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Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry

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LINKING INTELLECTUAL PROPERTY RIGHTS IN DEVELOPING COUNTRIES WITH RESEARCH AND DEVELOPMENT, TECHNOLOGY TRANSFER, AND FOREIGN DIRECT INVESTMENT POLICY: A CASE STUDY OF EGYPT'S PHARMACEUTICAL INDUSTRY

*Sahar Aziz**

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I. INTRODUCTION

The World Trade Organization (WTO) was formed in order to establish a set of international rules and norms for conducting trade among nations. The objective of the organization is not only to strive towards a more harmonious and equitable playing field within the global market, but to "rais[e] standards of living, ensur[e] full employment, and expand the production of and trade in goods and services. . . ."¹ Despite the organization's recognition "that there is need for positive efforts designed to ensure that developing countries, especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development,"² many WTO agreements have created discord between developed and developing nations with respect to implementing these goals.

One particular WTO agreement, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), has created a great deal of debate about the usefulness of international intellectual property rights. Will they result in increased trade and fairer global competition or will they simply strengthen the West's hold on the international economy as they increase western multinationals' profits and weed out competitors from developing nations? Although the process for developing and ratifying TRIPS was preceded with extensive debate among WTO members,³ there remain a number of disagreements among nations in regard to the interpretation and enforcement of TRIPS. The main divide exists between developed nations and developing nations due to their diverging national interests, which stem from their different levels of economic development.⁴ The developing nation members, with their limited research, development, and manufacturing capacities, took a leap of faith when they committed to adopting and enforcing strong, non-discriminatory minimum standards of intellectual property rights.⁵ Although it will take years to confirm whether this commitment will result in the foreign investment and domestic economic growth they aspire to obtain, these nations are under potent domestic pressure to produce tangible results in a short timeframe. However, these expectations cannot be met simply by strengthening intellectual property laws, but require numerous other changes to interrelated legal regimes.

1. Agreement Establishing The World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 155, 33 I.L.M., Preamble.

2. *Id.*

3. See JOHN H. JACKSON, WILLIAM J. DAVEY & ALAN O. SYKES, JR., *LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS: CASES, MATERIALS AND TEXT* 962-64 (4th ed. 2002) (describing the various disputes between developing and developed nations).

4. *Id.*

5. Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 DUKE J. COMP. & INT'L L. 109 (1998).

This Note focuses on TRIPS' impact on the pharmaceutical industry as well as health care in developing nations. By using Egypt as a case study, this Note aims to emphasize that the benefits of TRIPS for developing nations depends on the linkage between intellectual property rights (IPR) and other legal regimes, particularly drug regulation, technology transfer, and foreign direct investment (FDI) policies. The failure to adopt a holistic approach to the creation of effective and beneficial intellectual property rights regimes will merely increase the western pharmaceuticals' market share and increase drug prices in developing nations.⁶ By asking whether Egypt, versus foreign multinational companies, is likely to benefit from its new IPR law (that is for the most part TRIPS compliant)⁷ one has to analyze the entire context in which the law exists. This in turn will expose the importance of various factors relevant to fulfilling the expected benefits of stronger IPRs in developing nations in general.

Consequently, Section I provides a brief description of the ongoing debate between the developed and developing nations in regard to the costs and benefits of international pharmaceutical patents. Section II outlines and describes the controversial provisions in TRIPS and how they are addressed, adequately or inadequately, in Egypt's new IPR law. Section III then analyzes the context in which the new IPR law is being introduced including the structure of Egypt's pharmaceutical industry and national health care system. Section IV addresses other legal regimes and policies, such as research and development, technology transfer, and competition policy, which are inextricably linked to the efficacy of intellectual property rights. Finally, Section V offers recommendations on how Egypt can fully benefit from its commitment to TRIPS and its new IPR law, which can then be extrapolated to other developing nations in similar circumstances.

II. THE INTERNATIONAL DEBATE BETWEEN DEVELOPED AND DEVELOPING NATIONS ON PHARMACEUTICAL PATENTS

A. *Developed Nations' Perspectives*

The global pharmaceutical industry is a technology intensive and science-based industry, which can be divided into three categories: chemicals (or bulk

6. See *id.* at 112-13 (admitting that developing countries' interests in promoting foreign direct investment, trade, and technological expertise is linked to numerous broader programs including stronger IPR regimes).

7. Hadia Mostafa, *Standing Up For Your Rights*, BUSINESS TODAY EGYPT, Aug. 2002, available at www.businessodayegypt.com/issues/02087BEB/02087BEB.asp (last visited Oct. 11, 2003); see *infra* subpart II of this note for ways in which it may not be TRIPS compliant.

drugs), intermediates, and formulations (or medicine ready for consumption).⁸ Only a few developed countries (Belgium, France, Germany, Italy, Japan, Netherlands, Sweden, Switzerland, UK, and USA) in the world have the sufficiently sophisticated pharmaceutical industry and significant research base necessary to conduct complex research and development activities.⁹ The remaining nations can either reverse engineer already discovered drugs, produce therapeutic ingredients and finished goods, or do nothing with regard to producing even the most basic pharmaceutical products.¹⁰

These factors have created a small group of pharmaceutical multinational enterprises (MNE) worldwide¹¹ that possess significant influence in the formation of their home nation's domestic policy, particularly in the United States.¹² Hence it is predominantly their business concerns that determine developed nations' approaches to implementing IPRs on an international scale. As the focus of competition is increasingly on innovation and invention, the cost of creative activities is increasing, as is the ease of copying these activities.¹³ For example, the large up-front investments of \$200 to \$500 million, which amount to approximately 18% of product sales, necessary to develop a new chemical entity¹⁴ can only be returned through higher profits captured during the patent period. Patents create more certainty of potential profits at the end of the research cycle and decrease the risk of investment.¹⁵ Therefore, the most effective way of protecting profit margins from being eroded by cheap generic drugs is through internationally enforceable patent rights.¹⁶ These business

8. Assad Omer, *Access to Medicines: Transfer of Technology and Capacity Building*, 20 WIS. INT'L L.J. 551 (2002).

9. *Id.*; see THE AMERICAN CHAMBER OF COMMERCE IN EGYPT, THE EGYPTIAN PHARMACEUTICAL INDUSTRY 1 (2001), available at <http://www.amcham.org> (last visited Oct. 13, 2003) (stating that the United States controls 40% of the total world sales in pharmaceuticals) [hereinafter Amcham].

10. Omer, *supra* note 8, at 551.

11. See KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 52-54 (Institute for International Economics 2000) (describing the international pharmaceutical industry as being hierarchical and very competitive. There are a small number of large MNEs based in the USA, Switzerland, Germany, United Kingdom, and Japan that conduct most of the private sector R&D. The remaining majority of pharmaceuticals are based worldwide and predominantly produce generic drugs.).

12. Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1075-78 (1996).

13. MASKUS, *supra* note 11, at 2.

14. *Id.* at 52-54; Jayashree Watal, *Pharmaceutical Patents, Prices, and Welfare Losses: Policy Options For India Under The WTO TRIPS Agreement*, INSTITUTE FOR INTERNATIONAL ECONOMICS 733, 739 (2000).

15. Jean O. Lanjouw, *Intellectual Property And The Availability of Pharmaceuticals in Poor Countries* 12 (CENTER FOR GLOBAL DEVELOPMENT, Working Paper No. 5, 2002).

16. MASKUS, *supra* note 11, at 2; see also JACKSON ET. AL., *supra* note 3, at 926 (citing a 1988 study by the United States International Trade Commission that concludes that \$24 billion is lost annually due to inadequate intellectual property protection abroad).

considerations have translated into significant pressure by developed nations onto developing nations to strictly conform to TRIPS via domestic laws in return for other concessions.¹⁷

However, much of the developed nations' discourse justifying international IPRs does not revolve around their MNEs' economic interests, for obvious political reasons, but rather emphasizes the global benefits of intellectual property rights in general.¹⁸ By providing private firms with a monopoly over the sale and distribution of their patented goods for a fixed period of time,¹⁹ IPRs are supposed to create incentives for research and development (R&D) activities²⁰ in every nation's private sectors. Developing nations' ensuing concerns with high pharmaceutical prices and inaccessibility to important medicines are countered with the theory that too much access caused by weak IPRs will create more inaccessibility in the long run, resulting in the stagnancy of new drug discoveries.²¹ Ultimately, the economic incentives derived from monopoly power of individual pharmaceuticals will benefit overall global welfare through the discovery of new drugs and therapies that cure debilitating, if not fatal, diseases.²²

Developed nations emphasize their belief that these benefits will not be limited to their MNEs, but will also assist local firms in developing nations to establish their own R&D activities, which will be better suited to local needs.²³ Many scholars note that one particular disadvantage of the current laxity in IPR

17. Michelle M. Nerozzi, *The Battle Over Life-Saving Pharmaceuticals: Are Developing Countries Being 'TRIPPed' By Developed Countries?*, 47 VILL. L. REV. 605, 616-17 (2002); MASKUS, *supra* note 11, at 4. See Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries and Doha "Solution,"* 3 CHI. J. INT'L L. 47, 59 (2002) (citing concessions in textiles and agriculture as one incentive for developing nations to sign onto TRIPS).

18. See Sykes, *supra* note 17, at 55-59 (providing a general discussion of the pros and cons of intellectual property rights from an economic perspective).

19. JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 291 (Kluwer Law International 2001); MASKUS, *supra* note 11, at 40-41. For patents, 20 years is the international standard protection period. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Article 33 Legal Instruments, Results of the Uruguay Round vol. 31 (1994), 33 I.L.M. 81 (1994) [hereinafter TRIPS].

20. See Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering?"* (NATIONAL BUREAU OF ECONOMIC RESEARCH, Working Paper 6366, 1998) (admitting that the stimulation of R&D is a possible welfare benefit, but not a guarantee), available at www.nber.org/papers/w6366 (last visited Oct. 11, 2003).

21. MASKUS, *supra* note 11, at 30.

22. *Id.* ("The main goal of an intellectual property system should be to create economic incentives that maximize the discounted present value of the difference between the social benefits and the social costs of information creation, including the costs of administering the system."); A survey of 12 manufacturing industries (including the chemical industry) concluded that 30% of inventions would not have been developed without patent protection because research and development is high and imitation is easy. *Id.* at 43.

