FTAs, the United States originator need not have sought to register the drug at all in the relevant country for marketing approval. The drug may simply remain off the market altogether because the would-be local producer cannot overcome the data exclusivity barrier for the specified period, usually at least five years.¹¹²

Other provisions in some FTAs can effectively extend the nonuse period by adding on another five year "waiting period." This result is

107. See Mercurio, *supra* note 98, at 225-26; Correa, *NEGOTIATING HEALTH*, *supra* note 23; Abbott, *NEGOTIATING HEALTH*, *supra* note 105.

108. See Mercurio, *supra* note 98, at 226-27; Correa, *NEGOTIATING HEALTH*, *supra* note 23.

109. See *supra* notes 68-70; *supra* Part C(1)(b).

110. See Mercurio, *supra* note 98; Correa, *Unfair Competition Under the TRIPS Agreement*, *supra* note 46.

111. TRIPS Agreement, *supra* note 29, art. 70.1.

112. See Mercurio, *supra* note 98, at 227.

achieved by prohibiting the generic manufacturer from relying on data provided for regulatory approval in another country for a specified five year period (assuming that country requires local registration within that five year period).¹¹³ Such provisions enable an originator company to register the drug in its home country, wait five years, and then submit the drug for marketing approval in other FTA countries, whose generic industries must then wait out another five years of market exclusivity derived from clinical test data protection.¹¹⁴

Moreover, the “new chemical entity” language used in TRIPS and some of the early FTAs has given way to language mandating data protection for any new *product* in recent agreements.¹¹⁵ Here is where originators of older, pre-existing products have the greatest opportunities to obtain exclusive marketing rights, without any new expenditures on R&D or clinical trials.

The data exclusivity provisions, like the linkage provisions, can also be used to undermine the FTA state’s otherwise clear rights to impose compulsory licenses to address public health issues. To the extent this tactic succeeds, it defeats the public health safeguards otherwise adopted by the Doha Declaration on the TRIPS Agreement and Public Health,¹¹⁶ as well as the implementing legislation, in both a waiver and a pending Amendment to Article 31 of the TRIPS Agreement.¹¹⁷ These multilateral flexibilities were meant to enable countries without manufacturing capacity to obtain needed medicines from other countries through back-to-back compulsory licenses.¹¹⁸

Still other TRIPS-plus provisions in FTAs can directly or indirectly affect access to generic medicines by imposing patent term extensions, express limits on the power to invoke compulsory licenses, and limits on parallel imports.¹¹⁹ With specific regard to data exclusivity provisions, the cumulative effect of these FTAs is, as Professor Mercurio observes, to make “the cost of the resulting [generic] drugs . . . rise considerably as

113. See, e.g., Oman–U.S. FTA, art. 15.9.1(b) (2004); Australia–U.S. FTA, art. 17.10.1(c) (2005).

114. See Mercurio, *supra* note 98, at 227-28.

115. *Id.* at 228.

116. See *supra* note 57; Timmermans, *supra* note 11; Mercurio, *supra* note 98, at 228-29.

117. See *supra* note 58. See also Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT’L L. 79, 82 et seq. (2004) [hereinafter Correa, *Bilateralism in Intellectual Property*].

118. See Abbott & Reichman, *supra* note 59.

119. See Mercurio, *supra* note 98, at 229-35; Abbott, *supra* note 105. These provisions are beyond the scope of this Article.

well as [to] delay the generics introduction into the [relevant] marketplace.”¹²⁰

b. Recent Constraints on USTR's Negotiating Mandate

As explained in a previous article, the new majority in the U.S. Congress intervened in 2007 to modify some of the most extreme provisions set out in signed but theretofore unratified FTAs¹²¹ (including that with Colombia¹²²). This new template removes most of the language providing extraterritorial effect for the submission of regulatory data in the United States (and elsewhere) for pharmaceuticals,¹²³ which, if properly implemented, could avoid the extra five year “waiting period” discussed above. There is also some ambiguous language linking the term of marketing exclusivity in an FTA country whose generic producers rely on bioequivalence to the term available in the country whose approval was relied upon, under certain conditions.¹²⁴

Other sources report an understanding to the effect that the data exclusivity provisions in these still to be ratified agreements should not, of themselves, restrict the FTA countries' ability to invoke compulsory licenses.¹²⁵ This remains to be seen. If true, its impact on previously

120. Mercurio, *supra* note 98, at 227. He adds that “duplication of testing is arguably unethical, as it simply is repetition . . . where the safety and efficacy of a product has already been determined.” *Id.* See also Timmermans, *supra* note 11.

121. See generally Abbott & Reichman, *supra* note 59, at 962-65.

122. See, e.g., U.S. TRADE REPRESENTATIVE, BIPARTISAN AGREEMENT ON TRADE POLICY: INTELLECTUAL PROPERTY (May 2007), available at http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file945_11283.pdf, but note that the legislation implementing the Peru FTA was signed into law on December 14, 2008, United States-Peru Trade Promotion Agreement Implementation Act, Pub. L. No. 110-138, 121 Stat. 1455.

123. See Abbott & Reichman, *supra* note 59, at 964.

124. See *id.* at 964-65.

125. See Office of the United States Trade Representative, Trade Facts, Bipartisan Agreement on Trade Policy: Intellectual Property Provisions, May 2007, available at http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file312_11283.pdf; *Brand-Name Drug Industry Alarmed At IPR Precedent of FTA Template*, INSIDE U.S. TRADE, May 18, 2007.

The [bipartisan Congressional] agreement contains three main provisions: a reduced period of time in which generic companies are restricted from using brand-name test data to approve generic drugs, an end to the requirement that a foreign health regulator would have to certify that a generic drug does not violate a patent before extending marketing approval, and language giving countries the option of extending patent duration if a patent approval does not happen on a timely basis. These elements apply only to FTAs negotiated with Peru, Panama and Colombia as developing countries, but do not apply to the FTA with Korea as an industrialized

ratified FTAs must also be clarified.

In any event, most of the provisions discussed above will remain in effect, depending on the particular terms of specific FTAs, regardless of the template applicable to agreements yet to be ratified. A minimum period of five years' marketing exclusivity can thus generally be expected,¹²⁶ with the consequences discussed above. Moreover, the U.S. FTAs, which operate in favor of the European Union and other countries by dint of the MFN clause of TRIPS,¹²⁷ may be further reinforced by the European Union's own bilateral trade agreements—so-called European Partnership Agreements (“EPAs”)—which may add serious enforcement obligations to the normative provisions under review.¹²⁸

Developing countries that enter into FTAs with the United States or into EPAs with the European Union along the lines of those currently proposed will thus be constrained “to provide a very strong market dominant position for pharmaceutical originator companies, and . . . to create substantial obstacles to the introduction of generic products.”¹²⁹ Among these obstacles, the market exclusivity provisions attributable to clinical test data remain particularly troubling.

D. A Missed Opportunity: The Cost-Sharing Alternative

Sad as this survey of FTA provisions is, it becomes even sadder to think that a better negotiating strategy, if adopted early on, might at least have attenuated some of the potential harm to public health and consumers documented above. To this end, the developing countries might have counter-offered some measure of added protection for clinical trial data when negotiating FTAs without acquiescing in the exclusive rights model. A logical alternative would have been to recognize the alleged “free rider” problem by acquiescing in a reasonable royalty for use of the originator's clinical trial data during a specified period,¹³⁰ as already occurs in U.S. law for test data pertaining

country.

Id.

126. See Abbott & Reichman, *supra* note 59, at 964.

127. See *supra* note 103 and accompanying text.

128. See Abbott & Reichman, *supra* note 59, at 965-69.

129. *Id.* at 969.

130. This strategy was first proposed by Reichman in meetings at Bellagio, Italy and New Delhi, India and quickly endorsed by James Love and Robert Weissman. See Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 145; Robert Weissman, *Data Protection: Options for Implementation*, in *NEGOTIATING HEALTH: INTELLECTUAL*

to pesticides and fertilizers.¹³¹ Such an approach would have invoked the concept of “liability rules”—that is, take and pay rules—rather than exclusive property rights, which require the owner’s consent to specified uses of the property in question.¹³²

1. An Early U.S. Proposal Envisioned a Liability Rule

In the late 1980s, the United States multilateral trade negotiators had submitted a proposal that required nonuse of trade secrets “submitted to carry out governmental functions” or for “commercial or competitive benefit” of either the government or third parties “except with the right holder’s consent, *on payment of the reasonable value of use*”¹³³ or if a reasonable period of exclusive use was given the right holder. The initial United States position thus appeared willing to consider a cost-sharing or “liability rule” approach, based on compensatory royalties, as an alternative to the exclusive property right approach embodied in NAFTA. This proposal would have been consistent with some pre-existing American practice with regard to test data for fertilizers and pesticides, which obtain a period of data exclusivity followed by another period of free use by any second comer who pays equitable compensation.¹³⁴

If this approach were applied to clinical trials for medicines, it would enable governments and generic producers to rely upon both test data and positive regulatory outcomes elsewhere in order to market equivalent or competing products otherwise permitted under international intellectual property law, “provided that the second

PROPERTY AND ACCESS TO MEDICINES 151-78 (Pedro Roffe et al. eds., 2006) [hereinafter Weissman, NEGOTIATING HEALTH]; James Love, *Four Practical Measures to Enhance Access to Medical Technologies*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 241-56 (Pedro Roffe et al. eds., 2006) [hereinafter Love, NEGOTIATING HEALTH]. See, most recently, Aaron X. Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPS Agreement*, 45 HARV. INT’L L.J. 443 (2004); Taubman, *supra* note 30, at 598.

131. See U.S. Federal Insecticide, Fungicide and Rotenticide Act [hereinafter FIFRA], 7 U.S.C. §§ 136-136(y) (2004).

132. See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972); Jerome H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743 (2000) [hereinafter Reichman, *Of Green Tulips*].

133. Reichman, NEGOTIATING HEALTH, *supra* note 23, at 144-45 (citing authorities). See also Weissman, NEGOTIATING HEALTH, *supra* note 130.

134. See FIFRA, 7 U.S.C. §§ 136-136(y) (2004); Weissman, NEGOTIATING HEALTH, *supra* note 130.

comers paid a reasonable royalty to the data originators to help defray their costs of R&D.”¹³⁵ Such an approach would address any perceived free rider problem that arises from the enormous costs of conducting clinical trials for new pharmaceutical products under existing FDA standards, without creating barriers to entry or other anti-competitive effects flowing from the inability of local governments to implement the flexibilities that the TRIPS Agreement makes available.

Notwithstanding these advantages, no cost-sharing proposals appeared in the FTAs concluded with the United States before 2007, nor, until recently, was there evidence that developing countries had seriously put such proposals forward. One reason is that acceptance of a cost-sharing approach would arguably diminish the victory achieved in obtaining the so-called “misappropriation approach,” embodied in Article 39.3 of the TRIPS Agreement as it stands, which the 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’s claim to additional compensation for generating data.¹³⁶

The problem with this position is that resistance to the exclusive rights model has largely failed. Governments that are eager to sign FTAs thus find themselves saddled with ever harsher exclusive rights clauses without even attempting to fall back on counter proposals sounding in compensatory liability principles.

Recently, however, the Korean government successfully negotiated a cost-sharing clause for clinical trial data in its Free Trade Agreement with the European Free Trade Association (“EFTA”) countries,¹³⁷

135. Reichman, *NEGOTIATING HEALTH*, *supra* note 23, at 145.

136. *Cf.* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 *YALE J. HEALTH POL’Y L. & ETHICS* 193, 197 (2005) (arguing the case for deviations from stringent intellectual property law and policies to “permit . . . the broadest possible dissemination of pharmaceutical innovation” in poor countries).

137. *See* Annex XIII (Article 3) to the EFTA-Korea FTA, *available at* <http://www.worldtradelaw.net/fta/agreements/eftakorfta.pdf>:

The Parties shall protect undisclosed information in accordance with Article 39 of the TRIPS Agreement. The Parties shall prevent applicants for marketing approval for pharmaceutical and agricultural chemical products from relying on undisclosed test or other undisclosed data, the origination of which involves a considerable effort, submitted by the first applicant to the competent authority for marketing approval for pharmaceutical and agricultural chemical products, utilizing new chemical entities, for an adequate number of years from the date of approval, except where approval is sought for original products. *Any Party may instead allow in their*

although this Agreement has not yet been implemented in practice. The Indian government is also reportedly exploring the compensatory liability approach as one of several options, while otherwise resisting data exclusivity in ongoing negotiations with USTR.¹³⁸ If the Indian Government eventually threw its weight behind this compromise approach, it might inspire other Asian governments to follow its lead.¹³⁹ For this reason, it is worth exploring further how such an option might be implemented in practice.

