

# Egypt's Pharmaceuticals – Tripping Over TRIPS?

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By

Farida H. Mortada

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The powerful forces of technological innovation and economic globalization have transformed intellectual property rights (IPR) into the most strategic economic resource of the future. The link between IPR and international trade, transfer and dissemination of technology, investment, and growth has caused protracted controversy over the current intellectual property regime that was instated with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Developing countries especially have reiterated their concern about the consequences of the agreement on their economies and the development of their domestic, infant, high-tech industries, in particular with regards to patent protection for pharmaceuticals, reflecting a growing “suspicion that the TRIPS Agreement is a component of a policy of technological protectionism intended at consolidating an international division of labor, where the industrialized nations generate innovations and developing countries are the market for the resulting products.”<sup>1</sup>

Nevertheless, the developed world has argued that “stronger intellectual property protection would serve to stimulate research, which would, in the long run, be beneficial to both firms and consumers in less developed countries.”<sup>2</sup> The argument of the developed world won the day, and on April 15, 1994, the world's trade ministers finally concluded the Uruguay Round of multilateral trade negotiations in Marrakesh with the signing of the trade accord that included the TRIPS Agreement, which constituted the cornerstone of the current system of intellectual property rights protection. The objectives of TRIPS as presented in Article 7 of the agreement, indicate that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”<sup>3</sup>

Patents for pharmaceuticals form only part of the TRIPS agreement, giving patent holders monopoly rights over their inventions, as they provide the inventor with the legal means to prevent others from “making, using, offering for sale, selling, or importing” any new invention, whether it involves a product or a process.<sup>4</sup> In exchange for the patent, the inventor must describe the details of the invention in the application and thereby disclose it to the public. As a consequence, patents lead - by design - to the increase in the price of life-saving medicines. According to the World Trade Organization Fact Sheet on TRIPS and Pharmaceutical Patents in 2006, TRIPS “attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations.”<sup>5</sup> While it was argued by the developed world that the higher prices were supposed to spur technological innovation, unfortunately, those prices made vital medicines unaffordable to billions of people in the developing world, who could not compete with the dominant pharmaceutical monopolies because of the “unprecedented financial resources at their disposal and their supreme research capabilities,” which have been found lacking in developing countries.<sup>6</sup>

With the signing of the TRIPS Agreement, Egypt was committed to bring its IPR legislation into compliance with TRIPS, which was achieved in 2002 with the issuance of Law No. 82 on the Protection of Intellectual Property Rights, and which has entered into force since 1 January 2005. Thereby, Egypt shifted from a patent regime that granted only pharmaceutical process protection for a period of 10 years (1949 Law on Patents and Industrial Drawings and Designs) to the TRIPS-compliant patent regime that makes no distinction between process and product patents and that extends patent protection to twenty years from the filing date.<sup>7</sup>

The new patent regime that increasingly allows the monopolization of intellectual property in the hands of a few powerful patent holders raises the question of how to ensure the availability of new, life-saving medical treatments for aids, cancer, heart diseases and the like at affordable prices to the Egyptian public. While the process patent regime under the 1949 law provided considerable latitude in guaranteeing access to medication, by allowing local pharmaceutical firms to manufacture cheap, generic versions of patented drugs to meet domestic demand, the move to the TRIPS product patent regime rendered this production illegal, crowding out a great number of local manufacturers, and increasing imports of these drugs. As a result, “the price of newly patented drugs is set to rise sharply [...], imposing a significant social and economic cost.”<sup>8</sup>

The pharmaceutical sector in Egypt is one of the oldest strategic sectors in the country, founded in 1939 with the establishment of the Misr Company for Pharmaceutical Industries.<sup>9</sup> Supplying 30% of the total regional market, Egypt has grown into the largest pharmaceutical producer and consumer in the MENA region.<sup>10</sup> Nevertheless, despite the growth in pharmaceutical production that Egypt has witnessed over the last few years, the advancement in production has not been accompanied by advancement in research and development that would lead to technological and scientific innovation in the local pharmaceutical production, leaving Egypt dependent on the dissemination of technology and the use of knowledge of patented pharmaceutical products and processes. With the adoption of the TRIPS patent regime, this dissemination and use of knowledge is impeded, as advancement in local research and development will depend on the decision of the patent holder to disclose the details of the invention and to transfer the technology of production through the granting of voluntary licenses to local manufacturers. Hence, the cost of research and development will sharply increase with the expected increase in the cost of voluntary licenses, which will ultimately cause a slow-down in follow-on research and an overall suspension in technological process in the Egyptian pharmaceutical industry.<sup>11</sup>

It thus appears that the challenges facing the pharmaceutical sector in Egypt under the TRIPS patent regime are two-fold. On the one hand, the global extension of intellectual property rights raises concerns about measures to balance the conflict between commercial interests of the powerful patent-holders and their protected right to monopoly and of society's interests in having consistent access to affordable medication, often for life-threatening diseases. On the other hand, the question arises of whether the TRIPS patent regime will provide stimulus to research and development in developing countries, thereby contributing to the promotion of technological progress and innovation as set out in the objectives of the TRIPS Agreement.