23. *Id.* at 33-34.

laws in developing nations is the lack of focus by pharmaceutical MNEs on diseases prevalent in developing nation illnesses.²⁴ For example, currently 99% of the global disease burden is concentrated in the low and middle-income countries, but only 4.3% of global health-related R&D expenditures address those diseases.²⁵ Therefore, IPRs will support innovative behavior that adapts existing technologies to local needs of which the cumulative effect can ignite growth in knowledge and economic activity.²⁶ The local firms will also have an equal opportunity to sell their products abroad in order to reap the higher profits currently enjoyed by western MNEs that own the majority of existing pharmaceutical patents.²⁷

Additional expected benefits from this process include the dissemination of knowledge through required patent disclosures, which can be used as inputs for more innovation,²⁸ the transfer of technology through foreign direct investment from wealthy to poor nations with stable IPR regimes,²⁹ and the facilitation of contracting between firms which will increase the production of drugs and the efficiency of the R&D process for new drugs.³⁰ IPR laws may also prove to be of more assistance to local firms than international firms in protecting their intellectual property because the former do not have the large resources necessary to prevent infringement nor the option to withdraw from the market as a means of protecting their profit base.³¹

Finally, the creation of global IPRs is supposed to provide developing nations with more access to up-to-date technologies through technology transfer.³² Weak IPR regimes cause developing nations to have retarded technological development limited to outdated technologies and become isolated from new technologies with the only solution being to build their own technological knowledge from scratch, a nearly impossible mission given their

24. Lanjouw, *supra* note 20, at 2-5, 7 (acknowledging that stronger IPRs in developing nations will lead to R&D on "neglected diseases" as well as the development of products more tailored to the specific needs of poor countries).

25. Lanjouw, *supra* note 20, at 8-9 (also noting that only 0.2% of global R&D is spent on pneumonia, diarrheal diseases, and tuberculosis which are all prevalent in developing countries and account for 18% of the total global disease burden).

26. Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 U. ILL. L. REV. 457, 460 (2001).

27. MASKUS, *supra* note 11, at 40-41.

28. *Id.*; Lanjouw, *supra* note 20, at 5.

29. See Lanjouw, *supra* note 20, at 1, 5 (concluding that MNEs will be more willing to license patented innovations to local manufacturing firms for production); see also MASKUS, *supra* note 11, at 181 (qualifying the technology transfer benefits to developing nations with strong imitative and manufacturing capabilities, hence the least developed countries are unlikely to experience much technology transfer).

30. Lanjouw, *supra* note 20, at 5.

31. MASKUS, *supra* note 11, at 190.

32. Omer, *supra* note 10, at 558; see also TRIPS *supra* note 19, at art. 66.2.

economic constraints.³³ On the other hand, with strong IPRs, foreign MNEs should be more willing to commit to foreign direct investment,³⁴ joint ventures, and licensing agreements in developing countries.³⁵ Developed nations emphasize that the possibility of an increase in foreign direct investment (developing nations' most preferred form of technology transfer) "in complex but easily copied technologies [such as pharmaceuticals] is likely to increase as IPRs are strengthened."³⁶ Through the shipment of advanced inputs to subsidiaries, MNEs will indirectly share blueprints, product designs, and skilled producer services with the local market.³⁷ Technology transfer can also occur through trade in technologically advanced inputs that will raise importers' productivity and reduce their production costs.³⁸ Without strong IPR laws, not only will FDI hesitate to move east and south, but many foreign producers may refuse to export their high-tech goods in order to protect their global profit margins. Therefore, the onus is on the developing world to create a business environment friendly to the needs of wealthy, western multinationals.

B. Developing Nations' Perspectives

Although the aforementioned arguments facially appear to be sound and reasonable, developing countries often emphasize the disparity between what is theoretically supposed to occur after the implementation of IPRs and what actually materializes.³⁹ They complain that IPRs have a negligible impact on R&D incentives in their economies as they simply raise prices on patented drugs,⁴⁰ transfer rents to foreign pharmaceutical patent holders, and create dead-weight losses as the consumers willing to pay the marginal cost of medicines are

33. MASKUS, *supra* note 11, at 55.

34. See Maskus, *supra* note 5, at 111 (defining foreign direct investment as "the establishment or acquisition of production subsidiaries abroad by multinational enterprises"); see also Nerozzi, *supra* note 17, at 621 (citing a 1994 World Bank study that 86%-100% of developed country pharmaceutical companies based their decisions on whether or not to invest in a country on the amount of patent protection offered to them by the host country).

35. MASKUS, *supra* note 11, at 138.

36. Maskus, *supra* note 5, at 133.

37. MASKUS, *supra* note 11, at 137.

38. *Id.* at 150.

39. UNITED NATIONS COMMITTEE ON TRADE AND DEVELOPMENT, *The TRIPS Agreement and The Built-In Agenda: Background Paper*, 4 (Jan. 1, 2002) ("several developing countries wish to re-open the TRIPS Agreement which they consider has proven to be unable to reach its main objectives and has put a disproportionate burden on developing countries without providing them with commensurate benefits"), available at www.unctad.org/sections/comtdip/docs/en/webcdpbkgd3_en.pdf (last visited Oct. 11, 2003); see also JACKSON ET. AL., *supra* note 3, at 926 ("[d]eveloping countries tend to have lower levels of human capital . . . thus [have] perhaps less capacity in relation to their size to generate commercially valuable innovations.").

40. See Maskus, *supra* note 26, at 469 (citing the increase in pharmaceutical prices in India, of up to 50%, after the implementation of patents).

priced out of the market.⁴¹ Moreover, the claim that more global R&D will be directed towards developing nations' diseases may prove to be illusive due to the low per capita incomes of their consumers. One expert on India predicted that if you assume there are 20 MNEs in a market as large India, each MNE would earn \$2-3 million per product, which is significantly less than the required \$200 to \$500 million R&D expenditures. Therefore, "R&D for pharmaceuticals [that are] relevant only to a few developing countries [will] less likely take place, even with full TRIPS implementation."⁴² Another scholar notes that the losses experienced from the transfer of monopoly rents from developing nations to developed nations greatly exceed any benefits to developing nations of the new drugs entering the market due to patent protection.⁴³ For example, "to compensate for the loss of domestic surplus . . . as a result of higher drug prices for existing patented products, a threefold increase in the number of equivalent new products reaching [developing countries] would be required."⁴⁴

The issue at the forefront of this debate is the accessibility to essential medicines.⁴⁵ Before TRIPS was ratified, developing nations' ability to imitate foreign products and technologies without paying royalty fees was their primary means of making medicine affordable for their large, poor populations as well as a means of limiting the costs of health care.⁴⁶ The lack of national health care insurance magnifies the importance of cheap medicine since most consumers pay for drugs directly from their low GDP per capita incomes.⁴⁷ These GDP per capita incomes⁴⁸ are much lower than developed nations per capita incomes

41. Sykes, *supra* note 17, at 3; Lanjouw, *supra* note 20, at 16; Robert J. Gutowski, *The Marriage of Intellectual Property And International Trade in The TRIPS Agreement: Strange Bedfellows or a Match Made in Heaven?*, 47 BUFF. L. REV. 713, 755 (1999).

42. WATAL, *supra* note 19, at 739.

43. FREDERIC M. SCHERER, *INDUSTRY STRUCTURE, STRATEGY, AND PUBLIC POLICY* 362-66 (John Greenman ed., Harper Collins College Publishers 1996).

44. F. M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, 53 VAND. L. REV. 2245, 2259 (2000).

45. UNITED NATIONS COMMITTEE ON TRADE AND DEVELOPMENT, *The TRIPs Agreement and the Built-In Agenda: Background Paper*, 3 (Jan. 1, 2002), available at www.unctad.org/sections/comdiv/docs/en/wbecdbpbgd3_en.pdf (last visited Feb. 24, 2003) [hereinafter UNCTAD]. See generally Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) (stating the concerns of developing countries with regard to the drawbacks of stronger intellectual property regimes), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited Oct. 11, 2003) [hereinafter Doha Declaration].

46. MASKUS, *supra* note 11, at 33-34, 53-54; see Watal, *supra* note 14, at 747 (describing a simulation of the Indian pharmaceutical market concluding that prices are likely to increase and welfare is likely to decrease after the enforcement of patent rights).

47. Lanjouw, *supra* note 20, at 10; see MASKUS, *supra* note 11, at 33-34 (noting that higher pharmaceutical prices will raise costs to health care providers and consumers).

48. See THE WORLD BANK, 2002 WORLD DEVELOPMENT INDICATORS 18-20 tbl. 1.1 (listing various gross national income per capita for developed as well as developing countries).

when they decided to fully implement IPRs in their economies.⁴⁹ Therefore, developing nations feel unduly coerced into prematurely implementing a legal regime that has not been preceded with the same degree of economic development and industrialization that existed in developed nations preceding their enforcement of IPRs.⁵⁰

In addition to specific public health concerns, developing nations have broader macroeconomic issues such as the erosion of the terms of trade, competitive abuses by foreign MNEs, and employment losses within the generic drug-producing firms.⁵¹ As technology importers, developing nations are concerned that stronger IPRs will expand the market power of foreign providers of information and new products, giving them more leverage to increase prices on their goods. As MNEs repatriate these higher profits abroad, the nation experiences a larger trade deficit and outflow of foreign currency, causing a decrease in the nation's terms of trade.⁵² However, this phenomenon is highly dependent on the market structure, demand elasticity, and competition policies within the economy,⁵³ which reemphasizes the importance of linking IPR regimes with other policies in order to avoid simplistic conclusions by either side about their interactions.

The increased market power may also lead to competitive abuses such as the "cartelization" of horizontal competitors through licensing agreements that fix prices, limit output, or divide markets,⁵⁴ patent pooling,⁵⁵ and cross-licensing agreements between competing licensors.⁵⁶ Individual and patent-pooled licensors can also hinder the entrance of new competing technologies through exclusive grant-back provisions,⁵⁷ purchase exclusive rights to competing technologies and products as a means of increasing market power and creating

49. Lanjouw, *supra* note 15, at 39 tbl. 1.

50. See Maskus, *supra* note 26, at 460 (describing how Japan's post-war patent system promoted Japanese technical progress by encouraging incremental and adaptive innovation in order to promote diffusion of knowledge throughout the manufacturing sector).

51. MASKUS, *supra* note 11, at 33-34.

52. *Id.* at 159; Lanjouw, *supra* note 20, at 1.

53. See MASKUS, *supra* note 11, at 159 (defining the market structure to include the number of total firms competing with rights holders, the type of competition, the ease of market entry and exit, quality differentiation among products, openness to trades, and wholesale and retail distribution mechanisms).

54. *Id.* at 206-07.

55. Dorothy G. Raymond, *Benefits and Risks of Patent Pooling For Standard Setting Organizations*, 16 SUM ANTITRUST 41 (2002) ("A patent pool is an agreement by multiple owners of IPR to interchange licenses or to grant licenses to third parties. . . . Patent pools can enable the spread of technology, lower consumer prices, and foster competition, but they can also limit innovation, restrict output, and raise prices.").

