Facilitating Trade in Drugs: An account of the WTO's agreement on patents and public health

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Abstract:
This paper tells the story of the controversial 30 August 2003 decision of the World Trade Organization (WTO) General Council on intellectual property (IP) rules and flexibility for addressing public health emergencies. It provides a brief history on multilateral agreements governing intellectual property and international trade, as well as outlines the emergence of the IP agreement within the WTO. Then, it describes how WTO members clashed over IP issues related to the HIV/AIDS pandemic, explains the essence of their disagreement and chronicles how they attempted to strike an accord that balances the objectives of commerce and health.

Introduction

> *An ambulance pulls up outside the WTO building. An African woman emerges, hooked up to an emergency intravenous drip of generic medicine. But suited trade delegates from the US, Canada, the European Union and Switzerland, egged on by drug company lobbyists whispering in their ears, "Cut the tube that leads to her arm". She protests holding out the WTO's "Doha Declaration" she was told would guarantee her access to affordable medicines. But drug company lobbyists remind the trade delegates: "She doesn't have the right disease. She doesn't come from a poor enough country. She can't prove she won't sell the drug to a rich tourist. She hasn't got the proper authorization." [1]*

Staged by Oxfam in November 2002, the stunt dramatized concerns that negotiations on the WTO's intellectual property agreement threatened to undermine important legal flexibilities guaranteed in the previous round of negotiations and further restrict access to medical treatment for some of the world's most poverty and disease-stricken people. While it may seem alarming that a commercial instrument, such as patent protection, could impede access to lifesaving medicines, attempts to balance the interests of producers and consumers of patented medicines created a political morass that left players on virtually all sides frustrated, angry, and worried about the future.

Where did the fight about IP begin?

The impetus for the Intellectual Property (IP) fight was the long-standing challenge of simultaneously encouraging innovation and making cutting-edge information, ideas, and products readily available to those who need them. To achieve these ends, governments created IP protection. IP is a creation of the mind - it is ideas that have value in the marketplace. Since the costs of generating new ideas are largely upfront costs, once an idea has been generated, the cost of sharing it is virtually zero. IP would be accessible to consumers at no cost, absent a system for designating rights to the generators of IP. For this reason, IP protection awards monopoly rights to the generators of IP, for some specified period of time, as a means of preserving the economic incentive to invest in research and development. At the same time, IP protection provides universal access to new ideas (either through the requirement that inventers disclose information about their invention when they apply to governments for protection or through the distribution of the final product) so that researchers and innovators may build on the latest knowledge and information and, ideally further human progress.

At the international level, IP protection began in 1883 with the Paris Convention, the first major treaty that granted national treatment - or the same protection for the nationals of other states as they provide to their own nationals - for industrial property, such as inventions, trademarks, and industrial designs. The Paris Convention was followed by the Berne Convention in 1886, which provided protection for literary and artistic works, such as novels, plays, musical works, drawings, paintings, and sculptures. Over time, the administrative arrangements for these treaties merged and ultimately became the World Intellectual Property Organization (WIPO) in 1967. Seven years later, the United Nations formally recognized the WIPO as "a specialized agency and as being responsible for taking appropriate action in accordance with its basic instruments, treaties and agreements." [2]

For all intents and purposes, WIPO became the global governing body responsible for encouraging the development and protection of intellectual property. Its activities centered on developing new norms and standards for intellectual property protection and encouraging states to conform to them. [3] However, countries were not obliged to sign the WIPO administered treaties and WIPO lacked enforcement capacity. This shortcoming in IP protection fueled the drive of major IP producers to explore avenues for more effective and consistent protection.

Enter the WTO.

In 1995, the burgeoning global economy brought with it an overhaul of the multilateral trading system and adoption of IP protection by the WTO. The original system of international trade was born out of the Bretton Woods

Agreement, an agreement aimed at promoting economic cooperation following the Second World War, by establishing the World Bank, the International Monetary Fund and an International Trade Organization (ITO). The trade framework that ultimately emerged was narrower in scope than the plan for the ITO, which would have covered rules on employment, commodities, investments, restrictive business practices, and services. It became known as the General Agreement on Tariffs and Trade (GATT), entered into force in 1948 and focused mostly on reducing tariffs on goods. [4] The GATT facilitated decision making between contracting parties through a series of negotiations known as "trade rounds." There were seven rounds leading up to the round that established the WTO, which lasted from 1986 to 1994 and became known as the Uruguay Round.

On January 1, 1995, the WTO came into existence and revamped the multilateral trading system in several respects. First, it provided protection for IP, in response to the growing threats of piracy and patent infringement, particularly with the proliferation of trade in high technologies. Second, it covered trade in services, including those relating to transportation, communications, and finance. Third, it created a process known as a "single undertaking," which departed from the GATT tradition of structuring negotiations around unilateral concessions, where contracting parties could pick and choose which agreements to sign. Instead, the Uruguay Round negotiations took place on all trade issues simultaneously, so that concessions made in one area could further negotiations in another, ultimately leading to a single package of agreements on which countries could vote up or down. Fourth, the WTO overhauled the dispute settlement mechanism in the GATT by creating more detailed rules and procedures and the possibility of compensating for injury through retaliation. [5]

The changes to the multilateral trading system were far-reaching and controversial. Whereas the GATT consisted of 23 contracting parties, the newly-formed WTO began with 123 members (now 149), representing a much greater diversity of interests and capacities to engage in world trade. Even though not all members participated in negotiations equally, for reasons such as a lack of staff resources or access to exclusive meetings for only the most powerful, all members voted on a single package of agreements. In the end, many developing countries felt as if they had been forced to adopt a new trade agreement which tipped in favor of the more powerful, industrialized members for two reasons. First, it seemed to disproportionately benefit the domestic industries of more industrialized countries, as they have historically been the primary creators of IP and have more highly developed services industries. Second, the agreement required changes in domestic laws, which some developing countries lacked the technical capacity to implement.

In 2001, discussions about launching a new round of negotiations illuminated discontentment with the Uruguay Round agreement. For example, Indian Commerce Minister, Murasoli Maran, opposed launching a new round because he noted that, "imbalances will become worse and intolerable" and that "developing countries . . . already paid the price by agreeing to some of the contentious issues in the Uruguay Round of trade negotiations." [6] The Prime Minister of Malaysia, Datuk Seri Dr Mahathir Mohamed concurred when he stated that "developing countries were already disadvantaged by the imbalances contained in the Uruguay Round agreements." [7]

What did the TRIPS actually do?