2. Implementing a Compensatory Liability Regime

Acting on this author's previous proposals,¹⁴⁰ Robert Weissman and James Love began working on more detailed implementing strategies.¹⁴¹ As Weissman convincingly argued, 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. "In 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 brand name companies for conducting clinical tests."¹⁴²

Moreover, by counter-offering with a liability rule, developing

national legislation applicants to rely on such data if the first applicant is adequately compensated.

Id. (emphasis added). EFTA has reportedly made this option a standard practice in their FTA negotiations. See ICTSD/UNCTAD RESOURCE BOOK, *supra* note 103.

138. However, such an option does not appear in SATWANT REDDY & GURDIAL SINGH SANDHU, REPORT ON STEPS TO BE TAKEN BY GOVERNMENT OF INDIA IN THE CONTEXT OF DATA PROTECTION PROVISIONS OF ARTICLE 39.3 OF TRIPS AGREEMENT, INDIA MINISTRY OF CHEMICALS AND FERTILIZERS (MAY 31, 2007). According to the Government of India, "[t]he Department of Health & Family Welfare would give wide publicity to the recommendations in the Report and carry out consultations with stakeholders before proposing appropriate amendments to Drugs & Cosmetics Act 1940 and its Rules." GOVERNMENT OF INDIA, MINISTRY OF CHEMICALS & FERTILIZERS, DEPT. OF CHEMICALS AND PETROCHEMICALS ANNUAL REPORT, 2007-2008 §2.44(c), available at <http://chemicals.nic.in/AREng0708.pdf>. Nonetheless, India continues to resist data exclusivity as of April 2008. See, *USTR pushes for drug data protection*, THE TIMES OF INDIA, April 15, 2008.

139. See generally, Jerome H. Reichman, Intellectual Property in the Twenty-First Century: Will Asia Lead or Follow?, Paper Presented at the Conference on the Changing Role of Intellectual Property in Asia: Moving Beyond Producers and Consumers, University of Illinois (March 1, 2008).

140. See *supra* notes 130 & 132.

141. Weissman, NEGOTIATING HEALTH, *supra* note 130; Judit Rius Sanjuan, James Love & Robert Weissman, A Cost-Sharing Model to Protect Investments in Pharmaceutical Test Data, CPTech Pol'y Brief No. 1, April 3, 2006 (rev. ed., May 18, 2006).

142. Weissman, NEGOTIATING HEALTH, *supra* note 130.

country negotiators could leverage the fact that U.S. law already establishes a version of this cost-sharing approach for agricultural chemical compound registration, under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”).¹⁴³ Under this regime, as explained by Weissman, “[a]fter the expiration of an exclusivity period, generic entrants [would] 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.”¹⁴⁴

Consistent with these premises, Weissman suggests language to implement a “cost-sharing approach.”¹⁴⁵ His method quite literally focuses on the actual cost of producing the data, usually in Organisation for Economic Co-operation and Development (“OECD”) markets, where the data originator seeks first marketing approval. The amount to be paid an originator company would result from evidence of (1) the verifiable costs of the tests or data, (2) “a reasonable estimate of the country’s likely share of the global market,” and (3) “the amount of global revenue the product has generated to date, and in the previous 12 months.”¹⁴⁶ Actual costs may also reflect a risk premium to cover possible failures in initial testing over time and some compensation for the benefit of early market entry (as compared to the amount of time needed in case of independent replication of clinical trials).¹⁴⁷

Weissman’s approach would thus seek to determine the proportionate global market share to be allocated to generic competitors on the basis of market size. One problem with it is the risk

143. This Act states:

The [Environmental Protection Agency] administrator, without the permission of the original data submitter, [may] consider any 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. . . . [T]he 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.

FIFRA, 7 U.S.C. § 136a(c)(1)(F)(iii), *supra* note 45. But note that liability for equitable compensation can only occur in the five years after the original ten-year period of complete exclusivity of § 136a(c)(1)(F)(i) (which can be extended to thirteen years total under § 136a(c)(1)(F)(ii)).

144. See Weissman, *NEGOTIATING HEALTH*, *supra* note 130, at 151-78; *cf.* Reichman, *Of Green Tulips*, *supra* note 132.

145. See *id.*, at 162-63. Weissman’s proposals would 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. Weissman also acknowledges that, under FIFRA, U.S. arbitrators are willing to consider a “risk premium” to reflect the costs of testing that result in unapproved products. See *id.* at 157, Box 9.2.

146. Sanjuan, Love & Weissman, *supra* note 141, at 8-9.

147. See ICTSD/UNCTAD RESOURCE BOOK, *supra* note 103, § 3.3.2, at 538.

of overcompensation, although this factor itself depends on whether one views the demand for payment as merely a form of compensation for lost revenue or, alternatively, as a form of regulatory reward over and above the patent system.¹⁴⁸ Viewed as compensation for lost revenues, Weissman proposes caps on the aggregate amount of revenue to be recovered, and he would disallow any compensation at all if the originator company held a valid patent on the product in the relevant territory. In other words, Weissman sees compensation as a viable claim only when, for one reason or another, the originator company had failed to obtain a relevant patent in the country at issue.¹⁴⁹

One may doubt that negotiators in developing countries could actually obtain such caps, in part because originator companies may already receive double compensation in the European Union and the United States (depending on the circumstances), in which case they would be recognizing an inconsistent principle abroad. Moreover, Weissman's approach, based on market size, does not directly assess the relative capacity to pay of the country in question.

Since Weissman's initial proposals in 2003, Professor Aaron Fellmeth has devised an elegant but still more complicated set of "fairness" formulas drawing on the law and economics literature.¹⁵⁰ Fellmeth analyzes several different models, including a "Simple Divisions Royalties Model" and a more refined "Re-adjustable Royalties Model." The latter takes into account such factors as the initial costs of R&D, the time value of money, the number of participants in the scheme, and their ability to pay.

One problem with both of these approaches is that determining the true costs of pharmaceutical R&D for any purpose, especially drug price appraisals or negotiations, has proved a daunting task never satisfactorily resolved to date.¹⁵¹ *A fortiori*, developing countries' authorities would face major difficulties in determining R&D costs accruing on the part of the data originator. Even if this variable were established with some degree of credibility, it would remain nearly

148. See *supra* note 49; *infra* note 181 and accompanying text (discussing views of Prof. Rebecca Eisenberg).

149. Weissman, *NEGOTIATING HEALTH*, *supra* note 130, at 157. Even this approach begs the question of how much "compensation" or "reward" had been obtained in other countries.

150. See Fellmeth, *supra* note 130, at 478-500.

151. For a noteworthy illustration of the difficulties by an OECD task force, see OECD, *PHARMACEUTICAL PRICING POLICIES IN A GLOBAL MARKET* (2008) (Executive Summary), available at <http://www.oecd.org>.

impossible to determine how much of the expenses attributable to data incurred by the originator company had in fact been recouped or exceeded in developed country markets.

For this reason, a simpler approach may prove more desirable, if only to avoid litigation and other transaction costs. On this approach, a reasonable royalty model could be adopted instead, which would oblige generic producers to pay a flat percentage of gross sales, or a flat percentage above marginal costs of production, as a tithe for the right to rely on the originators' test data results for a specified period of time, to last no longer than five years. On this approach, the compensation to be paid is linked to the value of the data to each company, as reflected in the resulting sales.¹⁵² Given that Canada used to impose a standard four percent royalty on a license of right to use *patented* pharmaceuticals until 1992,¹⁵³ one could envision that figure as an outer limit, one that also indirectly takes account of the fact that many originator companies will already have recouped the bulk of their R&D expenses in developed countries anyway. However, if relative ability to pay were factored in, as would be desirable, the reasonable royalties could range from, say, one to four percent, depending on where a given country fell in the per capita GDP poverty index.

The principal disadvantage of this approach is that it would give only an approximation of the originator's true R&D costs. For that and other reasons,¹⁵⁴ it could be seen as "overcompensation," all the more so in that revenues obtained in developed markets are pocketed without regard to these accounts. However, intellectual property law is accustomed to such approximations, which in this case have the twin virtues of avoiding the quixotic hunt for "true" costs (and the related litigation costs certain to ensue) and of finessing the conceptual debate about "rewards" versus "compensation," to be examined below.

152. Sanjuan, Love & Weissman, *supra* note 141, at 7, 9, have also endorsed this scheme in the alternative. They note that some FIFRA arbitrators have used this approach in connection with agricultural test data. *Id.* at 7 (noting possible adjustments for risk of investment and cost of capital). See also *In the Matter of the Arbitration Between Microgen, Inc. and Lonza, Inc.*, Arbitrator's Decision and Award, Docket No.: 23-171-00003-96, Before the American Arbitration Association, May 10, 2000.

153. See JEROME H. REICHMAN WITH CATHERINE HASENZ AHL, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: THE CANADIAN EXPERIENCE (ICTSD, Geneva, October 2002), available at http://www.ictsd.org/pubs/ictsd_series/prs/cs_reichman_hasenzahl.pdf. This figure rose to six percent in some cases decided in the 1990s.

154. Sanjuan, Love & Weissman, *supra* note 141, at 9, also suggest a royalty based on four percent of net sales of the generic product as a baseline indicator, if this alternative were adopted.

Suffice it to say that, in a world where private pharmaceutical companies continue to labor under the duty to supply clinical test data as a de facto public good, their efforts to coerce generic competitors to share that burden against their will are probably more efficiently discharged by a simple liability rule based on a reasonable royalty than by a true cost-sharing formula. The deeper questions concern the need to rationalize the process by which this essential public good is to be produced in the first place, a topic that this Article will soon address in depth.

II. RETHINKING THE ROLE OF CLINICAL TRIAL DATA REGIMES

A. *The Flawed Logic of Marketing Exclusivity*

The foregoing discussion shows that “marketing exclusivity” (as the protection of clinical test data is called in the United States) or “data exclusivity” (as it is labeled in the European Union)¹⁵⁵ has become an increasingly accepted alternative to patents. While there has been considerable discussion in both the United States and the European Union about the modalities of implementing this de facto *sui generis* intellectual property regime and about the benefits of transnational harmonization of these modalities, there has been relatively little deep analysis of the logic, nature, or validity of the regime itself, as an institution of domestic and global intellectual property law.¹⁵⁶

1. Evaluating the Incentive Rationale

Partly, this inattention to fundamentals may stem from the regulatory nature of the regime in the United States, which to some extent has shielded it from the more intense public scrutiny likely to accompany intellectual property bills that must wend their way through congressional committees.¹⁵⁷ While considerable public debate was generated in the European Union when the initial EC Directive of 1986 was replaced with a revised and consolidated Directive of 2001,¹⁵⁸ this

155. Junod, *supra* note 9, at 502.

156. For efforts to raise awareness of the relevant issues, see Scafidi, *supra* note 23, and Timmermans, *supra* note 11. See also Taubman, *supra* note 30.

157. However, recent proposals to extend long-term data exclusivity to biologics have generated intense public debate. See, e.g., Jessica R. Underwood, *What the EU Has That the U.S. Wants: An Analysis of Potential Regulatory Systems for Follow-On Biologics in the United States*, 10 DEPAUL J. HEALTH CARE L. 419, 441-51 (2007).

158. Council Directive 87/21, 1987 O.J. (L 015) 36-37 (EC), amending Council Directive 65/65, 1965 O.J. (L 22) 369 (EC); Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal

debate seems to have largely focused on implementation issues in regard to efforts that attempted to rationalize problems arising in the past.¹⁵⁹ The European Commission's revised Directive of 2004 expressly aimed to increase incentives to offset the competitive decline of the EU pharmaceutical sector with respect to the U.S. sector at the turn of the century.¹⁶⁰ In the absence of searching economic, philosophic, or systematic legal analysis, at least until recently,¹⁶¹ the discussion has often taken the largely unelaborated need for an additional incentive mechanism for granted. Over time, this "need" has acquired an aura of inevitability as the institution itself spreads from country to country and region to region under the auspices of FTAs,¹⁶² with the diabolical multiplier effect of the TRIPS Agreement's MFN provision.¹⁶³

Congress originally justified the introduction of marketing exclusivity as a device for encouraging "the development and testing of unpatentable pharmaceuticals."¹⁶⁴ Among the concerns known at the time were the uncertain status of biotechnological inventions and second uses of patented medicines (i.e., new therapeutic indications of known compounds), both of which categories subsequently obtained a more solid status in U.S. and EU patent law.¹⁶⁵ Over time, this

Products for Human Use, OJ EC, 28 Nov., L311/67.