56. MASKUS, *supra* note 11, at 206-07.

57. Patricia A. Martone & Richard M. Feustel, Jr., *The Patent Misuse Defense – Does It Still have Vitality?*, 708 PLI/PAT 213, 242 (2002) (defining grant back provisions as "require[ing] the licensee to grant back to the licensor rights that the licensee may acquire or develop").

horizontal mergers, and initiate bad-faith litigation and opposition proceedings as a means of harassing and discouraging competitors from entering the market.⁵⁸ Although the degree of impact from such practices depends on the market structure and regulatory framework of a nation, they are particularly detrimental to developing nations with weak institutions. Hence the reduction in competition ultimately harms consumers by increasing the prices of goods, which is particularly devastating with respect to access to basic medicines.

Finally, the link between strong IPRs and technology transfer is not as direct as some proclaim. There are immediate opportunity costs to implementing stronger IPRs. The elimination of imitative activities does stop some level of learning, albeit a much lower level than if true FDI existed, by the locals that is produced via reverse engineering.⁵⁹ The jobs created by imitative and copying activities will also be eliminated in countries with pre-existing high unemployment rates.⁶⁰

Although stronger IPRs may indeed encourage more participation of foreign firms with superior technological capabilities, the manner of participation is what matters. A patent must be worked locally to induce technology transfer.⁶¹ Foreign direct investment that results in “the successful learning of information and the know-how to use it by one party from another party”⁶² is what developing nations hope to receive in return for strengthening their IPRs. The spillover effects of on-the-job training, expanded management expertise, the learning of new technologies, and the training of suppliers are additional incentives for seeking FDI.⁶³ Therefore licensing agreements, which some economists believe are more likely to result from stronger IPRs and subsequent increased certainty in contracting, insufficiently transfer information, know-how, and technology to the market.⁶⁴

As the aforementioned discussion highlights, the issues relating to TRIPS and global IPRs are complex and can be articulated in significantly different ways depending on a nation’s economic and social constraints. One must fully understand the details of a nation’s disposition in order to appreciate the burdens it faces in meeting its international commitments while maintaining its national

58. MASKUS, *supra* note 11, at 206-07.

59. *Id.* at 136.

60. See THE WORLD BANK, *supra* note 48, at 60-62 (listing unemployment rates for numerous developing nations).

61. Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT’L L. 365, 374 (2002).

62. MASKUS, *supra* note 11, at 136.

63. *Id.* at 152.

64. See *id.* at 123 (recognizing that as IPRs increase, MNEs no longer have to worry about local imitation of their products, therefore they are more willing to license out production to local firms since it is often cheaper than setting up a subsidiary due to non-IPR related costs).

integrity and economic survival. The following sections will shift to a more focused analysis of what one particular developing country, Egypt, is experiencing with respect to TRIPS. A brief comparison of Egypt's new IPR law with TRIPS will be followed by an assessment of the legal and social context in which this new law was passed.

III. A COMPARISON OF TRIPS WITH EGYPT'S NEW INTELLECTUAL PROPERTY LAW

A. A Brief Description of TRIPS Standards

The Agreement on Trade-Related Intellectual Property Rights was adopted on April 15, 1994 at the Uruguay Rounds in Marrakesh, Morocco. The agreement set out to establish minimum international standards, versus complete harmonization, for intellectual property rights with the requirement that individual member nations enact local laws to enforce the agreed upon rights.⁶⁵ Although it incorporates previous agreements such as the Paris Convention for the Protection of Industrial Property of 1967, Berne Convention for the Protection of Literary and Artistic Works of 1970, and the Washington Treaty,⁶⁶ TRIPS aims to improve perceived weaknesses in these agreements.⁶⁷ Under its purview of protection are copyrights, trademarks, geographical indications, industrial designs, patents, integrated circuits, and undisclosed information or "trade secrets."⁶⁸ Member nations must provide the procedures, remedies, and dispute resolution processes associated with the enforcement of intellectual property rights. For example, each member nation must allow for civil injunctive remedies to prevent infringement of rights, provide a means by which rights holders can gain the cooperation of customs authorities to stop infringing goods from entering the nation, and establish contact points in relevant agencies in order to distribute information about counterfeit or pirated goods.⁶⁹ All laws, measures, and decisions affecting the enforcement of intellectual property rights

65. Nerozzi, *supra* note 17, at 611.

66. See TRIPS, *supra* note 19, at art. 1(3), 2; see Gutowski, *supra* note 41, at 718-25 (describing the history of the Paris and Berne Conventions and how they lead up to the adoption of TRIPS); see also Benedicta Callan, *Pirates on the High Seas: The United States and Global Intellectual Property Right*, COLUMBIA INTERNATIONAL AFFAIRS ONLINE, at www.ciaonet.org/book/callan/index.html (last visited Oct. 7, 2003).

67. Nerozzi, *supra* note 17, at 611; see Gutowski, *supra* note 41, at 724 (listing "lack of harmonization, disparate national treatment, and deficient enforcement and dispute resolutions" as shortcomings in the Paris and Berne Conventions).

68. See generally TRIPS, *supra* note 19, at Part II §§ 1-8 ("Standards Concerning the Availability, Scope, and Use of Intellectual Property Rights").

69. Callan, *supra* note 66.

must be published and available to the public. Because TRIPS aims for minimum standardization rather than complete harmonization, the national IPR legal and regulatory regimes of individual member nations can vary to accommodate local constraints as long as the general provisions of TRIPS are adhered to.⁷⁰ However, it is this inherent flexibility that has caused the ongoing debates, as discussed in the previous section,⁷¹ among nations with respect to textual interpretation.

Under TRIPS, patents can be obtained for any invention, whether it is a product or a process, that is new, involves an inventive step, is non-obvious, and is useful or capable of industrial application.⁷² The rights of the patent holder, which must last at least 20 years from the date of filing of the patent application, include the right to prevent unauthorized persons from making, using, selling, or importing any product covered by the patent. If the patent is for a process, then the patent holder can stop unauthorized use, sale, or importation of products directly obtained through that process.⁷³ However, products or processes that endanger the public order or morality; diagnostic, therapeutic drugs, or surgical methods; plants and animals; and biological processes are not necessarily eligible for patent protection.⁷⁴

Furthermore, the agreement does take into consideration the problems of developing nations as exemplified in the extended transition periods granted for implementation of TRIPS provisions,⁷⁵ exclusion of certain items from patentability,⁷⁶ compulsory licensing under certain conditions,⁷⁷ parallel importing,⁷⁸ and technical and financial cooperation in favor of developing member nations.⁷⁹ These provisions have caused the most heated debates among member nations, and thus will be discussed in detail in the following section.

70. NATHAN ASSOCIATES INC., EGYPT: OBLIGATIONS AND COMMITMENTS UNDER THE GATT/WTO AGREEMENTS 50-51 (Aug. 1999) (document on file with author).

71. See *supra* subparts I(A-B) for a detailed discussion on controversies between developed and developing nations.

72. TRIPS, *supra* note 19, at art. 28.

73. NATHAN ASSOCIATES INC., *supra* note 70, at 50.

74. TRIPS, *supra* note 19, at art. 27; Callan, *supra* note 66.

75. TRIPS, *supra* note 19, at art. 66 (allowing least developed countries to enjoy a transitional period of 10 years from the date of application).

76. See UNCTAD, *supra* note 45, at 2 (“plants and animals may be excluded from patentability, however, micro organisms cannot”). Consequently, developing countries want to clarify the definition of microorganism in order to ensure greater legal certainty, avoid biopiracy, and assure fair access to genetic resources. *Id.*

77. TRIPS, *supra* note 19, at art. 31.

78. TRIPS, *supra* note 19, at art. 6 (excluding the issue of parallel imports from the dispute settlement system).

79. Nerozzi, *supra* note 17, at 612.

B. An Overview of Egypt's Intellectual Property Law 82 of 2002

Law No. 82 of 2002 Promulgating Intellectual Property Law was passed on June 2, 2002 after a seven-year drafting process and two years of formal debate.⁸⁰ The new law constituted a comprehensive and historic improvement in the legal rights of inventors, artists, and entrepreneurs.⁸¹ The section on patents replaced the outdated Law 132 of 1949,⁸² which only protected the manufacturing process rather than the finished pharmaceutical or agricultural chemical product.⁸³ Additional shortcomings of Law 132 include an overly broad compulsory licensing provision, a forfeiture requirement if the patent is not worked two years after the issuance of the first compulsory license, a fifteen-year term of protection, and a definition of infringement that did not include the use, sale, or importation of products made using the processes patented in Egypt.⁸⁴ Although the new law resolves some of these issues, there remains pressure from abroad to change some provisions, particularly compulsory licensing, parallel imports, and enforcement provisions, which will be discussed in more detail below.

Each ministry is currently developing its own executive regulations⁸⁵ to implement and enforce the provisions of the law.⁸⁶ Because these executive

80. *Egypt Considers New Patent Law*, 8 NO. 11 J. PROPRIETARY RTS. 19 (1996); Emad Mekay, *Egypt: Poverty, Police, and the Ballad of Intellectual Property*, INTER PRESS SERVICE, 2002 WL 4912920, Feb. 19, 2002; see ECONOMIST INTELLIGENCE UNIT, *No Protection, No Investment*, BUSINESS MIDDLE EAST, Aug. 1, 1998, at 2, http://stote.eiu.com.cart.asp?action=browse&layout=cart_article_list&product_id=23574802 (last visited Oct. 11, 2003) (stating that United States' experts have been working with the Egyptian government since 1993 in drafting a new patent law).

81. Law 82 of 2002 is divided into four books that are individually assigned to a specific ministry's profile for enforcement purposes. Book one addresses patents, utility models, semiconductor topography, and undisclosed information and falls under the Ministry of State for Scientific Research and the Ministry of Health. Book two deals with trademarks, appellations of origin, and industrial designs, which fall under Ministry of Internal Trade and Supply. Book three covers copyrights and neighboring rights and is under the purview of the Ministry of Culture and Communications as well as the Ministry of Information Technology. Finally, book four focuses on plant varieties and is applied by the Ministry of Agriculture and Land Reclamation. UNOFFICIAL TRANSLATION OF THE EGYPT'S IPR LAW, PUBLISHED IN THE OFFICIAL JOURNAL ISSUE, No. 22 BIS- Dated 2nd of June 2002 (copy on file with author) [hereinafter Law No. 82 of 2002].