The WTO's Agreement on Trade Related Aspects of Intellectual Property (TRIPS) established minimum standards for intellectual property protection relating to copyrights, trademarks, geographical indications, industrial designs, patents, layout designs, trade secrets, and anticompetitive practices in contractual licenses. [8] Unlike IP protection in the WIPO, which lacked enforcement capacity, the TRIPS agreement had *teeth* for two reasons. First, the TRIPS agreement required that *all* members adopt procedures and remedies in their domestic laws, guaranteeing that individuals could seek enforcement of IP protection in judicial and administrative settings. [9] Second, the TRIPS agreement was backed by the newly-bolstered dispute settlement mechanism in the WTO, which provided members an avenue for recourse when other members failed to conform to the provisions of the agreement. In contrast, the WIPO could neither force members to sign agreements, nor could it enforce the agreements that members elected to sign.

Like other changes that accompanied the establishment of the WTO, the TRIPS agreement underscored the divide between developed and developing countries. Developed countries, making up the vast majority of net exporters of IP, sought a far-reaching agreement that forced developing countries to adopt and enforce existing international IP conventions. On the other hand, developing countries, comprised largely of net importers of IP, worried that IP protection would strengthen the monopoly power of multinational corporations and ultimately result in higher prices for many products in their countries. [10]

Developing countries were joined in criticizing the TRIPS agreement by some members of the academic community. London School of Economics scholar, Dr. Razeen Sally argued that the effect of the TRIPS "is to close, not open, markets" and that "strong patent protection in particular increases prices and transfers rents from poorer developing countries to multinational enterprises headquartered in the West." [11] He was joined by Colombia Economist Jadish Bhagwati, who stated that "intellectual property protection is not a 'trade' issue; the WTO ought to be about lowering trade barriers and tackling market access problems." [12]

Enter the HIV/AIDS pandemic.

Soon after the Uruguay Round, a political battle over the implications of bringing IP protection in the WTO began to germinate around the issue of access to medicines, most notably antiretroviral drugs (ARVs). During this period, 36.1 million people worldwide were living with HIV/AIDS. [13] Of these, 90 percent were in developing countries and 75 percent were in sub-Saharan Africa. [14] The international community was stepping up efforts to deal with the pandemic, through instruments such as the Millennium Development Goals, [15] the UN Declaration of Commitment on HIV/AIDS, [16] the Joint United Nations Program on HIV/AIDS (UNAIDS), [17]and the International Partnership against AIDS in Africa (IPAA). [18]

At the country level, governments began developing laws to make medicines more accessible to victims of disease. However, the pharmaceutical industry began to question the legality of some of the domestic laws in light of the newly-adopted TRIPS agreement. In 1998, the Pharmaceutical Manufacturers Association, comprised of thirty-nine pharmaceutical companies, filed a suit against Nelson Mandela and the South African government to block implementation of the South African Medicines Act. [19] The Act was aimed at making drugs more affordable by offering patients generic medicines and empowering the government to import medicines from other countries in cases where they were available for purchase at lower prices. [20]

At the time of the case, more than 4.5 million people in South Africa were infected with HIV/AIDS and most lacked access to treatment. Numerous NGOs, including Médicins Sans Frontières (MSF), Treatment Action Campaign (TAC), Health GAP Coalition, Third World Network (TWN), Oxfam, and Consumer Project on Technology (CPTech), mobilized by circulating petitions, staging protests, and writing letters. Rumor has it, even Mike Moore, then-Director-General of the WTO, rebuffed the pharmaceutical industry representatives asking them why they did not bother to sue Gandhi and Jesus too. [21] Three years later, the pharmaceutical companies negotiated a settlement with the South African government and withdrew the case.

Brazil also had a confrontation over a national law relating to access to medicines. In 1996, Brazil passed a law to further its policy of providing universal distribution of HIV/AIDS drugs to its estimated 600,000 residents infected with HIV/AIDS. [22] The law permitted the government, under certain conditions, to authorize domestic production of medicines without the permission of the patent holder. The US government filed a complaint in the WTO, backed by the pharmaceutical industry. In the wake of political pressure exerted by many of the same NGOs that were active in the South Africa case, and failure to effect a change in the Brazilian law through the WTO dispute settlement mechanism, the US withdrew its complaint in July 2001. [23]

TRIPS and public health in the new round.

The persistence of HIV/AIDS, paired with legal battles over the domestic laws of South Africa and Brazil, made TRIPS and public health a major issue when the WTO launched the next round of negotiations in Doha, Qatar in November 2001. The overriding problem was that the TRIPS agreement did not clearly delineate countries' options for simultaneously addressing public health crises and satisfying its obligations to protect IP. Consequently, one central objective for negotiations was to resolve the ambiguity in the TRIPS agreement.

At the Doha Ministerial Conference, WTO members responded to the need for clarification by endorsing the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration "recognized the gravity of public health problems afflicting many developing countries and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics" and stressed the need for an agreement "supportive of WTO members' right to protect public health and . . . promote access to medicines for all." [24] It delegated responsibility for resolving the ambiguity to the TRIPS Council, the WTO body which administers the TRIPS agreement. Specifically, it instructed the Council to "find an expeditious solution" and report to the General Council before the end of 2002. [25]

The crux of the problem.

As with many international agreements, the TRIPS agreement was reached through "constructive ambiguity," leaving certain provisions open to various interpretations for purposes of achieving consensus. In the debate on TRIPS and public health, much of the disagreement focused on a particular legal instrument, known as "compulsory licensing." A compulsory license is authorization by a government to produce a patented product without the consent of the patent holder. [26] Compulsory licensing is unpopular with patent holders because it can threaten the monopoly rights afforded to them by IP protection. Article 31 of TRIPS set restrictive conditions under which a country can issue a compulsory license. Specifically, it provides that in "situations of national emergency or other circumstances of extreme urgency," countries can issue a compulsory license to manufacturers for the production of pharmaceuticals. [27] It also set forth a series of conditions for countries issuing a compulsory license, including obligations to notify the patent holder, outline the scope and duration of manufacturing operations, and provide an appropriate level of compensation to the patent holder.

However, Article 31 limited compulsory licensing to production for a country's domestic market, as section (f) says that "any such use shall be authorized predominately for the supply of the domestic market of the Member authorizing such use." [28] As a result, countries lacking the capacity to produce pharmaceuticals domestically could not take advantage of the compul-

sory license provisions under the TRIPS agreement. They were left with four options. First, they could continue to purchase medicines from the patent holder, though they were cost-prohibitive for many countries and the very problem the TRIPS and public health negotiations were attempting to address. Second, they could attempt to import medicines from countries where the patent holder sold them at lower prices, a practice known as parallel importing, which was also wrought with legal controversy. [29] Third, in the short-run, they could issue a compulsory license to a foreign manufacturer, in a country where pharmaceuticals were not yet protected by patents. Countries that had not yet adopted patent laws were not constrained by the provisions of the TRIPS agreement. [30] However, eventually all WTO members would be required to comply with the TRIPS agreement. Fourth, arguably, they could import medicines from a country that had patent protection, providing the amount did not exceed that which was produced predominately for the supply of the domestic market. Yet, under any of these scenarios, there was neither a guarantee that these countries could supply other markets, in addition to their own, nor supply medicines at an affordable price.