159. Junod, *supra* note 9, at 502-17.

160. Directive 2004/27/EC, *supra* note 46, art. 10; Pugatch, NEGOTIATING HEALTH, *supra* note 10, at 105-08 (describing "8+2+1 formula" of the current regulation, also including a Bolar-type provision allowing experimental reverse-engineering of the patented molecule for purposes of marketing approval before expiry of the patent).

161. For a critical analysis, see, e.g., Correa, *Unfair Competition Under the TRIPS Agreement*, *supra* note 46; Reichman, NEGOTIATING HEALTH, *supra* note 23. For a profound enquiry that recognizes the many different and contradictory interests at stake, see Taubman, *supra* note 30. For a favorable analysis on economic grounds, see, e.g., Fellmeth, *supra* note 130, and Rebecca Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007). But see Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMM. & TECH. L. REV. 1 (2007). See also Skillington & Solovy, *supra* note 20.

162. See, e.g., Taubman, *supra* note 30, at 601-04.

163. TRIPS Agreement, *supra* note 29, art. 4 (no exception for regional trade agreements as under GATT).

164. See *Allergan Inc. v. Alcon Labs.*, 324 F.3d 1322, 1325 (Fed. Cir. 2003), *cert. denied*, 540 U.S. 1048 (2003) (citing H.R. Rep. No. 98-857, pt. 1, at 29 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48).

165. Junod, *supra* note 9, at 484-86. However, the systematization of biotechnology in European patent law took much longer than in the United States and was not settled until the Biotech Directive of 1998. See Council Directive 98/44, 1998 O.J. (L 213) 13-21 (EC). Presumably, data exclusivity helped fill this gap in the European Union. As for second uses, see Richard F. Kingham & Grant H. Castle, *Data and Marketing Exclusivity for Pharmaceuticals in the European Community*, 55 FOOD & DRUG L.J. 209, 223 (2000) on this

38 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1

“supplementary incentive” rationale has been applied to pharmaceuticals whose effective patent life was shortened by lengthy delays for regulatory approval,¹⁶⁶ to so-called orphan drugs,¹⁶⁷ and most recently, to biologics (large-molecule biogenetic pharmaceuticals), which may require protracted and risky clinical trials and whose suitability for bioequivalent generic manufacturing remains controversial.¹⁶⁸

Marketing exclusivity as a provider of substitute compensation for undertaking the costs and risks of clinical trials has also been used to justify tough FTA provisions affecting the developing countries, where many existing pharmaceutical patents were not yet recognized under the TRIPS Agreement for one reason or another.¹⁶⁹ This reasoning echoes one of the early justifications in the European Union, when some member countries—such as Spain and Portugal—did not grant pharmaceutical patents at all.¹⁷⁰ But these justifications appear weak in that all countries (except a few Least-Developed Countries) must now protect pharmaceutical inventions (created after 2005 at the latest);¹⁷¹ while the notion that the European Commission and Council should supplement national public health schemes premised on price controls by imposing data exclusivity provisions raises both constitutional questions and concerns about regulatory capture that lie beyond the scope of this Article.

Viewed as a gap-filling alternative to patents rooted in the incentive rationale, the data exclusivity regimes reveal a number of internal contradictions that critics have pointed out. For example, the inability to patent any given pharmaceutical may indicate relatively low public

point.

166. Eisenberg, *supra* note 49, at 351-59.

167. See Grabowski, *Increasing R&D Incentives*, *supra* note 19, at 458-59.

168. Grabowski, Data Exclusivity, *supra* note 54; Abbott, *NEGOTIATING HEALTH*, *supra* note 105.

169. TRIPS Agreement, *supra* note 29, art. 70 (no retroactivity; no pipeline; only a mailbox for new patents during transitional phase; plus a market exclusivity requirement for patents in the mailbox unrelated to clinical test data). See also Taubman, *supra* note 30, at 596 (stressing free-rider problem), 597-98 (contrasting developing countries' demands for protection of traditional knowledge with their denial of claims for “misappropriation” of clinical test data).

170. Junod, *supra* note 9, at 502 (citing James Love, *TACD on Pharmaceutical Registration Data Exclusivity* (Draft), available at <http://www.essentialdrugs.org/edrug/archive/200001/msg00075.php>).

171. TRIPS Agreement, *supra* note 29, arts. 27, 65.1, 65.4, 66.1 (plus later extensions), 70; Abbott & Reichman, *supra* note 59, at 928-29, 975-76, 976 n.239 (noting exemption of LDCs from duty to provide patent protection of pharmaceuticals until 1 January 2016).

health utility, as when minor improvements are made to an existing patent, often as an excuse to prolong or “evergreen” that same patented product.¹⁷² More generally, the number of unpatented products attracting data exclusivity at any given time seems relatively small in relation to the total number of products—patented or not—that are similarly protected.¹⁷³ As a result, so much double compensation seems built into a *sui generis* right that applies across the board to both patented and unpatented medicines that, even if one buys into the notion that two conceptually distinct incentives are at issue,¹⁷⁴ it tends to obviate the validity of the distinction in practice.

However, these arguments are not necessarily conclusive. Some incremental improvements may elicit big therapeutic benefits without attracting patent protection in some jurisdictions, especially those that resist product patents for new uses of known substances. Conversely, even new chemical entities that do meet patentability standards may yield relatively minor advances in therapeutic benefits. To the extent that a marketing exclusivity regime provides needed incentives at all—admittedly a serious question—it could validly perform that function in certain cases, especially if the relation to patent duration were “capped,” as was permitted under the first EC Directive,¹⁷⁵ or if the short term of duration—five years in the United States¹⁷⁶—made it unlikely to extend beyond the term of patent protection, where it exists, in most cases.

In this same vein, one must also factor in the potential social costs of the drive for so-called “quality patents,” which seems likely to elevate the very low nonobviousness standard in the United States during the 1990s to higher, more stringent levels, especially after the Supreme Court’s recent decision in the *KSR* case of 2007.¹⁷⁷ To the extent that more incremental improvements to existing pharmaceuticals were denied patents on grounds of obviousness in the future, the marketing

172. Junod, *supra* note 9, at 495.

173. *See, e.g., id.*, at 487-88. In the period 1998 to February 2004, 27 out of 137 FDA approved drugs were developed without “substantial patent protection.” *Id.* at 487.

174. *See, e.g.,* Taubman, *supra* note 30.

175. Council Directive 87/21, *supra* note 158, discussed in Junod, *supra* note 9, at 503.

176. 21 U.S.C.A. §§ 355(3)(E)(ii), 355(5)(F)(ii) (2008).

177. *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007). “[A]s progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.” *Id.* at 1746. *See* Symposium, *Nonobviousness—The Shape of Things to Come*, 12 LEWIS & CLARK L. REV. 323 (2008).

exclusivity regime for clinical trials could increasingly supply the sole incentives for overcoming the risk of market failure for an ever-widening class of pharmaceuticals that, in the past, had sometimes proved to yield surprising therapeutic benefits. Occasionally, indeed, it is the second or third variation on a common medical theme that gets it right from the standpoint of optimal delivery.¹⁷⁸ Absent alternative incentives, this type of innovation could become progressively less attractive to venture capital under a more rigorous nonobvious standard. Moreover, according to Professor Henry Grabowski,¹⁷⁹ the long incubation period for biologics, and the corresponding risk of Phase III clinical test failures, puts the breakeven point so high that investors want Congress to deliberately extend market exclusivity beyond effective patent life as an inducement to risk averse venture capitalists¹⁸⁰ (although this camp conveniently omits any mention of the government funds pouring into this same field).

My point is that the incentive rationale for market exclusivity, although usually overstated in its conventional form, has just enough legs or legitimacy in enough circumstances that it must be addressed head on, and not entirely dismissed out of hand as an irrelevant appendage to the patent system. Recently, moreover, the incentive rationale has been given a new twist by a distinguished authority that arguably reinforces any legitimacy it otherwise possessed. Professor Rebecca Eisenberg argues that market exclusivity is part of an interrelated group of regulatory provisions that not only force drug companies to conduct clinical trials and submit results to independent experts, they positively stimulate producers to conduct more and better trials than they otherwise would be inclined to do, which redounds to the benefit of the overall innovation process.¹⁸¹ Like Professor Grabowski in regard to biologics, Professor Eisenberg thus sees value in strengthening the incentives that flow from data exclusivity, as distinct from patents, to improve the quality of clinical trials. But she would

178. For example, see Genentech's patent application in Europe for "the intermittent administration of insulin-like growth factor (IGF) I to avoid tachyphylaxis (rapid loss of drug efficacy with continued use) during the treatment of a chronic disease[.]" Mary Ann Liebert, *Genentech's Method of Using Growth Factor May Be Patentable in Europe*, 25 *BIOTECH. L. REP.* 18 (2006).

179. See Grabowski, *Data Exclusivity*, *supra* note 54.

180. *Id.* See also Henry Grabowski, David Ridley & Kevin Schulman, *Entry and Competition in Generic Biologics*, 28 *MANAGE. DECIS. ECON.* 439, 440 (2007). But the extent to which the costs of trials for biologics greatly exceed that of small molecules has not been conclusively established.

181. Eisenberg, *supra* note 49, at 366-87.

impose the condition that these extra benefits must also result in much greater disclosure and transparency with regard to clinical test results than currently occurs, which, in her view, could greatly reduce the aggregate costs of conducting clinical trials.¹⁸²

Needless to say, there are more problems with these arguments than we have space to address here. For example, Ariel Katz suggests that positive clinical trial results already perform such a crucial “certification” guarantee against “lemons” that pharmaceutical companies ought to be grateful for the opportunity to shoulder the costs, heavy as they may be.¹⁸³ More tellingly, the apologists for marketing exclusivity seldom mention the almost thirty billion dollars a year¹⁸⁴ of federal funds that the National Institutes of Health (“NIH”) spend on upstream research in order to reduce the enormous risks inherent in early stage medical research.¹⁸⁵ Because this federal funding policy often leaves only the downstream research burdens to the pharmaceutical companies, especially the so-called “billion dollar barrier” of clinical trials,¹⁸⁶ it is largely the costs of clinical trials that justifies strong pharmaceutical patents—and correspondingly high pharmaceutical prices—in the first place.

Given that the originator pharmaceutical companies themselves never cease reminding us of this fact when justifying the benefits of existing patent law against reforms desired by other industries, especially the information technology sector,¹⁸⁷ arguments that focus on the need for ever greater incentives for clinical trials as such often have a hollow ring to them. They enable the originator companies to have it both ways, without accounting for the excess profits that overlapping regimes can yield in many, if not most cases.

182. *Id.* at 380-85; see most recently, Rebecca S. Eisenberg, Patents and Public Health: The Significance of Data Exclusivity, paper presented to the Workshop on Trade Secrecy, Conference of the Engelberg Center on Innovation, Law and Policy, NYU Law School (February 20-21, 2009).

183. Katz, *supra* note 161.

184. *Health Issues and Opportunities at NIH: Hearing Before the S. Subcomm. Labor, Health and Human Services, Education Appropriations* (2008) (testimony of Elias A. Zerhouni, M.D., Director, NIH), available at http://appropriations.senate.gov//2008_07_16_-Labor_Testimony_of_Dr_Elias_A_Zerhouni_at_the_July_16_NIH_Hearing.pdf.

185. See, e.g., Rai et al., *Pathways Across the Valley of Death*, *supra* note 44, at 4.

186. DiMasi et al., *supra* note 5, at 181 (“Assuming the same growth rates . . . per approved drug for R&D relevant to approvals in 2001 . . . capitalized pre-approval cost would be US\$ 1.1 billion.”).

187. Arti K. Rai, *Building a Better Innovation System: Combining Facially Neutral Patent Standards with Regulation of End Product Therapeutics*, forthcoming in the HOUSTON L. REV., available at <http://ssrn.com/abstract=1160198>.

Nevertheless, to the extent that the incentive rationale for data exclusivity has some legs or legitimacy in at least a narrow range of cases, it gives rise to two fundamental questions. First, is a *sui generis* exclusive property right the proper way to provide the kind of additional incentives said to be needed? A second and more profound question is, if clinical trials are such an essential public good that we must scrape the bottom of the intellectual property barrel to stimulate the private sector to provide it adequately, why do we insist on charging that sector with this task in the first place?