82. Egyptian Patent Law No. 82 of 1949, <http://www.reldekki.com/lib02.html> (last visited Oct. 7, 2003).

83. ECONOMIST INTELLIGENCE UNIT, *Still Under Scrutiny*, BUSINESS MIDDLE EAST, June 1, 2000, at 3.

84. ECONOMIST INTELLIGENCE UNIT, *No Protection, No Investment*, BUSINESS MIDDLE EAST, Aug. 1, 1998, at 2.

85. An executive regulation in the Egyptian legal context is equivalent to an administrative regulation formulated by an administrative agency.

86. Niveen Wahish, *IPR: The Mother of Invention?*, AL-AHRAM WEEKLY ON-LINE, June 21-27, 2001, at <http://weekly.ahram.org/eg/> (last visited Oct. 7, 2003).

regulations were still being negotiated at the time of the writing of this Note,⁸⁷ the issues discussed here are based on the various ways that the text of the law may be interpreted and the consequences of such interpretations. It is worth mentioning that Egypt has decided to take advantage of the ten-year transition period offered to developing countries under TRIPS, which postpones full implementation of a TRIPS compliant law until January 1, 2005 but requires compliance with the mailbox, exclusive marketing rights, and undisclosed information provisions as of January 2000.⁸⁸

1. Compulsory Licensing

TRIPS Article 31 allows member countries to grant compulsory licenses in limited circumstances. A compulsory license is an annulment of patent rights by a judicial or governmental authority, causing a temporary deprivation of a patentee's monopoly over the original subject matter. Therefore, recipients of compulsory licenses may make, use, and sell the otherwise patented subject matter before the expiration period of the compulsory license.⁸⁹ Because the language of Article 31 does not specify or place clear restrictions on the purposes for granting compulsory licenses⁹⁰ and a compulsory license may reduce the market price of a medicine by 75 percent,⁹¹ the issue has become very controversial.⁹² In general, developed nations, including the United States, want to limit this remedy to violations of competition laws or national emergencies whereas developing nations want to include public health and economic crisis as legitimate justifications for granting compulsory licenses.⁹³ Developed nations also prefer to apply closely textual interpretations to Article

87. Mostafa, *supra* note 7.

88. The decision to take advantage of the additional five-year grace period was hotly debated in the Egyptian Parliament beginning in 1999. Nermien Al-Ali, *The Egyptian Pharmaceutical Industry After TRIPS – A Practitioner's View*, 26 *FORDHAM INT'L L.J.* 274, 295-96 (2003); Emily Downes, *New Industries Demand Improved Protection*, *MANAGING INTELLECTUAL PROPERTY*, Issue 97, at 39 (Mar. 2000).

89. Nerozzi, *supra* note 17, at 612.

90. TRIPS, *supra* note 19, at art. 31 ("in the case of a national emergency or other circumstances of extreme urgency"); Champ & Attaran, *supra* note 61, at 366.

91. Naomi B. Bass, *Implications of the TRIPS Agreement For Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 *GEO. WASH. INT'L L. REV.* 191, 200 (2002).

92. *Id.* at 198-201.

93. See Sara M. Ford, *Compulsory Licensing Under The TRIPS Agreement: Balancing Pills and Patents*, 15 *AM. U. INT'L L. REV.* 941, 950-54 (2000) (describing South Africa's experience with the AIDS crisis and its subsequent issuance of compulsory licenses for HIV/AIDS drug therapies); see also David P. Fidler, *Neither Science Nor Shamans: Globalization of Markets and Health in The Developing World*, 7 *IND. J. GLOBAL LEGAL STUD.* 191, 209-11 (1999) (describing the ensuing political conflict after South Africa and Thailand permitted compulsory licensing for patented HIV/AIDS drugs).

31(b) regarding the working of a patent with respect to compulsory licensing.⁹⁴ They support the view that as long as the patent is worked in any one of the WTO member nations there is no grounds for invoking Article 31(b) as a basis for compulsory licensing, placing this approach in direct opposition to developing nations' local production requirements.⁹⁵

Article 23 of Egypt's Law 82 of 2002 exercises a broad interpretation of TRIPS Article 31. The basis for granting compulsory licenses without the need for prior negotiation with the patentee include non-commercial public uses necessary to preserve "national security, health, food, and environmental safety" and "confronting cases of emergencies and extreme urgent circumstances," which is more or less TRIPS compliant. However, the provision permitting compulsory licensing "to support the national effort in a significant sector for economic, social and technological development, without unreasonable prejudice to the patentee rights"⁹⁶ expands TRIPS' "national emergency and other circumstances of extreme urgency"⁹⁷ to include economic, social (i.e. public health), and technological issues. Such language may be setting the stage for broad public health exceptions to patent-holders' rights similar to those invoked by Brazil or South Africa with respect to AIDS/HIV medicines.⁹⁸

Egypt's working standards for a patent are narrowly construed. "If the patentee did not exploit the patent in Egypt directly or under his/her authorization the exploitation was not sufficient following four years from the date of filing the patent application or three years from the grant date whichever is longer[,]"⁹⁹ then a compulsory license will be issued. If the patentee ceases to exploit the patent without an acceptable reason for over a year, a compulsory license will be issued. Egypt's law defines exploitation as "the manufacturing of the product subject matter of production in Egypt, or using the manufacturing process subject matter of the protected patent invention"¹⁰⁰ and excludes

94. TRIPS, *supra* note 19, at art. 31(b) ("if . . . the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time").

95. WATAL, *supra* note 19, at 316-17 (citing art. 68(I) of Brazilian Patent Law, art. 43 of Argentine Law). Note also that New Zealand issues compulsory licenses if there is a failure to supply the market on reasonable terms and Germany issues them if there is no other substitute for the treatment of a disease. *Id.*

96. Law No. 82 of 2002, *supra* note 81, at art. 23, sec. I(3).

97. TRIPS, *supra* note 19, at art. 31.

98. See generally Bass, *supra* note 91, at 206-23 (describing in detail the controversy over compulsory licensing for HIV/AIDS in Brazil and South Africa); see also Jose Marcos Nogueira Viana, *Intellectual Property Rights, The World Trade Organization And Public Health: The Brazilian Perspective*, 17 CONN. J. INT'L L. 311 (2002) (justifying Brazil's use of compulsory licensing toward HIV/AIDS drugs for security and public health interests).

99. Law No. 82 of 2002, *supra* note 81, at art. 23, sec. IV.

100. *Id.* at art. 23, sec. IV.

importation.¹⁰¹ This language is likely to invite protest from MNEs who do not want to perform foreign direct investment in a nation, but do want to preserve their patents and import their goods.

A final justification for issuing compulsory licensing under Law 82 is “the lack of supply of patented drugs to satisfy the country’s needs, or because the decline in its quality, or irregular incline of its price, or in the event that the invention drug is related to critical cases or chronic or endemic or epidemic diseases. . . .”¹⁰² Although the patent holder has the right to immediate notification in this instance,¹⁰³ the government will possess a significant degree of leeway that will impede her freedom to make market-based decisions in pricing or sales. Egypt may have decided to use the aforementioned language in order to avoid falling victim to global reference pricing. Many governments in developed nations, including the United States, base their price controls on pharmaceuticals on a global reference price that averages in the price of a drug in the various countries it is sold. Therefore, if a price in a particular country (or countries) is so low that it will decrease the global reference price, then the pharmaceutical company may either raise the price to the levels found in developed countries or withdraw from the market altogether in order to preserve its primary profit base in developed countries.¹⁰⁴ Either option may prove to be catastrophic to the developing nation’s public health.

2. Compensation for Compulsory Licensing

An intimately related issue to compulsory licenses is the determination of compensation owed to the patent holder in return for monetary losses incurred. TRIPS Article 31(h) states that, “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the *economic value of the authorization*” (emphasis added). Egypt’s law states, “[t]he patentee is entitled to a fair compensation against the exploitation of the invention. The *economic value of the invention* must be considered while determining said compensation” (emphasis added).¹⁰⁵ The difference in text has sparked the debate of how to determine the compensation.

Pharmaceutical companies from developed countries want to be placed in the same position monetarily as they would have been had the compulsory license not been issued. This translates into the full market value of the license,

101. THE WORLD TRADE ORGANIZATION, COUNCIL FOR TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, *Review of Legislation*, Nov. 14, 2001, IP/C/278/Add.2 (responding to a question posed by Switzerland to the Permanent Mission of Egypt).

102. Law No. 82 of 2002, *supra* note 81, at art. 23, sec. II.

103. *Id.*

104. Lanjouw, *supra* note 20, at 11.

105. Law 82 of 2002, *supra* note 81, at art. 24(8).

incorporating the costs of development and lost profits.¹⁰⁶ Factors they believe should be considered include: the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention, the efficacy and innovative nature and importance to the public health of the invention or products using the invention, the degree to which the invention benefited from publicly funded research, the need for adequate incentives for the creation and commercialization of new inventions, the interests of the public as patients and payers of health care services, and the public health benefits of expanded access to the invention.¹⁰⁷

The Egyptian government, on the other hand, may decide to limit the remuneration to the profits earned from the temporary use by the compulsory license recipient.¹⁰⁸ Or it may refuse any compensation to a pharmaceutical company with no plans to invest in the domestic market, claiming it has suffered no loss and hence is not entitled to compensation.¹⁰⁹ These diverging interpretations have unsurprisingly initiated significant controversy within the ongoing executive regulation negotiation process.

3. Parallel Imports (Gray Markets)

TRIPS Article 6 purposely punts the issue of exhaustion by stating, “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”¹¹⁰ Exhaustion limits the rights of a patent holder in controlling the importing, exporting, and distribution of the patented item.¹¹¹ A national exhaustion scheme gives the patent holder control over importing, exporting, and distribution of the patented item so long as the patent holder has not released the patented item into the market. But as soon as the patent holder releases the item into that *nation's* market, then it is considered fully exhausted and the patent holder no longer has that type of control, allowing anyone to import or export the item.¹¹² On the other hand, if a country chooses international exhaustion the patent holder loses control of distribution once he or she puts the item into the market anywhere in the world.¹¹³

106. Susan v. Vaughan, *Compulsory Licensing of Pharmaceutical TRIPS: What Standard of Compensation?*, 25 HASTINGS INT'L & COMP. L. REV. 87, 105 (2001).

107. H.R. 1708 Sec 2(a)(d), 107th Congress (2003), available at www.thomas.loc.gov (last visited Oct. 11, 2003).

108. Vaughan, *supra* note 106, at 105.

109. *Id.* at 108-09.

110. TRIPS, *supra* note 19, at art. 6.

111. Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets As a Limit On Patent Rights*, 14 FLA. J. INT'L L. 217, 251 (2002) (also known in US law as the first sale doctrine).