How did the TRIPS Council attempt to solve the problem?

The Doha Declaration on the TRIPS Agreement and Public Health included two instructions for the WTO body responsible for administering the TRIPS Agreement, the TRIPS Council. First, the Declaration directed the TRIPS Council to extend the deadline by which Least Developed Countries (LDCs) were required to implement IP protection on pharmaceuticals until 2016. LDCs are among the fifty least developed countries in the world and are designated as such by the United Nations; thirty-two of these belong to the WTO, many of which lacked the capacity to manufacture pharmaceuticals. [31] On June 27, 2002, the Council issued the extension, preserving the option for LDCs to import, and in some cases produce, generic pharmaceuticals without the permission of patent holders.

Second, the Declaration mandated that the TRIPS Council design a plan to expand access to medicines for countries without domestic manufacturing capacity. However, finding a solution required that the Council consider several issues, including:

1. ***Price*** - The overall objective of the Doha Declaration on the TRIPS Agreement and Public Health was to improve access to medicines. While several obstacles impede access, such as infrastructure for the delivery of medicines and availability of qualified health personnel, price is the obstacle that IP protection rules influence. Since IP protection awards monopoly rights to patent holders, it affects the number of suppliers in the market, the level of competition for business, and ultimately price. Hence, the WTO could encourage lower drug prices by modifying provisions of the TRIPS agreement to provide exceptions to monopoly rights.

Since compulsory licensing was permitted under the TRIPS agreement, it was one instrument that could help make medicines more affordable. It promised to increase competition by allowing countries with manufacturing capacity to authorize additional suppliers to enter the market. It encouraged competition and in some cases, enabled countries to obtain price reductions with patent holders by threatening to issue a compulsory license. In the end, the major challenge for the TRIPS Council was to extend the compulsory licensing mechanism to countries lacking manufacturing capacity.

2. ***Capacity*** – The Doha Declaration on the TRIPS Agreement and Public Health sought a solution for "WTO members with insufficient or no manufacturing capacity." [32] However, it was unclear what constituted "manufacturing capacity." As members endeavored to define "capacity," they considered a number of different factors, including, countries' respective levels of economic development, monetary values of drugs and medicines, and histories of discovery and marketing of chemical entities. [33] The debate was further complicated because only a handful of countries produced the active components in a medicines that are responsible for their effect. This fact begged the question - should those countries, which import active ingredients for pharmaceutical production also be deemed to have manufacturing capacity? [34]

Even if the WTO settled on a definition for manufacturing capacity and created a system for assessing whether member countries had adequate capacity, another challenge still remained - while some countries might have the capacity to produce certain medicines, it did not necessarily mean they could produce any and all medicines, in light of technological and economic constraints. Several NGOs, including CPTech, Oxfam, MSF, and Health Action International (HAI), raised this issue in a letter addressed to delegates of the WTO. The letter highlighted a statement by a WTO dispute settlement body, in a related case, which acknowledged that "smaller countries that did have generic industries did not have domestic markets sufficiently large to enable those industries to operate on an economic scale." [35]

3. ***Scope of Diseases*** – The Doha Declaration on the TRIPS agreement and public health specifically recognized "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." Naturally, countries with a large pharmaceutical industry, and the pharmaceutical companies themselves, sought to limit the conditions under which countries could circumvent patent protection, particularly by curtailing the flexibility provided by

the "other epidemics" clause of the Declaration. As one company warned, "extensive use of these exceptions/ flexibilities…would quickly negate the intellectual property-related incentives that are needed to develop the next generation of pharmaceutical therapies." [36]

On first glance, it seems that the Declaration targeted a select group of the world's most pressing health challenges. However, in legal terms, it was unclear which diseases qualified as "other epidemics." The US worried that this clause could be used for breaking patents on "any drugs for any disease, including 'lifestyle' drugs for erectile dysfunction, baldness, or obesity." [37] While at one level it seemed ridiculous that countries would use flexibilities under the TRIPS in this way, newspaper articles attest to attempts to provide local generic manufacturers with permission to produce Viagra, without the permission of the patent holder, in Egypt and China. [38]

At the same, developing countries viewed attempts to narrow the scope of diseases, as reopening an issue that had already been settled in negotiations over the language of the Declaration. According to a representative from Brazil, "it was not in the purview of the Council to re-examine what had been agreed upon in the Declaration." [39] Moreover, developing countries feared losing the right to define for themselves what constitutes a public health emergency and the flexibility needed to respond to unforeseen health challenges. As the South African Ambassador later noted, "it is neither practicable, nor desirable to predict the pharmaceutical product needs of the members desiring to protect the public health." [40]

4. ***Coverage*** – The Doha Declaration on the TRIPS agreement and public health was a response to "public health problems afflicting many developing and least-developed countries," particularly those with "insufficient or no manufacturing capacities in the pharmaceutical sector." [41] To ensure that the Declaration facilitated access to medicines for the intended countries, the Council considered limiting the scope of countries that could utilize a solution. One method for accomplishing this objective was to target countries identified in the WTO as developing and least developed. However, developing countries comprised about two-thirds of the membership in the WTO and included a diverse range of income levels, some of which might be more likely targets for additional flexibilities under the TRIPS agreement and some of which might not. [42] In contrast, LDCs were among the neediest countries in the world and were designated as LDCs by the United Nations. [43] Since the Council's first action was to delay implementation of the agreement for LDCs, the remaining challenge was to decide which developing countries the solution should target and how they should be targeted.

The Doha declaration and IP issues: Access to drugs. A temporary solution or permanent fix?

Towards forging agreement.

