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CHAPTER THREE

Access to Medicines in Egypt: A Human Rights Approach to IP, Trade and Health

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When the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was ratified by Egypt in 1995, significant changes resulted in the domestic intellectual property (IP) regulations. A new IP law was passed in 2002 to ensure the country's IP regime was TRIPS-compliant and to update the previous law that had been in place since 1949. Such developments ushered in a new era of IP protection in Egypt that, in turn, has posed challenges to the protection of access to medicines.

Adopted by the World Trade Organization (WTO) in 1995, TRIPS is the most comprehensive multilateral agreement addressing IP protection and enforcement. TRIPS raised the bar on pharmaceutical patent protection in developing countries, granting patent-holding drug companies the exclusive right to produce and market new drugs for a period of 20 years. During this time, the patent prevents competitors from producing less expensive generic versions of the same medicine.

This chapter explores the ways in which Egypt, the Arab region's most populous nation and also its largest drug consumption market, is managing to maintain relatively low prices. To date, Egyptians continue to have access to relatively inexpensive medicines because of government price controls and subsidization. In recent years, however, the Egyptian government has been pressured to implement "TRIPS-plus" provisions that would further limit pharmaceutical competition. These pressures have been exerted both in bilateral trade negotiations and in the form of protracted and expensive litigation by multinational pharmaceutical manufacturers against both the Ministry of Health and local generic drug producers. In the face of such pressures, it is essential that Egypt adopt

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a unified and carefully considered policy focused on guaranteeing access to medicines.

The best foundation for such an approach is to base Egypt's access to medicines policy explicitly in the human rights framework. Having ratified the International Covenant on Economic and Social Rights (ICESCR) in 1982, which commits States parties to protect the right to health, Egypt is legally obligated to ensure medicines are available and affordable to all individuals within its jurisdiction. In a March 2009 report, the UN Special Rapporteur on the right to health, Anand Grover, emphasized that "access to medicines forms an indispensable part of the right to health" (Grover 2009, para. 10). The report of the Special Rapporteur specifically addressed the ways in which Free Trade Agreements (FTAs) and TRIPS-plus provisions negatively impact access to medicines and called on states to resist such negative effects and to develop and implement laws and policies that protect the right to health. As recommended by the Special Rapporteur, the Egyptian government should develop a consistent and predictable policy on public health, trade and intellectual property that is firmly based on, and informed by, human rights. A rights-based IP policy would require Egypt to ensure that its laws and practices explicitly affirm the primacy of human rights over trade and IP related interests. In addition, government officials from multiple departments must coordinate their approach so that policies regarding issues such as drug pricing and patents are underpinned by Egypt's commitment to respect, protect and fulfill the right to health. Finally, a rights-based approach also necessitates greater transparency and public participation so that civil society and all interested stakeholders can be involved. Only with this firm foundation will Egypt be able to resist increasing pressures to place the commercial interests of pharmaceutical manufacturers over the obligation to protect the right to health.

This chapter proceeds in four parts. The first part assesses the current level of access to medicines in Egypt within the context of the country's pharmaceutical industry and public health policies. Next, the authors present key court cases related to Egypt's implementation of its TRIPS obligations, examining the extent to which judges have been sensitive to the implications of IP law for access to medicines. This second part concludes that Egyptian judges have, so far, done well in limiting the negative impacts of TRIPS on drug affordability, but without explicitly addressing the right to health. Third, the chapter looks at the increasing pressures being exerted by developed countries to limit pharmaceutical competition in Egypt

through bilateral trade negotiations. Here we find cause for concern, given the uncertain status of public health priorities in trade negotiations. In the fourth and final part, we conclude by advocating a way forward for Egypt that is based explicitly on the prioritization of human rights commitments.

Economic and policy context of access to medicines in Egypt

Egypt has a subsidized healthcare system with state insurance policies covering most, although not all, of the population. Reasonably priced medicines have long been widely available in Egypt, in part because of a strong local pharmaceutical industry. Additionally, drug prices are state-controlled through an official Drug Pricing Committee, which sets the retail price for drugs. The government also subsidizes medicines to ensure that they remain affordable. Despite that, individuals in Egypt still rely heavily on private pharmacies and many purchases are unsubsidized. It is therefore critical that the drugs available in private pharmacies are affordable, so that every sector of society is able to access needed medicines.

Overview of healthcare provision

A major financier and provider of healthcare in Egypt is the Ministry of Health (MOH), which runs a nationwide system of health services ranging from outpatient clinics to large urban hospitals, providing a mixture of inpatient and outpatient care. The MOH services are subsidized through public funding and provided largely free or at a low user fee to all citizens (Rannan-Eliya et al. 1999). While such subsidization helps to protect access to medicines in Egypt, this access is undermined by extremely low levels of government spending on healthcare. The MOH-commissioned National Health Accounts (NHA) of 2005 found that the government only allocated 4.4% of public expenditure to the MOH (MOH 2006).

Efforts have been made to expand and improve public healthcare through the state's Health Insurance Organization (HIO). The HIO is a social insurance agency that was established in 1964. It collects compulsory contributions from all employees and employers in the formal sector. Despite the existence of this program, and a stated goal to cover all Egyptian citizens under the HIO, insurance coverage in Egypt remains fragmented and incomplete. While 77% of Egyptians are covered by some form of health insurance, this figure includes adults with work related insurance, children who receive school

health insurance and newborns who receive specialized insurance from the government (El-Zanaty and Associates 2002, 62). Public coverage through the HIO is currently limited to approximately 50% of the population, focused mainly in the small urban, formal sector (Salah 2007, 28).

Because of the lack of quality public healthcare and insurance coverage in Egypt, and the consequent reliance on private pharmacies, the Egyptian population has a higher than average household spending on healthcare; out of pocket expenditure is as high as 58.8% of total medical expenditure in Egypt according to 2006 data (WHO 2009). The poorest economic bracket reportedly devotes the highest percentage of household expenditures to medical treatments at 10.8% per year (Rannan-Eliya et al. 1999, 30). Egyptian citizens in the low-income bracket are not, therefore, guaranteed access to medicines despite existing efforts.¹

Overview of the pharmaceutical market

Patients in Egypt have traditionally benefited from low prices on drugs, due in large part to a strong local generic pharmaceutical industry and a price control regime run by the state. In 2006, The American Chamber of Commerce in Egypt reported that “Egypt’s retail drug prices are currently among the lowest in the Middle East” (AmCham 2006, 23). The same report noted how the profits of pharmaceutical producers in Egypt have been negatively affected by “government efforts to ensure the affordability of drugs for low-income citizens” (AmCham 2006, 31).

Egypt has built a pharmaceutical industry that is a dominant force within the Middle East and North Africa (MENA) region. In 2005, Egypt’s private pharmaceutical market was judged to be the second most valuable in the Middle East region (AmCham 2006, 10). Its local drug manufacturing industry supplies 30% of the market in the MENA region, making it the largest domestic drug manufacturing base in the area (AmCham 2006, 10).

There are three main categories of pharmaceutical companies in Egypt: 1) public sector companies affiliated to the Drug Holding Company (DHC); 2) local private sector companies; and 3) multinational corporations (MNCs). Approximately half of the drug sector market share, in dollar terms, is

1 A USAID study also found that out-of-pocket spending was higher for women than for men (the latter were more likely to have some form of insurance through employers) and that the highest medical expenditures in Egypt were among individuals aged 50-69 (quoted in Rannan-Eliya et al. 1999, 28-29).

controlled by 10 companies – six of which are MNCs and four of which are local companies (AmCham 2006, 11). Unpublished information for the year 2005 from the DHC Sector of Planning, Systems and Statistics shows that although the public sector accounts for only 13.6% market share in dollar terms, it covers 23.1% of the local drug consumption needs (quoted in Dessouki 2008, 278). The remainder of the market consumption need is covered by the MNCs, with around 20.6% share; local private companies, with 51.5% share; and imported drugs, with 4.9% share (ibid.).