112. *Id.*

113. *Id.*

In Egypt's case, Article 10 states that the patentee's right in excluding others from importing, exporting, using, selling, or distributing the product "shall be exhausted if the patentee marketed or licensed said product to third party/others." It does not specify the applicable jurisdiction for marketing and licensing activities, nationally or internationally. However, the Permanent Mission of Egypt in the WTO replied to a question pertaining to exhaustion posed by the United States with, "[t]he patent rights are 'exhausted' if the patent owner has marketed the invention (i.e. actually put the protected product on the market for circulation in the normal channels of commerce) *anywhere* in the world"¹¹⁴ (emphasis added). Therefore, once a party legally obtains the patented item from the patentee, anywhere in the world, it may argue that it is free to export or import it to whomever it chooses. From the patentee's perspective this is problematic because she may sell it to an authorized purchaser who then sells it to a third party who then engages in parallel exporting to another country with similar or weaker laws.

This process of re-exporting to another country creates gray markets. Gray markets are the unauthorized distribution of a good or service. They are created when a business imports a good for a low price (due to its nation's lower GDP per capita) from the patent holder and subsequently exports it to another country to be sold for a price higher than the business purchased it for but lower than the price offered by the patent holder. Consequently, the gray market goods compete with the patent holder's goods and compromise her profit margins in the higher priced market.¹¹⁵ This specific situation is unlikely to occur in the United States because US patent law protects patent holders from parallel imports, allowing them to sue the US importer.¹¹⁶ However, if the exchange takes place between Egypt, applying an international exhaustion approach, and another country with weak IPR laws, then the US company would have no power to prevent this exchange.¹¹⁷

As a consequence, the pharmaceutical may raise the price of the drug in Egypt, in order to thwart any profitability from parallel trading. Hence, Egyptian consumers will bear the burden for the lower prices obtained in the importing nation. The patent holder will no longer engage in price discrimination among poor and rich nations, which will price out poor consumers.¹¹⁸

114. THE WORLD TRADE ORGANIZATION, COUNCIL FOR TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, *Review of Legislation*, Nov. 14, 2001, IP/C/278/Add.2 (referring specifically to an interpretation of art. 11 of Law No. 82 of 2002).

115. Ghosh, *supra* note 111, at 218; WATAL, *supra* note 19, at 297. For example, an Egyptian company legally imports or locally purchases a drug from a United States company for \$6 in order to export it back to the United States for \$10 when that same drug is sold by the United States company at \$15.

116. Lanjouw, *supra* note 15, at 20.

117. Ghosh, *supra* note 111, at 253.

118. Sykes, *supra* note 17, at 63-64.

Egypt may then react to the price increase by issuing a compulsory license based on Law 82 of 2002 Article 23 Section Two's "irregular incline in its price" justification. And if the patent holder responds by refusing to sell or produce the drug in Egypt, then Article 23 Section Four's provision for failing to exploit the patent domestically may also initiate a compulsory license. The patent holder is thus placed in a quandary when it comes to protecting her profits with respect to gray markets.¹¹⁹

4. Enforcement of Intellectual Property Rights

TRIPS addresses wealthy nations' specific concerns with IPR enforcement deficiencies in developing nations' domestic laws. For example, TRIPS compliant laws should address the inability to obtain evidence to prove infringement, indeterminable delays in bringing a case to trial and getting a final judgment, the inability to get preliminary injunctions, inadequate damage awards and criminal sanctions, and the lack of enforcement at the borders to prevent importation of infringing goods.¹²⁰ Consequently, TRIPS Article 41 requires that enforcement include "expeditious remedies to prevent infringement and remedies which constitute a deterrent to further infringement [and] . . . procedures . . . shall not be unnecessarily complicated or costly, or entail unreasonable time limits or unwarranted delay." Articles 42, 43, 44, and 45 address fair and equitable procedures, evidence, injunctions, and damages respectively.

With respect to damages, Article 181 of Law 82 of 2002 may fail to meet the TRIPS requirements. Article 32 of Law 82 of 2002 imposes a fine of 20,000 to 100,000 Egyptian pounds (approximately \$3700 to \$18,000)¹²¹ for first time offenders. Recidivism is penalized with imprisonment of no less than three months and a fine of 40,000 to 200,000 Egyptian pounds.¹²² Western commentators believe this is an insufficient deterrence considering the high profits gained from patent drug infringement.

However, the new law does include new provisions that provide for temporary injunctions against the violator until the case goes to court.¹²³ Equitable procedures are also available to patentees since they may ask the judge to "order conservative procedures concerning the products and goods subject matter of

119. It is worth mentioning that gray markets create quality control issues. The US company may be legally selling a lower quality version of the drug to Egypt in order to compensate for the lower prices. But if this product is then re-exported to a higher priced market that is receiving a higher quality version of that good, then consumer deception and potential litigation may ensue. Ghosh, *supra* note 111, at 220; WATAL, *supra* note 19, at 297.

120. WATAL, *supra* note 19, at 333.

121. See THE GLOBE AND MAIL, *Report on Business: Money and Markets Foreign Exchange*, Feb. 24, 2003, at B10 (citing the currency exchange rate on February 23, 2003 of 5.5 Egyptian pounds per US\$1).

122. Law No. 82 of 2002, *supra* note 81, at art. 32.

123. *Id.*; Mostafa, *supra* note 7.

the claim [in order to] . . . preserve the condition of such goods and products . . .”¹²⁴ and to “order appropriate conservative procedures to fulfill rendered fines or compensation in addition to ordering the destruction of confiscated subject matter. . . .”¹²⁵ Finally, non-disclosure agreements are now subject to Egyptian law and enforceable in Egyptian courts, which saves foreign companies the time and resources of going abroad to enforce their rights.¹²⁶

Despite the legal improvements in the law, there remain institutional and financial obstacles to efficient enforcement. For example, the Patent Office is not automated, there is a shortage of trained patent examiners (those available are poorly trained), and there are not enough judges to handle all of the cases and appeals.¹²⁷ Overcoming these limitations is an expensive feat. In 1996, an Egyptian spokesman to the United Nations estimated a cost of \$98,000 to increase patent personnel and purchase necessary equipment, \$192,000 to prepare the judiciary for patent enforcement, and \$1,000,000 to train and develop customs authorities.¹²⁸ For a developing country with a pre-existing budgetary crisis,¹²⁹ these expenses serve as formidable impediments to effective enforcement of the new IPR law.

The Patent Office also lacks the necessary communication link with the Ministry of Health to ensure that health regulatory authorities do not provide marketing authorization for unauthorized copies of products subject to patent protection.¹³⁰ Foreign pharmaceuticals are particularly concerned with the Ministry of Health’s interference with the patenting process.¹³¹ Under the old law, the Ministry of Health participated in patent application processing in collaboration with the Patent Office.¹³² The new law’s text grants the Patent Office sole jurisdiction over patent applications,¹³³ with some exceptions. If the invention “possess[es] health value”¹³⁴ then the Ministry of Health may oppose

124. Law No. 82 of 2002, *supra* note 81, at art. 33.

125. *Id.* at art. 35.

126. *Id.* at arts. 42, 63; Mostafa, *supra* note 7.

127. Downes, *supra* note 88, at 4; *see also* INTERNATIONAL INTELLECTUAL PROPERTY ALLIANCE, 2003 SPECIAL 301 REPORT EGYPT 94 (2003) (citing the lack of transparency, the snail’s pace adjudication process, and the lack of training as major obstacles to intellectual property rights enforcement), at <http://www.iipa.com/rbc/2003/2003SPEC301EGYPT.pdf> (last visited Oct. 11, 2003).

128. Al-Ali, *supra* note 88, at 283.

129. *In The Shadow of Iraq*, MIDDLE EAST ECONOMIC DIGEST, Aug. 9, 2002, available at 2002 WL 7406212 (last visited Oct. 11, 2003).

130. PHARMACEUTICAL RESEARCH MANUFACTURERS OF AMERICA, *PhRMA Special 301 Submission Priority Watch List Countries: Middle East, Africa, South Asia* 64, www.phrma.org/international/resources/2002-02-22.45.pdf (last visited Oct. 7, 2003) [hereinafter PhRMA].

131. ECONOMIST INTELLIGENCE UNIT, *Failing Grades*, BUSINESS MIDDLE EAST, Jan. 1, 2001, at 1.

132. Wahish, *supra* note 86.

133. Law No. 82 of 2002, *supra* note 81, at art. 16.

134. *Id.* at art. 17.

the granting of a patent. This will inevitably involve the Ministry in reviewing patents albeit for a limited purpose. The Ministry of Health also decides on a case-by-case basis if the patent should be subject to a compulsory license.¹³⁵ But most importantly, the Ministry of Health controls the drug registration process and price-control system (discussed in detail in Subsection III (C)), which impacts a drug manufacturer's profits as much as her patent rights. This important separation of authority necessary to avoid inconsistent treatment among patent holders is likely being addressed in the executive regulations currently under negotiation.

IV. THE EGYPTIAN CONTEXT IN WHICH INTELLECTUAL PROPERTY RIGHTS EXIST

A. *The Political Debate on Intellectual Property Rights*

Unsurprisingly, passage of the new IPR law in Egypt did not occur in the absence of public controversy and opposition. The Egyptian government faced significant political pressure from public sector generic pharmaceutical manufacturers. They launched a major lobbying campaign against the new law in order to protect their generic drug production.¹³⁶ This powerful opposition group obtained public support by claiming that intellectual property rights would raise the price of medicine, cause unemployment, and force the local factories to shut down.¹³⁷ Pharmacists also believed that new therapies would take years to become available to most Egyptians due to the increase in prices.¹³⁸ Such allegations are particularly sensitive in a country where 23% to 35% of households live below the official poverty line.¹³⁹ Even a former Minister of Health was staunchly against patent protection, claiming it was an unnecessary evil and would result in foreign dominance of a key national sector and higher prices for the poor.¹⁴⁰

Despite such strong opposition, the law managed to pass due to a variety of factors. First, the number of patent applications by local parties doubled from 1995 to 2000 due to improvements in the economy. This surge in applications indicated an increase in innovation of intellectual property as well as a

135. *Id.* at art. 23.

136. Susan Postlewaite, *Egypt Changes the Way It Does Drugs*, IP WORLDWIDE, Aug. 2002, at 16.

137. ECONOMIST INTELLIGENCE UNIT, *No Protection, No Investment*, BUSINESS MIDDLE EAST, Aug. 1, 1998, at 2.

138. Hadia Mostafa, *A Tough Pill to Swallow*, BUSINESS TODAY EGYPT, Aug. 2002, available at <http://www.busetodayegypt.com/issues/0208/4D57/02084D57.asp> (last visited Oct. 11, 2003) (discuss predictions of price increases).