2. Why a *Sui Generis* Exclusive Property Right?

However strong or weak the case for an incentive rationale to justify clinical data generation may be, policymakers take a big leap of faith when they uncritically seek to address this need by means of a *sui generis* exclusive property right. Historically, such regimes have compiled a dismal record as legislators shift between copyright-like and patent-like regimes over time.¹⁸⁸ These hybrid regimes typically generate unintended effects of under or over protection without ever satisfactorily resolving the underlying problems of market failure. Conceptually, moreover, patent-like *sui generis* regimes inevitably harbor irresolvable economic contradictions with the mature patent paradigm, which never go away.¹⁸⁹

Consider that the patent law allows an invention to escape the discipline of free competition only because the inventor has contributed a new and useful technical achievement that routine engineers operating in the relevant field could not themselves have developed.¹⁹⁰ By disclosing such an invention to the public in return for a legal monopoly, the inventor helps to elevate the existing state of competition to its next

188. See, e.g., Jerome H. Reichman, Symposium, *Design Protection and the New Technologies: The United States Experience in a Transnational Perspective*, 19 U. BALT. L. REV. 6 (1990); Jerome H. Reichman, *Design Protection After the Copyright Act of 1976: A Comparative View of the Emerging Interim Models*, 31 J. COPYRIGHT SOC. USA 267 (1984); Jerome H. Reichman, *Design Protection in Domestic and Foreign Copyright Law: From the Berne Revision of 1948 to the Copyright Act of 1976*, 1983 DUKE L.J. 1143.

189. See, e.g., Jerome H. Reichman, Symposium, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432 (1994) [hereinafter Reichman, *Legal Hybrids*]; Jerome H. Reichman, *Charting the Collapse of the Patent-Copyright Dichotomy: Premises for a Restructured International Intellectual Property System*, 13 CARDOZO ARTS & ENT. L.J. 475 (1995); Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT'L L.J. 151 (1999).

190. See *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007); *Wal-Mart Stores v. Samara Bros.*, 529 U.S. 205 (2000); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964) (Sears-Compco Doctrine).

highest level.¹⁹¹ Given these premises, however, the practice of extending patent-like exclusive rights, with all the social costs they entail, to “sweat of the brow” research results that fail the test of nonobviousness will not withstand either logical or economic analysis.¹⁹²

However important their public health functions certainly are, clinical trial results merely improve upon existing technological know-how, without adding an inventive step to the prior art. The *sui generis* intellectual property right in question thus protects investment as such, not a technological achievement. Using exclusive property rights that block second comers for this purpose blurs the boundaries between rights holders¹⁹³ and risks generating exorbitant social costs,¹⁹⁴ unless there is no other way to attain the desired public health goals of safety and efficacy.

To avoid these conceptual errors, I have long urged policymakers to sharpen the distinction between exclusive rights that aim to stimulate technological progress and alternative measures that aim to protect investments as such.¹⁹⁵ This distinction is particularly important in cases where second comers may too easily capture the fruits of investment by avoiding or circumventing the cost structure that legitimate competitors must otherwise defray.¹⁹⁶ In such cases, addressing the risk of diminished investment by first movers ideally calls for a pro-competitive

191. See Michael Lehmann, *Property and Intellectual Property--Property Rights as Restrictions on Competition in Furtherance of Competition*, 20 INT'L REV. INDUS. PROP. & COPYRIGHT L. 1 (1989).

192. Reichman, *Of Green Tulips*, *supra* note 132, at 1755 (discussing problem of cumulative and sequential innovation).

193. See, e.g., JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* 88-89 (Princeton Univ. Press 2008); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEXAS L. REV. 989 (1997); Reichman & Dreyfuss, *Harmonization Without Consensus*, *supra* note 91, at 102-22.

194. See, e.g., MICHAEL HELLER, *THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES* (Basic Books 2008). Cf. also Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

195. See, e.g., Reichman, *Legal Hybrids*, *supra* note 189; Reichman, *Of Green Tulips*, *supra* note 132.

196. See, e.g., Jerome H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 VAND. L. REV. 51 (1997); Jerome H. Reichman, *Database Protection in a Global Economy*, 2002 REVUE INTERNATIONALE DE DROIT ECONOMIQUE 455-504; Pamela Samuelson, Randall Davis, Mitchell D. Kapor, & Jerome H. Reichman, *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308 (1994). See also Leo Raskind, *The Misappropriation Doctrine as a Competitive Norm of Intellectual Property Law*, 75 MINN. L. REV. 875 (1991).

44 *MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW* [Vol. 13:1]

remedy that compensates for the losses from undisciplined free-riding without creating barriers to entry for second comers willing to recognize the first comer's contribution when themselves investing in follow-on activities.¹⁹⁷

By focusing attention on the need to protect investment, rather than on stimulating a particular level of technical achievement, policymakers concerned about market failures would logically weigh the relative costs and benefits of liability rules,¹⁹⁸ that is "take now and pay later" rules,¹⁹⁹ against those of *sui generis* exclusive property regimes.²⁰⁰ In this vein, I have elsewhere proposed a "compensatory liability regime" that would allow the first innovator a short period of immunity from wholesale duplication, followed by a brief but relatively longer period in which follow-on improvers could freely enter the market by paying a reasonable royalty to the first comer in exchange for the privilege of adding onto his or her initial contribution.²⁰¹ In such cases, one may view the second comer's compensatory royalties either as a pro rata contribution to the first comer's costs or as the product of a de facto partnership between the innovator, who took the first investment risk, and the second comer, who improves upon the former's technical outcome.²⁰²

197. This, of course, was the logic of traditional trade secret law itself, which conferred only "take and pay" remedies in the sense that those who misappropriated another's secret know-how by dishonest means had to repay the saved costs of reverse engineering by honest means. See RESTATEMENT (3D) OF UNFAIR COMPETITION § 45 (1995); Reichman, *Legal Hybrids*, *supra* note 189; Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L.J. 1575 (2002).

198. See, e.g., Calabresi & Melamed, *supra* note 132.

199. See, e.g., Robert Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1302 (1996).

200. See EUROPEAN PATENT OFFICE, SCENARIOS FOR THE FUTURE 84-97 (2007) ("Blue Skies" Scenario), available at <http://www.epo.org/topics/patent-system/scenarios-for-the-future.html>.

201. See Reichman, *Of Green Tulips*, *supra* note 132. See also Jerome 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 337-66 (Keith Maskus & Jerome H. Reichman eds., 2005); Jerome H. Reichman, *Saving the Patent System from Itself*, in PERSPECTIVES ON THE HUMAN GENOME PROJECT 289-304 (F. Scott Kieff, ed., 2003).

202. Liability rules also look particularly attractive in certain pre-competitive situations, where efforts are made to pool resources for basic upstream scientific research without forfeiting opportunities for financial gain through posterior but unforeseen commercial applications. See, e.g., Rai et al., *Pathways Across the Valley of Death*, *supra* note 44; Jerome H. Reichman, Tom Daederwerdere & Paul F. Uhler, *Designing the Microbial Commons*, Conference on the Microbial Commons, University of Ghent, 2008; Jerome H.

The application of these principles to clinical trial data seems particularly compelling, given that we are dealing with regulatory outcomes that may become secondary barriers to the marketing of pharmaceutical inventions²⁰³ that were developed in response to the prospects of downstream exclusive rights in the form of patents. Typically, these inventions were also a product of upstream government funding in the form of university research grants.²⁰⁴ With regard to clinical test data, in other words, the issue is not how to stimulate further technical innovation at all—it is how to protect the inventor’s downstream investment in the enormous costs and risks of conducting clinical trials that must meet ever more stringent standards of public health and safety.

If it could be empirically demonstrated that the costs and risks of clinical trials—minus the benefits that accrue from a product patent, if any, and from the ensuing certification against “lemons”²⁰⁵—failed to provide originator pharmaceutical companies with a sufficient return on investment, the proper remedy would surely not be to add yet another exclusive property right to the mix, with all its attendant social costs for both innovation and consumers. Rather, the logical solution is to directly address the risks of diminished investment by allowing generic competitors who lawfully enter the market (after any lawful patents expire) to share the costs of these same trials for a relatively short period of time, without erecting new barriers to entry or otherwise delaying the price reductions to patients that competition automatically tends to generate.

At times, the originator company may develop improvements or second uses for which no patent becomes available, especially after the Supreme Court’s tightened nonobvious standards filter through the system.²⁰⁶ Assuming that the product in question delivered real

Reichman & Paul F. Uhler, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 L. & CONTEMP. PROBS. 315 (2003). For a relevant and revealing economic analysis, see generally Brett M. Frischmann, *An Economic Theory of Infrastructure and Commons Management*, 89 MINN. L. REV. 917 (2005).

203. See Taubman, *supra* note 30, at 601.

204. Marcia Angell, *The Truth About the Drug Companies*, 45 JURIMETRICS J. 465, 467 (2005) (“The few innovative drugs usually stem from publicly-funded research done at government or university labs.”).

205. Katz, *supra* note 161.

206. See *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007); *Nonobviousness—The Shape of Things to Come*, *supra* note 177. For pre-KSR likelihood, see Junod, *supra* note 9, at 486 (“The impression left . . . is that patents are so easy to obtain that marketing exclusivity

therapeutic benefits, the protection of investment in clinical trials might afford the only incentive available and the sole remedy for an incipient market failure.²⁰⁷ But even in these cases, which appear to have been relatively rare in the past,²⁰⁸ there is no reason to reward the investor with the very patent-like monopoly he failed to achieve on the merits. The most that a market failure due to the risks of a second comer's ability to rely on the innovator's prior regulatory approval could logically justify is a cost-sharing tax on competitors (and consumers) in the form of a liability rule along the lines described above.²⁰⁹

These premises apply with even greater force to the originator pharmaceutical companies' demands for *sui generis* data exclusivity rights in developing countries under the aegis of bilateral and regional FTAs that have mushroomed in the post-TRIPS era.²¹⁰ Given that originator pharmaceutical companies will have recouped their investments and made their profits by charging high prices in developed countries, it is hard to justify any further protection of investments in R&D beyond territorial patents in the developing countries.²¹¹ Because in these countries there is "a large pool of unpatented pharmaceutical products," data exclusivity can "become a partial substitute for patent protection."²¹² But there is nothing "unfair" in allowing second comers to exploit the goodwill accruing to unpatented products.²¹³ If the regulatory authorities in developing countries allow generic producers to rely on bioequivalence with products approved elsewhere (a reliance rooted in both foreign regulatory outcomes and the relevant scientific

is not necessary. . . . [A] firm can get not one, but several, twenty-year patents for all aspects of its drug, without—at least in practice—being unduly encumbered by the nonobviousness requirement.”).

207. Unless the government covered the costs of clinical trials in the first place, in which case the unpatentable improvement should compete profitably on the open market if it actually delivered therapeutic benefits. *See infra* Part II.B.2.a.

208. *See Junod, supra* note 9, at 485-86.

209. As previously noted, FIFRA already employs such a regime for pesticides, and USTR initially proposed such a regime for article 39.3 of TRIPS. *See, e.g., Fellmeth, supra* note 130, at 479-83.

210. *See supra* note 95 and accompanying text.

211. *But see Fellmeth, supra* note 130, at 496 (rejecting data exclusivity as a de facto attempt “to subsidize wealthy foreign drug developers” but accepting the view that generic manufacturers in developing countries should “pay their fair share of the costs of using trade secrets in their country”).

212. Correa, *Unfair Competition Under the TRIPS Agreement, supra* note 46, at 70.

213. *See Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 (1938); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964) (Sears-Compco Doctrine); *Wal-Mart Stores v. Samara Bros.*, 529 U.S. 205 (2000).

literature), it is hard to see why they should be charged anything at all for the alleged “use” in their countries of so-called trade secrets that they have never actually seen at all.²¹⁴

Nevertheless, to the extent that, rightly or wrongly, some protection of clinical test data has become a nonnegotiable cost of doing business under FTAs with the United States, developing country governments should stand firm on counter proposals offering only a cost-sharing liability rule and not an exclusive property right.²¹⁵ To this end, Professor Aaron Fellmeth has lately published a still more refined “Readjustable Royalties Model,” which factors the developing countries’ ability to pay into the calculus of reasonable royalties.²¹⁶

Unfortunately, developing-country trade negotiators have not generally adopted this cost-sharing approach, perhaps in the mistaken belief that they could resist USTR’s pressures for data exclusivity on other grounds. As a result, the intellectual property chapters in most FTAs that have so far been concluded embody variations on the exclusive property regimes previously described.²¹⁷ It remains to be seen whether Asian countries, such as Korea and India, which offer strong market-access incentives of their own, will turn the tide by successfully defending a liability rule in lieu of an exclusive property right.²¹⁸

Even that auspicious outcome, however, would not necessarily provide an adequate solution to the questions posed at the outset of this enquiry. To be sure, a liability rule would address any claims sounding in the incentive and fairness rationales—whatever their validity might be²¹⁹—without generating the subsidies, barriers to entry, and other social costs attendant upon a data exclusivity regime. But such an approach, still begs the second question posed earlier, namely, why should the private sector be obliged to provide and pay for clinical test data in the first place? It is to this fundamental question that we must turn now, in the concluding section of Part II.

