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Robert Galantucci
Fordham University School of Law

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Robert Galantucci*

* J.D. Candidate, Fordham University School of Law, 2008; B.A., Villanova University, 2005. I would like to acknowledge the IPLJ Editorial Board and Staff for their part in the preparation of this Note, especially Bruce Wingate and Melanie Constantino. Thanks also to Professor Paolo Galizzi for his comments on an early draft of this paper. Finally, I would like to thank my family for their continued support and guidance throughout law school.

INTRODUCTION

In early 2006, when the United States began to negotiate a free-trade agreement (FTA) with Malaysia, many Malaysians took to the streets to protest the commencement of the discussions.[1] The diverse coalition of demonstrators included people living with HIV/AIDS, consumers, health activists and human rights groups.[2] Their concerns—that differences between a U.S. bilateral trade arrangement and the preexisting global intellectual property (IP) standards could have dangerous implications on public health—are shared by economists at the World Bank, NGOs, and trade negotiators in Geneva.[3] One key apprehension regarding the FTA is the potential effect of the agreement's IP provisions on the pharmaceutical industry.[4] The IP terms[5] afford greater exclusivity rights to originator drug companies, and prevent increased competition from generic manufacturers.[6] With less competition, pharmaceutical prices may rise beyond the budgets of thousands of Malaysian citizens,[7] many of whom are victims of the country's severe AIDS and tuberculosis epidemics.[8]

As of 2005, there are an estimated 69,000 people in Malaysia living with HIV/AIDS,[9] and a UNAIDS report warns that there are elements that could cause Malaysia's epidemic to erupt suddenly.[10]

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1 Chee Yoke Heong, *Malaysians Protest Against Free Trade Talks with U.S.*, FTA MALAYSIA, June 13, 2006, http://www.ftamalaysia.org/article.php?aid=66 [hereinafter *Malaysians Protest Talks*].

2 *Id.*

3 Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 349 (2005) (internal citations omitted).

4 *See Malaysians Protest Talks*, *supra* note 1.

5 For a discussion of the IP terms that the U.S. will attempt to negotiate, see *infra* Parts I.A and I.C–D.

6 *See infra* Parts I.D–E.

7 *See Malaysians Protest Talks*, *supra* note 1.

8 *See* UNAIDS/WHO, AIDS EPIDEMIC UPDATE: DECEMBER 2006—ASIA, http://data.unaids.org/pub/EpiReport/2006/05-Asia_2006_EpiUpdate_eng.pdf

9 *See id.*; *see also* UNITED NATIONS GENERAL ASSEMBLY, SPECIAL SESSION ON HIV/AIDS, MONITORING THE DECLARATION OF COMMITMENT ON HIV/AIDS—COUNTRY REPORT: MALAYSIA 5 (2005), http://data.unaids.org/pub/Report/2006/2006_country_progress_report_malaysia_en.pdf. [hereinafter UNAIDS-REPORT].

10 *See* UNAIDS-REPORT, *supra* note 9, at 1; *see also* S. Singh & N. Crofts, 5(3) *HIV Infection Among Injecting Drug Users In North-East Asia*, AIDS CARE 273, 273–74,

High risk behavior, especially intravenous drug usage, has contributed to the rise in incidence of HIV.[11] The increase in HIV was especially strong among Malaysians with the lowest levels of income and fewest years of schooling.[12] This public health situation, which particularly affects the most vulnerable parts of Malaysia's population,[13] makes the prices of life-saving medications a vital consideration in the country's FTA negotiations with the U.S.

In the U.S.-Malaysia trade discussions, the United States Trade Representative (USTR) will undoubtedly push for increased levels of IP rights.[14] These "ironclad" IP protections are accompanied with promises of increased foreign direct investment,[15] but the primary inquiry must be whether the new provisions will interfere with Malaysia's ability to address its public health needs. Acknowledging Malaysia's unique social, economic, and industrial characteristics, this paper evaluates the prospective impact that a trade agreement with the U.S. could have on public health, paying particular attention to the provisions on data exclusivity as well as marketing approval and patent linkage requirements. Part I of this note presents (A) background on the TRIPs agreement and regional/bilateral trade agreements, (B) the current public health environment in Malaysia, (C) an outline of the broad policy considerations of pharmaceutical exclusivity rights, and (D)–(E) the relevant IP protections present in the TRIPs agreement, and in regional and bilateral trade agreements. Part II discusses the ramifications of U.S.-FTA-level IP provisions, and the positive and negative implications that the heightened IP regime may have on the pharmaceutical industry in Malaysia. Part II.A outlines the benefits of a U.S.-Malaysia FTA that follows an approach closer to

available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8218462&dopt=Abstract.

11 *See* UNAIDS-REPORT, *supra* note 9, at 11.

12 Singh & Crofts, *supra* note 10, at 273–74. Malaysia AIDS Council chairperson, Datuk Paduka Marina Mahathir, noted that "we have an epidemic that is growing bigger and faster than ever before." Martin Khor, *Tackling AIDS with Cheap Generic Drugs*, THIRD WORLD NETWORK, Dec. 6, 2004, http://www.twnside.org.sg/title2/gtrends35.htm.

13 Singh & Crofts, *supra* note 10, at 273–74.

14 *See infra* Part I.A.

15 Christopher J. LaFleur, U.S. Ambassador to Malaysia, Luncheon Address at the Johor Corporation: An FTA for the Future (Apr. 27, 2006).

that of the TRIPs agreement in regard to pharmaceutical IP standards. Part II.B, on the other hand, considers the benefits of adopting the stronger data exclusivity/linkage regime that is regularly advocated by the USTR and the pharmaceutical research and development industry. Part III argues the FTA is likely to have a negative effect on access to pharmaceutical products in Malaysia. Part III also addresses a number of key points in the U.S.-Malaysia FTA negotiations that can help balance the pharmaceutical industry's requirement of investment incentives with the public's need for affordably priced medicines. Part IV concludes that the free-trade agreement will likely contain IP protections that are in excess of the level most appropriate for Malaysia's social and economic needs.

I. LEGAL AND SOCIAL CONTEXT FOR THE U.S.-MALAYSIA FTA

A. International Trade Agreements and Intellectual Property Rights

In 1994, with the creation of the World Trade Organization (WTO), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) established a comprehensive IP regime that imposed minimum IP requirements on all member states.[16] TRIPs required nations to employ strict IP protections where in many cases comparable domestic laws did not exist, or where they were not nearly as demanding as the provisions expounded in TRIPs.[17] Among the most divisive issues, and one that has received a great deal of publicity, was the potential effect that TRIPs-level patent protection would have on pharmaceutical costs and availability.[18] Under the new rules, companies were able to obtain the exclusive right to manufacture and sell the pioneer drugs

[16] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, art. XXIX, Annex 1C, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPs Agreement].

[17] Clark A.D. Wilson, *The TRIPs Agreement: Is It Beneficial to the Developing World, or Simply a Tool Used To Protect Pharmaceutical Profits for Developed World Manufacturers?*, 10 J. TECH. L. & POL'Y 243, 245 (2005).

[18] *See* Keith E. Maskus, *Access to Essential Medicines and Affordable Drugs: Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT'L L.J. 563, 564 (2002).

that they developed anywhere in the world.[19] Additionally, generic drug manufacturers were therefore prevented from entering the market and prices were able to remain artificially high.[20] As a result, many WTO member countries, particularly those countries facing high prevalence of AIDS, malaria, and tuberculosis, feared that their governments and patients would be unable to afford the drugs needed to combat pandemics and to meet other medicinal needs.[21] Exorbitantly high drug prices in the developing world clearly illustrated that there were market failures in delivering affordable, life-saving medications.[22]

In addition to the global TRIPs agreements conducted under the auspices of the WTO, countries are increasingly entering bilateral and regional free trade agreements (FTAs).[23] There is a trend in FTAs to establish IP protections that are in excess of those provided by the TRIPs agreement.[24] These provisions are known as "TRIPs-plus" conditions.[25] These agreements allow countries with greater bargaining power to negotiate trade policies without having to deal with organized opposition to their demands and without the same transparency that takes place with WTO negotiations.[26] Terms that would have been, and often were,[27] rejected in the TRIPs negotiations often appear in bilateral trade agreements because the smaller nations feel that despite their concessions they are ultimately better off having some degree of

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19 *See* TRIPs Agreement, *supra* note 16, art. XXIX, Annex 1C, art. 27.1.

20 *See* Wilson, *supra* note 17, at 250.

21 *See generally* Maskus, *supra* note 18.

22 *Id.*

23 *The Domino Effect of US FTAs: Public Health Groups, Members of Congress claim CAFTA will choke Access to Medicines*, INTELLECTUAL PROPERTY WATCH, Apr. 4, 2004, http://www.ip-watch.org/weblog/index.php?p=8&res=1024&print=0 [hereinafter *The Domino Effect of US FTAs*].

24 *See id.*

25 *Id.*

26 *See* Abbott, *supra* note 3, at 349; *see generally* DONALD G. RICHARDS, INTELLECTUAL PROPERTY RIGHTS AND GLOBAL CAPITALISM: THE POLITICAL ECONOMY OF THE TRIPS AGREEMENT 112–40 (M.E. Sharpe 2004).

27 *See* CARLOS MARÍA CORREA, SOUTH CENTRE, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 53–54 (2002), *available at* http://www.southcentre.org/publications/protection/protection.pdf.

free trade relations.[28] The United States in particular has been aggressively pursuing such agreements and has concluded eighteen FTAs since 1985.[29] Eleven other countries have held talks with the U.S. regarding the establishment of future trade agreements.[30]

One of the U.S.'s key trade goals is to conclude a free trade agreement with Malaysia.[31] While negotiations are conducted with little transparency,[32] certain provisions of the future FTAs can be anticipated based on prior agreements that the USTR concluded.[33] The USTR uses these past FTAs as blueprints for future trade negotiation, so it is unlikely that the U.S. would fail to include similar provisions in new trade agreements.[34] In addition to relying on the precedent of earlier FTAs, there are further indications that the U.S. would not deviate from its stringent IP provisions.[35] In fact, it is likely for the U.S. and Malaysia to agree to IP provisions that are at least as strict as the prior FTAs because Malaysia's plan for economic development specifically aims to place more emphasis on knowledge intensive sectors of the economy.[36] In signing the Trade Investment Framework

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[28] Rahul Rajkumar, *The Central American Free Trade Agreement: An End Run Around the Doha Declaration on TRIPs and Public Health*, 15 ALB. L.J. SCI. & TECH. 433, 474 (2005) (explaining that less developed nations make IP concessions in exchange for market access in the U.S.).