139. ECONOMIST INTELLIGENCE UNIT, *supra* note 137.

140. *Id.*; Downes, *supra* note 88; Mostafa, *supra* note 7.

subsequent desire for protection.¹⁴¹ Second, foreign investors, in particular the members of the Pharmaceutical Research and Manufacturers of America (PhRMA), informed Egypt that its weak IPR regime deterred them from investing \$300 million in Egypt's pharmaceutical sector.¹⁴² A number of reform-minded legislators in the Parliament took such missed opportunities seriously and managed to get the law through.¹⁴³ Third, a new Minister of Health, who is a respected academic, was recently appointed. His appreciation for the need to attract foreign investment by strengthening pharmaceutical patent protection played a key role in convincing the public of the benefits of the new law.¹⁴⁴ Finally, Egypt feared that Jordan's recent passage of a new IPR law would divert potential investment and deny Egypt the opportunity of becoming a regional pharmaceutical manufacturing center.¹⁴⁵

In order to fully appreciate the impact of this new law on Egypt's economic growth prospects, as well as the reason why the new law is so controversial, one must understand the highly concentrated market structure of Egypt's pharmaceutical industry and its deficient health care system.

B. The Local Pharmaceutical Industry and Health Care Insurance

The pharmaceutical industry is one of the oldest strategic industries in Egypt and the largest producer of pharmaceuticals in the Middle East and North Africa region. Established in 1939, the sector underwent significant growth in the 1980s as new pharmaceutical factories began locally manufacturing pharmaceutical products for local consumption as well as export to the Arab and African markets.¹⁴⁶ The sector is composed of eight public production companies, three public support services companies (importing, distributing, and packaging), and twenty-two private production companies. It is highly concentrated with the top nine (foreign) companies controlling 45% of the market and the top five of those controlling 32% of the market.¹⁴⁷ Egypt exports 6% of its production of which 74.9% is exported to the Middle East and North Africa region.¹⁴⁸

141. Downes, *supra* note 88.

142. ECONOMIST INTELLIGENCE UNIT, *Egypt: Patent Pending*, BUSINESS MIDDLE EAST, Jan. 16, 2001, at 1. Note that with stronger IPR laws, PhRMA members would also reclaim their annual losses of \$100 million from patent infringements in Egypt and increase their market share from 18% to 25%. ECONOMIST INTELLIGENCE UNIT, *supra* note 131, at 2.

143. Mostafa, *supra* note 7.

144. Mostafa, *supra* note 138.

145. ECONOMIST INTELLIGENCE UNIT, *supra* note 142.

146. AmCham, *supra* note 9, at 3.

147. *Id.* at 24-27.

148. *Id.* at 15.

Public sector companies control 17.6% of local production and export 63% of the nation's total pharmaceutical exports.¹⁴⁹ Public sector firms have been losing market share to the private sector, primarily foreign firms, due to inefficient distribution channels, high operating costs, heavy governmental control and restrictions on expenditures, highly restricted R&D expenditures of 1%-2%, weak marketing and sales efforts, overstaffing, and sale of drugs below cost for socio-economic reasons.¹⁵⁰ The consequent loss of revenues has placed more pressure on them to export. Moreover, since at least 200 drugs are currently produced by Egyptian drug companies (private and public) without the payment of royalties to the multinational pharmaceutical companies that discovered the drugs through their own research and development,¹⁵¹ public sector firms have reason to fear further erosion of market share upon implementation of the new IPR law.

Although the public firms' concern with elimination from the market is legitimate, it may be misdirected. The real threat to their success may not be as simple as the presence of stronger IPRs, but their sub-standard managerial, packaging, advertising, and quality control standards. To some extent, they will lose their sources of revenue from on-patent generic drugs. But fully relying on patent infringements for revenue is not sustainable in the long run. As the costs of operations increase, due to their inefficient business structure, any potential profits gained from producing a lower-cost, generic drug will be undermined. If the government absorbs the losses in order to keep the prices of drugs low, the public will ultimately suffer in other ways as the country's overall budget deficit increases. Hence, a false sense of security regarding the affordability of medicine is created among the population. Yes, the price of drugs is currently affordable but perhaps at the expense of a higher quality health care system or an adequate physical infrastructure.

But price does matter. Only 59% of Egyptians are covered by health insurance of which 4% are covered by private health insurance and 55% by sub-standard public health insurance.¹⁵² The public health insurance scheme entitles the recipient to a doctor and a hospital bed, but the quality of the services is so low that most resort to private services paid at their own expense.¹⁵³ That brings the number of people that pay for medicines straight from their pockets to 98%, which resulted in a low per capita consumption of LE57.81 (approximately

149. *Id.* at 5.

150. *Id.*

151. Mohamed Raouf Hamed, *To Make the Medicine Go Down*, AL-AHRAM WEEKLY ON-LINE, May 24-30, 2001; Ahmed Fekry, *Drug Manufacturers Warn of Bankruptcies*, MIDDLE EAST TIMES, Feb. 24, 2002, <http://www.metimes.com/2k3Assue2003-39/methaus.htm> (last visited Oct. 7, 2003).

152. *Id.* at 21.

153. ECONOMIST INTELLIGENCE UNIT, *Life at the Bottom*, MIDDLE EAST BUSINESS, Vol. 350, Issue 8111, at 10.

\$16.76) in 1998.¹⁵⁴ These low consumption levels exist notwithstanding that the price of drugs are as low as \$1-\$2 per package, which are among the lowest prices in the world.¹⁵⁵ Given Egypt's low GDP per capita of \$1,490¹⁵⁶ and that 49.6% of the 70 million Egyptians live below the upper poverty line,¹⁵⁷ any increase in price may decrease consumption levels to unacceptable lows particularly with respect to diabetes, renal and heart diseases, and cancer. Add to that the recent elimination of food subsidies and the increasing cost of living.¹⁵⁸ These factors combined impose a heavy burden on consumers as they struggle to meet their most basic needs. Due to the country's inadequate political transparency and notorious record of government corruption, consumers may nonetheless choose to have the lower priced drugs because they do not believe that the savings gained from addressing the macroeconomic inefficiencies will be passed onto them in other forms.

Nevertheless, the Egyptian government decided in 1995 that privatization and reform of public sector pharmaceutical companies was an integral part of reforming the overall economy.¹⁵⁹ Therefore, even in the absence of IPRs, public sector pharmaceutical companies will have to reform their internal management systems, obtain the marketing and sales skills to prepare them to compete in the global market, and invest more money into R&D.¹⁶⁰ They will have to improve their quality assurance tests to meet international quality standards if they want to continue exporting their products abroad.¹⁶¹

If these weaknesses are properly addressed, then the addition of strong IPRs may indeed prove beneficial to local firms. For example, public sector companies import most of their active ingredients, machinery, spare parts, and equipment. The cost of these inputs will decrease in the presence of strong IPRs. Foreign pharmaceutical patent holders will no longer be forced to increase the price of inputs as a means of recouping lost profits from finished drugs.¹⁶² The public sector also focuses on export markets, which is unlikely to exist in MNEs with strict orders from headquarters to limit service to the domestic market.¹⁶³ If public pharmaceuticals do invest in R&D and patent new products, these exports may become a significant source of profits and a vital

154. Amcham, *supra* note 9, at 24 (comparing this to \$34.10 in Kuwait and \$35.40 in Qatar the same year).

155. Postlewaite, *supra* note 136.

156. THE WORLD BANK, *supra* note 48, at 18 tbl. 1.1.

157. Al-Ali, *supra* note 88, at 307.

158. ECONOMIST INTELLIGENCE UNIT, *supra* note 153.

159. Amcham, *supra* note 9, at 8.

160. *Id.* at 23.

161. *Id.*

162. *Id.* at 6.

163. *Id.* at 8.

source of foreign currency for Egypt – assuming the profits are reinvested into the Egyptian economy.

Ten of the twenty-two private sector pharmaceutical producers are domestic firms. These firms control 8.9% of total private sector sales. They too import a large percentage of their primary elements, 80%-85%, in order to produce end-use products for final consumption.¹⁶⁴ They export these drugs free of margin ceiling limitations that are imposed on locally sold products.¹⁶⁵ Because most of their production is over the counter and generic drug (of on-patent drugs), the new law will appreciably impact their operations. They will be forced to innovate their own formulas and patent them, sign licensing agreements with foreign pharmaceuticals to produce their patented drugs domestically, or simply go out of business.

If the first scenario is to occur, these firms will need the research and development training and financing necessary to engage in drug innovation. How and whether this will occur will likely depend on the government's willingness to directly fund their R&D endeavors, form public-private R&D partnerships, and reform the price control system.¹⁶⁶ If the predominant effect is the proliferation of licensing agreements, then actual technology transfer will need to take place in order to produce the desired increase in productive capacity within the local pharmaceutical industry.¹⁶⁷ And if the least desired result of bankruptcy occurs, then the Egyptian government will most certainly face a major political crisis.

C. Regulatory Obstacles to Efficiency

With respect to drug regulation, TRIPS' guidelines are limited to the principles of non-discrimination and most favored nation treatment.¹⁶⁸ Each individual nation, "in formulating or amending their laws and regulations, [is free to] adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. . . ."¹⁶⁹ Therefore, price controls, drug registration and approval, and import-export regulations are left to the discretion of the individual WTO members, "provided that such measures are consistent with the provisions [of TRIPS]."¹⁷⁰

164. Amcham, *supra* note 9, at 6-8.

165. *Id.* at 6.

166. Aziza Sami, *A Bleak Prognosis*, AL-AHRAM WEEKLY ON-LINE, May 31-June 6, 2001, at <http://weekly.ahram.org.eg/2001/536/ecl.htm> (last visited Oct. 13, 2003); see *infra* subpart III(C) for detailed discussion of Egypt's price controls.

167. See generally *infra* subpart IV(B) (providing a detailed discussion of technology transfer).

168. TRIPS, *supra* note 19, at arts. 3, 4.

169. *Id.* at art. 8.

170. *Id.*

The Egyptian pharmaceutical industry exists within a complicated regulatory environment. The government exercises strict control over the types of drugs that can be imported into the country, which often results in the banning of some finished drugs.¹⁷¹ Importers must obtain an import license to bring in a specified quantity of a drug at a specified price. Imported raw materials are subject to a 5% customs duty and a 1% sales tax unless they are to be used for the production of an essential drug thereby subjecting them to a 1% customs tax and no sales tax.¹⁷²

New finished drugs must be registered. Under the old law, registration took up to three years after submitting all the relevant research documentation to the Ministry of Health.¹⁷³ However, foreign firms were more susceptible to persevering through this process because local firms simply submitted a document showing a slight variation in the manufacturing process of an existing drug, gave the drug a new name, and received approval much quicker.¹⁷⁴ Whether this phenomena is a form of discriminatory treatment between foreign and domestic firms is debatable since there is a substantive difference between registering an entirely new drug and registering a slight variation of an existing registered drug. Nonetheless, this issue should be resolvable under the new IPR law's non-discrimination provision.¹⁷⁵ The more pressing issue lies in the registration process itself. If Egypt is serious about attracting foreign direct investment and assisting its own private sector's profitability, the registration process must be reformed to decrease the amount of time taken to bring a new finished product to the market, whether by a foreign or local party.