Although Egypt's production of medicines covers more than 90% of its domestic consumption, these medicines are not always the most up to date or technologically advanced drugs (Fayyad 2002). Reflecting limited domestic manufacturing capacity, at least 85% of chemical compounds are imported for assembly, packaging and distribution in Egypt (Abdelgafar 2006, 107, AmCham 2006). Average spending on research and development (R&D) is limited to 1.3% of total spending for public sector companies and 3% for private ones (Abdelgafar 2006, 107). Despite recurrent pledges since the 1960s by foreign subsidiaries to introduce new technologies for domestic manufacture in Egypt, these promises remain unfulfilled (ibid., 108). In the absence of such technologies and bearing in mind the poor level of R&D, the learning process remains slow in the sector and reinforces dependency on foreign materials and technologies. This situation is becoming more critical with the enforcement of the IPR protection provisions of the TRIPS Agreement and will threaten Egypt's ability to protect the right of all the individuals within its borders to enjoy "the highest attainable standard of physical and mental health" (ICESCR 1966, Article 12).

Drug accessibility and availability

Acknowledging the importance of low-priced medicines, the MOH requires pharmaceutical manufacturers to supply government healthcare facilities with large quantities of discounted medicines through institutional sales, also known as national tenders or reverse auctions. Such sales mean that the Egyptian government often pays less than what buyers on the private market pay for the same medicine (AmCham 2006). The MOH typically purchases only the lowest-priced medicines, which are then dispensed in the internal pharmacies of MOH facilities.

A study commissioned by the World Health Organization (WHO) and Health Action International (HAI) in 2007 found that Egypt achieved low

public sector procurement prices compared to an international reference price (WHO/HAI 2007). Based on the standard price survey methodology, the study compared drug prices in Egypt with reference prices taken from the *2003 Management Sciences for Health (MSH) Drug Price Indicator Guide*. This guide draws from price lists of large, nonprofit generic medicine suppliers to developing countries. Researchers classified as unaffordable any of the public sector patient prices that were over 1.5 times the international reference price. Egypt's price ratio for generic drugs surveyed in the MOH's Central Medical Stores ranged from 0.4 to 5.8 with a median price ratio of 1.18 in relation to the reference price, setting it well below the affordability cut-off point of 1.5. The study, which included 34 essential substances based on the WHO/HAI standard core list of medicines, also found that the cost of a month's treatment using generic medicines costs the equivalent of only half a day's wage of an unskilled Egyptian worker (WHO/HAI 2007).

While the findings of the survey appear promising in the case of Egypt, it is important to note several qualifying circumstances. First, patients at public facilities in Egypt generally pay a service fee in which medicines are included. Public sector prices thus do not reflect the full price paid by the consumer, but simply the procurement price paid by the MOH. Second, figures on availability in public facilities are incomplete. The WHO/HAI study found that the procurement price list for the MOH Central Medical Stores contained only 20 of the 34 standard substances studied in the survey. In addition, data was not collected from areas outside Cairo, but was obtained from only four government facilities that were all within the Greater Cairo Area (WHO/HAI 2007). This limited geographical scope likely biased the findings, as government spending is lower in poorer, rural governorates. There is therefore a greater likelihood that shortages would be experienced in the areas not covered by the study. Despite these gaps, this measure of affordability does give an indication of the low prices public facilities pay for medicine relative to wages in Egypt.

Public sector firms play an important role in making affordable drugs accessible. While these firms are commonly criticized for the "poor profitability, the relative inefficiency, and the low labor productivity," they constitute 30% of the local drug consumption needs at affordable prices (Abdelgafar 2006, 98). Throughout the 1990s, however, capital investments in the public pharmaceutical sector have been decreasing by an average of 2.4% each year (ibid., 106). This has commonly been attributed to the

government's general trend to promote privatization, but also to the MOH's recurrent failure to reimburse these companies for purchased drugs, amounting to LE350 million in 2000 (ibid.).

While the public pharmaceutical sector is imperfect, the private pharmaceutical sector creates even greater barriers for access to medicines. According to the WHO/HAI study, private sector retail pharmacy prices for the lowest priced generics were, on average, 68% higher than public sector procurement prices for the same medicines (WHO/HAI 2007, 3). The study also showed that an unskilled government worker would pay between 0.1 and 12.6 days' wages for a month's treatment with standard therapies at a private pharmacy. In one example, treatment for depression with fluoxetine cost roughly 12.6 days' wages with the innovator brand drug and two days' wages with the lowest priced generic substitute (WHO/HAI 2007, 2). Such prices place a heavy burden on families with modest incomes.

Drug pricing system

The Egyptian government uses a variety of strategies to keep many medicines at an affordable price, including drug pricing and subsidization through the public sector. According to a study by the US-based National Economic Research Associates, price controls in Egypt manage to keep drug prices at a quarter of those in the United States, and at half those in other developing countries (Abdelgafar 2006, 136).

The MOH has compiled a list of "essential" and "non-essential" drugs which is updated every two years. In a media interview, the Minister of Health, Hatem El-Gabali, explained that his Ministry:

[C]ontrols drugs on the essential list, including insulin, antibiotics, cardiac, hyper-tension and hypo-tension drugs. [...] Other drugs, such as vitamins, are on the non-essential list, and the ministry controls the pricing, and is responsible for the availability, of only one or two kinds. Other drugs are not regulated by the ministry at all, because they are considered non-vital to the people's well being. (Leila 2006)

While the MOH is charged with negotiating procurement prices for drugs purchased for the public sector, it has also established a Pricing Committee to set the retail price at which the drug will be sold in both private and public

pharmacies.² The MOH's National Drug Policy mandates this committee to achieve "the availability of safe and effective drugs at the lowest possible cost [...] [by] rationalizing the drug pricing system" (MOH 2004-05). This is a cost-plus system in which the Pricing Committee fixes the retail price of the drugs based largely on manufacturing expenses, which vary according to the drug in question. Other inputs, such as taxes and profit mark-ups, are often calculated as a fixed percentage mark-up on all drugs within a given category (WHO/HAI 2007).

Ministerial Decree 314/1991 allows the MOH to set a profit margin of 15% for essential drugs and between 25% and 40% for over-the-counter drugs such as vitamins and painkillers (Ministerial Decree 314/1991, Abdelgafar 2006, 136). Although this decree is technically still in force, more recent Ministerial Decrees regarding the Pricing Committee do not make explicit reference to the concrete figures of Decree 314. For example, Ministerial Decree 148/1996, as well as its successor, Ministerial Decree 96/2004 (which is applicable today), instructs the Committee to undertake the necessary research to determine the prices of medicines "taking into account its economic cost, as well as the pricing guidelines approved by the Minister of Health" (Ministerial Decree 148/1996, Ministerial Decree 96/2004).³

A regulatory affairs specialist, responsible for the registration of drugs in a local pharmaceutical company, explained that the process starts with companies setting their suggested price in the registration form submitted to the MOH's Pricing Committee. During the registration process, the company and the MOH engage in informal bargaining until an agreement is reached on the final retail price of the medicine (Adly interview 2009). The absence or nonimplementation of a coherent and transparent pricing policy often leads to pricing decisions based solely on the discretion of the Pricing Committee. In addition, according to Basma Abdelgafar, an expert in IP issues in Egypt, "when a product is therapeutically distinct there is

2 The Drug Pricing Committee was first established and regulated through Ministerial Decree 404/1976, which was later amended by decrees 177/1994, 148/1996 and, most recently, 96/2004.