To broaden access to technology and to ensure the availability of life-saving medicines at affordable prices, Egypt must employ the flexibilities in the TRIPS agreement that were set out in Articles 30 and 31, and as they were interpreted by the Doha Declaration in 2001, which reiterated that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health [...] and to ensure access to medicines for all."<sup>12</sup> In the agreement, TRIPS grants flexibilities that allow governments a scope of freedom in the enforcement of the protection granted under its provisions in order to meet social goals, especially in cases of national emergencies, anti-competitive practices, or if the right-holder refrains from supplying the invention.<sup>13</sup> In these situations, governments can issue compulsory

licenses that allow the local production of patented drugs at affordable prices, without the consent of the original patent holder, yet under a number of conditions that are aimed to protect the legitimate interests of the patent holder. According to a report on the pharmaceutical sector in Egypt, issued by the American Chamber of Commerce in 2006, the strength of the Egyptian pharmaceutical market lies in the fact that it “is ‘factor-driven’, gaining its competitive edge from low labor and infrastructure cost, which implies that pharmaceutical companies can produce low-priced products for mass consumption.”<sup>14</sup> Thus, Egypt can guarantee through the granting of compulsory licenses that generic versions of vital expensive drugs become affordable to the public on the one hand, and that local manufacturers will be able to develop their technological know-how through the imitation of the patented product or production process on the other, triggering local innovation.

As argued by Nobel-prize winning economist Joseph E. Stiglitz in his book *Making Globalization Work*, “intellectual property is not an end in itself, but a means to an end: it is supposed to enhance societal well-being by promoting innovation.”<sup>15</sup> Stiglitz yet recognizes the profound asymmetry in the technological and research capabilities between the developed and the developing world. Further, the implementation of the TRIPS Agreement has shown that intellectual property has not fulfilled its expected impact on spurring investments in research to produce drugs that attack diseases prevalent in developing countries; rather, investments by pharmaceutical monopolies in research for life-style drugs has been given primacy over research in disease-related drugs. Anna Lanoszka argues in her article “The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries, that the “strong global patent regime as prescribed and monitored by TRIPS, constitutes a likely obstacle to the development of a local pharmaceutical industry” in developing countries.<sup>16</sup> It is time, therefore, to allow Egypt a wider scope in deciding the most appropriate domestic intellectual property policies and to release the Egyptian pharmaceuticals from the chains of the current inefficient and inequitable system of research funding, in order to allow the country to develop its own innovative pharmaceutical industry, given the points of strength it enjoys.

Therefore, Egypt needs to establish its own research, development, and innovation funds that place significant emphasis on the encouragement of local scientists to embark on the development of pharmaceutical technology and to encourage innovation in drugs related to acute diseases in the country, such as Hepatitis C.<sup>18</sup> As introduced by Stiglitz in his book, a prize system, “in which researchers are rewarded for the value of their innovations, would move incentives in the right direction.”<sup>17</sup> With the issuance of compulsory licenses and the resulting

broader access to technology, local scientist will have the opportunity to use their knowledge and employ their potential in developing follow-on research, innovations based on other innovations, making important discoveries that benefit the developing economy. It is noteworthy to mention that last August, an Egyptian scientist, Dr. Sherif Salah Abdel Aziz, registered an international patent, patent no. 92466/2008, for an innovation in the treatment of Hepatitis C. It is thus clear that the support offered to those who make important discoveries in Egypt is vital to the achievement of technological progress and to the further growth of the country's pharmaceutical industry.

It is argued that the TRIPS Agreement seeks to impose a standardized intellectual property regime on the world, without showing particular regard to the fact that the circumstances of developing and developed countries differ significantly.<sup>19</sup> Over the years following the implementation of TRIPS in Egypt and in other developing countries, one could not fail to notice that the standardized intellectual property regime has inflicted high social costs that far outweighed its benefits. Prospects for technological innovation and regular access to medication in Egypt and similar developing countries will not be achieved under a single standard for intellectual property law. Therefore, there is a growing need to adjust the intellectual property regime to reflect the interests and concerns of the different countries of the developing world, which begins with the idea of fairness in the dialogue between the developed and developing world, as expressed by Stiglitz, and the adoption of a balanced IPR regime that shows a certain level of sensitivity towards the special needs of developing countries.<sup>20</sup> Elimination of the intellectual property regime is not suggested here, but this is an appeal to a revision of the TRIPS patent regime, that recognizes the rights of the developing world to access to medication, that induces better economic performance and that guarantees opportunities to foster technological innovation in the developing world.

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1 Lanoszka, Anna. "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries." *International Political Science Review*, Vol. 24, No. 2, April 2003, p. 182.

2 Mishra, Veena. "Product Patents and Pharmaceuticals." *Economic and Political Weekly*. Vol. 36, No. 48 (Dec. 1-7, 2001), p. 4464.

3 TRIPS Agreement

4 Ibid.

5 WTO Fact Sheet on TRIPS and Pharmaceutical Patents, 2006, 6 Lanoszka 183.

7 Egyptian Initiative for Personal Rights (EIPR). "Egypt's State Responsibility to Protect the Right to Health after the Implementation of the TRIPs Agreement." 2005.

8 Mishra 4464.

9 American Chamber of Commerce in Egypt (AmCham). "Pharmaceutical Sector Development in Egypt." December 2006.

10 EIPR

11 Stiglitz, Joseph E. "Patents, Profits, and People." Making Globalization Work (New York: W. W. Norton and Company, 2006) 110.

12 Doha Declaration

13 WTO Fact Sheet.

14 AmCham.

15 Stiglitz 118.

16 Lanoszka 193.

17 Stiglitz 124.

18 "Patent for Treatment of Hepatitis C." Al-Wafd. 17 Nov. 2008.

19 Stiglitz 119.

20 Lanoszka 194.