Egypt also sets price controls on pharmaceuticals, which is a legitimate practice under TRIPS.¹⁷⁶ The Pharmaceutical Pricing Committee at the Drug Planning and Policy Center sets prices with the aim to keep medicine affordable to the majority of the population. Because the process revolves more around social concerns, the pharmaceutical's profitability objectives are overlooked. The prices do not adequately reflect the fair market value with respect to R&D costs, promotion spending, inflation, currency devaluation,¹⁷⁷ and the changes in costs of raw materials. In 1996, the Government of Egypt (GOE) made some reforms to the price-setting system by adopting a cost-plus formula that allowed

171. PhRMA, *supra* note 130, at 64; ECONOMIST INTELLIGENCE UNIT, *supra* note 84.

172. AmCham, *supra* note 9, at 10.

173. Postlewaite, *supra* note 136.

174. *Id.*

175. See Law No. 82 of 2002, *supra* note 81, at art. 4 ("Every natural or legal person whether or Egyptian or foreign nationals . . . are entitled to the rights of applying for patent at the Egyptian Patent Office and enjoy all rights granted by this law.")

176. Lanjouw, *supra* note 15, at 22.

177. See PhRMA, *supra* note 130, at 65 (citing major reductions in profitability in the sector due to the recent 60% devaluation of the Egyptian pound).

for a fixed profit margin above the cost of ingredients, but it continued to exclude the other variables that contribute to production costs.¹⁷⁸

The adverse effect of this price-setting scheme is a reduction in R&D by foreign and domestic firms because they cannot recoup those costs through sales.¹⁷⁹ The limited potential profits deter prospective manufacturers of patentable pharmaceuticals from setting up shop in the country and stifle the importing of new products.¹⁸⁰ Additionally, monitoring and enforcement of these price controls is costly as it adds more bureaucracy to an already strained business environment.¹⁸¹ Because allowing the market to completely control prices may result in inaccessibility to medicine by a significant portion of the population, one scholar suggests a selective use of price control for the products with few affordable therapeutic alternatives. Therefore, the price-controlled segment will be too small to jeopardize the introduction and availability of newer, more effective pharmaceuticals into the market.¹⁸² Ultimately, if the GOE wishes to fully exploit the benefit of the new IPR law, it will have to address this important issue through dialogue and cooperation with the private sector.

V. STRONGER INTELLECTUAL PROPERTY RIGHTS IS NOT ENOUGH

A. *Strengthening Research and Development Capabilities*

Although the aforementioned description of Egypt's IPR reforms appears to represent a significant step towards "reduc[ing] distortions and impediments to international trade[.]"¹⁸³ it is insufficient to bring about the expected benefits to both the Egyptian private sector and the Egyptian consumer. The IPR regime must be complemented and linked with other legal regimes dealing with research and development, technology transfer and competition policy. One cannot disregard that the developed nations' reasoning in support of IPRs¹⁸⁴ is based on the pivotal assumption that domestic pharmaceuticals in developing nations, public or private, have the technical as well as financial resources to conduct adequate research and development activities. However, this is rarely the case, and Egypt is no exception. The domestic sector's technical capability is limited to the production of therapeutic ingredients and finished goods and

178. AmCham, *supra* note 9, at 9.

179. *Id.*

180. WATAL, *supra* note 19, at 742.

181. *Id.*

182. *Id.*

183. TRIPS, *supra* note 19, at Preamble.

184. See *infra* subpart I(A) (providing detailed discussion of developing countries' concerns regarding strengthening intellectual property regimes).

lacks a sophisticated research and development base.¹⁸⁵ Pharmaceuticals operating in Egypt allocate less than 2% of their revenues to research and development activities, due in part to the defective price setting structure.¹⁸⁶ Local pharmaceuticals depend on imports for 85% of their raw materials, making their costs heavily based on external economic factors.¹⁸⁷ Moreover, Egyptian higher education, the main component in creating the necessary human resources, is in urgent need of reform and upgrading.¹⁸⁸ In 1987, there were only 3,782 Egyptian research scientists per million inhabitants compared to 466,211 in the United States or 29,509 in India.¹⁸⁹

These debilitating factors will not miraculously be resolved by mere IPR regime reforms. Although stronger IPR legal regimes will create financial incentives and legal certainty for current and new entrants into the market, that is not enough to produce the objectives of economic growth and improved public welfare sought by developing nations. A robust system of national and international linkages among practitioners needs to be established. Egypt should also tap into the ongoing transformation of industrial firms in wealthy nations. As these firms transition from vertically integrated firms to outsourcing and subcontracting to individuals and businesses in the developing world, Egyptian businesses can utilize the new IPR law to earn the trust of MNEs concerned with their trade secrets and patented products.¹⁹⁰

Technology policies that link Egyptian scientists and practitioners with each other as well as with their foreign counterparts should be adopted.¹⁹¹ For example, the GOE should focus on creating incentives for cooperation between research and development institutions, universities, and industry. Favorable tax treatment and economic rewards, an obvious one being the monopoly power created by patent, should be granted to local entrepreneurs.¹⁹² The policies' incentive structures should also attract financing for research and development activities. Egypt can learn from the United States' experience by providing public funding for R&D activities through direct sponsorship.¹⁹³

185. Omer, *supra* note 8, at 551 n. 4.

186. AmCham, *supra* note 9, at 20.

187. *Id.* at 21.

188. UNITED NATIONS DEVELOPMENT PROJECT, ARAB HUMAN DEVELOPMENT REPORT 65 (2002), www.undp.org/rbas/ahdr/chapter5.pdf (last visited Oct. 7, 2003) [hereinafter Arab Human Development Report].

189. *Id.* at 67.

190. *See id.* (noting that Asia and Latin American subcontractors greatly benefited from this process).

191. *See id.* at 66 (noting the establishment of linkages and policies in Brazil, China, and the Republic of Korea as a means of strengthening their national knowledge base).

192. *Id.* at 70.

193. *Id.* at 71 ("more than 45% of all R&D efforts in the United States over the last 20 years have been funded directly by government agencies").

To the GOE's credit, new polices have recently been passed to support information technology. National plans include promoting infrastructure, encouraging foreign and local investment, providing Internet services to schools, and establishing a free zone for information and communication technology (known as Smart Village).¹⁹⁴ Similar approaches and attitudes are required with respect to the needs of the technology intensive and science based pharmaceutical industry.

B. Encouraging Effective Technology Transfer and Preventing Anti-Competitive Practices

As subparts I (A) and (B) of this Note mention, a primary incentive for developing countries to reform their IPR regimes is to encourage technology transfer.¹⁹⁵ More specifically, nations want an effective transfer of skills and intangible know-how that will lead to an increase in production capabilities by local market participants.¹⁹⁶ TRIPS Article 7 states "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology . . . in a manner conducive to social and economic welfare" and Article 8 states that "[a]ppropriate measures [consistent with other provisions] . . . may be needed to prevent the . . . adverse affect [to] the international transfer of technology." In addition, a WTO Working Group on Trade and Transfer of Technology (of which Egypt is a member) was created to "examine and recommend measures that might be taken to increase flow of technology to developing countries. . . ."¹⁹⁷ Therefore, signatories are encouraged to adopt policies that will encourage the transfer of technology along with the strengthening of IPRs.

In Egypt's case, technology transfer in the form of foreign direct investment continues to lag behind expectations. The decrease in foreign direct investment inflows illustrates that the nation is still in the unavoidably lengthy process of transforming these legal incentives into tangible results.¹⁹⁸ Consequently, Egypt passed a new Commercial Code Law No. 17 of 1999,

194. *Id.* at 71, 77; Cam McGrath, *Communication – Egypt: Silicon Oasis Rises in the Desert*, INTER PRESS SERVICE, Jul. 16, 2002.

195. WATAL, *supra* note 19, at 386.

196. Omer, *supra* note 8, at 561.

197. THE WORLD TRADE ORGANIZATION, WORKING GROUP ON TRADE AND TRANSFER OF TECHNOLOGY, WT/WGTTT/W/2, (Apr. 15, 2002) [hereinafter WTO WORKING GROUP ON TRADE AND TRANSFER OF TECHNOLOGY].

198. See Maskus, *supra* note 5, at 153 (showing Egypt's decreasing FDI inflows at \$948 million in 1987, \$734 million in 1990, and \$598 million in 1995); *British Direct Investments in Egypt at \$26 Mln Q1 FY2002*, EGYPTIAN NEWS DIGEST, Feb. 7, 2002, at 2003 WL 3950525 (stating that Egypt attracted \$428.2 million in foreign direct investment in 2001-2002 down from \$509.4 million in 2000-2001).

which included provisions specifically addressing technology transfer.¹⁹⁹ The provisions permitted the invalidation of any restriction on “the freedom of the importer of technology . . . in its use, development, acquaintance of the product or its advertisement”²⁰⁰ placed in a technology transfer contract. Examples of invalid contract restrictions include:

- 1) Prohibiting the improvement or modification to the imported technology to suit local conditions;
- 2) The prohibition of acquiring similar technology or competing technology;
- 3) Limitations on production volume, price, method of distribution, and export;
- 4) Required interference of the supplier in the importers business operations;
- 5) Exclusive supply arrangements for raw materials, equipment, machines, or spare parts from the supplier alone; and
- 6) Restrictions on the sale of the production.²⁰¹

The supplier also has to supply the importer with information, data, and technical documents needed to assimilate the technology into the local market and provide the importer with technical services for the operation of the technology. Finally, the supplier has the obligation of providing the importer with spare parts for machines and equipment supplied, if she produces them, or advise the importer on other sources.²⁰² This is particularly relevant to Egypt because the majority of capital equipment and machinery used in production is imported.²⁰³

These complementary laws, however, may simply gather dust given the competitive realities in the global market. Foreign firms are loathe to reveal any trade secrets or technical information that may easily be imitated and compete with their products. Therefore, the legal certainty brought about by IPRs, which encourage information dissemination by guaranteeing patentees legal remedies for infringement, will give technology transfer polices vitality.²⁰⁴ Because

199. Tarek F. Riad, *Egypt: Technology Transfer Provisions in Law No. 17 of 1999*, ARAB LAW QUARTERLY, 418-22 (2000) (publishing Commercial Code Law No. 17 of 1999, Articles 72-87 in their entirety).