[29] *See* Robert McMahon, *The Rise in Bilateral Free Trade Agreements*, COUNCIL ON FOREIGN RELATIONS, June 13, 2006, http://www.cfr.org/publication/10890/. Of the eighteen negotiated agreements, four have not yet entered force and three are awaiting Congressional approval. *Id*. *See also* Katherine A. Helm, Note, *Outsourcing the Fire of Genius: The Effects of Patent Infringement Jurisprudence on Pharmaceutical Drug Development*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 153, 154 (2006) (enumerating regional and global trade agreements in which the U.S. has participated).

[30] *See* McMahon, *supra* note 29.

[31] *See* Press Release, Office of the USTR, United States Malaysia Announce Intention to Negotiate Free Trade Agreement (Mar. 3, 2006), *available at* http://www.ustr.gov/Document_Library/Press_Releases/2006/March/United_States,_Malaysia_Announce_Intention_to_Negotiate_Free_Trade_Agreement.html.

[32] *See* Abbott, *supra* note 3, at 349.

[33] *See infra* notes 34–40 and accompanying text.

[34] *See* Office of the USTR—Trade Agreements Home, http://www.ustr.gov/Trade_Agreements/Section_Index.html (last visited Mar. 18, 2007).

[35] *See infra* notes 36–40 and accompanying text.

[36] *See* THE ECONOMIC PLANNING UNIT, PRIME MINISTERS DEPARTMENT, NINTH MALAYSIA PLAN 2006–2010, PUTRAJAYA (2006) at 268 [hereinafter MALAYSIA-ECONOMIC PLAN], *available at* http://www.epu.jpm.my/rm9/html/english.htm (noting the

Agreement to initiate negotiations between the governments, both countries recognized that IP rights were going to be a major part of the trade agenda.[37] The American Malaysian Chamber of Commerce similarly acknowledged that Malaysia would be adopting stronger IP protections as a result of the trade agreement.[38] The USTR also made it clear that the nation believes that "economies demand pacts that . . . strengthen intellectual property rights," and therefore the U.S. will make progress on these pressing IP rights issues through the upcoming U.S.-Malaysia Free Trade Negotiations.[39]

The USTR's desire to strengthen IP laws in FTAs is illustrated in its 2006 "301 Report" on IP rights standards, wherein the USTR specifically expressed concern over the fact "that Malaysia has enacted neither protection against unfair commercial use of undisclosed test and other data submitted by pharmaceutical companies seeking marketing approval for their products, nor a coordinated mechanism between the health authorities and patent office to prevent the registration of unauthorized copies of patent-infringing products."[40] In fact, these two IP protections, data exclusivity and patent linkage,[41] have been included in every U.S. FTA to date.[42] As FTAs require contentious and extensive

recent increase in patent registration, and the policy reasons that favor further measures to continue increasing the role of intellectual property).

[37] *See* Trade and Investment Framework Agreement Between the Government of the United States of America and the Government of Malaysia, U.S.-Malaysia, preamble, annex, May 10, 2004, *available at* http://www.ustr.gov/assets/Trade_Agreements/TIFA/asset_upload_file922_10023.pdf.

[38] *See* AMCHAM Malaysia-US Chamber Public Submission on the US-Malaysia FTA, (May, 19 2006), *available at* http://www.amcham.com.my/Portal/DialoguePosition_List.aspx?ctg=2041885b-0a81-4861-83ff-e505d43c10d7 (then click the link of the document's title).

[39] Ambassador Karan K. Bhatia, Deputy U.S. Trade Representative, Remarks to the Asia-Pacific Council of the American Chambers of Commerce, Manila, The Philippines (Mar. 16, 2006), *available at* http://www.ustr.gov/assets/Document_Library/Transcripts/2006/March/asset_upload_file469_9143.pdf.

[40] Office of the USTR, 2006 Special 301 Report—Watch List, http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asset_upload_file190_9339.pdf (last visited Mar. 18, 2007).

[41] *See infra* Parts I.C–D for a detailed treatment of what these IP rights require of the parties.

[42] *The U.S.-Malaysia Free Trade Agreement*, PENANG ECONOMIC MONTHLY, May 2006, at 8, *available at* http://www2.seri.com.my/Economic%20Briefing%20-%20Pg

negotiations, the USTR noted that while there may be a temptation for some parties "to lower their standards[,] [w]e won't."[43] The U.S. has no intention of proposing anything less than its typical, stringent IP standards in its current negotiations with Malaysia.

A number of common FTA provisions are relevant to pharmaceutical prices and delivery of medical treatment, including patent term extensions and expanded scope of patentable subject matter.[44] For the purposes of this paper, however, the likely U.S.-Malaysia FTA terms relating to data exclusivity and marketing approval will be the focus, as these terms were specifically noted by the USTR as deficiencies in Malaysia's IP regime.[45] These provisions delay generic drug manufacturers in getting approval to market their product, thus keeping the market free from competition—even when a patent term has expired.[46] In addition, data exclusivity may impact the ability of a government to issue a compulsory license, which is considered a valuable mechanism for reducing drug prices.[47]

B. Intellectual Property and the Pharmaceutical Industry

The pharmaceutical industry's progress depends on expensive research and development (R&D) costs.[48] It maintains that effective IP protections are necessary to allow companies to recoup

%20Econ%20Rept/EconBrief2006-05.pdf (stating that "[d]ata exclusivity is one of the provisions in all U.S. FTAs[].").

43 Bhatia, *supra* note 39.

44 *See* Abbott, *supra* note 3, at 350.

45 *See infra* Parts I.C–D.

46 *See infra* Parts I.D–E for a detailed treatment of what these IP rights require of the parties.

47 *See infra* Parts II.A.3 and III.B.3 for a detailed treatment of how data exclusivity/patent linkage can impact a country's ability to issue compulsory licenses.

48 COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 19 (2006), *available at* http://www.who.int/intellectualproperty/report/en/ [hereinafter CIPR]. Allowing inventors to "appropriate the returns from their intellectual creations . . . [by granting] a time-limited monopoly" is known as the incentive function of patent protection. *Id*. Many argue that without this mechanism the collective society would see less innovation, and a temporary increase in price would outweigh the costs of that lack of innovation. *Id*. at 19–20. *See also id*. at 19–21 (providing a brief discussion of the various other justifications for patent protection, including the transactional, disclosure, and signaling functions).

these expenses by excluding others from selling their medical inventions for a limited period of time.[49] Studies estimate that the lengthy development process of a new drug costs from $110 to $880 million.[50] With patent protection, and other forms of exclusivity, many countries hope to stimulate a homegrown market that has the capacity to conduct R&D and produce necessary pharmacological ingredients.[51] Also, of special significance to developing countries, IP protections can enhance foreign direct investment in domestic markets.[52]

Opponents of stringent IP regimes often argue that the increase in pharmaceutical costs that result from the granting of exclusivity outweigh the resulting increases in innovation and investment.[53] This is especially true for smaller markets or less technologically advanced countries where IP protections alone may do little to stimulate innovation.[54] Those who are against increased patent protection also point out that the asserted costs of R&D may be exaggerated.[55] Based on financial reports from 2004, "the seven largest US pharmaceutical companies spend, on average, only fourteen percent of their revenues on R&D while thirty-two percent is spent on marketing, advertising, and administration."[56] The profits realized in the major markets alone more than recoup

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[49] *See* CIPR, *supra* note 48, at 32.

[50] Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, 481 (2004). *See also* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22(2) J. HEALTH ECONOMICS 151, 166 (2003) (estimating the cost of bringing a drug to market to be $403 million).

[51] *See* CIPR, *supra* note 48, at 32.

[52] *See* FTA WATCH, OVERVIEW OF BILATERAL FREE TRADE AND INVESTMENT AGREEMENTS 8 (2006), http://www.bilaterals.org/IMG/pdf/Overview.pdf. "A number of [Asian governments]—such as Singapore, Korea, Malaysia, and Thailand—are particularly trying to position themselves as hubs for the new trade and investment flows" through trade agreements. *Id.*

[53] CIPR, *supra* note 48, at 25.

[54] *Id.*

[55] OXFAM INTERNATIONAL, OXFAM BRIEFING PAPER 86, PUBLIC HEALTH AT RISK: A US FREE TRADE AGREEMENT COULD THREATEN ACCESS TO MEDICINES IN THAILAND 13 (2006), http://www.oxfam.org/en/policy/briefingpapers/bp86_thailand_publichealth, 17–19.

[56] *Id.* The report notes that the companies "report more in profits—18 percent of revenue—than they spend of R&D." *Id.* (citations omitted).

the expenses associated with drug development.[57] It is also argued that the "[d]eveloping countries in Asia, Africa, and Latin America together account for only about 11 percent of the world pharmaceutical market," and therefore the benefits to developed-country pharmaceutical firms will be limited.[58]

C. Public Health and the Pharmaceutical Industry in Malaysia

The Malaysian health care system is heavily subsidized by the government, which assists in providing access to medicines for a largely impoverished population.[59] However, "[t]he Ministry of Health estimates that . . . [public and private healthcare expenditures] would need to rise to about 7 [percent] of GDP by 2020 to match developed country standards."[60] This increase will "put great strain on the government's finances" and delays in receiving medical treatment may become "permanent feature[s] of the system."[61]

In 2004, Malaysia was one of the first countries to issue a compulsory license, a mechanism that allows a government to authorize generic drugs to enter the market despite the existence of a valid patent.[62] According to the Health Ministry, the increased competition reduced the costs of treating patients with the patented brand name drugs from $261 to $197 per month.[63] The decrease in cost of treatment using generic drugs was even more drastic, falling to $45 per month, which was a mere 17.4% of the costs based on the 2001 price of the equivalent patented products.[64] With the same level of resources dedicated to providing HIV treatment, the government could effectively treat six patients for

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57 *Id.*

58 *Id.*

59 *See* UNAIDS—Malaysia, *supra* note 8, at 8.