3 The National Drug Policy directs the Pricing Committee to regulate and control drug prices based on four factors: 1) actual costs, based on costs of manufacturers/importers plus a fixed mark up; 2) control of profit margins, including standard mark-ups for importers/manufacturers, distributors, and pharmacies; 3) comparison with prices in other countries or other drugs in the same therapeutic category (benchmark or reference pricing); and 4) direct price negotiation with manufacturers of patented drugs and other single source medicines which have no therapeutic substitutes (MOH 2004-2005, 54).

greater price discretion" (Abdelgafar 2006, 136). Firms negotiating over therapeutically distinct drugs typically manage to reach a price that offers substantial profits (Adly interview 2009).

Subsidization policies

The Egyptian government subsidizes a number of key commodities in order to assist lower-income families. In 2007, the government was subsidizing "278 pharmaceuticals for the treatment of chronic diseases such as tumor, renal failure, hepatitis and high blood pressure, in addition to subsidizing insulin and imported infant milk" (Egypt State Information Service 2007). The subsidies system works through the government commissioning a pharmaceutical distribution company – the Egyptian Company for the Sale of Drugs, owned by the Drug Holding Company – to distribute the medicines at set prices. Although the value of subsidy amounts to LE120 million, the government only pays around LE72 million. The LE48 million deficit is borne by the distributing company, which manages to cover for this financial shortfall by compelling pharmacies to purchase other medicines in addition to the subsidized ones, making use of its monopoly and of the pharmacies' keenness to obtain these medicines (Fayyad 2002, 254).

Article 18 of Egypt's intellectual property law also allows for the creation of a fund for the subsidization of medicines (Law 82/2002). The MOH decided to establish the medicines subsidization fund to ensure the stability of the price of medicines so that they remained accessible to the poor. In seven years since the promulgation of the law, however, the fund has not been put into operation, an oversight that also highlights the absence of a coherent policy dedicated to actively protecting the right to health (Fayez interview 2009).

Pharmaceutical litigation and the role of the judiciary

As the previous section discussed, Egypt has adopted a number of measures to keep medicines affordable, both before and after TRIPS. These efforts have produced generally positive results, although the poor still face significant barriers, suggesting the need for more explicit emphasis on access to medicines as a human right. This second section examines the current state of Egyptian jurisprudence on IP and health, inquiring whether courts are doing their part to assure access to medicines.

Egypt's judiciary has come to play a major role in recent years in adjudicating claims related to the control of knowledge in the area of the manufacture and

marketing of medicines. Even before the TRIPS Agreement took effect with regard to pharmaceutical products in January 2005, Egyptian courts began receiving and hearing a number of important lawsuits challenging decisions by health authorities or practices of local producers of generic medicines. This section highlights three of these court cases in the period since 2001, drawing on original court documents and parties' submissions. This type of litigation is in no way exclusive to Egypt. Multinational pharmaceutical producers have been using litigation in a number of countries, both developing and developed, seeking judicial precedents establishing TRIPS-plus protections that are not explicitly contained in domestic laws or trade agreements.

In many other countries, such court cases are often high profile, attracting extensive media coverage and academic research. They also usually represent rallying points for human, patient and consumer rights groups and other civil society advocates. Those groups endeavor to use court cases to expose the strategies and motivations of large multinational pharmaceutical companies seeking to prolong their market monopoly to the maximum possible extent. Conversely, the cases reviewed in this section have received little public attention in Egypt. Research and analysis about their origins, developments and outcomes are almost nonexistent. A thorough look at these cases is essential, however, to understanding the actual effect of the TRIPS Agreement on access to medicines in Egypt.

TRIPS self-execution: the first legal challenge

Notably, the first health related legal challenge filed in court after Egypt's ratification of TRIPS came from a local generic company, which protested some of the earliest steps taken by the government to implement the agreement. The case was brought by Apex Pharma against Egypt's Prime Minister and other officials in 2001, before the promulgation of the 2002 IP law. The complaint challenged the government's first decree granting exclusive marketing rights to a foreign patent applicant. Exclusive marketing rights give holders of foreign patents the sole authority to sell or distribute a substance even prior to the consideration of their Egyptian patent claim. Other companies are legally prevented from making, using or selling the same substance. The effect is a monopoly over a particular drug, as if the patent had already been granted.

The TRIPS Agreement allowed for a 10-year transitional period in relation to pharmaceutical patents. Countries availing themselves of this period were required to establish a "mailbox" as soon as the agreement entered

into force. The mailbox meant that applications for patents could be filed immediately, notwithstanding the fact that no applications would be examined until January 2005 (WTO 1994, Article 70(8)). Article 70(9) of TRIPS mandates member states in this category, including Egypt, to grant exclusive marketing rights to products whose applications are pending under the mailbox. These exclusive marketing rights remain in place for a period of five years or until the application is granted or rejected, whichever period is shorter (WTO 1994, Article 70(9)).

While TRIPS entered into force in Egypt in 1995, the mailbox was only established in the year 2000, by virtue of Decree No. 547/2000 of the Prime Minister. The Decree incorporated the relevant TRIPS provisions related to the mailbox and mandated the Chair of the Academy of Scientific Research and Technology (ASRT), the parent institution of Egypt's Patent Office, to grant the exclusive marketing rights stipulated in Article 70(9) to applicants that meet the Article's criteria. For the exclusive marketing rights to be granted, a patent application must have been filed and a patent and marketing approval given for the same product in another member state (WTO 1994, Article 70(9)).

The first such grant was issued in August 2001 for the multinational US-based company Eli Lilly, one of the world's ten largest pharmaceutical producers. The drug was Olanzapine, produced under the commercial name Zyprexa, a medicine used for the treatment of short-term schizophrenia and related psychosis. Eli Lilly had filed a patent application for the product in the mailbox in 1996 (CAJ 2003).

Apex Pharma, which had applied for the registration and marketing of a generic version of the same drug under the name Olapex, brought a challenge before the Court of Administrative Justice (CAJ), which has jurisdiction over disputes involving state authorities. The 2001 lawsuit (No. 282/56) argued that the Prime Minister had no authority to issue decrees implementing an international agreement without parliamentary approval. The plaintiffs also protested that they had intended to sell the generic product at one-fifth of the price of Eli Lilly's brand name drug, and that the exclusive market authorization would thus inhibit competition by more affordable generic versions of the same medicine (CAJ 2003). The Court, however, found against the plaintiffs on 11 March 2003, upholding the challenged decrees. The Court reasoned that Egypt, having ratified the TRIPS Agreement, came under an obligation to implement it immediately and that the appealed decree fell under the government's duty to respect its contractual obligations (CAJ 2003).

Apex Pharma appealed the decision before the Supreme Administrative Court (SAC), which is Egypt's court of last resort in administrative matters. Here they secured a favorable decision on 25 December 2004. The SAC ruling in case no. 6965/49 did not address the substantive matter of access to affordable medicines and public health policy priorities. Instead, the decision was based on the procedural ground that the government should have sought parliamentary approval before establishing the implementation regime of TRIPS. This step had, by then, actually taken place in 2002, when the government presented to Parliament the IP Law No. 82. In its reasoning, the SAC stated:

Whereas the matters addressed by these decrees are considered to be among matters reserved in principle for the legislative authority, since they interfere with the rights and liberties of individuals; and whereas the elements of these decrees were not based on any laws, [...] the decrees therefore constituted a grave violation of the Constitution and the law (SAC 2004).