In 2002, the Chair of the TRIPS Council, Ambassador Eduardo Perez Motta (Mexico), engaged in a process commonly used in the WTO to facilitate agreement. He held numerous small meetings and consultations with members and then proposed a compromise in the form of a draft text. In December, he circulated the draft text, which garnered wide support on several points. It proposed to waive the TRIPS requirement that compulsory licensing be used predominately for the domestic market. The waiver would allow countries to import generic medicines from foreign manufacturers under a compulsory license. In addition, the draft proposed safeguards against abuse and the diversion of products to unintended markets. These would require, among other things, that members using the waiver: (1) specify the names and expected quantities of products; (2) confirm that the importing member has insufficient manufacturing capacity; (3) utilize special labeling, marketing or packaging to distinguish products from the rest; and, (4) post details about the conditions of the compulsory license on a specified website.[44]

Yet, many countries were skeptical about the text. While there was broad consensus on the major provisions, several developed and developing countries remained uncomfortable with the details of the draft. For example, developing countries contended that the safeguards were too onerous. In particular, a group of African countries argued that provisions, which required special labeling and markings for medicines produced under compulsory licenses, would "further increase production and compliance costs" and ultimately compromise the effectiveness of the solution. [45] Some developed countries considered the draft overly broad, particularly with respect to the scope of diseases. A representative from Canada noted that "members still needed to distinguish between those [diseases] that were epidemics and those that were not." [46] Nevertheless, all members were willing to support the draft text except for one- the US, which walked away from negotiations at midnight on December 20, 2002. In her statement before the Council, the US representative explained that "her delegation was willing to join the consensus on all parts of the draft except the scope of diseases." [47]

Rumors among some insiders suggest that key officials in the Office of United States Trade Representative (USTR), which manages trade issues on behalf of the President, supported the draft text. Yet, political pressure from pharmaceutical industry executives on the White House led to the USTR's rejection of the proposed agreement. While the rumors cannot be corroborated, the pharmaceutical industry clearly exercised considerable power. In December 2002, the industry had recently contributed $60 million for Republican campaigns in the mid-term election, allowing the more conservative party to expand their majority in the House of Representatives and regain control of the Senate. [48]

Breaking the deadlock.

Director-General Supachai Panitchpakdi proposed that the TRIPS Council overcome the deadlock on the scope of diseases and reach an agreement by February 11, 2003. [49] To this end, the US, the EU, and Japan each brought new policy initiatives to the WTO at the start of the new year. The US proposed a moratorium on WTO challenges to poor countries for using compulsory licensing in response to "HIV/AIDS, Malaria or Tuberculosis or other infectious epidemics of comparable scale and gravity." [50] The moratorium was intended to serve as an interim solution, allowing LDCs and lower-income developing countries to authorize foreign-based generic manufactures to produce patented medicines for a narrow set of diseases. [51] However, the EU delegation considered the moratorium a "face-saving exercise," which had "limited substantive value" because it did not provide the legal footing for generic producers to export medicines. More specifically, the EU suggested that even if WTO members joined the moratorium, it lacked "the legal backup at the domestic level" for generic producers to sell medicines to needy countries. [52]

Instead, the EU proposed to add a footnote to the TRIPS agreement, specifying that it apply to a more flexible definition of at least 22 infectious diseases, including HIV/AIDS, Tuberculosis, Malaria, Measles, Influenza, and Meningitis. In addition, the EU proposed that the World Health Organization serve in an advisory role to the WTO on the scope of diseases. [53] According to a representative of the EU, the proposal was not designed "to restrict the scope of the Declaration, but to preserve it" and that the only difference between the draft text and the EU proposal was that "for those public health problems not appearing on the list, the WHO could be called upon, in case of any doubt, to give its opinion." [54] Japan offered a proposal similar to the EU proposal, calling for application of the TRIPS and public health agreement to 22 epidemics. [55]

The TRIPS Council missed the February 11th deadline for an agreement, in spite of the new policy initiatives, as well as the efforts of the TRIPS Council Chair, Ambassador Motta. The Chair had been working to forge an agreement by leaving the draft text from December 2002 intact, while crafting an interpretive statement to accompany the agreement, known as a Chair's statement, which "recognized the importance of patent protection as incentive for drugs development while reaffirming the rights of governments to protect public health." [56]

However, before Ambassador Motta's could complete negotiations on the statement, his term as Chair expired and Ambassador Vanu Gopala Menon (Singapore) took over. The new Chair built on the work carried out by his predecessor by also leaving the draft text intact and focusing on a Chair's statement. To help devise the statement, he convened a small group of representatives from the five countries of the US, Brazil, India, Kenya and South Africa. These countries were particularly relevant to the discussion either for their pharmaceutical manufacturing industry or the widespread suffering from diseases in their respective countries. More specifically, the US was home to the largest pharmaceutical company in the world, Pfizer, and comprised a market valued at some $200 billion a year and growing. [57] Furthermore, since the US was the only member to reject the December 2002 draft text, breaking the deadlock was largely a matter of finding agreement between the US and everyone else. Brazil's aggressive HIV/AIDS program engendered large-scale domestic production of generic medicines- it involved government manufacturing of ARVs for distribution, free of charge, to HIV/AIDS victims. [58] In addition, the US and Brazil had previously engaged in a legal battle over Brazil's HIV/AIDS program. India was one of the largest generic drug producers in the world, with an industry valued at £2.7 billion. [59] Manufacturers of patented medicines had long complained about India's lax enforcement of IP protection. Kenya had firsthand experience with the devastation of AIDS, as more than 2 million of its adults and children lived with AIDS and the disease claimed approximately 600 lives or more per day. [60] Its Ambassador to the WTO, Amina Mohamed, often spoke on behalf of a group of African countries in the WTO, known as the African Group, which were also dealing with the far-reaching impacts of the AIDS pandemic. [61] South Africa was also home to tremendous suffering from HIV/AIDS, as 4.7 million of its population of 40 million was HIV-positive. [62] In addition, the relationship between the government and pharmaceutical companies was combative, as evidenced by the legal dispute over the importation of medicines. [63]

By the Spring of 2003, the context for discussing TRIPS and public health began to change. Members became more concerned about unforeseen health emergencies when Severe Acute Respiratory Syndrome (SARS), a respiratory illness, emerged in Asia. It spread to 8098 people in 26 countries in just a matter of months, causing 774 deaths, as well as major disruptions in travel and health services. [64] According to a representative from Kenya, in light of SARS, "an urgent solution was needed." [65]

In May 2003, the World Health Assembly also acknowledged the need for a solution to the TRIPS and public health issue in the wake of SARS. The Assembly resolved that "in order to tackle new public health problems with international impact, such as the emergence of SARS, access to new medicines with potential therapeutic effect and to health innovations and discoveries should be universally available without discrimination." [66] Furthermore, it urged members to: (1) reaffirm that public health interests are paramount in both pharmaceutical and health policies; (2) consider adapting legislation to use the full flexibilities of the TRIPS agreement; (3) continue to work towards a reaching a solution on the TRIPS agreement and public health; and, (4) establish conditions to spur the development of new medicines for diseases affecting developing countries. [67]

In the same month, a group of more than 70 countries from the African, Caribbean and Pacific Group of States (ACP), issued a letter to the TRIPS Council, criticizing the US for blocking the adoption of the draft text in December 2002 and stressing the need for an agreement. [68] In addition, the letter requested "that the issue of TRIPS and public health be addressed satisfactorily" before the next ministerial conference and "that all WTO stakeholders be mobilized to ensure urgent and adequate resolution to the issue." [69]

In June 2003, in Cairo, the WTO held a mini-ministerial meeting, which is an informal meeting of trade ministers, held prior to a formal ministerial meeting to promote consensus-building on various trade topics. During the meeting, the US abandoned its endeavor to limit the scope of diseases. According to then-US Trade Representative, Robert Zoellick, the US changed its position because the scope of disease was no longer an issue with the pharmaceutical industry. [70] According to one report, The USTR managed to "convince its industry to give up its demand on reducing the coverage of disease." [71] As a result, Ambassador Menon began to plan for brokering an agreement. He indicated that US seemed comfortable with the draft text, but wanted more assurances that the agreement would not be misused. [72] At this point, he would begin working to incorporate assurances in the Chair's statement.