60 THE ECONOMIST INTELLIGENCE UNIT, INDUSTRY FORECAST: ASIA AND AUSTRALIA—MALAYSIA 60 (2005) [hereinafter EMI-M].

61 *Id.*

62 Khor, *supra* note 12.

63 *Id*. *See also* THAILAND MINISTRY OF PUBLIC HEALTH, THAILAND HEALTH PROFILE 430, http://www.moph.go.th/ops/health_48/CHAP10.PDF (last visited Mar. 18, 2007) (using the 90% reduction in the cost of a drug after the period of market exclusivity to illustrate the foreseeable cost escalation associated with adopting a stringent intellectual property regime).

64 Khor, *supra* note 12.

the price that it once cost to treat one person.[65] With a tight healthcare budget, one which will likely need to expand in the coming years, the price of pharmaceuticals will be a key factor in medical treatment programs.[66]

So while there is arguably potential for increased economic growth through participation in FTAs, there may also be severe social implications for developing countries as a result of the agreements' IP provisions.[67] This impact may be even more extreme in those cases where the FTA's IP protections are substantially in excess of the TRIPs Agreement's requirements.[68]

Two key IP protections that affect the pharmaceutical market—and that are priorities in the U.S.-Malaysia trade negotiations—will be discussed in turn. Section I.D will discuss clinical test data protection, and Section I.E will discuss linkage requirements between drug registration and patent status.

D. Clinical Test Data Protection in U.S. Trade Agreements

1. What is Clinical Test Data?

Before a pharmaceutical can be marketed for sale, the originator of the drug must demonstrate its "efficacy and safety for its intended therapeutic use."[69] This requires "extensive testing on animals and humans in pre-clinical and clinical trials, as well as toxicology, manufacturing feasibility and other scientific studies."[70] The final stages of development, when human testing is

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65 *Id.*

66 *See* EMI-M, *supra* note 60, at 62. This increase in spending is to account for an increase in the elderly population, a growing awareness of the role of healthcare services, continued urbanization, and increased incidents of cardiovascular disease. *Id.*

67 *See generally* MEDICAL SANS FRONTIERES, TOO LITTLE FOR TOO FEW: CHALLENGES FOR EFFECTIVE AND ACCESSIBLE ANTIRETROVIRAL THERAPY (2006), http://www.accessmed-msf.org/documents/MSF%20Toronto%20IAC.pdf [hereinafter MSF] (discussing accessibility in the context of HIV/AIDS treatment).

68 *Id.*

69 INT'L FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOC., ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 2 (2000), http://www.ifpma.org/documents/NR83/DataExclusivity.pdf [hereinafter IFPMA].

70 *Id.*

undergone, may require hundreds of human test subjects.[71] While statistics as to the time and costs of this data gathering vary,[72] it is clear that the process is "risky, laborious, and expensive."[73]

2. TRIPs Provisions on Clinical Test Data Protection

The TRIPs Agreement's provision on test data protection, Article 39 Paragraph 3, stipulates that "[m]embers, when requiring, as a condition of approving the marketing of pharmaceutical[s,] . . . the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use."[74] Unfair commercial use includes (1) creating confusion with the activities or goods of a competitor, (2) falsely discrediting a competitor, or (3) misleading the public as to the nature and suitability of goods.[75] The data protection afforded by the TRIPs Agreement differs from that of the U.S. FTAs in that TRIPs applies only to "unfair trade practices," and that the member country must only prevent "disclosure."[76] The U.S. FTAs, on the other hand, provide "*exclusive* rights to the originator."[77] It is clear that during the negotiations of the TRIPs Agreement the U.S. government, as well as business communities from the U.S., Europe, and Japan, proposed that the Agreement provide for data exclusivity.[78] However, these proposals were rejected.[79] Countries favoring stronger data protections were

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[71] Aaron Xavier 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, 468 (2004).

[72] *See* DiMasi et al., *supra* note 50, at 166; IFPMA, *supra* note 69, at 2 (estimating the cost to be around $500 million dollars).

[73] Fellmeth, *supra* note 71, at 468.

[74] TRIPs Agreement, *supra* note 16, art. XXIX, Annex 1C, art. 39.3.

[75] *See* Paris Convention for the Protection of Industrial Property art. 10, Mar. 20, 1883, as last revised July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

[76] MSF, *supra* note 67, at 3.

[77] *Id.* Under TRIPs, "WTO members do *not* have an obligation under Art. 39.3 to confer exclusive rights to test data . . . as pointed out by many experts." *Id.* at 4 (citing Correa, *supra* note 27, at 44).

[78] *See* Correa, *supra* note 27, at 53–55. Unlike the proposals, which requested protection for any "commercial or competitive benefit," the final draft of Article 39 only applied to "unfair commercial use." *Id.*

[79] *See id*. at 53–54.

unable to secure such terms in the multilateral negotiations, but they are now imposing these terms on nations through bilateral agreements.[80]

3. FTAs Provisions on Test Data Protection

While proponents of exclusivity for clinical test data were not entirely successful in the negotiations leading up to the TRIPs agreement, they have since fared much better in bilateral negotiations.[81] Recent U.S. FTAs provide data exclusivity for a minimum of five years, and in some cases a three-year extension is available.[82] For example, Article 16.8 of the U.S.-Singapore FTA, which contains a standard data exclusivity provision, reads:

> If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, the Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product . . . .[83]

In other words, when a generic manufacturer applies for marketing approval it cannot rely on the earlier test data that was submitted in the application of the original drug manufacturer's application. It is important to note that this provision is not part of a patent regime; instead it is a parallel form of IP protection that can exist even when a pharmaceutical product is not patented.[84]

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80 *See supra* notes 23–30 and accompanying text.

81 *See* MSF, *supra* note 67, at 3.

82 *See* CARSTEN FINK & PATRICK REICHENMILLER, THE WORLD BANK GROUP, TRADE NOTE: TIGHTENING TRIPS: THE INTELLECTUAL PROPERTY PROVISIONS OF RECENT US FREE TRADE AGREEMENTS 5 (2005) (providing a table cataloguing the IP provisions that have been included in eight recent FTAs).

83 Singapore Free Trade Agreement, U.S.-Sing., May 6, 2003, at 196, *available at* http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/Section_Index.html [hereinafter Singapore FTA].

84 *See* MSF, *supra* note 67, at 2–3.

> Compared to more traditional intellectual property rights such as patents and copyrights, data exclusivity is very unusual since it does not require any

Therefore, even if the original drug is off-patent, a generic company will not be able to get marketing approval for its product unless it generates its own test data or waits until the exclusivity period runs.[85] In addition to the impediments data exclusivity causes in allowing generic companies to enter the market, it also may prevent countries from using compulsory license grounds to exempt generic manufactures from patent protections in order to meet public health demands.[86]

E. Patent-Registration Linkage Requirements in U.S. FTAs

Patent-Registration Linkage ("linkage") is "the practice of linking drug marketing approval to the patent status of the originator's product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term unless by consent of the patent owner."[87]

Essentially, even if a generic company has prepared clinical test data (or is permitted to rely on the data of an earlier registrant) it still would not be able to register its product because the Drug Regulatory Agency (DRA) has determined that the originator's patent is still in effect. Linkage provisions thus pose two problems for the second applicant by (1) requiring the national regulatory

> inventive activity for it to be granted. Data protection is instead only based on the fact that an investment has been made by the originator in carrying out the necessary tests to demonstrate . . . their new medicine[']s suitability for sale to the public].

Id. at 3.

[85] *See* Carlos Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 92 (2004).

[86] The TRIPs agreement provided member states with a number of mechanisms, called flexibilities, to insure that IP protection would not hinder a government from pursuing compelling state objectives, such as insuring the health of its public. *See id.* at 94. U.S. FTAs include many of these flexibilities, though in many instances they vary as to what ground they will allow a country to make an exception to a patent right. *See* OXFAM, *supra* note 55, at 17–19. An example of one such flexibility is compulsory licensing, whereby a government (or authorized third party) is allowed to produce a drug that is under patent, in order to deal with a public health crisis. *Id.* However, it is unclear whether these emergency drugs would ever be able to reach the market in light of the data exclusivity provisions which would require the producer to generate its own clinical testing data before the drug regulatory agency would give the drug market approval.

[87] CONSUMER PROJECT ON TECHNOLOGY, RESPONSE TO THE 2006 PHRMA "SPECIAL 301" SUBMISSION FOR CHILE 4 (2006) [hereinafter CP-TECH].

agency to make an assessment on the validity of the patent, and by (2) putting the burden on the applicant to prove that the originator's patent is invalid.[88] Such provisions therefore force the DRA to act as "patent police,"[89] a role that is clearly beyond the expertise of a nation's health authority.[90]

The linkage terms in U.S. trade agreements are epitomized by the U.S.-Chile FTA, which provides that, in regard to pharmaceuticals that are under patent, the parties shall, in addition to preventing a grant of marketing approval, "make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent."[91] When the patent holder is notified of such application, a protracted judicial or administrative battle may arise between the parties,[92] thus further delaying the ability of the generics to enter the market.

Whereas test data protection appeared in TRIPs, and is being extended by FTAs, the linkage requirements contained in U.S. FTAs are entirely unprecedented both in TRIPs and in the national legislation of many of the U.S.'s trading partners.[93] Despite the establishment of minimum levels of global IP standards in the TRIPs Agreement, even stronger IP protections for pharmaceuticals are consistently included in subsequent FTAs that have been concluded.[94] The positive and negative impacts of these expanded IP protections will vary depending on the market and legal regime in which they are applied.[95]

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88 *See* CP-TECH, *supra* note 87, at 4.

89 *See* OXFAM, *supra* note 55, at 18.

90 Correa: *Bilateralism*, *supra* note 85, at 89.

91 Chile Free Trade Agreement, U.S.-Chile, art. 17.10.2(b), Jan. 1, 2004, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/asset_upload_file912_4011.pdf [hereinafter Chile FTA].