214. See, e.g., Timmermans, *supra* note 11, at 206 (arguing that “while . . . generic manufacturers indirectly rely on the originator’s safety and efficacy data,” they “do not use the originator’s data—in fact they do not even have access to them”); Bayer, Inc. v. Canada, 1 F.C. 553, T-1154-97. *But see* Fellmeth, *supra* note 130, at 496.

215. See *supra* text accompanying notes 140-54 (discussing proposals by Reichman, Weissman, Love, and others).

216. Fellmeth, *supra* note 130, at 482-96.

217. See *supra* text accompanying notes 108-20.

218. Maskus & Reichman, *The Globalization of Private Knowledge Goods*, *supra* note 97, at 14.

219. See, e.g., Taubman, *supra* note 30.

B. From Private to Public Goods: The Most Logical Reform

At the outset, this Article evidenced the soaring costs of clinical trials in the United States, which a well-known study estimated as high as one billion dollars per approved new chemical entity (when adjusted for the four out of five failure rate currently reported).²²⁰ Since then, the questions on the table have been whether, in order to recoup these costs, the originator pharmaceutical companies should be entitled to a second revenue stream from a *sui generis* data exclusivity right, in addition to patents, and if so, the extent to which international intellectual property law should recognize a similar right under either the TRIPS Agreement or the proliferating FTAs that have succeeded it. Now, instead, it is time to step back and ask what might be fundamentally wrong with this entire picture.

American consumers already pay the highest prices in the world for patented pharmaceuticals largely because they are routinely told they must cover the soaring costs of pharmaceutical research and development.²²¹ Because the NIH and the Department of Energy alone spend more than thirty billion dollars a year to defray the costs of basic research in nonprofit institutions,²²² it follows that the bulk of the costs chargeable to American consumers must pertain to clinical trials conducted to meet public health and safety regulations.²²³ Why, then, are the results of these trials increasingly untrustworthy, distorted, or outright fraudulent?²²⁴ And why, if American consumers must cover the high costs of clinical trials, are much poorer consumers in developing countries increasingly denied affordable medicines—including off-patent generics—on the grounds that, they, too, must help defray the burgeoning costs of the same increasingly unreliable clinical trials?²²⁵

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.²²⁶ So long as this market-

220. DiMasi et al., *supra* note 5.

221. *See, e.g.*, Angell, *supra* note 204.

222. *See supra* note 44 and accompanying text.

223. *See, e.g.*, Grabowski, *Increasing R&D Incentives*, *supra* note 19; Grabowski, *Data Exclusivity*, *supra* note 54.

224. *See, e.g.*, Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 *IND. L.J.* 623 (2007); Angell, *supra* note 204, at 466-67; *supra* notes 1-3 and accompanying text.

225. *See, e.g.*, Correa, *Bilateralism in Intellectual Property*, *supra* note 117, at 83.

226. *See* Lewis et al., *The Case for Public Funding*, *supra* note 32.

distorting anomaly persists, clinical data as a guarantor of public safety will remain undersupplied, 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 rippling legislative distortions and high social costs that now take the form of pseudo-intellectual property rights.

In what follows, I describe a proposal to treat clinical trials as a public good that was jointly developed by Professors Tracy Lewis, Anthony So, and myself.²²⁷ Our approach would provide a longer-term solution to a deep structural problem in national and international drug supply chains by rationalizing the treatment of clinical trials from a political economic perspective. It would also 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.

1. Public Disclosure: Only the First Step in a Broader Reform

Recent revelations about the suppression of adverse findings in the clinical testing of new medicines pending FDA approval have led many to call for mandatory disclosure of all clinical trial results.²²⁸ As previously noted, Professor Eisenberg would craft the data exclusivity right so as to provide pharmaceutical companies additional incentives to conduct better quality trials in exchange for public disclosure of the results.²²⁹ These proposals move in the right direction towards

227. Part II.B of this article is largely based on two versions of an earlier article, one published and another unpublished longer version. For the short, published version, see Lewis et. al., *The Case for Public Funding*, *supra* note 32. The longer version, with revisions and updates, is substantially reproduced here for the first time. See also Dean Baker, *The Benefits and Savings from Publicly-Funded Clinical Trials of Prescription Drugs*, Center for Economic and Policy Research (March 2008), available at <http://www.cepr.net> (a "paper . . . in large part inspired by . . . [the] plan" set out in Lewis, Reichman, & So, *The Case for Public Funding*, (2007)).

228. See, e.g., Pierre Azoulay, *The Changing Economics of Clinical Development*, Paper Presented at the Program on Science, Technology, and Global Science, The Earth Inst. at Columbia Univ. (May 20, 2004); Press Release, AMA, *AMA recommends that DHHS establish a registry for all US clinical trials* (June 15, 2004), <http://www.ama-assn.org/ama/pub/article/1616-8651.html>; Press Release, American Academy of Child and Adolescent Psychiatry & American Psychiatric Association, *Leading Medical Groups Endorse Public Clinical Trials Registry* (Sept. 9, 2004), http://www.aacap.org/press_releases/2004/0909.htm. See also *Senators Introduce Legislation That Would Establish Clinical Trial Registry Database*, MEDILEXICON, Oct. 9, 2004, <http://www.pharma-lexicon.com/medicalnews.php?newsid=14711>; *Medical journals to require clinical trial registration*, NEW SCIENTIST, Sept. 9, 2004, available at <http://www.newscientist.com/news/print.jsp?id=ns99996378>.

229. Eisenberg, *supra* note 49, at 366-72.

addressing the selective disclosure of pharmaceutical testing results, study design biases, and other questionable practices.²³⁰ However, disclosure is not the main problem but rather a symptom of a much deeper structural problem.

Mandatory disclosure without addressing this deeper problem yields a less than optimal approach to rationalizing the regulatory machinery governing the supply of pharmaceutical products. Requiring mandatory disclosure of clinical trials will not eliminate the inherent conflict of interest underlying the commercial provision of drugs and medicine or the fundamental inefficiencies the current system promotes. So long as drug companies retain primary responsibility for conducting or funding clinical trials, they will be tempted to selectively disclose information and to avoid research programs that could reveal unfavorable outcomes. Nor would a disclosure requirement alone ensure that the stakeholding company will conduct all the tests deemed most beneficial to public safety.²³¹

For example, until the National Heart, Lung, and Blood Institute funded the Women's Health Initiative, the risks and benefits of postmenopausal hormone therapy remained inadequately assessed by randomized clinical trial procedures despite its widespread use.²³² Equally troubling, drug company sponsors completed Phase IV clinical trials necessary for upgrading to regular approval in only six of twenty-three fast-track approvals of cancer drugs.²³³ There are few incentives to undertake costly testing if the results might only serve to narrow use of the drug to a smaller subgroup of patients or prove unfavorable to its continued use.

A better alternative to calls for mandatory disclosure is to remove

230. See, e.g., Harris, Gardner, *Spitzer Sues a Drug Maker, Saying It Hid Negative Data*, N.Y. TIMES, June 3, 2004, at A1; Peter Juni et al., *Risk of cardiovascular events and rofecoxib: Cumulative meta-analysis*, THE LANCET, Nov. 5, 2004, <http://image.theLancet.com/extras/04art10237web.pdf>. See also Dong BJ, Gambertoglio JG, Gee L et al., *Bioequivalence of Levothyroxine Preparations: Industry Sponsorship and Academic Freedom*, 277(15) JAMA 1200-01 (1997).

231. Lewis et al., *The Case for Public Funding*, supra note 32. See also Baker, supra note 227, at 3 (citing Turner et al., 2008; Bodenheimer, 2000; Cho & Bero, 1996; among others).

232. See, e.g., Writing Group for the Women's Health Initiative Investigators, *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results From the Women's Health Initiative Randomized Controlled Trial*, 288 JAMA 321-33 (2002); Lawrence M. Brass, *Hormone Replacement Therapy and Stroke: Clinical Trials Review*, 2004 STROKE 35.

233. Thomas G. Roberts, Jr. & Bruce A. Chabner, *Beyond Fast Track for Drug Approvals*, 351(5) NEW ENG. J. MED. 501 (2004).

the direct link between the test sponsor (the drug company) and the drug testers. One approach would be to establish an independent testing agency to conduct clinical trials under specified conditions of transparency. Unlike the current system, drug companies would no longer directly compensate the scientists evaluating their own products. Instead, the scientists would now work for the testing agency, supported by general funds collected from the pharmaceutical industry.²³⁴ This separation of clinical trials from sponsorship could attenuate the conflict of interest problem, and it would better ensure objective processing with full disclosure of results under the aegis of a national testing facility than the current system.²³⁵

Even if the competitive logistics of such an approach posed no unsolvable problems, however, it would insufficiently rationalize the drug supply and pricing process, and thus fail to realize the potential benefits of treating clinical trials as a public good.²³⁶ To this end, the federal government, rather than the drug companies, should fund the bulk of the costs of clinical trials. This thesis follows from a careful examination of both the economics of drug supply as well as the political economy of prescription drug programs at home and abroad, as explained below.

2. The Case for Treating Clinical Trials as a Public Good

At the outset, it seems clear that the information gleaned from the clinical testing of drugs and therapies is a public good in the sense that each individual citizen benefits from such information without reducing its value to others.²³⁷ At the same time, the results of the testing process reveal information that improves the conduct of R&D in the industry as a whole without disturbing the validity of underlying patents that

234. Lewis et al., *The Case for Public Funding*, *supra* note 32, at 1.

235. *Cf., e.g.*, Uwe E. Reinhardt, *Perspectives on the Pharmaceutical Industry*, 20(5) HEALTH AFF. 136, 145-47 (2001) (suggesting creation of financially independent pharmacoeconomic research institutes to assess costs and benefits of new and existing drugs).

236. *Cf., e.g.*, Uwe E. Reinhardt, *An Information Infrastructure for the Pharmaceutical Market*, 23(2) HEALTH AFF. 107, 109 (2004) (stressing importance of treating information about pharmaceutical effectiveness as a public good). In his 2004 article, Professor Reinhardt proposed the creation of a publicly funded research organization to evaluate the cost effectiveness of drugs and to disseminate the results. *Id.* Lewis, Reichman, and So believe the public good rationale he expounds should be expanded to cover the production and dissemination of clinical trial data as such. Lewis et al., *The Case for Public Funding*, *supra* note 32.

237. *See, e.g.*, Reinhardt, *supra* note 236, at 109 (stressing non-excludable and non-rivalrous character of “information that facilitates the proper functioning of a healthcare market—such as that for drugs”). *See also* Taubman, *supra* note 30.

protect the products and processes of innovative firms.²³⁸

Like peer-reviewed basic research results, which have always been recognized as a public good, peer-reviewed clinical trial results should promote surer decisions about the safety and therapeutic value of both single products and product groups while stimulating follow-on innovation and providing guidance for better clinical practice. Yet, despite these potential public benefits, our current system saddles private companies with the burdens of clinical testing and thus renders the results artificially scarce and excludable. This approach ignores economic principles teaching that privately supplied public goods will typically be underprovided.²³⁹ In this context, undersupply evokes cases in which a head-to-head comparison between therapeutically equivalent drugs was not studied; an adverse drug reaction was not explored; a specified clinical indication was not appropriately narrowed; or the possibility of use for a neglected disease was not pursued.²⁴⁰

Those concerned that current clinical testing practices fail to meet public health needs may nonetheless question a proposal for public support of drug testing. The response is that the practice of shunting the provision of such a crucial public good as clinical trials to the private pharmaceutical sector has become unsustainable over time.²⁴¹ Rather than continue this market distortion, the most rational reform is to shift some portion of the cost of clinically testing new pharmaceutical products to the public sector, with a view towards rationalizing the supply chain for medicines and to lowering the prices of drugs to consumers to levels more reasonably related to their actual R&D costs.

a. The Drug Companies' Costs Would Decline with Government Funding of Clinical Trials

The total direct cost of drug testing should fall with public funding, oversight, and full disclosure of clinical trial results, especially of unfavorable or negative results. Such a program would enable investigators to exploit economies of scale and scope in testing, would minimize unnecessary redundancies, and would allow researchers to interpret and compare the results of different tests. Public disclosure of trial results should further reduce research and development costs as

238. Lewis et al., *The Case for Public Funding*, *supra* note 32, at 1-2.

239. See, e.g., Reinhardt, *supra* note 236, at 109 (stating that “the private sector typically does not produce these [public information] goods in socially efficient quantities”).