On the surface, the case appears to be a legal dispute over whether TRIPS was a self-executing treaty, where ratification is sufficient for immediate enforceability, or whether it required implementing legislation before it became part of Egyptian law. As stated, the second view ultimately prevailed and the matter resolved when the domestic IP law was adopted, including a provision regulating the mailbox and related exclusive marketing rights (Law 82/2002, Article 44). The case could, however, have held greater precedential importance had the SAC decided to address the substantive issue of the state's obligation to ensure access by citizens to affordable treatment.⁴

Nevertheless, the case retains importance as the first known incident where Egypt's judiciary became alerted to the potential disputes arising from the application of TRIPS. The outcome showed the judiciary's willingness and ability to monitor the implementation of the agreement and, in this case, to strike down government decisions. The fallout from this case continued, however, as discussed below.

4 At the time the decision was rendered, the drug in question was being sold without competition at LE300 (US\$55), compared to the significantly cheaper price proposed for the generic version, which was LE60 (US\$11) (Dessouki 2008, 165).

Round two: Eli Lilly vs Minister of Health and Others

The broader impact of the SAC ruling in the Olanzapine case summarized above was to nullify the Prime Ministerial Decree allowing for temporary protection of pharmaceutical products during the transitional period. Apex Pharma proceeded immediately with the registration and marketing of its generic version, Olapex. Although the case was concluded in December 2004, Apex was only able to conclude the MOH registration and pricing procedures in May 2005; it was not until one year after the ruling that the generic version finally entered the market (MOH interview 2006).

At this point, Eli Lilly knew it was a matter of months before their patent application would be granted or rejected. Nevertheless its lawyers immediately sought a court injunction preventing Apex from marketing the cheaper generic. First, they filed a court motion requesting that the implementation of the SAC 2004 ruling be suspended. One week later, on 24 January 2006, they wrote to the Minister of Health requesting that the registration and marketing approvals granted to Apex be revoked pending the outcome of the new court motion. The MOH declined, stating that Olapex approvals were only granted following the SAC's nullification of Eli Lilly's exclusive marketing rights (CAJ 2008). Eventually, in April 2006, Eli Lilly filed a new court case before the Court of Administrative Justice against the Minister of Health, the Prime Minister, the Chair of ASRT and Apex Pharma arguing that it was unlawful to proceed with the marketing of Olapex pending the outcome of Eli Lilly's motion filed against the 2004 SAC decision (no. 22218/60). The suit requested that the generic Olapex be immediately withdrawn from the market, as well as financial compensation of LE5 million (US\$900,000) to be paid jointly by MOH and Apex (Eli Lilly 2008). This lawsuit appears to be Egypt's first TRIPS related legal challenge by a multinational pharmaceutical corporation.

The CAJ started hearing the case in June 2006. Four months into the case, on 31 October 2006, the Egyptian Patent Office approved Eli Lilly's application and granted a patent for their brand name product, Zyprexa, until 2016, two decades since obtaining marketing approval in February 1997 (Eli Lilly 2008). Eli Lilly decided, however, to proceed with the case, demanding financial compensation for the few months in early 2006 during which the Egyptian generic was able to compete. Strategically, continuing the litigation served two purposes. First, the potential establishment of a favorable judicial precedent: specifically, that drug regulation authorities

may not approve a generic drug while a related patent dispute is active before Egyptian courts. Second, an award of damages would give health regulatory authorities a reason to become extremely cautious before registering generics in the future, for fear of similar litigation. Either outcome would effectively delay the launch of future generic drugs, decreasing competition and price reduction.

In a ruling issued on 20 December 2008, the Court found that the MOH decided to register the Egyptian generic at a time when Eli Lilly had no special rights related to the drug, since that decision was adopted only following the nullification of Eli Lilly's exclusive marketing rights; therefore, the government was not liable for any results emanating from this decision. The Court also dismissed Eli Lilly's procedural argument that the generic drug's approval was granted while a motion was still pending before courts. The ruling reasoned that the motion had no legal effect because it was filed before a civil court which had no jurisdiction over the matter, as opposed to the administrative court. The ruling avoided setting a firm precedent, but signaled that Egypt's administrative court judges were disinclined to allow the abuse of litigation as a procedural tactic to delay the entry of generic competition (CAJ 2008).

Data exclusivity on trial: Pfizer vs EIPICO

In 2002, the US-based multinational company Pfizer, the world's largest research-based pharmaceutical manufacturer, attempted to use Egyptian courts in order to establish TRIPS-plus protection for data exclusivity. Data exclusivity refers to the policy followed in some countries of requiring off-patent manufacturers of a drug to independently reproduce the clinical trials demonstrating the drug's safety and effectiveness, rather than merely demonstrating that the generic drug is chemically equivalent to the one already registered. Because these trials are very expensive and time consuming, the ultimate effect of a data exclusivity policy is to delay the entry of generic competition, even after the patent has expired, or where a patent application has been denied.

The case involved Lipitor, often referred to as the world's best selling drug, used to lower cholesterol. Pfizer had registered the drug in Egypt and obtained market authorization in June 1998, submitting a patent application for it two months later. In December 2000, while Lipitor's patent application sat in Egypt's mailbox, a generic version of the drug, Ator, was registered by

the Egyptian International Pharmaceutical Industries Company (EIPICO). Pfizer decided to challenge this decision in court claiming that the generic was registered on the basis of confidential clinical data provided by Pfizer to the drug registration authorities.

Although Lipitor was not under patent in Egypt, Pfizer's data exclusivity argument asserted that: 1) such clinical test data fell under "undisclosed information" protected by the TRIPS Agreement and its predecessor, the Paris Convention of 1967; 2) drug regulatory authorities must grant exclusive rights to the originator providing this data by refraining from relying on it for a certain period of time; and 3) regulatory authorities must require generic producers to repeat the same clinical trials and regenerate the same data when attempting to register a generic version of a drug during that period of data exclusivity (Pfizer 2003), which usually lasts for five years (in the United States) or 10 years (in the European Union).

These arguments run contrary to the established practice in most developing countries, including Egypt, where generic producers are only obliged to submit to regulatory authorities data on the bioequivalence of the generic. In other words, generic producers must only show that the submitted drug works in the same way as the originator's version, implying that it meets the same safety and efficacy standards already proved by the originator's clinical trials.

According to the WHO, requiring data exclusivity and generic producers to regenerate test data as a prerequisite for registering their products is objectionable on a number of grounds. First, it would lead to significant delays in the registration and marketing of cheaper generics. Second, it would substantially raise the retail price of generic drugs, due to the high cost of reconducting these clinical trials. Third, it would violate medical ethics because it means repeating clinical trials involving humans without any scientific or public health value but for purely commercial reasons. Finally, granting data exclusivity rights would, in practice, force most generic producers to delay the launch of their products until the end of the data exclusivity period because they cannot afford to conduct the trials (WHO 2006). The effect is a *de facto* patent for unpatented drugs, which in turn delays generic competition and the resulting reductions in prices (*ibid.*).