92 *See* Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, 14 IND. INT'L & COMP. L. REV. 613, 709 (2004) (explaining that notifying the original applicant is likely to encourage patent owners to "make mischief" for the parties subsequently seeking market approval).

93 *See* Correa: *Bilateralism*, *supra* note 85, at 90–91.

94 *See supra* Parts I.A, I.D–E.

95 *See infra* Parts II–III.

II. THE EFFECTS OF THE FTA'S INTELLECTUAL PROPERTY PROTECTIONS ON DRUG PRICES AND PUBLIC HEALTH IN MALAYSIA

A. The FTA's Strict Intellectual Property Provisions May Make It More Difficult for Malaysians to Acquire Affordable Medications

The U.S.-Malaysia FTA will entail certain increases in IP protection that will have three important ramifications for the costs of pharmaceuticals. First, data exclusivity will allow patent owners to lengthen their period of monopoly beyond the twenty year grant, and will even allow a five-year market exclusivity period for pharmaceuticals that are not under a patent.[96] Second, the linkage requirements will delay the entry of generic drugs into the market even after a patent term has run.[97] Finally, the compulsory licensing mechanism, one that Malaysia has used before,[98] may no longer be available.[99] These impediments to increasing competition in the drug market will make many drugs more expensive, putting the most vulnerable Malaysians at risk.[100] The implications of each provision will be discussed in turn. The potential impact of these provisions on compulsory licensing will be treated separately.

1. Regulatory Data Protection Will Effectively Extend Periods of Exclusivity, and Allow Market Exclusivity for Non-Patentable Chemical Entities

In Malaysia, a pharmaceutical manufacturer must provide (1) Administrative Data and Product Information, (2) Quality Data, (3) Clinical Test Data, and (4) Non-Clinical Test Data in its registration application before its pioneer drug is approved for sale.[101] A subsequent generic manufacturer, however, only needs to provide information on the first two categories, as well as a

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96 *See infra* Part II.A.1.

97 *See infra* Part II.A.2.

98 *See supra* Part I.C.

99 *See infra* Part II.A.3.

100 *See supra* Part I.B.

101 *See* MINISTRY OF HEALTH—NATIONAL PHARMACEUTICAL CONTROL BUREAU, DRUG REGISTRATION GUIDANCE DOCUMENT (MALAYSIA) 35 (2004) [hereinafter DRGD].

showing that its drug is therapeutically equivalent to the original.[102] The subsequent generic manufacturer need not repeat the clinical testing, which will obviously arrive at the same results that the original (chemically identical) drug's tests generated.[103] With a data exclusivity provision, such as those in U.S. FTAs, a generic manufacturer would have to independently generate all the test data in order to register its product.[104] Because compiling this data is costly and expensive, it is unlikely that a generic manufacturer would be economically able to carry out these tests.[105] It would have to wait for the exclusivity period to run, thus delaying the entry of its drug into the marketplace.[106]

An originator drug that receives regulatory approval late in its patent term would have the data exclusivity period (at least five years) tacked on to however much time remains on its patent.[107] For instance, the Singapore FTA provides that, "[w]here a product is subject to a system of marketing approval . . . and is also subject to a patent in the territory of that Party, the Party shall not alter the terms of the [data exclusivity] protection . . . ."[108] Therefore, the term of patent exclusivity may be exhausted, but nonetheless the clinical data still explicitly receives protection.[109] This exclusivity is provided even if a product is unpatented, or where a patent was granted incorrectly.[110]

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[102] *See id.* at 25, 35.

[103] *See id.* at 35.

[104] *See supra* Part I.D.3.

[105] *See* Rajkumar, *supra* note 28, at 465 (observing that "[l]ow-capitalized generic companies in small developing countries facing limited prospective revenues are generally not able to afford this expenditure").

[106] SISULE MUSUNGU & CECILIA OH, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 125 (2005) [hereinafter CIPRH REPORT].

[107] *Id.*

[108] *See* Singapore FTA, *supra* note 83, at 196–97.

[109] *Id.* at art. 16.8(4)(a). The Singapore FTA also has a requirement specifically included for pharmaceuticals which stipulates that patent terms should be extended in light of any "unreasonable curtailment of the patent term as a result of the marketing approval process[.]" *Id. See* 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, 349 (2004).

[110] Rebecca S. Eisenberg, *Pharmaceutical Innovation and Cost: An American Dilemma: The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 728 (2005).

In addition to the standard five-year exclusivity term, some recent FTAs have also included a three-year extension of data protection for "new clinical information."[111] Unlike the typical five-year term, the further period of exclusivity is not limited to "new" originator drugs.[112] This three-year protection of data even applies "to previously reviewed or approved pharmaceuticals."[113] While the additional three-year term is not included in all FTAs, unlike the standard data exclusivity provision, its inclusion is supported by a number of key players in the U.S.-Malaysia FTA negotiations, including the American Malaysian Chamber of Commerce and the Pharmaceutical Association of Malaysia (PhAMA).[114] The term that PhAMA proposes reads:

> Where the Authority grants registration and license for an application for a drug which includes an active ingredient that has been earlier approved in another application submitted to the Authority, based on confidential supporting information containing new clinical information . . . essential to the approval of the application, the Authority shall not, for a period of 3 years . . . register or grant license to another person in respect of that or a similar drug product on the basis of that earlier grant or the confidential supporting information submitted.[115]

This provision requires DRAs to provide data exclusivity for information submitted as part of new drug applications, even for non-originator drugs that are not patentable, such as "new indications or other changes in a previously approved product that require conducting new clinical trials to win [DRA] approval."[116] This protection can also be used to extend patent terms when an originator company delays until the end of its period of test data exclusivity, and then submits a subsequent application for drug

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111 *See* Scafidi, *supra* note 109, at 350.

112 *Id.*

113 *Id.*

114 PHARMACEUTICAL ASSOCIATION OF MALAYSIA, DATA EXCLUSIVITY: RECOMMENDATIONS FOR IMPLEMENTATIONS 1 (2006), http://www.phama.org.my [hereinafter DE-PhAMA].

115 *Id.* at 3.

116 *See* Eisenberg, *supra* note 110, at 727.

registration.[117] This tactic could be used, for example, if a company were to switch a medicine from prescription to over-the-counter use.[118] The company would provide the test data for a "new use" of the same drug, and then have a three year period of market exclusivity.[119] When the initial patent or data exclusivity term (whichever was still in effect) came to an end, a generic company could sell the original drug, but it would be prohibited from selling the drug in the newly approved capacity.[120] Therefore, in the previous example, the generic company could not gain approval for the over-the-counter (OTC) indications.[121] The generic company would only be able to continue selling its prescription variant, which may not be able to compete with the originator's OTC product.[122]

Both the three- and five-year periods of data exclusivity can prevent a generic company from getting its competing drugs to the market in a timely manner.[123] Usually, the cost of re-conducting clinical trials is prohibitively expensive.[124] However, even if a generic manufacturer was able to produce its own test data, clinical trials typically take six to eight years to complete.[125] The originator would thus have complete control of the market during these periods, even without the protection from a validly granted patent.

2. Linkage Requirements Will Delay Access to Affordable Medicines

The practice of linking patent registration and DRA approval prevents a drug manufacturer from obtaining market approval for a

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[117] *Id.* at 728.

[118] *Id*. at 728–29. Further, a company may also be eligible to get the same type of test data protection if it were to register the same drug for a new medicinal use. *Id*. at 729.

[119] *Id.* at 728–29. *See, e.g*., Press Release, Kline & Co., Impending Wave of Rx-to-OTC Switches Offers Significant Opportunities for Drug Companies (Aug. 15, 2002) (examining the strategic considerations of drug companies in timing their regulatory approval so as to prolong their market exclusivity).

[120] *See* Eisenberg, *supra* note 110, at 729–30.

[121] *Id.* at 729.

[122] *Id.*

[123] *See* notes 98–103 and accompanying text.

[124] *See* Rajkumar, *supra* note 28, at 468.

[125] *See* Baker, *supra* note 92, at 709.

drug while the original version of that drug is still under patent, unless "by consent or with the acquiescence of the patent owner."[126] Linkage requirements are prominent in U.S. trade agreements.[127] The requirements prevent the timely entry of generic drugs into the market by forcing generic companies to wait until the patent period has expired before submitting an application to a DRA.[128] Thus, subsequent applicants can no longer have their drugs approved during the pioneering product's patent term so that upon expiration of the patent the drug can immediately enter the market.[129] Thus, the length of time it takes to get marketing approval is basically an added period of market exclusivity for the patent holder.[130] For example, in Malaysia the National Pharmaceutical Control Bureau typically takes twelve to eighteen months to complete the drug registration process.[131] The effective length of a patent owner's market exclusivity would typically be twenty-one to twenty-one and one half years, instead of the standard twenty-year patent term.[132]

Furthermore, DRAs have no expertise in determining the validity of patents, and thus their role in determining drug safety and efficacy should not be concerned with patent law implications.[133] The United States' FTAs, which require regulatory agencies to make patent infringement decisions, "ignore[] that patents are private rights . . . [and] it is the patent owner who needs to act before the courts if he wants to interfere with the application procedures of a non licensed third party."[134] Even the most advanced regulatory agencies like the U.S. Food and Drug Administration concede that they are incapable of

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126 *See* Singapore FTA, *supra* note 83, at 197.

127 See FINK & REICHENMILLER, supra note 82, at 5 (showing that the U.S. trade agreements with Singapore, Chile, Morocco, Australia, Bahrain, as well as CAFTA, all include linkage provisions).

128 *Id.* at 2.

129 *See, e.g.*, Singapore FTA, *supra* note 83, at 196.

130 *See supra* Part I.E.

131 Ames Gross, Pharmaceuticals in Asia: Regulatory and Safety Updates (May 4, 2005) (presentation slides available at http://www.pacificbridgemedical.com/publications/Asia_Drug_and_Safety_2005.pdf).

132 *See id.*

133 *See* Correa: *Bilateralism*, *supra* note 85, at 89.