What about everyone else?

Members of civil society and WTO members, who were not privy to the meetings of the five countries negotiating the Chair's text, began to worry when they realized that an agreement was forthcoming. Because they were excluded from meetings, they tried to figure out what exactly was being negotiated. Trade representatives sought information from their colleagues. Some NGO's were permitted by the Secretariat to enter the WTO and speak with representatives coming and going from meetings. One representative later noted that civil society exerted considerable influence by asking questions, lobbying representatives, and reporting on negotiations. For example, NGO's, such as CPTech and TWN, remained in the halls of WTO at all hours of negotiations, speaking with representatives, and providing detailed updates on negotiations on their websites.

In August, the US, Brazil, India, Kenya, and South Africa completed their draft of the Chair's statement and released it for other members to review. It purported to outline the "shared understanding of Members regarding the decision . . . and the way in which it [would] be interpreted and implemented." [73] Moreover, it specified the following: (1) the decision should be used in the pursuit of public health rather than for commercial objectives; (2) all reasonable measures should be taken to prevent diversions from the markets for which the products were intended; (3) Members should seek to resolve any issues arising from the decision "expeditiously and amicably;" (4) information relating to the implementation of the decision should be brought to the TRIPS Council in its annual review; and (5) twenty-three developed countries agreed not to import pharmaceuticals under the agreement. [74]

When the civil society received copies of the draft statement, several groups announced their concern. MSF suggested that, "rather than allowing the poorest countries to make effective use of compulsory licensing, this text seeks to throw up as many obstacles and discouragements as possible, and opens the system up to constant political intimidation from powerful members." [75] Oxfam said that "the statement contained 'burdensome conditions' on top of what was already a restrictive text, and was unlikely to benefit the developing countries it was designed to help." [76] Civil society was joined in their opposition to the proposed statement by some representatives, but it didn't seem that there was much they could do to stop its approval, as it was quickly garnering the support of trade ministers and high-ranking officials in the country's capitals.

One last-ditch attempt.

The TRIPS Council was expected to adopt the agreement on August 28, 2003. Concerned that the proposed agreement was bad for developing countries, a staff member of one NGO pleaded with a like-minded representative from the Philippines not to give up on "the good fight." The representative indicated he would try to find a way to address the impending course of events.

On August 28th, when the TRIPS Council took up the agreement, the representative from the Philippines raised his microphone, requesting to be recognized. He read a statement, indicating that while the Philippines would support the agreement, the Chair's statement did not, in fact, outline a shared understanding of the membership. His country had a different understanding of the agreement, which he proceeded to delineate for the Council. [77] Among other things, he noted that:

The Chair's statement indicated that members should take all reasonable measures to prevent product diversion, but many developing countries were ill-equipped to fully take responsibility for trade diversion. His country

understood that the obligation of developing countries was on a "best-endeavor basis."

While the Chair's statement indicated that the Agreement should not be used as an instrument for pursuing industrial or commercial policy objectives, the Philippines understood that a policy designed to circumvent patent rights or monopolistic-rights was inherently an instrument of industrial policy.

His country understood that special packaging and coloring requirements, aimed at safeguarding products against trade diversion, threatened to increase costs, and make the system more difficult to use for both importing and exporting members.

After he read the statement, consensus began to unravel and the Council meeting was adjourned. As it turned out, other developing countries also had questions about the Chair's text. It took two days of political haggling and unseen pressuring, for proponents to rebuild the consensus. On August 30, the Philippines retracted its statement and the WTO passed the agreement. It consisted of a waiver, which was exactly the same waiver the WTO considered in December 2002. It permitted countries to import pharmaceuticals manufactured under compulsory licenses and contained several safeguard provisions for patent holders. Also, the agreement contained the Chair's statement and the commitment by 23 countries not to use the system for importing medicines. While the WTO celebrated the agreement, wide disagreement remained over whether it balanced effectively the interests of IP protection and public health.

In December 2005, WTO members made the agreement of 30 August 2003 an amendment to the TRIPS agreement requiring parties intending to import or export medicines manufactured under compulsory licenses to notify the TRIPS Council, which makes the notifications publicly available on the WTO website. This amendment will be formalized when two-thirds of the Members ratify it. To date, three countries have ratified the amendment: the US, Switzerland, and El Salvador.

Author declaration

This case study was written by Gina Vea, Programme Officer of Intellectual Property at the International Centre for Trade and Sustainable Development. This paper was written before taking up the current position and does not reflect the views of the organization. It benefited greatly from the input from colleagues at the Terry Sanford Institute of Public Policy at Duke University

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Is Intellectual Property a Catalyst for Development? - The case of biotechnology sector in Malaysia and Singapore.

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Abstract

Intellectual property protection is often regarded as a catalyst for endogenous development and developing countries are being encouraged to a have proper intellectual property system that also includes patents registration. There is however a controversy whether a patent system will effectively encourage domestic firms to innovate and contribute to local economic development or whether it just benefits foreign investors and their off-shore production. Malaysia and Singapore are two countries in Southeast Asian committed to promote biotechnology as a catalyst for future economic growth. The two countries may be different in many ways but their approaches to stimulate technological innovation by means of a strong intellectual property system are quite similar. The article shows that patent systems are now increasingly being used by local firms in Malaysia and Singapore, yet foreign firms continue to have by far the largest share of patents.

Introduction

Intellectual property is said to be a catalyst for economic development. Take the patent system for example. The granting of patents originated in Europe in the 15th century where European economies issued letters of patent to local and foreign inventors to attract them to invest in their particular country. Patents were granted as monopoly rights to foreign and local investors in return for them bringing in their technology. The system was used to protect the trade of glassmaking in Venice, the industry of silk-making in Lyons and the glassmaking, weaving and shipbuilding in the early period of the Industrial Revolution in England.