Contrary to the argument put forward by Pfizer and other proponents, data exclusivity has no basis in the TRIPS Agreement. Article 39(3) places an obligation on regulatory authorities only to protect such data from

“disclosure” and from “unfair commercial use” (WTO 1994). Since generic producers never gain access to this data submitted by originators to regulatory authorities, neither protection is breached when a generic manufacturer submits bioequivalence studies. The WHO has concluded that:

From the perspective of public health and access to medicines, it is preferable not to grant data exclusivity. Moreover, there is no requirement under international law that countries grant data exclusivity; countries only have to provide for data protection. (WHO 2006)

This understanding of Article 39(3) of TRIPS was reflected in Egypt’s 2002 IP law, in Articles 56-57. Pending the drafting and parliamentary approval of the bill, the issue was regulated through a Decree of the Prime Minister (No. 2211/2000) “Regarding the Confidentiality of Information Related to Agricultural and Pharmaceutical Chemical Products,” which in turn used the language and requirements of Article 39(3).

Interestingly, Pfizer did not initiate its lawsuit against EIPICO immediately after the generic was registered and received market approval. The case was filed on 18 June 2002, 18 months after the generic Ator entered the market and exactly two weeks after the IP law had been promulgated and entered into force. The timing might suggest that foreign pharmaceutical companies, including Pfizer, had hoped that the national IP law would establish periods for data exclusivity similar to those applied in the US and Europe; once that hope evaporated the companies turned to courts to push them to effectively write data exclusivity into the law (Zagazig Court 2003).

Although the lawsuit was in effect a challenge to the registration and market approval granted to the generic Ator by the MOH, Pfizer chose not to sue the Ministry, but rather the generic producer. Pfizer may have been trying to avoid the negative publicity associated with suing health authorities for providing the public with a cheaper medicine. This could also explain why the lawsuit was filed in the rural city of Zagazig, where EIPICO’s factories are based, rather than in Cairo, where the headquarters of both parties are located. Pfizer may also have been trying to avoid a direct confrontation with the Egyptian government.

Suing a private company, rather than the government, also meant that the case would be heard before a civil court, as opposed to the administrative judiciary system. Pfizer may have decided to use this case as a test for

the capacity of civil courts outside the big urban centers to deal with complicated patent claims. EIPICO's lawyers requested that the civil court transfer the case to the CAJ since it involved an administrative decision, but the request was not granted.

The case (no. 1855/2002) was thus heard by the Zagazig Court of First Instance. Pfizer's first brief explicitly framed the claim as one of "unfair competition," due to the significant discrepancy in the retail price of Ator compared to that of the originator's Lipitor. The brief protested that "without engaging in any serious investments [...] [EIPICO] is selling the pharmaceutical product that is based on the scientific matter Atorvastatin, owned by the complainant, at a price that is 40 percent below than that of [Pfizer's]" (Pfizer 2003). Pfizer demanded the immediate cease of the manufacture, distribution and advertising of Ator, as well as LE6 million (US\$1 million) in civil remedies to compensate for lost sales (Zagazig Court 2003).

Throughout the lawsuit, the role of academic experts on patents was prominent. At the first hearing in October 2006, EIPICO's lawyers submitted to the Court an expert report obtained from a private research unit at the pharmacology school of Ain Shams University in Cairo. The report clarified the technical issues and supported the claim of the respondent company that it was possible to manufacture Atorvastatin without reliance on undisclosed data. The report gave numerous examples of other companies around the world who have produced generic versions of the drug (SCA 2007).

Confronted by novel and complicated technical and legal issues, the Court decided that it was unable to reach a decision on the matter without relying on independent expert advice. The Court therefore mandated the Chair of the National Research Center in Cairo, a state-run institute affiliated to the Ministry of Scientific Research, to appoint a "commission of three experts on chemical pharmacology and drug manufacture" to examine the matter and submit a report to the Court with recommendations (Zagazig Court 2003, 4). Six months later, the commission submitted a detailed and meticulously researched 70-page report with a large volume of annexes. This document untangled the complicated web of IP issues and explained all the relevant provisions in both the TRIPS Agreement and Egyptian laws. The report concluded that there was no violation of any laws in the practice of EIPICO (SCA 2007). On 30 April 2005, the Court endorsed the expert recommendation and found against Pfizer (Zagazig Court 2005).

The outcome of this case was positive in that it found against the attempt to prevent Egyptian pharmaceuticals from utilizing existing knowledge on essential drugs. However, the three-page decision once again missed an important opportunity to address the human rights dimension of the matter. The attorney representing EIPICO, Professor Hossam Al-Ahwany, attempted to alert the Court to the significance of the case on the first page of his first brief:

The fact is that this lawsuit is the first case to come before judiciary with regard to unfair competition in the field of drug manufacture, or what is referred to as “undisclosed information” by the legislature in the Law for the Protection of Intellectual Property (no. 82/2002). This case directly affects the health of Egyptian citizens, and the stance of foreign, multinational pharmaceutical companies. (EIPICO 2003)

The decision, however, merely summarized the facts of the case and declared that the Court accepted the technical views detailed in the expert report, making no reference to the public health concerns.

Seeking seizure: Pfizer vs Memphis and Delta

EIPICO was not the only local generic producer that Pfizer targeted with Lipitor related litigation based on claims of data exclusivity. In 2003, a privately owned company, Delta Pharma, collaborated with the public sector company Memphis Pharmaceuticals and Chemicals, to produce another generic version under the name Atorstat. Pfizer decided to take both companies to court. Given that the case against EIPICO was still pending before the Zagazig Court, Pfizer opted to test a swifter legal strategy: seeking a temporary order to halt the distribution of competing generics without giving the Court the opportunity to consider the substantive matter of data exclusivity.

On 13 May 2004, Pfizer filed a motion before the Court of Provisional Matters, which has the authority to issue temporary injunctions pending the consideration of substantive claims. The motion sought an immediate and temporary injunction to halt all production, marketing, sales and distribution of Atorstat and any other generic version of Lipitor within Egypt. The motion further asked the Court to include in the injunction a provision banning the exportation or importation of any drug based upon Atorvastatin (Pfizer 2004).

Clearly, Pfizer sought a rapid solution to stop the competition, rather than face the type of extended court fight unfolding before the Zagazig Court. A side benefit of this legal strategy was that it would test, for the first time, the enforcement of the provisional measures process stipulated in the new IP law.⁵ While the 2002 law gave petitioners the right to seek such an injunction from any “competent court,” Pfizer’s choice of the Court of Provisional Measure strongly suggests a preference for a court that, by its very jurisdiction, would not address the substantive issues underlying the claim.

The Court of Provisional Measures was not convinced that the matter merited such a drastic injunction without examination of the facts or merits of the case. Accordingly, the motion (no. 43/2004) was denied on 19 May 2004 (Cairo Court 2004a). Pfizer submitted a petition for reconsideration before the Northern Cairo Court of First Instance (Pfizer 2004). This petition was also denied on 28 November 2004, again without pronouncements on the facts (Cairo Court 2004b). Pfizer submitted a further appeal to the Appellate Court on 26 February 2005. By May 2005, however, the Zagazig Court had issued its above-mentioned decision on the EIPICO dispute. In light of that decision, the chances of success for the case against Memphis and Delta were low. This might explain why, in May 2005, Pfizer’s lawyers missed a number of scheduled hearings before the Northern Cairo Appellate Court, prompting the Court to close the appeal without rendering a decision.