134 *Id.* at 89–90.

assessing patent rights.[135] Additionally, by forcing DRAs to address such concerns, "the process is kept in bureaucratic darkness, as opposed to a drug company suing for patent infringement through the courts."[136]

The U.S. FTAs include provisions that surpass the requirements of the TRIPs regime—a multilateral agreement that was controversial in its own right. The linkage requirements are so strict that they are in excess of the United States' own national regulatory requirements.[137] As a result, linkage provisions in U.S. FTAs will delay market entry of drugs, and will place additional burdens on local DRAs.[138]

3. Data Exclusivity Could Potentially Be an Obstacle to the Issuance of Compulsory Licenses

Compulsory licensing is a mechanism used by governments to allow third parties to produce a product that is protected by a valid patent.[139] If a patent owner will not license the rights to produce his protected invention, then the government can authorize a third-party to manufacture the product.[140] The TRIPs agreement, which all WTO members, including Malaysia, have signed, provides for compulsory licensing in Article 31.[141] The Agreement requires that a third party must first make "efforts to obtain authorization from the right holder on reasonable commercial terms and conditions" before a compulsory license is granted.[142] If those

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[135] *See* UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON GOVERNMENT REFORM—MINORITY STAFF SPECIAL INVESTIGATIONS DIVISION, TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION, PREPARED FOR REP. HENRY A. WAXMAN (2005), http://democrats.reform.house.gov/Documents/20050609094902-11945.pdf (quoting 59 Fed. Reg. §§ 50338, 50343 (Oct. 4, 1994) (explaining that "FDA does not have the expertise to review patent information. The agency believes that its resources would be utilized in reviewing applications rather than reviewing patent claims.")).

[136] Kelly Hearn, *Drug Deal*, ALTERNET, May 25, 2005, http://www.alternet.org/story/22081/.

[137] *See* Correa: *Bilateralism*, *supra* note 85, at 93.

[138] *See id.*

[139] *See supra* note 62 and accompanying text.

[140] *See id.*

[141] *See* TRIPs Agreement, *supra* note 19, art. XXIX, Annex 1C, art. 31.

[142] *Id.* at art. 31(b).

efforts are not successful within a "reasonable period of time," then a valid compulsory license may be issued in accordance with TRIPs.[143]

The data exclusivity and registration linkage provisions in U.S. trade agreements may impact a government's ability to issue a compulsory license.[144] For instance, even if a license was granted, the two FTA provisions discussed above would prevent the second manufacturer from being able to get regulatory approval, and therefore the drug could not legally enter the market.[145] The TRIPs-Plus terms of U.S. trade agreements "make illusory the granting of compulsory licenses and non-commercial government use, as prospective compulsory licensees are unlikely to have sufficient incentives to replicate test data, and governments cannot normally wait until a new set of test data has been developed."[146]

B. The FTA's IP Provisions Probably Will Not Have an Adverse Affect on Malaysians' Access to Low-Cost Drugs

The U.S.-Malaysia FTA's TRIPs-plus provisions will increase available levels of IP protection.[147] By creating strong IP rights, research-and-development-based industry investments will increase, and Malaysia will not be prevented from having a vibrant generic drug market.[148] First, data exclusivity generally does not work to extend patent terms, and providing five-year market exclusivity periods for pharmaceuticals that are not under a patent is necessary to encourage companies to conduct research on new uses for previously patented drugs.[149] Second, linkage

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[143] *Id.* The requirement that a negotiation is attempted between the parties is waived in cases "of national emergency or other circumstances of extreme urgency . . . [or i]n the case of public non-commercial use[.]" *Id.*

[144] *See* Meir Perez Pugatch, *Intellectual Property, Data Exclusivity, Innovation and Market Access*, *in* NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 127 (Pedro Roffe et al. eds., Earthscan 2006).

[145] *See id.*

[146] Correa: *Bilateralism*, *supra* note 85, at 92; *see also* Rajkumar, *supra* note 28, at 473 (explaining that even if FTAs contain some of the "key loopholes" to patent rights contained in the TRIPs agreement, with the current "data exclusivity regime, none of these provisions matter anymore").

[147] *See supra* Part I.A.

[148] *See infra* Parts II.B.1–3.

[149] *See infra* Parts II.B.1.

requirements are already part of Malaysian regulatory practice.[150] Third, data exclusivity and linkage requirements will not hinder the compulsory licensing mechanism.[151] The FTA's provisions on drug regulatory data will not prevent access to low cost medicines, and are necessary to encourage investment and innovation. The implications of each provision will be discussed in turn.[152]

1. Data Exclusivity is Needed as an Incentive for Drug Innovators to Carry Out Expensive Clinical Tests on Off-Patent Drugs

Malaysia hopes to use IP to promote innovation and growth in research and technology fields.[153] Data exclusivity is viewed by the pharmaceutical industry as being critical to "enable Malaysia to have access to new therapies developed both locally and overseas that may otherwise not be available [, and] will create a favourable environment for biosciences investment . . . on par with other leading knowledge based countries[.]"[154] If protection is not provided for clinical test data, subsequent manufacturers who rely on that data have a competitive advantage by not having to spend the time and money to produce it themselves.[155] If the increase in competition from generics makes marketing of drugs unprofitable, then originator companies may not be willing to conduct the clinical trials at all, and the drug will never reach the market.[156] In addition to the instrumental considerations, there is also an equitable argument—simply that later manufacturers are unfairly "benefiting from the 'sweat of the brow' of the initial registrant."[157] Malaysia can benefit from data exclusivity because it will create an overall stronger domestic IP framework.[158]

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150 *See infra* Parts II.B.2.

151 *See infra* Parts II.B.3.

152 *See infra* Parts II.B.1–3.

153 *See* MALAYSIA-ECONOMIC PLAN, *supra* note 36, at 268.

154 DE-PhAMA, *supra* note 114, at 2.

155 *See* Fellmeth, *supra* note 71, at 468–69.

156 *Id*. at 469–70.

157 *Id.* at 469.

158 PHARMACEUTICAL ASSOCIATION OF MALAYSIA, DATA EXCLUSIVITY—A COMPETITIVE ADVANTAGE IN THE BIOSCIENCES ENVIRONMENT 3, http://www.phama.org.my/pdf_document/DATA%20EXCLUSIVITY.pdf [hereinafter PHAMA—COMPETITIVE ADVANTAGE] (last visited Mar. 21, 2007).

Therefore, the country will be more effective in attracting foreign investment, and in developing a national drug research-and-development-based industry.[159]

As patent and data exclusivity periods typically run parallel to each other, it is only in the case of a drug taking over fifteen years from patent issuance to reaching the market that any extension in exclusivity would arise.[160] However, a study of prescription drugs receiving marketing approval from 1998 to 2006 elucidates the importance of a non-patent exclusivity.[161] Of 137 drugs approved during the relevant time period, "for twenty-three drugs out of this 137 total, the period of marketing exclusivity extended past the expiry of the last patent."[162] If there is a long delay between the beginning of a patent term and the point at which the drug is ready for sale, the term may be so near expiration that a firm would choose not to incur the costs of bringing the drug to market.[163] The five-year data exclusivity protection at least insures drug developers a short period in which they are essentially guaranteed to have a market free of competition.[164]

Clinical test data protection in Malaysia is also valuable for chemical compounds that are not covered by a patent, as "more and more compounds which are not patent protected are being developed and . . . in these instances data exclusivity is the only available intellectual property protection."[165] For instance,

> had generic copies of TAXOL®, (paclitaxel), Bristol-Myers Squibb's anti-cancer drug, which did not have any patents on its active ingredient, been able to be approved immediately, [the originator] would not have had any incentive to incur the extensive costs (estimated at well in

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159 *Id.*

160 *See supra* Part II.A.1.

161 *See* Junod, *supra* note 50, at 486–88. The result of the study is available at http://www.pharmalaw.org/marketing%20exclusivity%20dates%20(12.3.04).doc (last visited Feb. 27, 2007).

162 *Id.* at 487.

163 *See id.* at 488.

164 *See id*. at 479.

165 PHAMA—COMPETITIVE ADVANTAGE, *supra* note 158, at 3.

> excess of $500 million) to develop, test and bring TAXOL to market.[166]

If an originator company will immediately be faced with generic competition upon the initial marketing of its product, then the company may not even bother conducting research and testing on new uses of off-patent substances or new indications.[167] But, with a guaranteed five-year period of marketing free from generic competition, pharmaceutical firms will continue to research new uses for products that are not protected by a patent.[168] Data exclusivity is a strong protection, that prevents generic companies from competing in the market before a pioneering company has had an opportunity to recoup its R&D costs.[169]

As the five-year term expires, firms can obtain an additional three years of exclusivity for a new indication of that same product, which can make it profitable to continue testing drugs even after they are no longer protected by a patent or the initial data exclusivity grant.[170] One example of where this could be an effective mechanism for creating further R&D incentives is when a new indication of a drug is actually operating in a different field from the originator drug.[171] For instance, a drug that originally was being used by dermatologists could effectively be prescribed for its use in a new capacity by cardiologists.[172] To continue testing a drug after it has been marketed and sold, pharmaceutical

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[166] INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 7 (2000), http://www.ifpma.org/documents/NR643/DataExclusivity_2000.pdf.

[167] *Id.*

[168] *See id.*

[169] *See* Junod, *supra* note 50, at 492–93 (assessing the difficulties associated with challenging clinical test data exclusivity).

[170] *But see* Eisenberg, *supra* note 110, at 728–30 (arguing that the three year exclusivity "is likely to have little effect on incentives to conduct clinical trials of new uses of previously approved drugs").

[171] John A. Tessensohn, *Reversal of Fortune—Pharmaceutical Experimental Use and Patent Infringement in Japan*, 4 J. INT'L LEGAL STUD. 1, 60 n.217 (1998).