The most famous and probably the first written law on patent was the Venetian Patent Law of March 19, 1474 [1]. It confirms the early recognition of the importance of foreign experts in bringing knowledge and investment to "benefit to the State". The Venetian Patent Law granted patent protection for 10 years. The Law also prohibited any form of infringement in any territory and not just in Venice [2]. The law was introduced to attract inventors and investors to Venice to generate new economic activities. At the time the law was introduced, Venice already had a glass-making industry which was monopolised by guilds. The guilds had their own rules which were restrictive thus restricting innovations.

The short lesson from history shows that patents were being used to attract foreign direct investments and spur local innovation that would eventually lead to higher economic growth. This article will argue that developing countries, such as, Malaysia and Singapore realised that intellectual property protection such as patents should be used to achieve both - attract foreign direct investments and encourage local companies to innovate. In a knowledge-based economy where intangible assets such as intellectual capital become increasingly important, the state increasingly plays the role of a mid-wife that facilitates birth of a home-grown technology industry.

Successful participation in the knowledge economy decreases the reliance on labour intensive activities and will encourage higher value-added production. In countries, such as, Malaysia and Singapore, continuing dependence on labour intensive activities will not ensure future economic growth as they stands in direct competitions with other economies in the region that offer cheaper labour costs. As they are more affluent, the two countries are also facing a shortage of skilled labour that comes along with the shift to a more knowledge-based economy which uses more skilled human resources.

Despite having access to one of the largest biodiversity resources in the world, both Malaysia and Singapore are still lagging behind in local R&D, thus stifling the growth of home-grown technology. It cannot be said that this is because of the patent system. However, it can be argued that the focus of the economy has been on other sectors, such as, infrastructure development. As there is growing competition from neighbouring countries offering cheaper labour costs, Malaysia and Singapore have to move on to high technology activities. The move to high technology activities requires R&D and higher spending on R&D.

The low amount of R&D spending per capita is a serious issue that must be addressed by the relevant countries. A critical determinant of the availability and accessibility of biotechnology innovations in developing countries is the countries' own national capacity in biotechnology research. National research capacity increases the ability to invent new technologies, to import and adapt agricultural technologies, to ensure that the public goods aspects of research are addressed and to appropriately regulate technologies [3].

Research capacity depends on wide portfolio - physical, human, and financial resources that facilitate the effective use of research. Research capacity is not limited to undertaking research projects, but encompasses engagement with a broader innovation system, including specifying, accessing, interpreting and applying research [4]. It also involves a spectrum of key elements and activities, including defining objectives and priorities in an identified sector; developing and implementing clear policy strategies for the identified sector and designing appropriate biosafety regulations; developing R&D management capacity; facilitating transfer of technologies, knowledge and skills to the private sector; and promoting international collaboration and technology transfer [5].

A common problem of high technology investment in Malaysia and Singapore is the fact that most are owned by foreign companies. This is because the two countries are at the early stage of the transition from low level manufacturing based economy into high technology based economy. Thus there is a dependency on foreign direct investment to bring in new technologies and to facilitate transfer of technology to the domestic sector, owned by Malaysians and Singaporeans. The transfer of technology will allow domestic players to learn from the new technologies and this will result in spin offs from the foreign owned companies.

There is no doubt that both countries are well known for their manufacturing prowess based on foreign investment and imported technologies. However, they have yet to be recognized as centres of world-class excellence in science and technology and research and development [6]. With the exception of Singapore, public spending on R&D averages less than 0.3 % of domestic income in the region, which is below the 2.5-3 % range in Japan and Korea [7]. Singapore has been successful in raising R&D expenditures to 1.8 % of domestic income [8]. Malaysia has little R&D expertise in general, not only in biotechnology. The present government's R&D expenditure is only 0.5 % of GDP. According to the numbers of the Knowledge-based Economy Master plan, the figure is even lower at 0.39 %. The Government is aiming to increase R&D spending in the field of science and technology to at least 1.5 % of the GDP by 2010 [9].

The use of biotechnology in Malaysia

Towards the later part of the 20th century and at the turn of the 21st century, Malaysia and Singapore have put more focus on biotechnology as a catalyst for the future economic growth. Although the focus is the same, the approach may be different.

Malaysia, which is ranked by the United Nations Environmental Programme (UNEP) as 14th in the mega-diversity countries, [10] will use this natural asset as a basis for the biotechnology R&D and commercialisation. Malaysia has the natural resources that are useful in R&D and the necessary motivation to develop a biotechnology industry. Yet, to make biotechnology an engine of economic growth, it also needs to invest in its human capital and the acquisition and attraction of new knowledge and technologies from abroad.

Malaysia has an important agricultural sector, which accounts for 12% of the GDP [11]. In the new Asian knowledge economy that is also slowing trickling down into the agricultural sector, Malaysia competes with its neighbours as well as China and India in exporting to the Asia Pacific region. Malaysia has produced a National Biotechnology Policy, which was launched on 28th April 2005. As the current Chairman of the Organisation Islamic Conference, Malaysia has a strong economic influence in the Moslem World and it intends to expand its markets in Middle East. Malaysia's leadership on "Halal" food is also recognized in the Organization of Islam Conferences [12].

The National Biotechnology Policy is to give impetus to developing the biotechnology sector into a new economic engine enhancing prosperity and wellness of the nation by 2020. The policy encompasses 3 phases: capacity building (2005-2010), creating business out of science (2011-2015), and turning Malaysia into global player (2016-2020). The policy document does not explain in detail what activities will take place in each phase.

To implement the policy, Malaysia has created Malaysian Biotechnology Corporation to oversee the implementation of the policies and initiatives. The Corporation will be a dedicated and professional one-stop agency responsible for developing the country's biotechnology industry. It is overseen by an Implementation Council and advised by an International Advisory Panel, both under the leadership of the Prime Minister of Malaysia. The Malaysian Biotechnology Corporation will coordinate biotechnology initiatives from all relevant government ministries, but will come under the purview of the Ministry of Science, Technology and Innovation. It will also work closely with relevant ministries to enhance biotech R&D and to help improve the regulatory environment.

The activities for the first phase (2005-2010) are best explained by the 9th Malaysia Plan (2006-2010) in particular, Chapter 6 of that Plan. The 9th Malaysia Plan states that 'The Ninth Plan will focus on implementing the NBP to develop Malaysia's niches in agriculture biotechnology, healthcare related biotechnology, industrial biotechnology and bioinformatics. In this regard, the promotion of foreign and domestic investments and close collaboration with foreign entities to access new technology, expertise and markets will be intensified.'[13]

Among the strategies employed by Malaysia are:

- ⇒ transforming and enhancing value creation in the agriculture sector through biotechnology;
- ⇒ capitalising on the strengths of biodiversity to commercialise discoveries in health-related products and position Malaysia in the growing bio-generics market;
- ⇒ nurturing growth opportunities in industrial bio-processing and bio-manufacturing;
- ⇒ leveraging on the convergence of technologies to grow the nascent bioinformatics industry;
- ⇒ creating an enabling environment with supportive institutional, regulatory and financial framework to facilitate the build up of a strong and diversified biotechnology industry;
- ⇒ enhancing human capital development to meet national needs; and
- ⇒ establishing R&D centres of excellence and accelerating technology development, diffusion and commercialisation.