The role of judges: challenges ahead

The cases reviewed above highlight the increasingly prominent role played by judges in enforcing and interpreting IP protections in Egypt. It is therefore essential to ensure that the training and capacity-building activities for judges on IP matters take into account human rights and public policy concerns as they relate to access to affordable medicines. Notably, none of the decisions

5 Article 33 of the 2002 IP law reads as follows:

The holder of a patent or a utility model may request the president of the competent court, as may be the case, to order conservatory measures against products or goods that are claimed to imitate a patented product, according to the detailed description established in the patent or utility model document. The necessary conservatory measures shall be ordered to preserve such products and goods in their state.

The aforementioned order may be issued before instituting the proceedings. Such order shall lapse if the proceedings are not instituted within eight days from the date of the injunction.

Article 62 of the law extends the application of Article 33 to the section on “undisclosed data.”

reviewed above addressed substantive issues of human rights and the state's obligation to ensure access to medicines. These pioneering cases all reached access-friendly outcomes, but solely on procedural grounds or through a general endorsement of expert testimonies.

In an interview with the authors, Judge Hassan Badrawi discussed the challenges faced by the Egyptian judiciary when dealing with IP cases post-TRIPS. Judge Badrawi is currently the Assistant Minister of Justice for Parliamentary Affairs and was the rapporteur of the drafting committee of the 2002 IP law. He has been advising the government for many years on IP issues, both at the Ministry of Justice and through his membership in the Minister of Health's Advisory Committee on Intellectual Property of Medicines. Judge Badrawi said that in deciding to bring cases before Egyptian courts related to patents and data exclusivity, foreign pharmaceutical companies were hopeful that the Egyptian judges' lack of expertise and knowledge of IP issues would lead to decisions in their favor. He explained: "Foreign companies knew perfectly well when they filed these court cases that the law was not on their side, but they were betting that judges don't know, don't understand. They were surprised to see how our judges were aware of the subject" (Badrawi interview 2009).

Judge Badrawi noted that the number of lawsuits filed by pharmaceutical companies decreased once it became evident that Egyptian judges understood the issues involved in IP litigation. The pharmaceutical companies also became more explicit in their demands: "First, they were adamant that what they were asking for was only the enforcement of TRIPS and tried to convince us of this. When they realized we were not falling for that, they finally admitted and started asking for TRIPS-plus" (Badrawi interview 2009).

While the judges in Egypt have proved to be more knowledgeable and resistant to pharmaceutical demands than expected, significant challenges still remain. One subject that has attracted growing attention in recent years and could appear in future cases in Egypt involves the relationship between competition policy and IP (Correa 2007). The patent/antitrust intersection is characterized by a classic tension: patents intend to eliminate competition to reward innovation, whereas antitrust intends to protect competition (Kaplou 1984). In determining the proper extent of IP protections, courts are often obliged to strike a balance between the benefits of protection and competition. It is difficult, however, to believe that courts have the technical capacity to

accurately balance incentives to innovate versus importance of dissemination (Elhauge and Geradin 2007). This is especially true in the case of developing countries, which typically have little or no tradition in the application of competition law and policies. Additionally, weak institutional structures may hamper effective implementation of the laws.

In 2005, Egypt adopted the Competition and Anti-Monopoly Law (no. 3/2005), which could possibly be harnessed to serve public health and access to medicines. If and when this law becomes more actively enforced, it could be effective in hampering anticompetitive practices in the pharmaceutical industry, ultimately promoting greater competition and lower prices. The TRIPS Agreement (Article 40) specifically provides for the possibility of regulating anticompetitive practices in licensing agreements. It is important that judges recognize Article 40 and apply Egypt's Competition and Anti-Monopoly Law in a manner that prioritizes the right to health and access to medicines.

TRIPS-plus proposals in bilateral trade agreements

The decrease in the number of TRIPS-plus court cases brought by multinational pharmaceutical companies in recent years has coincided with the intensification of pressures to include the same provisions in bilateral trade agreements. This section examines two free trade agreements where patent related TRIPS-plus provisions feature prominently. It will look at the provisions contained in agreements with the European Free Trade Association (EFTA) and the types of provisions that the US are likely to demand in any future US-Egypt FTA.

EFTA-Egypt Free Trade Agreement

On 13 June 2007, the Egyptian People's Assembly ratified a trade agreement with the European Free Trade Association (EFTA), an organization of four European states: Switzerland, Norway, Iceland and Liechtenstein. Egypt currently benefits from limited exports to EFTA states (US\$80,268 in 2007), mainly in agricultural commodities (EFTA 2007a). In contrast, imports from the EFTA states are more substantial (US\$453,022 in 2007), with Swiss pharmaceutical products ranking first at US\$82,654 (*ibid.*). As detailed by the previous chapter, the EFTA has recurrently used bilateral agreements to push for TRIPS-plus protections, including data exclusivity and restrictions on compulsory licenses.

As opposed to previous agreements with Chile, Lebanon and Tunisia, the data protection article of the EFTA-Egypt Agreement does not require data exclusivity.⁶ Instead, it uses the words of Article 56 of the Egyptian IP Law, protecting the data against “disclosure and unfair commercial use” (EFTA-Egypt 2007, Annex V, Article 3(e)).⁷ However, the EFTA-Egypt FTA fails to specifically provide for disclosure for the purpose of public health. Professor Frederick Abbott, a well-known international expert on IP and health, notes that this omission is not particularly problematic, however, because of the reference to Article 39(3) of the TRIPS Agreement that preserves this authority (Abbott interview 2009).

A second area of concern in EFTA agreements has to do with limitations on compulsory licensing, the grant by a government of permission to use a patented invention without the authorization of the rightsholder. The TRIPS Agreement does not limit compulsory licenses exclusively to the domestic market.⁸ Nevertheless, some EFTA agreements specify that compulsory licenses must be issued “only in order to satisfy the domestic market according to reasonable commercial terms,” including those with Morocco and Jordan (EFTA-Morocco 1997, Annex V, Article 3(1), EFTA-Jordan 2001, Annex VI, Article 3).⁹

- 6 An example of the way in which the provisions of some of the EFTA FTA agreements block marketing approval of generics on the basis of undisclosed data can be seen from the EFTA-Lebanese FTA which states that applicants are prevented from “relying on or referring to undisclosed test or other data submitted by prior applicants to the competent approval authorities[...] for a period, from the date of approval, of at least six years [...] unless the first applicant is adequately compensated” (EFTA-Lebanon 2004, Annex V, Article 4).
- 7 As discussed above, protection against *disclosure* need not prevent the Egyptian drug regulation authorities from *using* undisclosed data to assess the safety and efficacy of generic medicines.
- 8 Article 31(f) of the original TRIPS Agreement states that compulsory licenses should be “authorized predominantly for the supply of the domestic market of the Member authorizing such use.” This provision was regarded as imposing unreasonable restrictions on countries whose limited manufacturing capacity prevented them from making full use of the TRIPS flexibilities. The WTO General Council Decision of 30 August 2003 responded to this situation by modifying TRIPS to allow the import up to 100% of the generic medicine that has been produced under compulsory license in a different state, provided that certain strict conditions are met (WTO 2003).
- 9 While the EFTA-Egypt agreement contains no clear restrictions to prevent the issuance of compulsory license for drugs used in Egypt, restrictions in other FTAs may have consequences for Egypt's pharmaceutical exports. Egypt's pharmaceutical sector currently holds the largest domestic drug manufacturing base in the MENA region, supplying 30% of the total market and exporting to countries in Africa, Asia and Eastern Europe (AmCham 2006). As its manufacturing capacity develops, Egypt may have the opportunity to exercise its right to produce local generic copies of unaffordable drugs that are still under patent. Restrictions on compulsory licenses have the potential to close the door forever to access to these drugs by less developed countries that depend on Egypt's pharmaceutical industry for affordable medicines.