200. Tarek F. Riad, *The Legal Environment For Investment In Egypt In The New Millennium*, ARAB LAW QUARTERLY 117, 120 (2000).

201. *Id.*

202. *Id.* at 121.

203. See THE WORLD BANK, *supra* note 48, at 212 tbl. 4.3, 223 tbl. 4.6 (citing Egypt's manufacturing of machinery and transport equipment as 15% of total manufacturing in 1999 and Egypt's manufactured imports, which include capital equipment, as 77% of total imports in 2000).

204. Omer, *supra* note 8, at 558.

pharmaceutical production does not entail complex technologies or highly differentiated goods, foreign pharmaceuticals will find it more attractive to import their products via licensing agreements rather than set up shop in a developing country with complicated bureaucratic red tape, a costly and time consuming drug registration system, and an unfamiliar legal regime.²⁰⁵

On the other hand, the presence of stronger IPRs may increase the costs of acquiring and diffusing technology if suppliers can negotiate higher license fees and royalties due to their monopoly power.²⁰⁶ “Cartel-like restraints, exclusionary conduct and monopoly leveraging by dominant firms, practices, or mergers may chill technological innovation”²⁰⁷ as well as technology transfer. Taking into consideration these competition risks, Egypt’s technology transfer law appears to also serve as a competition policy.²⁰⁸ The second and fifth invalid contract restrictions previously mentioned address the risks associated with vertical licensing agreements. Although vertical-licensing agreements may ensure downstream product quality, they may also erode competition, as they become tie-in sales of unrelated products of technology that extend the scope of patent protection.²⁰⁹ The third invalid contract restriction addresses the risks of fixed pricing, limiting output, and division of market issues created via the cartelization of horizontal licensing agreements.²¹⁰

The technology transfer provisions, although useful, cannot substitute for a well-developed competition policy addressing numerous other competition related problems created by strong IPRs.²¹¹ As the GOE transitions from a centralized, state-run economy to a free market, an appropriate competition policy is necessary to address the pre-existing, as well as potential, allegations of anti-competitive practices in the Egyptian market. Mergers and acquisitions are often undertaken without adequate investigation regarding their impact on market conditions and fair competition.²¹² A draft competition law, which addresses these issues and sets up an impartial and independent Competition Commission, has been proposed to Parliament. In order to maximize the

205. MASKUS, *supra* note 11, at 127; AmCham, *supra* note 9, at 20.

206. Omer, *supra* note 8, at 558.

207. UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, *Competition Policy and The Exercise of Intellectual Property Rights*, TD/B/COM.2/CLP22, 3 (July 2, 2001), available at www.unctad.org/en/docs/c2clp22.en.pdf (last visited Feb. 24, 2003) [hereinafter UNCTAD2].

208. Egypt has not passed a formal competition law. Bahaa Ali El Dean and Mahmoud Moheildin, *On the Formulation and Enforcement of Competition Law in Emerging Economies: The Case of Egypt*, (THE EGYPTIAN CENTER FOR ECONOMIC STUDIES, Working Paper No. 60, 2 2001).

209. Keith E. Maskus & Mohamed Lahouel, *Competition Policy and Intellectual Property Rights in Developing Countries*, 23 THE WORLD ECONOMY 595, 604 (Apr. 2000).

210. *Id.*

211. *Id.* at 603-05.

212. El Dean & Moheildin, *supra* note 208, at 3, 23 tbl. 1 (listing recent acquisitions in Egypt by number and value).

benefits of stronger IPRs in Egypt, the draft competition needs to be passed and enforced in concurrence with the full implementation of Law 82 of 2002.²¹³

To the GOE's credit, passage of Law No.17 of 1999 successfully resulted in a public-private development agreement between the GOE and Siemens. Siemens plans to invest £E 1 billion to design, construct, and commission a new pharmaceutical plant during 2003 to 2005. Included in the deal is also technology transfer training for Egyptian employees and proactive efforts to export.²¹⁴ Moreover, passage of another commercial law, Law No. 8 of 1997 on Investment Guarantees and Incentives provides numerous incentives for Egyptians and foreigners to invest in specific sectors as well as eliminates some obstacles to foreign direct investment.²¹⁵ This law will likely prove very helpful once Law No. 82 of 2002 is fully and properly implemented. Pfizer, the largest pharmaceutical and health care product manufacturer in the world, declined to build a new, state-of-the-art production facility in Egypt because of its distrust of Egypt's willingness to enforce its new IPR law.²¹⁶ The fact that foreign firms are seriously considering foreign direct investment, but for the enforcement of IPRs, is a positive sign that Law No. 82 of 2002, in conjunction with other commercial laws, may produce the anticipated results.

VI. RECOMMENDATIONS AND CONCLUSION

Passage of Egyptian Law No. 82 of 2002 sent out a clear message to the international business community that Egypt is serious about its WTO commitments with respect to intellectual property rights. Despite this important development, intellectual property rights do not exist in a vacuum. They are closely linked and affected by competition policies, foreign direct investment laws, and regulatory schemes. Therefore, passing the law is only the first step. Egypt needs to "provide incentives to enterprises and institutions . . . for the purpose of promoting and encouraging technology transfer . . . in order to create a sound and viable technology base."²¹⁷ In order for this to come about, numerous related issues must be directly addressed and actions must be taken in order to maximize the benefits from the new law.

First, there needs to be internal improvements in the regulatory schema. The patent process should be linked with the drug registration process in order

213. *Id.* at 27-30 (describing the draft competition law currently in parliament).

214. Al- Ali, *supra* note 88, at 313.

215. Riad, *supra* note 199, at 117-20; *see generally* Samiha Fawzy, *The Business Environment in Egypt*, (THE EGYPTIAN CENTER FOR ECONOMIC STUDIES, Working Paper no. 34 1998) (discussing the various obstacles faced by the Egyptian private sector in its attempts to compete in the global market).

216. Mostafa, *supra* note 138.

217. TRIPS, *supra* note 19, at art. 66(2).

to speed up the latter process as well as assure consistent case handling.²¹⁸ The patent process should be solely controlled by the Patent Office, rather than the Ministry of Health, so as to avoid inconsistent treatment and delayed results.²¹⁹ Patent examiners and judges need to be properly trained to handle sophisticated patent applications and disputes.²²⁰ A national intellectual property council should be created to oversee the granting of compulsory licenses rather than placing the decision at the sole discretion of one ministry.²²¹ The price control system needs to be reformed to incorporate promotion spending, inflation, exchange rate changes, and costs of raw materials.²²²

Second, economic incentives and public policies need to be adopted in order to support the local pharmaceutical industry through the initial transition phase. The government should take an active role in developing R&D in the nation through more public-private partnerships, a national network of government and university officials, tax incentives, and direct funding of R&D activities.²²³ An emphasis can be placed on incremental product development rather than new products that require economies of scale.²²⁴ Exports should be encouraged through tax incentives and technical support programs that can prepare local firms competing in the global market for the first time. The local firms should be encouraged to specialize in the phyto-pharmaceuticals sub-industry by developing plant extracts and herbal drugs from Egypt's abundant plants.²²⁵

Third, other legal regimes need to be reformed. Adoption of an adequate competition law is necessary in order to protect the market from anti-competitive practices by patent holders.²²⁶ Commercial laws impacting foreign direct investment decisions are required to fully exploit technology transfer opportunities that arise from a stronger IPR regime. Insurance and health care policies need to accommodate the fundamental changes in the market that will inevitably take place. Adequate health insurance coverage needs to be expanded to cover

218. AmCham, *supra* note 9, at 20.

219. Wahish, *supra* note 86.

220. AmCham, *supra* note 9, at 27; Lanjouw, *supra* note 20, at 19 (noting that patent examiners need advanced degrees and work experience in the relevant sciences in order to properly perform their job duties).

221. Wahish, *supra* note 86.

222. AmCham, *supra* note 9, at 27.

223. *Id.* See WTO WORKING GROUP ON TRADE AND TRANSFER OF TECHNOLOGY, *supra* note 197, ¶¶ 14, 16 (supporting "capacity building through specific projects and programs and by establishing a scientific and technological infrastructure on a cooperative basis for both the public and private research facilities" and "joint research and technology upgrading efforts by enterprises and Governments").

224. AmCham, *supra* note 9, at 26.

225. *Id.*

226. *Id.* at 27; See generally UNCTAD2, *supra* note 207, at 20-23 (describing the various ways in which competition policies with respect to IPRs need to be developed in order to promote innovation).

a larger percentage of the disproportionately poor population and shield them from price fluctuations.²²⁷

It is essential that these issues are identified and the linkages are made so that poor, developing nations do not idealistically expect that merely changing their IPR regime will automatically produce the proclaimed benefits espoused by the wealthy, western nations. To its credit, some of these issues have been and are currently being addressed by the GOE. For example, laws pertaining to export promotion, money laundering, special economic zones, and chambers of commerce have recently been passed by parliament. Meanwhile, the Unified Corporate Tax Law, the Anti-Trust and Competition Law, the Unified Labor Law, the Anti-Dumping Law, and the Information Technology Agreement are currently undergoing parliamentary debate.²²⁸ Passing such laws is an important first step. However, due to Egypt's limited human and financial resources, the nation will inevitably face numerous obstacles as it attempts to properly address such a variety of inter-linked issues.

Ideally, the developed nations will protect its own economic interests in meeting the TRIPS objective to "reduce distortions and impediments to international trade . . . and ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade[.]"²²⁹ by actively supporting, financially and technologically, nations like Egypt in their challenging endeavor to fully and equally benefit from the strengthening of intellectual property rights. Otherwise, developing nations' fears of becoming mere consumer targets for wealthy pharmaceutical MNEs, (rather than producers and beneficiaries of intellectual property rights) may materialize. If so, governments of developing nations will understandably protect their own interests and exploit compulsory licensing authority to the detriment of MNEs, fail to address gray market issues, and allow weak enforcement mechanisms to prevail, undermining the long-term sustainability of international intellectual property rights.

227. Wahish, *supra* note 86; Niveen Wahish, *Health Care Trip-Up*, AL-AHRAM WEEKLY ON-LINE, March 7-13, 2002, at <http://weekly.ahram.org..eg/2003/576/ec4.htm> (last visited Oct. 13, 2003).

228. THE AMERICAN CHAMBER OF COMMERCE IN EGYPT, *Legislative Update*, at <http://www.amcham-egypt.org/BSAC/WatchBulletin/BackIssues/WBJul102.asp> (last visited Oct. 13, 2003).

229. TRIPS, *supra* note 19, at Preamble.