240. On the orphan drugs question, see Grabowski, *Increasing R&D Incentives*, *supra* note 19, at 459-60.

241. See *supra* notes 33-44 and accompanying text.

drug companies learn earlier which candidate medicines are therapeutically effective and which are not.²⁴²

Admittedly, some of the benefits from centralized clinical testing could be achieved without public sponsorship. One could require drug companies to pay for publicly supervised tests, and some cost savings would still presumably occur. However, public support of drug testing would provide additional dividends far exceeding the direct cost savings from a privately funded program of clinical testing, as shown below.

b. Lower Drug Company Costs Would Benefit Consumers in the Short Run

Drug companies' costs of developing and marketing new medicines should fall significantly with public funding of clinical trials and full disclosure of the results. Recent studies show the growing importance of these costs in determining the aggregate expense of bringing new drugs to market,²⁴³ in a lottery-like environment where "most drug candidates taken into testing fail."²⁴⁴

A reduction in the costs of supply and in the attendant risks of investing in failed drugs would enable companies to reduce the prices of successful new drugs while still earning a competitive return on investment.²⁴⁵ Public funding of clinical tests would also provide more transparent estimates of the total costs of drug supply, which would allow health insurers to more accurately assess what revenues were

242. See, e.g., Baker, *supra* note 227.

243. See, e.g., Grabowski, *Increasing R&D Incentives*, *supra* note 19, at 460 (stressing increase of R&D costs at an annual rate of 7.4% above inflation compared to 1980s and finding size and number of clinical trials "[a] major factor accounting for this growth in costs"); DiMasi et al., *supra* note 5. These authors found:

We may approximate the increases in cost per subject over time by examining the excess of medical care inflation over general price inflation. The medical care component of the CPI increased at an average annual rate of 6.73% from 1984 to 1997, while general price inflation (applying the price index used to deflate costs for this study) rose at an annual rate of 3.06% over the same period. Thus, other things being equal, these results suggest an increase of 11.4% per year in clinical trial costs. This compares to our finding of an 11.8% annual growth rate in out-of-pocket clinical period cost between DiMasi et al. (1991) and the current study.

Id. at 177. See also Patricia M. Danzon & Adrian Towse, *Theory and Implementation of Differential Pricing for Pharmaceuticals*, in *INTERNATIONAL PUBLIC GOODS AND TRANSFER UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME* 428 (Keith E. Maskus & Jerome H. Reichman eds., 2005) (R&D costs account for roughly 30% of total cost of new drugs).

244. See, e.g., Grabowski, *Increasing R&D Incentives*, *supra* note 19, at 460-61 (adding that, of those that survive, only a few "succeed in generating very large returns").

245. Lewis et al., *The Case for Public Funding*, *supra* note 32, at 3.

required for continued pharmaceutical innovation. Unlike programs for capping drug prices that require a full accounting of all drug company costs,²⁴⁶ this proposal would generate pressures on drug companies to reduce prices only in proportion to the observed cost savings generated by public funding and disclosure of clinical test results.²⁴⁷ These savings would affect the costliest component of the entire downstream R&D budget, and they would further reduce investment risks by building upon the federal government's already substantial funding of basic research.

While health providers would benefit from the lower costs of procuring prescription drugs, consumers are the primary beneficiaries of this program. Many consumers cannot afford the monopoly prices charged by patent protected drug manufacturers. A reduction in prices due to lowered costs of clinical testing would allow low income and uninsured patients greater access to medicines.²⁴⁸ The well known allocative distortions that arise from patent protected medicines would be reduced to the extent that public support of clinical testing forced drug prices to decline.

c. Long Run Efficiencies in Drug Discovery and Development

Analysts note with alarm that the overall rate of innovation for new medicines and therapies appears to be slowing, while the gap between R&D investment and output has widened.²⁴⁹ Moreover, existing projects do not routinely address socially important therapeutic needs, as when firms decrease or abandon R&D opportunities pertaining to antibacterial drugs despite evidence of mounting resistance to available

246. The difficulty of reliably establishing these costs is well established in the literature. See, e.g., Baker, *supra* note 227.

247. For detailed mechanisms to reduce prices in relation to government funding of clinical trials, see *id.*

248. *Id.* at 8-14. Under Baker's figures,

the potential savings from the Medicare prescription drug program are large enough by themselves to easily cover the expense of publicly financed clinical trials. However, there could also be savings for state and local governments if the federal government designed a system in which it also negotiated lower prices on the behalf of other units of government.

Id. at 13.

249. See, e.g., Rai et al., *Pathways Across the Valley of Death*, *supra* note 44 (citing *Treating the poor health of the industry*, IMS HEALTH, Sept. 29, 2004, http://open.imshealth.com/IMSinclude/i_article_20040929.asp; *Changing Patterns of Pharmaceutical Innovation*, NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT RESEARCH AND EDUCATIONAL FOUNDATION, May 2002, <http://www.nihcm.org/innovations.pdf>).

antibiotics.²⁵⁰ Although there are multiple contributing factors to this apparent slow down in pharmaceutical innovation,²⁵¹ rationalizing the clinical trial component of the drug supply chain would arguably stimulate more productive R&D and more affordable end products.

(1) Stimulating More Investment in Innovative R&D with Lower Costs and Better Information

Besides reducing the costs of clinical testing and greatly lessening the private sector's risks of developing drugs for clinical use, the heightened transparency resulting from a public-good approach should—as previously observed—enable private and public health care providers to press companies to reduce their prices.²⁵² A fall in prescription drug prices would reduce the variable profit the company earned on existing drug sales. As the unit profit from each additional sale declined, the marginal incentives to market medications to increase sales might also decrease, which could help to discourage wasteful expenditures on marketing and promotion.²⁵³

More importantly, if drug companies no longer had to defray the

250. Steven J. Projan, *Why is big Pharma getting out of antibacterial drug discovery?*, 6 CURRENT OPINION IN MICROBIOLOGY 427-30 (2003); Per Nordberg, Dominique L. Monnet & Otto Cars, *Antibacterial Drug Resistance: Options for Concerted Action*, in PRIORITY MEDICINES FOR EUROPE AND THE WORLD PROJECT: A PUBLIC HEALTH APPROACH TO INNOVATION (World Health Organization, Feb. 2005), available at <http://mednet3.who.int/prioritymeds/report/index.htm>.

251. See, e.g., Iain Cockburn, *The Changing Structure of the Pharmaceutical Industry*, 23 HEALTH AFF. 10 (Jan./Feb. 2004) (stressing unreplenished pipeline and other causal factors for past slow down); Rai et al., *Pathways Across the Valley of Death*, *supra* note 44 (discussing need to pool small molecule libraries for upstream basic research by university scientists using high-throughput screening technology).

252. See *supra* notes 247-48 and accompanying text.

253. Lewis et al., *The Case for Public Funding*, *supra* note 32. For evidence, see, e.g., Jun Ma, Randall S. Stafford, Iain M. Cockburn & Stan N. Finkelstein, *A statistical analysis of the magnitude and composition of drug promotion in the United States in 1998*, 25 CLINICAL THERAPEUTICS 1503-17 (2003).

The researchers analyzed nationally representative data on expenditures for the 250 most promoted medications in the United States in 1998 and the five most commonly used modes of promotion. During that year, the pharmaceutical industry spent \$12,724 million promoting its products in the United States, of which 86 percent was accounted for by the top 250 drugs and 52 percent by the top 50 drugs. Direct-to-consumer advertising was more concentrated on a small subset of medications than was promotion directed to professionals.

Id. Direct consumer advertising alone reportedly cost the pharmaceutical companies \$2.6 billion in 2003. See Jennifer Harper, *Drug ads provide a mixed blessing; But consumers do go to doctor*, WASH. TIMES, Apr. 30, 2004, at A08. Growth in promotion reportedly outstripped growth in research spending by more than 50 percent. See David Pauly, *Drug Companies' Cost of Pushing Pills Rivals R&D*, BLOOMBERG, Aug. 26, 2004.

cumulative costs of clinical trials, the threshold level of profitability for new candidate drugs—estimated by some to range between 800 million to one billion dollars—would likely fall by a considerable amount.²⁵⁴ This lower threshold could significantly reduce profit requirements that discourage the introduction and development of new drugs.

The resources drug companies now expend to market and protect existing drugs from competition could be redeployed to discover new and potentially more valuable medicines if the state bore some significant portion of the cost of clinical trials. Given lower testing costs and lowered risk premiums, firms could expect profits from a much broader range of products taken to market than at present, and incentives to discover such products would correspondingly increase in a less lottery-like environment.²⁵⁵

Moreover, with public disclosure of previous clinical trial results concerning related medicines, companies could better predict which candidate medications should be effective and safe for clinical use. For example, early disclosure of clinical trial findings that Vioxx posed greater risks than originally known might have prompted its worldwide market withdrawal, increased scrutiny of similar drugs, and accelerated R&D to find a better product in the same therapeutic class.²⁵⁶ More private funding for drug research and development might follow as drug companies improved at predicting clinical success earlier in the drug approval process.

To this end, a competitive framework for peer-reviewed, federal grant support of clinical trials could be designed to reward those lines of investigation that promised major pharmaceutical innovation or that answered important questions about clinical cost-effectiveness. Where therapeutic competition is lacking, public funding might lower the barrier to new entrants without undermining patent rights. In so doing, this public investment in clinical trials might amplify the benefits of lower drug prices through enhanced therapeutic competition that could impact existing, not just new, drugs on the market.²⁵⁷

254. *Accord*, Baker, *supra* note 227, at 14.

255. Lewis et al., *The Case for Public Funding*, *supra* note 32, at 4. *See also* Grabowski, *Increasing R&D Incentives*, *supra* note 19, at 460-61 (stressing lottery like atmosphere where most products fail to recoup R&D costs).

256. Matthew Herper, *Pfizer's Vioxx Problem*, FORBES, Oct. 15, 2004, http://www.forbes.com/2004/10/15/cx_mh_1015bextra_print.html.

257. Lewis et al., *The Case for Public Funding*, *supra* note 32, at 4.

(2) *A Secondary Market for Remedial Improvers*

Public funding and disclosure of clinical trial results could also stimulate a secondary collaborative market for finding remedies to investigational obstacles that thwarted development of promising medications. Various reasons account for drug company decisions to shelve products pending approval rather than completing the costly clinical testing process. Sometimes it is a marketing decision, while at other times, it is a clinical setback that mandates a new investigational course. A registry of the drugs failing clinical standards and of the data yielded by the tests could be made available for improvements by third parties after a suitable period of time.²⁵⁸

A company whose drug application had been denied or withdrawn would have a specified period to seek remedies to the deficiencies identified at trial, in order to qualify for a new round of testing. If the originating company failed to meet this requirement, the relevant data could be relegated to a legally defined semicommons open to would-be third party improvers. If any of the latter solved the problem and restored the candidate drug's chances of FDA approval, that successful improver could gain the right to market the drug in return for payment of a reasonable royalty to the originator company in case of commercial success to cover earlier costs of R&D.²⁵⁹ A version of this approach already exists for agricultural chemical test data in the United States. After a period of exclusivity, follow-on competitors may enter the marketplace by providing compensation to the originating company that invested in the line of research to help cover the costs of obtaining public safety data.²⁶⁰

258. See *supra* note 230; Marc J. Scheineson & M. Lynn Sykes, *Major New Initiatives Require Increased Disclosure of Clinical Trial Information*, 60 *FOOD DRUG L.J.* 525,535-540 (2005). But see the discussion of risks in Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 *IND. L.J.* 623 (2007).

259. See Reichman, *Of Green Tulips*, *supra* note 132. See also Rai et al., *Pathways Across the Valley of Death*, *supra* note 44; Reichman & Uhlir, *supra* note 202, at 315-440. If the original failed product were patented, the improver under such a "compensatory liability regime" would in effect obtain a tailor-made dependent compulsory license ("antiblocking" license) like those generally available for improvement patents in most developed countries (but not the United States). On this premise, the originator company might also receive a cross-license on the patented improvement. Cf. TRIPS Agreement, *supra* note 29, art. 31(1) (compulsory licenses for dependent patents).