With the promotion of biotechnology as the growth

sector, Malaysia hopes to create 100 companies with about 280,000 jobs and contribute towards 5 % of GDP by 2015 [14]. This is comparable to the contribution of some 50 medium-sized Malaysian companies in 2002 [15]. This is a modest target, considering that the sector will take about another 14 years to achieve its target. To achieve the target, Malaysia plans to conduct research and academic development activities in seven areas: molecular biology, plant biotechnology, animal biotechnology, medical biotechnology, environmental and industrial biotechnology, and bio-pharmacy and food biotechnology.

A local patent system is expected to assist and benefit local inventors and investors in their efforts to realise the potential of biotechnology. Malaysia signed the Convention on Biodiversity (CBD) on 12th June 1992 and ratified the same on 24th June 1994 [16]. As a country rich in biodiversity, Malaysia offers vast opportunities for bio-prospectors to make use of these natural resources and convert them into new products [17].

Genetic resources have long been a source of important raw materials in agriculture and medicine. They have continually provided the basis for both the improvement of agricultural crops and for traditional plant-based medicines. About 75% of the world population relies on traditional plant-based medicine for its primary healthcare [18]. It has been reported that 33% of drug products in the highly industrialized countries are derived directly from plants; most of these are tropical plants growing in equatorial countries such as Malaysia.

The rapid advancement in science and biotechnology has increased the potential uses of genetic resources and hence their actual and potential economic value, prompting a surge of interest in these resources and stimulating trade [19]. The growing biotechnology industry currently utilises genetic resources to develop new and improved drugs, crop varieties, industrial techniques and a myriad of other commodities. Its combined annual global market value was estimated to lie roughly between US$500 billion and US$800 billion in 1999 [20].

This is a combined value derived from the following sectors: pharmaceutical, botanical medicines, major crops, horticulture, crop protection products, and applications of biotechnology in fields other then healthcare and agriculture and cosmetics and personal care products. The global market value of drugs derived from genetic resources is estimated to be US$ 75-150 billion per year. The annual total value of sectors associated with the global seeds market, not limited to seeds using genetic diversity, is estimated at around US$ 45 billion, while the total output from the world's agro- ecosystem is equivalent to US$ 1.3 trillion per year [21].

A major issue for national implementation is the need to achieve a balance between controlling access to genetic resources and facilitating it. Malaysia will be concerned as to how it can capture a share of the benefits generated from genetic resources, and simultaneously tackle the unauthorised use of its genetic resources [22]

Prospectors from other countries must also protect local people and traditional knowledge, from misuse or piracy. Bio-piracy is still an unresolved issue, as developed countries are reluctant to curb it through rules in the international fora. For example, they have not adopted rules on the disclosure of origin of biological materials claimed in patent applications.

The European Union intended to introduce a rule to disclose the origin of genetic material used in patented inventions. An obligation of this type was incorporated in the draft of the European Union Directive relating to patents on biotechnology, as recommended by the European Parliament in July 1997, but was removed from the final text. However, Recital 27 of the Directive mentions an obligation to provide information as to geographical origin of biological material where this is known, without prejudice to patent validity.

Brazil, a leading mega-biodiversity country, has made several proposals to the WTO TRIPs Council, WIPO and the CBD to introduce provisions requiring disclosure of sources of genetic materials. Brazil is of the view that patent applicants for inventions relating to biological materials and/or associated traditional knowledge, under the existing relevant international treaties, should be required, as a condition for acquiring patent rights, to disclose: (i) the source and country of origin of the biological resources and associated traditional knowledge used in the invention; (ii) evidence of their compliance with prior informed consent under the relevant national regime; and (iii) evidence of their compliance with fair and equitable benefit sharing under the relevant national regime.[23]

Between 30th January and 3rd February 2006, the CBD, at the Ad Hoc Open Ended Working Group on Access and Benefit Sharing in Granada, discussed the draft International Regime on Access and Benefit-Sharing. Among the scopes of the regime is the plan to introduce a fair and equitable sharing of the monetary and non-monetary benefits arising out the utilization of genetic resources, and associated traditional knowledge in the context of mutually agreed terms. The draft proposes that:

a. The regime applies to all genetic resources and associated traditional knowledge, innovations and practices and benefits arising from the utilization of such resources. However, it will not apply to the plant genetic resources that subject to the International Treaty on Plant Genetic Resources for Food and Agricultures. It is also proposed that conditions for access to genetic resources shall be dependent upon or related to benefit sharing arrangements;
b. Access procedures shall be clear, simple and transparent and provide legal certainty to different kinds

of users and providers of genetic resources with a view to the effective implementation of article 15, of the CBD;

c. Parties or Countries of origin providing genetic resources, may establish measures requiring that access to such genetic resources shall be subject to prior informed consent; and

d. Mutually agreed terms for access to and specific uses of genetic resources may include conditions for transfer of such genetic resources to third parties, subject to national legislation of countries of origin.

It is also proposed that in accordance with article 8(j) of the CBD:

a. Parties may consider developing, adopting and/or recognizing, as appropriate, international, national and local sui generis systems for the protection of traditional knowledge, innovations and practices associated to genetic resources;

b. Parties to recognize and protect the rights, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities and ensure the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices; and

c. Parties should comply with the prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with article 8(j) of the Convention on Biological Diversity, subject to national legislation of the country where these communities are located.

The draft proposal also foresees the establishment of an international certificate of origin/source/legal provenance of genetic resources to be issued by the provider country or country of origin. The issues are still being discussed at the CBD and they are not expected to be resolved in the near future.

However, the need to address bio-piracy, which normally refers to foreign entities, should not prevent the possible use of biodiversity, in a sustainable manner. [24] Thus, there are rules which allow bio prospecting by foreign entities by collaborating with local concerns. For example, in the Malaysian state of Sarawak, foreign bio prospectors may collaborate with local institutions to conduct such activities.

Under Section 23 of the Sarawak Biodiversity Centre Ordinance 1997,

'no person is allowed, without a permit issued by the council and subject to such terms and conditions as may be stipulated in such a permit, to collect or take any plant or any part of a plant found on any State Land, protected forest, forest reserve or communal forest or collect any biological resources as may be specified by the Council for the purpose of any scientific study or experiment or for medicinal or pharmaceutical research or development.'

A permit is also required for ethno biological research.