Compared to other developing countries, therefore, Egypt succeeded in negotiating terms in its FTA with EFTA that do not undermine the accessibility of medicines. The insistence by Egyptian negotiators to not accept any TRIPS-plus provisions led to a significant prolongation of the negotiations with EFTA. According to a senior Swiss diplomat who followed the negotiations closely between EFTA and Egypt, and who spoke to the authors on condition of anonymity, the issue of patent protection of pharmaceuticals was “a very important element for the Egyptian government” and one of the main reasons that contributed to a “stalemate” after six rounds of negotiations between 1998 and 2004 (Swiss diplomat interview 2009). Negotiations were resumed in June 2006 and concluded after two rounds with the adoption of the agreement in Davos, Switzerland in January 2007.

Despite this success by Egyptian negotiators, provisions pertaining to the implementation of the EFTA-Egypt agreement could yet have serious consequences for the accessibility of medicines in Egypt. Article 23(4) of the FTA establishes a regular review mechanism to develop and implement the agreement’s intellectual property provisions of the agreement (EFTA-Egypt 2007). Article 23(5) further foresees technical assistance from the EFTA states, offering technical experts from EFTA direct access to the consulting parties in the case of disputes over development and implementation of the agreement. It is unclear whether or not experts from Egypt or members of Egyptian civil society who could represent the interests of the Egyptian patients will be given similar access. Should a dispute arise and the Joint Committee fail to “arrive at a commonly acceptable solution” within three months, Article 40(1) of the FTA allows parties to respond with undefined “provisional re-balancing measures” (ibid.). These provisions may constitute a back door means to exert further pressure upon Egypt to adopt TRIPS-plus implementations or interpretations.

US-Egypt Free Trade Agreement

In 2003, as a response to growing instability following September 11, President Bush announced his intention to encourage “an economically liberated Middle East,” leading to the reopening of talks between the US and Egypt to prepare for FTA negotiations (AmCham 2003). Shortly after Bush’s reelection in 2004, however, a letter sent by the Pharmaceutical Research and Manufacturers of America (PhRMA) called for the US to halt FTA discussions with Egypt. The letter, addressed to the United States Trade

Representative on 25 January 2005, protested the marketing approvals granted by the Egyptian Minister of Health, 'Awad Tageddine, to 850 generic medicines (EIPR 2005b). The letter highlighted pharmaceutical policy as a key area of conflict between the two countries' trade negotiators.

Other countries such as Jordan (2000), Chile (2003), Bahrain (2004), Australia (2004), Morocco (2004) and Central American-Dominican Republic (2005) have concluded FTAs with the US, which commonly feature TRIPS-plus provisions. Among the most notorious features of these agreements are the limitations on compulsory licensing, enforcement of data and market exclusivity, and linking market approval to patent status. Only two out of the six FTAs provide for the use of a patent without the authorization of the rightsholder (US-Jordan 200, Article 4(20), US-Australia 2004, Article 17(9)(7)). In most other FTAs, the compulsory license right reserved by TRIPS is made contingent upon permission given by the patent owner. The agreements also typically mandate a five-year period of data exclusivity, starting from the date marketing approval was granted to the patent holder (US-Chile 2003, Article 17(10)(1), US-Australia 2004, Article 17(10)(1), US-Bahrain 2004, Article 14(9)(1).

A third TRIPS-plus provision commonly found in these agreements is a requirement that the drug regulatory authority ensure that the medicines it approves for marketing do not violate any patents.¹⁰ The financing and organization of patent status monitoring and prosecution, previously considered a private interest undertaken by the patent holder, places a new burden on public agencies. Drug Regulatory Authorities (DRA) are unprepared for this responsibility, which will slow the process of approving generic drugs. In addition, putting such a responsibility on the DRA ultimately alters its mandate from ensuring the health of the patient to playing the role of the "patent police."

A few months after the letter sent by PhRMA to USTR on the issue of data exclusivity in Egypt, the Egyptian Prime Minister Ahmed Nazif spoke publicly about the issue. At a press conference held on 18 May 2005, Prime Minister Nazif received a question about difficulties in FTA discussions, to which he answered:

10 There is no linkage between marketing approval and patent status in the Jordan FTA, but every subsequent FTA includes such a connection.

Egypt is a state that respects its international obligations, including all the provisions of the agreement on the protection of intellectual property rights (TRIPS). Egypt has noticed that the US imposes more severe restrictions in this regard than those included in the international agreement. That is why the Egyptian government is conducting an assessment of the possible negative impacts on Egyptian society and the prices of medicines in case a bilateral free trade agreement is reached with the US. (EIPR 2005a)

This encouraging public statement highlighted that Egyptian officials were highly aware that the United States' demands in FTA discussions went beyond those required in TRIPS and would have a "possible negative impact" on access to medicines.

An Egyptian diplomat who was intimately involved in FTA discussions with the United States at the time, however, indicated that the Prime Minister's statement reflected only one trend within the Egyptian government. According to this source: "There was a position among some ministers and senior officials that advocated for the simplistic formula of 'quantification;' i.e. if the Americans insist they want excessive IP provisions in return for an FTA, let's calculate how much that would cost us and ask them for a cash advance" (Egyptian diplomat interview 2009). It appears that this quantification viewpoint did not ultimately prevail, or else was not acceptable to US negotiators. The United States halted discussions in late 2005, within one year of PhRMA's complaint.

In both the EFTA agreement concluded in 2007, and in the stalled negotiations with the United States, Egyptian negotiators resisted any measures mandating new IP protections that might negatively impact access to medicines. The interests of these trade partners, however, continue to lie in pushing for TRIPS-plus measures to benefit their own pharmaceutical industries. The next and final part of this chapter advances a proposal to put Egypt's access to medicines policy on firmer footing by explicitly grounding it in the right to health.

The way forward: a human rights approach

Even after the implementation of TRIPS, access to medicines has continued to be protected by Egyptian judges who have rejected the legal arguments of multinational pharmaceutical companies, and by Egyptian negotiators

who have succeeded in avoiding TRIPS-plus provisions in bilateral trade agreements. Foreign pharmaceutical companies, however, continue to have an interest in restricting generic competition. Efforts to push TRIPS-plus provisions are likely to continue through additional court cases and through negotiation, interpretation and application of bilateral trade agreements. In order to combat these efforts, it is essential to develop a coherent argument regarding the legal priority of access to medicines. One of the most powerful ways to shape this argument is to base it explicitly on international human rights commitments.

International human rights law is based on the principle that every state is obliged to respect, protect and fulfill the basic rights of individuals within its borders. In the case of access to medicines, the state should ensure that its laws, policies and practices affirm the primacy of human rights over trade and IP-related interests. In particular, the state has an obligation to respect, protect and promote the right to health. This right has been recognized by the United Nations as “a fundamental human right indispensable for the exercise of other human rights” (CESCR 2000, para. 1).