260. See FIFRA, 7 U.S.C. §§ 136-136y, at §§136a(c)(2)(B). See also Weissman, *NEGOTIATING HEALTH*, *supra* note 130, at 157; Fellmeth, *supra* note 130.

3. Implementing a Public Testing Program

The government should fund clinical tests to the fullest extent permitted by sound fiscal policy. The definition of products subject to this proposal should be broad enough to include drug treatments, vaccines, medical devices, and diagnostic or monitoring tests. The term “clinical trials” means Phases I through III as understood in current FDA practice, as well as post-approval Phase IV clinical trials.²⁶¹

a. Awarding Clinical Tests to the Most Qualified Scientists

Nothing in this proposal requires the government to physically conduct the tests under the aegis of a specialized agency, although this remains a possibility. One may anticipate that an industry comprised of the qualified and experienced scientists who have previously conducted clinical tests for the drug companies would emerge initially to perform clinical testing under this program. The primary role of the government would be to oversee competitive awards of testing contracts to worthy testing organizations—either public or private, but not affiliated with the drug companies—in accordance with public health priorities.

This approach builds on proven strengths of the federal government to administer extramural research grants, like those that the NIH routinely award. As already occurs in that grant-making process, scientific review panels would identify potential biases in study design, and, with inputs from the drug regulatory authority, insist on appropriate treatment comparisons by the designated clinical trial units.²⁶²

b. Revenue Neutral Financing with Cost Sharing and Social Funding Criteria

Government funding of clinical tests should be revenue-neutral in

261. Each phase of the clinical trial process is designed to answer distinct research questions. In Phase I, researchers testing a new drug or treatment in small groups for the first time seek to evaluate overall safety, determine a safe dose range, and identify side effects. During Phase II, use by a larger group of subjects focuses on effectiveness, further evaluations of safety, and finding the right dose. Phase III tests on large groups of people seek to confirm estimates of effectiveness, monitor side effects, compare the new product to commonly used treatments, and to collect more information bearing on safe usage. Phase IV studies are conducted after marketing of the drug or treatment in question to gather information about its effects on different populations and any side effects associated with long-term use. See the NIH resource information on clinical trials at <http://www.nlm.nih.gov/services/ctphases.html>.

262. Lewis et al., *The Case for Public Funding*, *supra* note 32, at 3.

principle.²⁶³ Public support of clinical testing could be financed directly by the reduced drug reimbursements the federal government should pay as the country's largest employer and provider of health insurance.²⁶⁴ If market forces and health insurers' pressures failed to secure the desired level of social returns, in the form of lowered drug prices, from the proposed public investment, additional safeguards could become necessary. Some combination of moral suasion, compulsory licensing, or other legal measures to address patent misuse and the larger public interest might then be invoked for this purpose.²⁶⁵ Yet, heightened transparency could make it costly for the drug industry to frustrate the goals of government funded clinical trials and thus render such safeguard measures unnecessary in practice. Moreover, even these measures – if required in extreme cases - appear relatively unobtrusive against the backdrop of growing demands for the price regulation schemes practiced abroad²⁶⁶ and for mounting calls for government control of the innovation process.²⁶⁷

263. *Id.* at 4.

264. For details, see Baker, *supra* note 227.

265. Jerome H. Reichman, *Comment: A Trilogy of Views about Compulsory Licensing of Patented Pharmaceutical Inventions*, SYMPOSIUM ISSUE, 37 J. L. MED. & ETHICS (forthcoming 2009); JEROME H. REICHMAN WITH CATHERINE HASENZAHN, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA, ICTSD/UNCTAD Issue Paper No. 5, Intellectual Property Rights and Sustainable Development Series (ICTSD/UNCTAD 2002), available at <http://ictsd.net/i/publications/11764/> (last visited Jan. 19, 2009).

266. Some observers argue that safeguards embodied in the Bayh-Dole Act of 1980 already provide the basis for federally authorized price controls of pharmaceuticals based on federally funded research results. See, e.g., 35 U.S.C. § 202(a)(i)-(iii) (2002) (power of NIH to restrict patenting of federally funded research results in "exceptional circumstances"); 35 U.S.C. § 203(1)(a), (b) (march-in rights under Bayh-Dole Act of 1980); Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls?*, 75 TUL. L. REV. 631 (2001). For the view that the Bayh-Dole Act provisions provide a potentially workable framework for regulating misuse of patents on federally funded research results, see Jerome H. Reichman, *Testimony Before NIH Public Hearing on March-In Rights Under the Bayh-Dole Act* (May 23, 2004). However, others believe that, in their present form, these same provisions are unworkable without serious administrative reforms. See Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003). See generally, Anthony So et al., *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, 6 PLOS BIOLOGY 2078 (Oct. 2008), available at www.plosbiology.org.

267. See, e.g., Hubbard & Love, *supra* note 92; Eduardo Porter, *Do New Drugs Always Have to Cost So Much?*, N.Y. TIMES, Nov. 14, 2004, at BU5; Dean Baker, *Financing Drug Research: What Are the Issues?*, CENTER FOR ECON. & POL'Y RES., Sept. 22, 2004, http://www.cepr.net/publications/patents_what_are_the_issues_9-20.pdf (reviewing four reform proposals).

It must be stressed that the drug companies should bear some share of the costs of conducting clinical trials, irrespective of the government's ultimate fiscal capacity. This safeguard is needed to discourage the wholesale testing of marginal drugs with little therapeutic value or of candidate medicines with little chance of clinical adoption. A process that reimbursed a progressively larger share of testing costs for those medicines that displayed the greatest potential benefits would encourage companies to select only the most promising medicines for clinical review at public expense. Moreover, the bulk of any reimbursements for Phase I and II trials could be delayed until, and conditioned on, the success of Phase III trials, with varying reimbursement formulas depending on the potential public benefits in case of success.

Any pharmaceutical company that failed to win a sizeable amount of government funding for any given product could, of course, proceed to conduct the relevant trials at its own expenses, as at present. Selective funding of clinical trials would thus afford the government some discretion in supporting the development of drugs with greatest potential social value that might otherwise be overlooked under a totally market-driven approach.²⁶⁸ An important factor in any such selection process would be the overall public health impact of the candidate drug. This factor would be measured by the relative burden of the underlying disease, by the availability of existing clinical options to treat it, by the need to stimulate greater competition within a given therapeutic class, and by the need to treat certain neglected diseases, including both rare or orphan diseases, by means that might otherwise not be developed absent government assistance.

c. Phased Implementation

Transforming clinical trials from an excluded private good to a non-excluded public good is an ambitious undertaking, one that would require gradual implementation. The first step would be to decouple drug company sponsorship from the management of clinical trials, by requiring the federal government to oversee the trials and dissemination of results under the aegis of a national testing program.

Second, the program would conduct pilot projects targeting drug candidates that promised the greatest social benefit from public testing. Drugs that offered innovative therapeutic benefits, or significant gains over existing treatments, would receive a preferred status. As the

268. Lewis et al., *The Case for Public Funding*, *supra* note 32, at 3.

program grew, public testing would expand to drugs that offered therapeutic alternatives in treatment areas where there were none.

Finally, after a set period, the pilot projects would be evaluated to identify the costs and benefits of public testing and dissemination for chosen drug groups, and to indicate other drug groups the program might include.²⁶⁹ Over time, however, the more fully that the federal government was able to absorb the aggregate costs of the clinical testing process, the greater would be the benefits along the drug supply chain as a whole.

d. Globalization of the Public Good Concept

By focusing attention on the public good nature of clinical trial data, the foregoing discussion necessarily locates the drive for data exclusivity within the larger context of clarifying the role of global public goods in an integrated world market for freely traded private goods and services. Here, we encounter mounting tensions between measures to stimulate an “incipient transnational system of innovation” through trade-related intellectual property rights and long-established governmental obligations to provide such public goods as health, education, food security, scientific research, environmental safety, and a well-functioning competitive economy.²⁷⁰

Increasingly, these tensions arise because privatized knowledge goods protected by international intellectual property rights function as inputs into domestic public goods, which inputs, if unregulated, may lead to high prices in poor countries and rising levels of deadweight loss.²⁷¹ While adversely affected developing countries struggle to resolve

269. *Id.* at 3-4.

270. See, e.g., Maskus & Reichman, *The Globalization of Private Knowledge Goods*, *supra* note 97; J. H. Reichman, Richard Lillith Memorial Lecture, *Nurturing a Transnational System of Innovation*, 16 J. TRANSNAT'L L. & POL. 143 (2007); Peter Drahos, *The Regulation of Public Goods*, in INTERNATIONAL PUBLIC GOODS AND TRANSFERS OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 46-54 (Keith E. Maskus & Jerome H. Reichman eds., 2005); Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821 (2006).

271. See, e.g., Okediji, INTERNATIONAL PUBLIC GOODS, *supra* note 101, at 142-87; Robert E. Evenson, *Agricultural Research and Intellectual Property Rights*, in INTERNATIONAL PUBLIC GOODS AND TRANSFERS OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 188-246 (Keith E. Maskus & Jerome H. Reichman eds., 2005); Hanns Ullrich, *Expansionist Intellectual Property Protection and Reductionist Competition Rules: A TRIPS Perspective*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 726-57 (Keith E. Maskus & Jerome H. Reichman eds., 2005); Richard Nelson, *Linkages Between the Market Economy and the Scientific Commons*, in INTERNATIONAL

these tensions by resorting to the so-called “flexibilities” within the TRIPS Agreement itself,²⁷² developed countries that count on rents from knowledge goods *qua* tradable assets press them to forego these flexibilities in the name of “respecting IPRs.”²⁷³ Gradually, the technology exporting countries have whittled down these flexibilities through TRIPS-plus provisions in bilateral and regional Free Trade Agreements.²⁷⁴

The drive to augment the protection of privately generated clinical trial data at the international level fits logically within this conceptual framework and exemplifies the relative indifference to distributional effects that often accompanies efforts to elevate international intellectual property standards without seating those who represent the public interest at the table.²⁷⁵ With specific regard to clinical trial data, however, these tensions between private and public goods seem easier to resolve than in many other cases.

As a relative newcomer to the international stage, the status of data exclusivity in intellectual property law remains unsettled and relatively unstable, as witnessed by its collocation under the rubric of unfair competition law within Article 39.3 of the TRIPS Agreement itself.²⁷⁶ If the treatment of clinical trial data as a private good in developed countries represents a fundamentally flawed concept, a resolute reform that recognized such data as a public good in the developed world could itself constitute a platform for rapid recognition of this same subject matter as a global public good.²⁷⁷

PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 121-38 (Keith E. Maskus & Jerome H. Reichman eds., 2005); Abbott & Reichman, *supra* note 59.

272. See, e.g., ICTSD/UNCTAD RESOURCE BOOK, *supra* note 103 (examining flexibilities in detail); HUGENHOLZ & OKEDIJI, *supra* note 101.

273. See, for example, the United States’ response to the grants of compulsory licenses on pharmaceuticals by Thailand and Brazil, as discussed in Abbott & Reichman, *supra* note 59, at 980.

274. See, e.g., Mercurio, *supra* note 98, at 215-38; Okediji, *supra* note 93. See also Reichman & Dreyfuss, *supra* note 91.

275. Peter M. Gerhart, *Distributive Values and Institutional Design in the Provision of Global Public Goods*, in INTERNATIONAL PUBLIC GOODS AND TRANSFERS OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 69-78 (Keith E. Maskus & Jerome H. Reichman eds., 2005). See also Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, J.L. MED. & ETHICS (forthcoming 2009); Jerome H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT’L L. 441 (2000).