[172] *Id. But see id.* (explaining that the "three-year exclusivity period may turn out to be illusory [because i]f there are generic products on the market approved for the pioneer use, despite the inability to disclose the newly protected use in labeling materials for generic copies, doctors may nonetheless engage in off-label use of the generic product for the protected use, thus destroying data exclusivity for the new use.").

companies require the economic incentive of a three year market exclusivity extension.[173]

2. Linkage Requirements Protect Patent Owners' Investments, and Create a More Efficient Regulatory Framework

By notifying patent owners when a generic company is making an application for approval, and requiring patent infringement issues to be resolved before marketing approval is granted, linkage requirements are beneficial to pioneer drug companies and the regulatory system.[174] First, notice is given to the holder of the relevant patent, allowing him or her to "take the patent status into account before launching a development program or submitting an application, and [it allows companies to ensure] that the regulatory agencies have the necessary information to fairly access the patent."[175]If there is insufficient communication between a DRA and a patenting agency, then there is the possibility that a product without authorization will enter the market.[176] Second, by enabling a strong administrative environment, regulatory agencies can handle complex disputes that would otherwise be a drain on the judicial system.[177]

If a generic product is granted regulatory approval, despite infringing on a valid patent, then the originator company will need to bring a judicial action to adjudicate the patent infringement when the infringement could have simply been prevented by the DRA.

3. It is Unlikely that the FTA Provisions Will Prevent Malaysia from Using Compulsory Licenses to Address Public Health Concerns

Amid concern that IP rights would stand in the way of providing life-saving medications to patients in the developing

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[173] *See* Junod, *supra* note 50, 496–97.

[174] PHARMACEUTICAL ASSOCIATION OF MALAYSIA ET AL., PATENT LINKAGE 2 (2006), http://www.phama.org.my/pdf_document/PL_FTA_March2006.pdf [hereinafter PL-PHAMA].

[175] *Id.*

[176] *See id.* at 3.

[177] *See id.*

world, in 2001 the WTO adopted the Doha Declaration on the TRIPs agreement and public health.[178] The Declaration provided that countries have "the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[179] The FTAs that the U.S. is pursuing will not interfere with the WTO's Declaration. The U.S. has made it clear through side letters that IP provisions in FTAs "do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all[.]"[180]

The proposition that data exclusivity would prevent a country from using a compulsory license was rejected in a letter from the U.S. Trade Representative to Congressman Sandy Levin (D-Mich.), which reiterated what was stated in the side letter on health to the U.S.-Morocco Agreement. The follow up letter reads:

> If circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPs/public health solution, the data protection provision in the FTA would not stand in the way . . . [the side letter is] a significant part of the interpretive context for this agreement and is not merely rhetorical . . . [a]ccording to Article 31 of the Vienna Convention on the Law of Treaties.[181]

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[178] *See* WORLD TRADE ORGANIZATION, DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH (2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[179] *Id.*

[180] The Dominican Republic-Central America-United States Free Trade Agreement, Understanding Regarding Certain Public Health, Aug. 5, 2004, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/asset_upload_file697_3975.pdf [hereinafter CAFTA Understanding]; *see also* U.S.-Morocco Free Trade Agreement, Side Letter on Public Health, June 15, 2004, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Morocco_FTA/Final_Text/asset_upload_file258_3852.pdf (containing nearly identical language to CAFTA's understanding).

[181] Letter from the United States Trade Representative, General Counsel, John K. Veroneau to Congressman Sandy Levin (July 19, 2004), *available at* http://thomas.loc.gov/cgi-bin/cpquery/T?&report=hr627&dbname=108&; *see* Fink & Reichenmiller, *supra* note 82, at 3.

While not part of the main text, side letters are read as part of the agreement between the two parties.[182] If there was a dispute settlement proceeding between the U.S. and Malaysia, it is likely that "any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty" would be considered part of the treaty obligations.[183] If the USTR does not include such an understanding in the current negotiations, it is also possible that the U.S.-Malaysia FTA could follow the model of the U.S.-Chile FTA which included a clause specifically dealing with public health; it provided that the parties have specified the terms of the agreements "[r]ecognizing the principles set out in the Doha Declaration on the TRIPs Agreement on Public Health."[184] The USTR has given its trade partners assurances that the need for strong IP protections will not interfere with the country's ability to take measures necessary to protect public health.[185]

III. BY ALLOWING PHARMACEUTICAL FIRMS TO EXTEND THEIR MARKET MONOPOLIES, THE U.S.-MALAYSIA FTA'S INTELLECTUAL PROPERTY PROVISIONS DO NOT PROPERLY BALANCE THE NEED TO ENCOURAGE INNOVATION WITH PUBLIC HEALTH CONCERNS

The U.S. is using bilateral trade negotiations to supplement the IP terms of the TRIPs agreement, particularly those relating to the protection of drug regulatory data.[186] Implementing the data exclusivity provisions required by the FTAs is not taken lightly, as the U.S. and EU are using trade sanctions to retaliate against

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[182] Vienna Convention on the Law of Treaties, art. 31, May 23, 1969, 1155 U.N.T.S. 331, *available at* http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf [hereinafter Vienna Convention].

[183] *Id.*

[184] Chile FTA, *supra* note 91, art. 17, preamble. *But see* Australia Free Trade Agreement, U.S.-Australia, May 18, 2004 and Singapore FTA, *supra* note 83 (neither containing a side letter on public health or any explicit mention of the Doha Declaration on TRIPs and Public Health).

[185] *See* CAFTA Understanding, *supra* note 180.

[186] *See supra* Parts I.A, I.C.3, & II.A.

developing countries that fail to apply the stricter requirements.[187] The U.S.-Malaysia FTA will make it more difficult for Malaysians to acquire low costs drugs by (1) extending periods of patent market exclusivity for originator drug companies by delaying regulatory approval for subsequent generic manufactures, and (2) limiting the role that the Malaysian government can play in increasing competition through the use of compulsory licensing.[188] These heightened requirements will be aggressively enforced, and will provide governments with far less leeway than agreed to under the TRIPs agreement.[189] For a country with pressing public health concerns,[190] and a robust generic market, the impacts of these provisions will be more drastic in Malaysia than in FTAs with other states or regions.[191]

The United States' FTAs that have been negotiated in recent years are largely similar in the field of IP requirements, as prior agreements serve as a framework for subsequent negotiations.[192] Data exclusivity and patent linkage will certainly be part of the negotiations, and it is more than likely that they will ultimately appear in the concluded agreement.[193] These predictable consequences of these FTA provisions will be discussed in Parts IV.A(1)–(2). Then, in Section IV.B, the more speculative question of how they will impact Malaysia's ability to use compulsory licensing will be assessed.

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[187] MEIR PEREZ PUGATCH, ICTSD-UNCTAD DIALOGUE ON ENSURING POLICY OPTIONS FOR AFFORDABLE ACCESS TO ESSENTIAL MEDICINES, INTELLECTUAL PROPERTY AND PHARMACEUTICAL DATA EXCLUSIVITY IN THE CONTEXT OF INNOVATION AND MARKET ACCESS 1 (2004), http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf (referring to the experiences of Israel, Turkey, and India, which have resulted in generic drugs manufactures being perceived as "national champions").

[188] *See supra* Parts II.1–3.

[189] *See supra* Parts I.C.2–3, I.D.

[190] *See supra* Part I.A.

[191] Even with a strong generic market, Malaysian drug prices were already 20–76% higher than in India. Douglas W. Bettcher, Derek Yach & G. Emmanueal Guindon, *Global Trade and Health: Key Linkages and Future Challenges*, 78 Bulletin of the World Health Organization 527 (2000) (citing A. Subramanian, *Putting Some Numbers on the TRIPs Pharmaceutical Debate*, 10 INT'L J. TECH. MGMT. 1, 1–17 (1994)).

[192] *See supra* notes 32–39 and accompanying text.

[193] *See id.*

A. Data Exclusivity

In the United States, Congress introduced marketing data exclusivity with the primary objective of encouraging "the development and testing of unpatentable pharmaceuticals."[194] This policy is circumvented by two unfortunate facts of the regulatory data protection laws that are being exported in trade agreements. First, there is no requirement that medical advances to off-patent drugs be innovative.[195] In fact, in the EU, the drug regulatory authority "has claimed that less than half of the 126 products approved . . . in its first five years 'could be considered innovative.'"[196] The only requirement for granting data exclusivity is that the product be a "new chemical entity," a concept "with a broader meaning than required under the TRIPs Agreement"[197] which "not surprisingly . . . favours the interests of the U.S. pharmaceutical companies."[198]

Second, beyond the policy of increasing R&D expenditures relating to off-patent drugs, data exclusivity protections increase the length of patent terms in a significant number of drugs.[199] An economic model used to determine the increase in drug prices in Peru as a result of the data exclusivity provision of a U.S. FTA estimates that seven years after the agreement came into effect, households would have to increase expenditures on medicines by $130.7 million "to maintain the same level of access to medicines."[200] In countries that have high proportions of their population in need of life saving medications, a delay in generic

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[194] *See* Allergan, Inc. v. Alcon Labs., 324 F.3d 1322, 1325 (Fed. Cir. 2003) (citing H.R. REP. NO. 98-857, pt. 1, at 29 (1984)).

[195] *See* Junod, *supra* note 50.

[196] *See id.* at 515.

[197] Correa: *Bilateralism*, *supra* note 85, at 87.

[198] *Id.*

[199] Junod, *supra* note 50, at 487.