Access to medications is a critical component of the right to health so that disease and sickness can be effectively tackled. In 2000, the UN Committee on Economic Social and Cultural Rights, which interprets and monitors the implementation of the ICESCR, issued General Comment No. 14, an authoritative legal opinion interpreting Article 12 of the Covenant. This Comment stipulated that the state has an obligation to make medicines available and affordable for all individuals within its jurisdiction (CESCR 2000, para. 12(b)). States Parties to the ICESCR also have an obligation to protect individuals from violations of the right to health by third parties such as international institutions and pharmaceutical corporations (*ibid.*, para. 33). Moreover, in his 2006 report to the UN General Assembly, the Special Rapporteur on the right to health elaborated on the responsibilities of states to ensure that “medicines are available, accessible, culturally acceptable and of good quality” (Hunt 2006, paras 47-51). Furthermore, the Millennium Development Goals (MDGs) identified efforts “to provide, in cooperation with pharmaceutical companies, access to affordable essential drugs in developing countries” as a central goal for development (Target 8(E)).

This legal obligation on states to ensure that basic medicines remain affordable and accessible inevitably leads to tensions with their trade obligations regarding intellectual property. In August 2000, the UN

Sub-Commission on the Promotion and Protection of Human Rights issued a statement recognized that “actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights in relation to, *inter alia* [...] restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health” (OHCHR 2000). Nevertheless, the primacy of human rights over trade related interests has been made explicit in a number of international instruments. In 2001, the ESCR Committee issued a General Statement on “Human Rights and Intellectual Property” that emphasized that “the realms of trade, finance and investment are in no way exempt from human rights principles,” and that both national and international intellectual property regulations, including TRIPS, must abide by international human rights law (CESCR 2001, para. 3).

Indeed, the TRIPS agreement does allow for a human rights sensitive approach to intellectual property regulation. Articles 7 (“objectives”) and 8 (“principles”) inform parties in their interpretation of TRIPS so that public health commitments are upheld. Article 7 emphasizes that any IP protection must be enacted “in a manner conducive to social and economic welfare” with “a balance of rights and obligations.” Article 8 further affirms that “members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition.” The Doha Declaration on TRIPS and Public Health further affirms in Article 4 that “the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all” (WTO 2001). In addition to general principles in support of the need to uphold the right to health, the TRIPS Agreement contains articles that limit patentability (Articles 2 and 3), make exceptions to the exclusive rights of patent holders (Article 30), and provide for compulsory licensing (Article 31).

An explicit human rights approach to IP, trade and health would require the Egyptian government to actively address the primacy of the right to health, despite potential conflicts with IP regulations. In order to promote, protect and fulfill the right to health, the government should, amongst other things, aggressively apply the provisions in TRIPS that protect the right to health and limit excessive patent protection. In his April 2009 report to the UN Human Rights Council, the Special Rapporteur on the right to health recommended that all states make full use of TRIPS

flexibilities (Grover 2009, para. 96). Although such flexibilities have been enshrined in Egyptian domestic law, the country has not actively employed them. In addition, the Egyptian government should take other active steps recommended by the Special Rapporteur, such as adopting pro-competition measures to ensure that there is no abuse of the pharmaceutical patent system (*ibid.*, para. 103).

A rights-based approach would also encourage the Egyptian government to formulate a consistent set of arguments for maintaining low drug prices. Officials from the Ministries of Trade, Health, Foreign Affairs and Scientific Research should work together to make the right to health a central element of public policy regarding access to medicines. Regular dialogue, consultation and coordinated action between such ministries would ensure that policymakers develop a strong, united position regarding drug pricing. Government entities such as the Drug Pricing Committee could then develop a more coherent and transparent system for the pricing of medicines.

The rights-based dialogue developed by these efforts and interactions could also be transferred to the Egyptian judiciary. Human rights arguments would provide judges with additional legal tools to utilize when adjudicating IP issues. The curricula created to train judges in IP issues should explicitly integrate the language and principles of human rights treaties. Courts would then be better prepared to address substantive issues regarding access to affordable medicines and public health priorities in their opinions, paying attention to the ways in which TRIPS-plus provisions violate the right to health and prevent Egypt from fulfilling its duties to protect access to medicines.

Formal, regular dialogue between different ministries regarding the interaction of IP issues, trade and the right to health would also strengthen Egypt's negotiating position in bilateral trade discussions. As mentioned in the previous chapter by Ahmed Abdel Latif, the Egyptian Ministry of Trade and the Ministry of Foreign Affairs have already established a coordination mechanism on IP issues that includes officials from different government sectors. Such coordination, however, does not officially occur during bilateral or regional trade negotiations. Egypt should establish more interaction between different governmental bodies so that a coherent stance can be adopted in FTA negotiations. Such interaction would, ideally, also include key stakeholders from other sectors such as specialized agencies, the private sector and civil society. By involving officials from the Ministry of Health and other groups such as civil society, the Ministry of Trade is more likely

to consider the right to health in trade matters. Also, as discussed below, such participation and information sharing is an important element in any rights-based strategy to access to medicines.

A human rights approach to IP, trade and health must prioritize principles of equality, nondiscrimination and participation, and should ensure transparency, accountability and inclusiveness in trade and IP policymaking. The right to information and participation is protected in a number of the major international human rights instruments, such as the International Covenant on Civil and Political Rights (ICCPR), ratified by Egypt in 1982. Article 19 of the ICCPR states that all individuals “shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds.” Article 25 states that all citizens have the right “to take part in the conduct of public affairs, directly or through freely chosen representatives.” IP, trade and health policies should all therefore involve maximum public participation and transparency. The Special Rapporteur on the right to health stressed the need for such participation, noting “the importance of including rights holders, particularly communities, in decision-making processes as they can offer a vast and diverse perspective to various issues central to the right to health” (Hunt 2009, para. 3).

As part of a rights-based approach to IP and trade, Egypt should also make the negotiation of IP and trade treaties more transparent and should encourage the participation of civil society, both during international negotiations and during the formulation of national drug pricing and other domestic policies. Such inclusiveness would allow for a full range of perspectives when IP regulations and agreements are formulated, and make it more likely that the right to health is effectively protected. This is especially important as many regulations in Egypt’s pharmaceutical industry are opaque and vague. There is also a lack of transparency regarding how the policies for trade and health are formulated.

This lack of transparency with respect to national drug pricing, for example, makes the process vulnerable to pressure from the multinational pharmaceutical industry. An opaque pricing system might also lead international pharmaceutical companies to avoid the Egyptian market entirely, a result that would not be in the best interest of individuals’ health. Such complex considerations can only be adequately addressed by guaranteeing maximum public participation and transparency during

policy decisions regarding drug pricing controls. Ideally, an independent drug pricing body would be established. Such a body would explicitly address human rights concerns and be capable of balancing the interests of producers and consumers in a way that inspires confidence and ensures maximum protection of the right to health.

There are other important ways in which transparency and participation should be promoted in an explicit human rights approach to IP, trade and health. One important role for civil society that has been encouraged by a number of international bodies would be to monitor the impact of TRIPS and other trade agreements on the price of medicines. Without concrete data that charts both the positive and negative effects of trade agreements, it will be difficult to formulate an effective and compelling policy to protect access to medicines (Hunt 2009, para. 64). The collection and analysis of data regarding the impact of TRIPS on the price of medicines would be particularly beneficial in a country such as Egypt that has a large market for generic drugs and where the impact of patents could be potentially substantial.

Egypt is well placed to become a champion of access to medicines and a leader in the movement to resist the pressures of pharmaceutical companies and developed nations. As the previous chapter by Ahmed Abdel Latif demonstrates, Egypt has long played an important role in global trade and IP negotiations, and has pushed to attain greater access to science and technology. Egypt has greater leverage than many other developing countries because of its economic and political weight. It therefore has the ability to formulate and adopt rights-based public policies that integrate IP, trade and the right to health. Pursuing this leadership role more fully would serve as an important model for other developing nations and could have a significant impact at the international level.

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