276. See Taubman, *supra* note 30; *supra* notes 71-80 and accompanying text.

277. See Joseph E. Stiglitz, *Knowledge As a Global Public Good*, in GLOBAL PUBLIC

Once policymakers began to view clinical trials from that angle, rather than as a private-sector obligation whose results and outcomes must be rendered artificially scarce,²⁷⁸ they could find dazzling opportunities to restructure the conduct and delivery of clinical trials on an efficient worldwide basis. For example, transnational testing agencies, perhaps governed by the World Health Organization (“WHO”), could achieve additional economies of scale and scope, which would drive the costs progressively lower for all participating countries. Transparency with regard to outcomes would then serve to advance medical research everywhere and could stimulate targeted development aid for public-private partnerships seeking to make essential drugs more affordable.²⁷⁹ State subsidies of clinical trials, and the resulting reductions in the price of drugs that would ensue, could take some of the pressure off growing tendencies to invoke compulsory licenses in poor countries²⁸⁰ and lead to enhanced public-private cooperation with regard to both drugs emanating from developed countries and drugs needed for diseases that occur predominantly in developing countries.²⁸¹

If clinical trials were treated as a global public good, however, it would remain necessary for governments around the world who participated in such a scheme to contribute a fair share to the aggregate costs of conducting such clinical trials, adjusted for relative capacities to pay and for per capita gross domestic product (“GDP”). Otherwise, any perceived free-rider problem would simply shift from the private to the public sector, without additional relief for taxpayers in the developed countries.

In this connection, the elegant “fairness” calculations recently devised by Professor Fellmeth would seem particularly relevant and

GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 308 (Inge Kaul et al. eds., 1999). See also TRIPS Agreement, *supra* note 29, art. 8.1.

278. Lewis, et al., *The Case for Public Funding*, *supra* note 32.

279. LONDON SCH. OF ECON. & POL. SCI., WELLCOME TRUST, THE NEW LANDSCAPE OF NEGLECTED DISEASE DRUG DEVELOPMENT 26-35 (Sept. 2005).

280. See, e.g., Abbott & Reichman, *supra* note 59. See also Klaus Stegemann, *International Price Discrimination and Market Segmentation for Patented Pharmaceuticals in the EU: A Social Welfare Analysis*, in INTELLECTUAL PROPERTY, PUBLIC POLICY, AND INTERNATIONAL TRADE 145-59 (Inge Govaere & Hanns Ullrich eds., 2007).

281. See, e.g., Drugs for Neglected Diseases Initiative (DNDi), New, Once-a-Day Fixed-Dose Combination Against Malaria Now Available (March 1, 2007), available at <http://www.dndi.org>; Jean-René Kiechel & Bernard Pecoul, *Innovative Partnership Brings New ACT Free of Patent*, Guest Blog, PLOS June 22, 2008, <http://www.plos.org/cms/node/208>.

worthy of careful scrutiny.²⁸² Fellmeth analyzes several different models, including a “Simple Divisions Royalties Model” and a more sophisticated “Readjustable Royalties Model,” which takes into account such factors as the initial costs of R&D, the time value of money, the number of participants in the scheme, and their ability to pay. Because his calculus, as it stands, is based entirely on private rights, it would have to be recast and transposed to a public sector framework that also took account of private inputs. Thought must also be given to a global regulatory framework that, at a minimum, should oversee the collection and distribution of payments by governments in exchange for access to clinical trial results developed anywhere under the scheme.²⁸³ This fascinating topic awaits future research and another article.

Nevertheless, if governments funded the bulk of clinical trials (in addition to current high levels of funding for basic research in developed countries), the heightened transparency pervading the supply chain should oblige originator pharmaceutical companies to lower prices everywhere to more accurately reflect their actual costs of production, their private R&D expenditures, and their marketing costs.²⁸⁴ If, instead, these companies—liberated to a large extent from the yoke of clinical trial costs—resisted pressures to reduce the prices of medicines in proportion to the public benefits received, while still earning revenues sufficient to cover costs and provide a competitive return on investment, that same transparency would expose them to liability for compulsory licensing and other legal measures available to address patent abuse and the larger public interest, as expressly envisioned by the TRIPS Agreement itself.²⁸⁵ It would also encourage demands for the price regulation schemes practiced in Canada and other developed countries²⁸⁶ and for greater government control of the innovation process as distinct from marketing concerns.²⁸⁷

282. See Fellmeth, *supra* note 130, at 478-500.

283. See PROVIDING GLOBAL PUBLIC GOODS: MANAGING GLOBALIZATION (Inge Kaul et al. eds., 2003); Kal Raustiala, *Compliance & Effectiveness in International Regulatory Cooperation*, 32 CASE W. RES. J. INT'L L. 387 (2000).

284. Lewis et al., *The Case for Public Funding*, *supra* note 32.

285. See, e.g., Abbott & Reichman, *supra* note 59; TRIPS Agreement, *supra* note 29, arts. 8.1, 8.2, 31, 40.

286. REICHMAN WITH HASENZAHN, *supra* note 153; OECD Study (2008), *supra* note 151, available at <http://www.oecd.org>.

287. See, e.g., Hubbard & Love, *supra* note 92; World Health Organization, Agenda item 11.6, *Global Strategy and Plan of Action in Public Health, Innovation and Intellectual Property* (May 24, 2008).

CONCLUSION

Article 39.3 of the TRIPS Agreement requires WTO Members to protect the secret clinical trial data that foreign pharmaceutical companies submit for regulatory approval of new chemical entities against “disclosure” and “unfair commercial use.”²⁸⁸ This provision does not prevent governments from authorizing the generic manufacture of bioequivalent products on the basis of foreign regulatory approvals and the relevant scientific literature. Nevertheless, governments must treat deposits of clinical test data by originator pharmaceutical companies as trade secrets and guard against their misappropriation by employees or third parties.²⁸⁹

The freedom to authorize production of bioequivalent generic drugs that developing countries possess under Article 39.3 of TRIPS, as it stands, has been shrinking rapidly under pressures from TRIPS-plus provisions concerning clinical test data inserted into bilateral and regional Free Trade Agreements.²⁹⁰ These FTAs tend to provide a de facto *sui generis* exclusive property right on the originator companies’ test data, irrespective of any patent rights they may or may not hold. Moreover, the FTAs’ data exclusivity regimes have grown more stringent over time, and once implemented into domestic laws, they can delay local generic producers’ entry into developing country markets even where no patents exist for periods of five to fifteen years.²⁹¹ FTA provisions on data exclusivity can also undermine other important flexibilities set out in the TRIPS Agreement, including the broad rights of WTO Members to impose compulsory licenses on patented pharmaceuticals under Article 31. In this and other respects, such FTA provisions conflict with the spirit of the Doha Ministerial Declaration on TRIPS and Public Health.²⁹²

Developing countries that have not yet committed to FTAs should remain wary of undervaluing the social costs of their intellectual property chapters, especially because any concessions made to the trading partner must be extended to all other WTO Members under the broad MFN clause set out in Article 4 of the TRIPS Agreement.²⁹³ Developing countries should particularly resist obligations that would

288. See *supra* note 73 and accompanying text.

289. See *supra* text accompanying notes 74-89.

290. See *supra* notes 97-98 and accompanying text.

291. See *supra* text accompanying notes 105-15.

292. See *supra* note 57; *supra* text accompanying notes 116-20.

293. TRIPS Agreement, *supra* note 29, art. 4.

limit regulatory approval of generic pharmaceuticals under Article 39.3, as it stands, and they should reject the data exclusivity framework that has emerged from recent United States FTAs with Latin American countries, among others. If some form of compromise on the issue of clinical test data becomes unavoidable, developing country negotiators should stand firm on cost-sharing counter-proposals that would at least avoid barriers to entry for generic producers.²⁹⁴

Attempts to justify the protection of clinical trial data as a separate and distinct subject matter of intellectual property law on the grounds of an incentive rationale, coupled with fairness considerations, appear dubious in the light of systematic legal and economic analysis. Although the costs of clinical trials have soared and may become unsustainable over time,²⁹⁵ originator pharmaceutical companies have benefited from comparatively strong patent protection and the power it gives to charge high prices to consumers in both developed and developing countries, largely because they must recoup these costs.

Moreover, government funding of basic medical research is so extensive in the United States at least that, in most cases, the downstream R&D costs of clinical trials are the main burden that originator companies bear, in addition to medicinal chemistry and marketing expenditures. Given the strong patents that already support medical research results, the case for an additional revenue stream from a data exclusivity right sounding in an incentive rationale looks like special pleading. To the extent that clinical test data protection may occasionally apply when patents were otherwise unavailable for various reasons, this justification would not support the logic of a patent-like exclusive property regime. At most, in view of soaring clinical costs, a “compensatory liability regime” might be envisioned in appropriately circumscribed factual situations.²⁹⁶ Such a regime could oblige competitors to share the costs of clinical trials for a specified period of time.

Even these fall back considerations should not normally apply to generic producers in developing countries who obtain regulatory approval from their governments by showing bioequivalence with drugs approved abroad, while otherwise meeting local health and safety requirements. If the drugs in question were patented in these developing countries, local marketing approval would not entitle

294. *See supra* text accompanying notes 134-54.

295. *See supra* text accompanying notes 34-44.

296. *See supra* notes 198-202 and accompanying text.

competitors to infringe the foreign patentees' exclusive rights to make, use, and sell the patented products.²⁹⁷ If, instead, no patents applied to the product in question, it is never "unfair" to reverse-engineer products that are not covered by territorial patents, so long as the second comer does not misappropriate trade secrets and adopts distinctive trademarks of its own that avoid confusion or deception of consumers.²⁹⁸

As matters stand, the originator pharmaceutical companies recoup the bulk of their R&D costs in the developed countries. The marketing of these products in developing countries, whether patented or not, should in principle proceed on a "high-volume, low profit margin" approach, and not on a "high profit-low volume" approach as usually occurs today.²⁹⁹ Adding a backdoor exclusive property right in clinical test data to the originator companies' legal arsenal only postpones needed price discrimination policies and further distorts the worldwide market for essential medicines.³⁰⁰

However, these reflections on abusive uses of intellectual property rights in poor countries should not obscure the fact that soaring costs of clinical trials pose a major problem for global public health. It should, instead, suggest that our whole way of thinking about the problems of regulatory approval for new pharmaceutical products needs to change. It is time to recognize that the conduct of clinical trials is a quintessential public good whose costs should be collectively defrayed by governments and whose results should be made universally available under the sharing norms of science.

In the long run, if developed countries were persuaded to treat clinical trials of new pharmaceutical products as public goods in their domestic laws, the developing countries should favorably respond to proposals to treat them collectively as a global public good. In that event, the latter's willingness to support the costs of such trials wherever conducted, on a capacity to pay basis, would counter current pressures

297. TRIPS Agreement, *supra* note 29, arts. 27-28.

298. Paris Convention, *supra* note 71, art. 4*bis* (independence of patents), 10*bis* (unfair competition norms). *See, e.g.*, *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 (1938); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964) (Sears-Compco Doctrine); *Wal-Mart Stores v. Samara Bros.*, 529 U.S. 205 (2000).

299. *See* MINISTRY OF PUBLIC HEALTH & NATIONAL HEALTH SECURITY OFFICE THAILAND, FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND (Feb. 2007), available at <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf>; Abbott & Reichman, *supra* note 59. For the economic logic that impels originator companies to charge high prices in poor countries, see Flynn, Hollis, & Palmedo, *supra* note 275.

300. *See, e.g.*, Outtersson, *supra* note 136.

for both secrecy and exclusive property rights, while helping to make clinical trial results available worldwide for follow-on R&D. It would also lead to economies of scale and scope that should reduce the costs of clinical trials worldwide. Above all, collective government funding could exert a powerful downward pressure on the prices of medicines, which currently express high risk premiums to cover the soaring costs of privately funded clinical trials in developed countries.

Global public health could be further enhanced if the results of failed clinical testing became available for improvements under the liability rules discussed above.³⁰¹ Rather than just shelving products with negative results or high risk premiums, resort to a non-exclusive licensing mechanism could enable companies everywhere to build on cumulative and sequential innovation in the pharmaceutical sector, while sharing both the costs of R&D and ultimate profits with first movers who had not altogether resolved problems of toxicity and safe delivery.

To the extent that funding for clinical trials of new pharmaceutical products became a global public sector responsibility, it would yield at least three additional benefits. First, by sharing clinical trial data under the open access norms of science, the costs of redundant investigations would be squeezed out of the global public health system. Second, instead of further elevating the prices of existing pharmaceuticals in developing countries by means of a pseudo-intellectual property right in clinical test data, a global funding system based on equitable contributions to the overall costs of conducting such tests would lower supply costs and make both patented and unpatented medicines universally more affordable.

Finally, as the private sector's costs of certifying candidate drugs for marketing approval went down, the breakeven point for investment in research to discover new drugs should correspondingly drop, with a progressive lowering of barriers to entry around the world. These phenomena would then intensify the incentive effects of existing international standards of intellectual property protection under the TRIPS Agreement and make it more feasible for small and medium-sized firms everywhere to compete in the global pharmaceutical market on the basis of research-driven drug discovery.

301. See *supra* text accompanying notes 258-60.