[200] JUAN PICHIHUA SERNA, ICTSD, WHO, AND THE WORLD BANK INSTITUTE, DEVELOPING A METHODOLOGY TO ASSESS THE IMPACT OF TRIPS-PLUS PROVISIONS ON DRUG PRICES: POSSIBLE IMPACT OF US-PERU FTA ON ACCESS TO MEDICINES DUE TO DATA EXCLUSIVITY PROTECTION FOR DRUGS 6 (2006), http://www.iprsonline.org/unctadictsd/dialogue/2006-07-31/9Peru%20Study-PichihuarevisedAug10.pdf. It is important to note that the study only considers the drugs for which the data exclusivity runs consecutively with their patent term, so the exact costs are skewed from a typical real world market. *Id.* at 1.

market competition—whether a one-year (linkage) or five-year (data exclusivity) delay—could keep drugs beyond the budget constraints of many citizens or third party purchasers (e.g., the government).[201] Plus, data exclusivity actually encourages drug companies to release improved variations of existing drugs slowly, so as to receive additional periods of exclusivity as its current term of exclusivity is near expiration.[202]

The argument that it is feasible for a generic company to simply produce its own clinical data is economically[203] and equitably[204] untenable. Even if it was financially possible for generic companies to reproduce clinical test data, as an ethical matter, requiring generic companies to reproduce clinical test data that is already in the archives of a drug regulatory authority is unacceptable.[205] Requiring a company to conduct clinical trials on life threatening drugs, when a regulatory authority already has information demonstrating the drugs' safety and efficacy, needlessly puts patients at risk.[206] Conducting duplicative tests also needlessly causes the suffering and death of twelve million animals per year. [207]

The benefits of data exclusivity are questioned even in the most advanced knowledge-based markets of the U.S., EU, and Japan; these are the nations with the healthiest populations and largest pharmaceutical R&D industries.[208] In light of Malaysia's need to have drugs be affordable and available as soon as possible, instead of allowing regulatory data protection to extend beyond the end of

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[201] *See, e.g.*, *id.* at 6.

[202] *See* Eisenberg, *supra* note 110, at 729.

[203] *See* Rajkumar, *supra* note 105 and accompanying text. The economic and practical considerations were discussed separately in Part I.C.3.

[204] *See* Fellmeth, *supra* note 71, at 474.

[205] *See supra* notes 69–73 and accompanying text; *see also Implementation of U.S. Bilateral Free Trade Agreements with Chile and Singapore: Hearing Before the Subcomm. on Trade of the H. Comm. on Ways & Means*, 108th Cong. (2003) [hereinafter Waxman Statement] (statement of Rep. Henry A. Waxman).

[206] *See* Fellmeth, *supra* note 71, at 474.

[207] *Id.* Twelve million animals are used each year to test drugs in the U.S. alone. *Id.* (internal citations omitted).

[208] *See generally*, PUGATCH, *supra* note 187 (discussing, in parts 1–3, the competing policy considerations that the U.S. and EU DRAs weighed in deciding on appropriate regulatory schemes).

a patent term, the data exclusivity and patent exclusivity periods should expire concurrently.[209] Alternatively, the data exclusivity could be administered with a sunset provision that would come into effect once the IP holder has received a predetermined percentage return on his or her investment.[210] Nearly twenty percent of pharmaceuticals receive extended market monopoly periods from data exclusivity.[211] A mechanism must be in place to limit any effective extensions to the previously established twenty-year patent term.[212]

B. Patent Linkage

Patent linkage provisions are detrimental to generic markets for many of the same reasons as data exclusivity.[213] However, while it was estimated that approximately one in five drugs will get their market monopoly extended with data exclusivity, linkage requirements will delay every single generic product's entry into the market if the originator drug is under patent.[214] The amount of time that linkage requirements add to the market exclusivity is however long it takes a country's DRA to approve a drug, as the approval process will no longer begin during the originator drug's patent term. In Malaysia, this delay will be approximately twelve to eighteen months, giving all patented medicines terms of twenty-one to twenty-one and a half years, instead of the twenty-year terms in accordance with the TRIPs Agreement.[215] This calculation does not even account for the cases in which data exclusivity or other extensions that patent law may provide are present.[216]

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209 *See generally supra* Part II.A.1.

210 *See Health Registration Data Exclusivity, Biomedical Research, and Restrictions on the Introduction of Generic Drugs, Before the Subcomm. on Labor, Health and Human Services, Education, and Related Agencies of the S. Comm. on Appropriations*, 105th Cong. (1997) (statement of James P. Love, Consumer Project on Technology), *available at* http://www.cptech.org/pharm/senhregd.html; Junod, *supra* note 50, at 515.

211 *See supra* notes 137–138 and accompanying text.

212 *See supra* notes 165–174 and accompanying text.

213 *Id.*

214 *See supra* Part II.A(2).

215 *Id.*

216 *See, e.g.*, FINK & REICHENMILLER, *supra* note 82, at 5 (noting that a number of FTAs grant exclusivity extensions for delays in the regulatory approval process).

Linkage requirements will have an impact on nearly all medications, and cumulatively will have an even more drastic effect than data exclusivity extensions. These provisions are certainly TRIPs-Plus, and, in practice "patent-registration linkage goes beyond the standards applied in developed countries."[217] One commentator observes that U.S. FTA IP standards

> raise[] questions about how bilateral the U.S. bilateralism actually is . . . . [In fact,] the absolute and automatic patent-registration linkage seems to go beyond U.S. law . . . . By creating through bilateral negotiations standards of protection higher than those applied domestically, the powerful U.S. pharmaceutical industry may be able to force an amendment of U.S. domestic law in ways simpler and less costly that [sic] through lobbying in Congress.[218]

Using FTAs to increase the level of IP protection in U.S. domestic law may not be effective unless Congress accedes to the goals of the USTR, and it is unlikely that Malaysia would attempt to force this issue by engaging in political criticism of it largest trading partner.[219] The fact that the linkage requirements propounded by the USTR exceed developed-nation standards, however, should be alarming to developing countries asked to implement these standards.

The disparity in bargaining power in bilateral agreements between the industrialized U.S. and developing countries is illustrated by one commentator who notes that "[w]hile the U.S. might have to yield to the EU, Japan or China on certain points in the WTO process, the absence of these players in bilateral trade negotiations means that the U.S. can extract whatever preferential terms of trade it wants."[220] Malaysia, on the other hand, may not have the option of ignoring or circumventing the FTA terms it

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[217] *See* Correa: *Bilateralism supra* note 85, at 90.

[218] *Id.* at 93.

[219] *See* Press Release, Office of the USTR, United States Malaysia Announce Intention to Negotiate Free Trade Agreement (Mar. 3, 2006), *available at* http://www.ustr.gov/Document_Library/Press_Releases/2006/March/United_States,_Malaysia_Announce_Intention_to_Negotiate_Free_Trade_Agreement.html; *see also* Rajkumar, *supra* note 28, at 450.

[220] Rajkumar, *supra* note 28, at 450.

feels are not suitable for its legal and social context.[221] The U.S. has not hesitated to coerce other nations into adopting heightened legal standards in trade agreements using economic sanctions.[222] The unyielding readiness of the U.S. to force compliance should be considered by nations, like Malaysia, who may be sacrificing much by implementing an inflexible IP regime.[223]

Proponents of patent linkage argue that at one point Malaysia's DRA was in practice using an unofficial linkage requirement to prevent generic application for approval.[224] This informal practice that was developed has begun to wane, however, and now "there appears to be a shift in this practice and . . . generic applications have been approved despite valid existing patents."[225] Unfortunately for generic competition in Malaysia, despite the trend in allowing generic drugs to be approved and thus ready for market access upon the expiration of a patent, the U.S. FTA will reinstate the abandoned linkage practice.[226]

C. Compulsory Licensing

The extension of exclusivity periods is not the only adverse effect that the data exclusivity and linkage requirements will

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[221] *See id.* (noting that only the most powerful countries are able to extract concessions from U.S. trade negotiators).

[222] *See id.* at 450, 455, 470–71 (citing U.S. trade sanctions being used as a method of pushing for increased intellectual property protection in Nicaragua and Guatemala). In Guatemala, the domestic legislature attempted to repeal its data exclusivity law and replace it with a new law that allowed for increased generic participation in the market. *Id.* However, "the USTR has prevailed in its efforts to force Guatemala to repeal the . . . legislation." *Id.* The United States will undoubtedly demand a "strict interpretation of the data protection provisions." *Id.*

[223] *See id.* at 450–51 (describing the "unpreparedness" of developing countries during bilateral trade negotiations).

[224] *See* PL-PHAMA, *supra* note 174, at 2; Kathleen Jaeger, President and CEO, Generic Pharmaceutical Association, Testimony Before the Interagency Trade Policy Staff Committee on the Proposed Free Trade Agreement with Malaysia: Generic Pharmaceutical Association (May 3, 2006), *available at* http://www.us-asean.org/US-Malaysia%20FTA/Generic_Pharmaceutical_Association.pdf.

[225] *See* PL-PHAMA, *supra* note 174, at 2 (noting that the linkage requirements were never codified anyway, so the drug control authority had no obligation to exercise patent linking practice).

[226] *See supra* notes 214–215, 224–225 and accompanying text.

entail.[227] As discussed in sections II.A.3 and II.B.3, there is speculation that compulsory licensing possibilities will be nullified by the strict exclusive rights granted for regulatory test data. Some FTAs include provisions that specifically address this legal ambiguity, and others include side letters that provide the U.S.'s understandings of these provisions.[228] Different FTAs have handled this issue in various ways, and as trade agreement discussions are conducted with little or no transparency,[229] it is impossible to say which approach the U.S. will take this time.[230] The three specific possibilities that appear in previous FTAs are (1) providing a main text clause that requires interpretations that conform with the Doha Declaration on TRIPs and Public Health,[231] (2) giving assurances in side letters that the TRIPs-Plus obligations will not interfere with national compulsory licensing schemes,[232] and (3) not providing any clarification or interpretive guidance on the interaction of data exclusivity/linkage and compulsory licensing.[233]

If there is a clause in the main text of the agreement referring to the Doha Declaration, which made it clear that compulsory licensing was a key attribute for developing countries to use in fighting health crises, then presumably the TRIPs-Plus obligations would not be permitted to interfere with compulsory licensing.[234] The ambiguities would likely be resolved in the favor of the developing country if the issue were brought before an ad-hoc dispute settlement body.[235]

If, however, the public health concerns were addressed in a separate side letter, the interpretive value would not be as clear.

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[227] *See supra* Parts II.A.3 & II.B.3.

[228] *See infra* Parts III.A.3 & III.B.3.

[229] *See The Domino Effect of US FTAs*, *supra* note 23 and accompanying text; Abbot, *supra* note 3.

[230] Abbott, *supra* note 3.

[231] *See* Chile FTA, *supra* note 91 and accompanying text.

[232] *See supra* Part III.B.3.

[233] *See supra* notes 139–146 and accompanying text.

[234] *See* World Trade Organization, Decision of the General Council of 30 August 2003, WT/L/540 and Corr. 1 (2003), *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[235] *See infra* notes 236–241 and accompanying text (discussing the questionable value of side letters when compared to main text terms within trade agreements).

First, side letters may be deficient because of the restrictive way that they are drafted.[236] In the CAFTA side letter, for example, the "USTR rewrote . . . the Doha Declaration to reflect a U.S.-preferred outcome to WTO negotiations," and does not fairly reflect the language of the Declaration itself.[237] The language used attempted to impose a "scope-of-diseases" limitation on when compulsory licenses could permissibly be used by a government.[238] Second, while the Vienna Convention requires that side letters be considered as part of the FTA's overall context, the side letters may also be seen as "merely signal[ing] the signing governments' *belief* that the intellectual property rules of the FTAs will not interfere with the protection of public health."[239] Further, the office of the USTR has informed World Bank staff that in its view the understandings do not create any "exemption that would allow parties to the FTAs to ignore obligations in the agreements' intellectual property chapters."[240] If side letters are understood as no more than a prediction by the U.S. government, then they provide no guarantees as to the true workability of the compulsory licensing mechanism.[241]

Another potential option is that the U.S.-Malaysia FTA could simply not address the negative implications that data exclusivity/patent linkage could have on compulsory licensing.[242] If a dispute arose between the parties to the agreement, there would

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[236] *See* Abbott, *supra* note 3, at 352.

[237] *Id.* at 352–53.

[238] *Id.* Furthermore, the side letter qualifies the terms of the Declaration by requiring that any use of a compulsory license must be "necessary." *See* CAFTA Understanding, *supra* note 180; CARLOS CORREA, INTERNATIONAL TRADE LAW AND DEVELOPMENT INSTITUTE, PROVISIONS IN FREE TRADE AGREEMENTS THAT MAY AFFECT ACCESS TO MEDICINES IN DEVELOPING COUNTRIES 8 (2006), *available at* http://www.idcid.org.br/wtoandbeyond/Provisions%20in%20Free%20Trade%20Agreements%20that%20May%20Affect%20Access%20to%20Medicines%20in%20Developing%20Countries%20-%20Carlos%20Correa.doc.

[239] FINK & REICHENMILLER, *supra* note 82, at 3 (emphasis added).

[240] *Id.* at 3, 10.

[241] *See supra* notes 236–239 and accompanying text. For example, the U.S.-Australia trade agreement does not mention the Doha Declaration. *See* Free Trade Agreement, May 18, 2004, U.S.-Austl., ch. 11, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/ asset_upload_file148_5168.pdf.

[242] *C.f. supra* notes 236–239 and accompanying text (describing the added assurances that references to the Doha Declaration in the main text and side letters provide).

be no assurances that Malaysia was acting within its sovereign rights by issuing a license.[243]

The FTA provisions on compulsory licensing are particularly important to Malaysia. Compulsory licenses have rarely been issued to manufacture generic drugs, but Malaysia has shown that it is willing to do so.[244] Even when licenses have not been used, a government threatening to introduce new competition has proved to be a powerful bargaining chip to force manufacturers to produce necessary quantities of a drug at an affordable price.[245] Malaysia, both because of its willingness to be flexible with patent rights, and because of its public heath situation, must have the legal means to issue compulsory licenses.[246] Whichever provision the FTA includes on data exclusivity and patent linkage, Malaysia's trade negotiators should insist on an understanding that allows the government to use TRIPs-type flexibilities.[247] Better yet, the FTA should indicate what additional steps a government must take to issue a license in light of the two stipulations on clinical test data exclusivity.[248]

IV. CONCLUSION

The multilateral TRIPs negotiations were concluded with a number of compromises between the developed and developing world, and ultimately "represent[ed] a victory of collective bargaining power" for developing countries.[249] Bilateral negotiations, conversely, allow a dominant country to impose its

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243 *See id.*

244 *See supra* Part II.A.

245 *See* William Onzivu, *Globalism, Regionalism, or Both: Health Policy and Regional Economic Integration in Developing Countries, an Evolution of a Legal Regime?*, 15 MINN. J. INT'L L. 111, 140 n.175 (2006) (giving a brief synopsis of the laws in South Africa and Brazil that create a framework wherein a government could issue a compulsory license) (citations omitted).

246 *See generally supra* Parts I.A, II.A.3.

247 *See generally supra* Parts I.A, II.A.3.

248 *See generally* Robert Weissman, *Data Protection: Options for Implementation*, *in* NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 151–78 (Pedro Roffe et al. eds., Earthscan 2006) (describing the different approaches that countries may take in implementing new data exclusivity protections).

249 Scafidi, *supra* note 109, at 342.

desired IP regime on a developing nation, instead of forcing parties to reach an international consensus before determining appropriate standards for the global economy .[250] By using FTAs the U.S. "is engaged in a systematic effort to increase international intellectual property protection, one country at a time."[251]

As in all IP regimes, a country's "regulatory system of marketing/data exclusivity should be . . . tailored to balance the conflicting interests it is supposed to take into account."[252] When developed countries like the United States try to strike this balance, they will inevitably have different priorities and concerns than a developing country.[253] On the other hand, there is a need to have some minimum level of IP rights in order to attract foreign investment and to develop homegrown research and development. The TRIPs Agreement mandated that patents must carry twenty-year terms, and also afforded developing countries a number of mechanisms to maintain flexibility with IP protections.[254] Free trade agreements are increasing the obligations of developing nations by effectively extending patent terms, and perhaps even eliminating compulsory licensing.[255]

After including U.S.-style drug regulation in FTAs with Chile and Singapore, even Congressman Henry A. Waxman (D-Cal.), who sponsored the U.S. version of the legislation, expressed concern that such a regulatory regime would be inappropriate in developing countries.[256] In a statement to the House Ways and Mean Committee, he observed that:

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[250] *See id.* at 343–44.

[251] *Id.* at 343.

[252] Junod, *supra* note 50, at 481.

[253] *See* Jacqueline Ann Surin, *Local drug makers may lose out under US FTA*, THE EDGE DAILY, July 17, 2006, *available at* http://www.theedgedaily.com/cms/content.jsp?id=com.tms.cms.article.Article_772db6e3-cb73c03a-110b6400-7d0bac10. Local generic manufacturers, private and public, will be adversely affected by the new IP protections. *Id.* For example, "'[t]he World Health Organisation predicted that Colombia's generic industry would lose up to 71% of its market share due to its US FTA, while one-third of Australia's generic companies had to close or merge when data exclusivity alone was introduced in Australia.'" *Id.* (emphasis added); *see also* Rupa Damodaran, *Malaysian manufacturers wary of US move on patents*, BUSINESS TIMES, MALAYSIA, Aug. 22, 2006.

[254] *See supra* Part I.C.2.

[255] *See supra* Parts I.A, II.A.3.

[256] Waxman Statement, *supra* note 205.

> devastating epidemics in the developing world, including AIDS, TB, and malaria are killing millions of people and crippling whole societies. Even in middle-income countries, leading killers like heart disease, diabetes, cancer and other conditions are going untreated because essential medications are unaffordable in these countries, costing many times the average citizen's annual income . . . . [T]o impose [the U.S. intellectual property] system on a country without a safety net, depriving millions of people of life-saving drugs, is irresponsible and even unethical.[257]

Malaysia is transitioning into a knowledge-based economy, and wants to encourage research and development-based investment. However, the level of IP protection that will be imposed by its FTA with the U.S. will go beyond what is necessary to accomplish these goals.[258] As patent terms for pharmaceutical products will effectively be increased from twenty years to twenty-one to twenty-five years, generic drugs will be delayed in entering the market, and prices will rise accordingly.[259] If, after the adoption of the FTA, market-determined prices of medicines become too expensive for Malaysian consumers, the government may no longer have the ability to issue a compulsory license.[260]

During the continuing trade discussions, even if Malaysia's negotiators accept longer exclusivity periods for originator drug companies, the price increases can be managed so long as a clause insuring the availability of compulsory licensing is insisted upon.[261] If compulsory licensing is in effect eliminated from the

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[257] *Id.*

[258] *See* Surin, *supra* note 253 (noting that "'Malaysian pharmaceutical manufacturers . . . are still decades away from inventing new medicines,'" and "98% of patents granted in Malaysia are to foreigners."); Weissman, *supra* note 248, at 165.

[259] *See supra* Part I.B.

[260] *See supra* Parts I.C, II.A.

[261] *See supra* notes 62–66 and accompanying text. It is difficult to gauge how effectively Malaysia will be able to bargain with the U.S. For example, Prime Minister Rafidah has downplayed Malaysia's relative weakness in bargaining power by implying that the Agreement is not vital to Malaysian interests, see *Malaysia threatens to halt FTA talks with U.S. after call to scrap Iran deal: report*, ASSOCIATED PRESS, Feb. 1, 2007, *available at* http://www.bilaterals.org/article.php3?id_article=7052&var_recherche=Malaysia+threatens+to+halt+. On the other hand, a parliamentary backbencher, Datuk Markiman Kobiran, has said that "[t]he reality is Malaysia cannot avoid [sic] signing a

government's arsenal of competition-increasing legal mechanisms, drug prices could dangerously escalate with no viable means of regulation.[262] As the U.S. is "Malaysia's largest trading partner and [its] largest foreign investor,"[263] the harsh reality of the bilateral negotiation forum is that the U.S.'s bargaining power may prevent Malaysia from extracting even those minimal concessions that are necessary for it to deal with public health crises.

FTA with any country including the US." *Table FTA Document In Parliament For Debate—Backbencher*, *BILATERALS.ORG*, Mar. 20, 2007, http://www.bilaterals.org/article.php3?id_article=7537&var_recherche=FTA+document+in+Parliament+.

[262] *See generally supra* Part I.C.

[263] Press Release, Office of the USTR, United States Malaysia Announce Intention to Negotiate Free Trade Agreement (Mar. 3, 2006), *available at* http://www.ustr.gov/Document_Library/Press_Releases/2006/March/United_States,_Malaysia_Announce_Intention_to_Negotiate_Free_Trade_Agreement.html.