Under Rule 3 of Sarawak Biodiversity Centre Regulation 1997, only the following persons are eligible for such permits to conduct bio prospecting in the state:

a. Malaysian citizen who is either of Sarawak origin or permanently resident in Sarawak; or

b. A corporation or body corporate established under any written law in Malaysia or educational institution registered with the Ministry of Education, Malaysia; or

c. A corporation or educational institutions incorporated under the laws of foreign country with the experience, expertise knowledge and facilities to undertake research on the biological resources of the State; or

d. Any person who has special qualifications or expertise in any particular field of research relevant to the biological resources of the State.

However, a person under paragraph (c) and (d) above must have sponsors who are Malaysian citizens of Sarawak origin, or permanently resident in Sarawak, or an institution or a corporation incorporated or registered in Sarawak. Such a sponsor shall undertake to the Council that he will comply with the provisions of the Ordinance, the Regulations, and the conditions of the permit.

The Regulation also prohibit any collection of biological resources for research or commercial purposes from any state land, national park, nature reserve, wildlife sanctuary, forest reserve, protected forest or communal forest or any marine and aquatic areas without permit. It also prohibits such biological resources from being exported for research and commercial purposes without permit.

Under Rule 14 of the Regulation, the Sarawak Government may impose a condition that the State Government have the rights to patents and intellectual property to any discovery resulting from the research undertaken and, where appropriate, the rights to share such rights with other parties to the research agreement; and the rights to license any patent or intellectual property referred to above and the entitlement to benefits derived there from. The State may also require that the bio prospectors arrange for programmes or make arrangements for the transfer of technology, skills and knowledge derived from any research covered by such agreement, including the training of scientists from the state and their participation in such research.

In Malaysia, traditional Malay, Chinese and Indian systems of medicine are practised. Cross-cultural utilization of traditional systems of medicine is also popular. In Malaysia, the market for traditional medicine is estimated to be RM 1 billion to RM 2 billion annually, which is larger than the market for modern medicine [25].

The use of biotechnology in Singapore

Singapore focuses on different sectors of biotechnology, such as, allowing stem cell research, pharmaceuticals and medicinal products. As seen from Table 1 below, despite the challenges posed by the financial crisis in the late 1990s and other unfavourable global factors, Malaysia and Singapore largely remain on track in terms of economic growth and charted a 4.4 % and 5.4 % growth rate respectively in 2005.

Malaysia's economy is expected to grow by another 6 % in 2006. Table 1 below also shows that there is a big per capita income gap between Malaysia and Singapore. The per capita income in Malaysia is around US$9,857 compared to Singapore's per capita income of US$24,853. This could explain the difference in the R&D spending in Malaysia and Singapore. Singapore being a small country with a small population may concentrate on a specialised field. Malaysia, with 13 different states and a population of nearly 26 million people will have spend more on other areas, such as, poverty eradication and infrastructure development.

Since there is an income gap and the gap in R&D spending between the two countries, both countries focus on different areas in the biotechnology sector. Malaysia originally plans to focus on areas that can use its biodiversity as an attraction for investors, whereas Singapore concentrates on biomedical manufacturing. However, as mentioned above, Malaysia is also interested to venture into certain areas that can be considered the niche of Singapore, such as bio-manufacturing. It is expected that Malaysia and Singapore will be able to foster strategic partnership in the future. [26]

The Economic Development Board of Singapore (EDB) is responsible for the country's biotechnology development policy. The EDB aims to make the country a world-class hub attracting 15 top biotech or pharmaceutical companies by 2010. One of its projects is an infrastructure project called "Biopolis", an 18 million square foot biomedical sciences hub, housing public research institutes, corporate R&D centres and start-ups. The EDB first developed the R&D infrastructure as well human resource training and technology facilities. A gradual shift towards the promotion of biotechnology investments is part of the second stage [27]. The National Biotechnology Program Unit was established in 1988.

The EDB's priority is to develop pharmaceuticals and diagnostic toolkits of high commercial value. Recent initiatives by the EDB emphasize biomedical research geared toward commercializing and promoting a start-up formation to make Singapore a regulatory haven for stem cell research [28]. Singapore has also established the Biomedical Research Council and a Biomedical Grid, a high-security network enabling biomedical research information to be shared and distributed between interested parties within the 'grid'.

Table 1 – Economic growth in Malaysia and Singapore.

Country	GDP growth rate (constant prices)	GDP per capita, (current prices)	
	Percent	US$	US$ PPP
Malaysia	4.4 Q3 2005	4,625 2004	9,857 2004
Singapore	5.4 Q3 2005	25,207 2004	24,853 2004

Source: ASEAN Secretariat

Singapore has attracted some pharmaceutical giants. Eli Lilly is spending US$ 140 million on research over five years and Novartis is spending US$119 million over five to ten years from 2002 [29]. With the help of various incentives to attract R&D from foreign investors, Singapore has managed to produce various innovations like urine-powered batteries [30] and body parts produced from stem cells. [31] In view of the competition, Singapore plans to spend S$12 billion over the next five years as compared to S$5 billion dollars between 2001 and 2005 [32]

In addition, Singapore offers grants for start up companies [33]. There are several other initiatives, such as, US $ 600 million to attract leading international companies to conduct R&D in the form of a Biomedical Science Investment Fund. In addition, Singapore BioInnovations (SBI) has investment commitments of US$ 21 billion for 13 new companies. SBI invested in three European, five Asian and fifteen US based companies. Singapore also has a policy to develop a manpower requirement [34].

Although Singapore does not have many natural resources for certain bio-based R&D, its position in the centre of Southeast Asia, close to Malaysia and Indonesia, which are rich in such natural genetic resources, allows Singapore to remain competitive and take full use of such an advantage. The availability of funds also attracts investors to the country.

The statistics from the government are very encouraging [35]: The Biomedical Sciences industry's manufacturing output grew to S$15.8 billion in 2004, a 33.2% increase over 2003. Pharmaceuticals contributed S$13.9 billion or 88% to the total manufacturing output, with employment expanding by 7.4% compared to 2003. Value-added also showed a robust 48% growth to reach S$10.1 billion. Employment grew by a healthy 6.7% to 9,225 in 2004. Medical Technology enjoyed a 6.0% growth in manufacturing output to reach S$1.9 billion in 2004. The latest figures show that the Biomedical Sciences industry's manufacturing output grew to S$18 billion in 2005, a 9.8% increase over 2004. Pharmaceuticals accounted again for 88% of the total while Medical Technology enjoyed a strong 10.6% growth to reach S$2.1 billion in output. Employment also expan-

ded by a healthy 8.6% to cross the 10,000 mark. Of the 10,200 jobs in the BMS manufacturing sector, 62% are in Medical Technology [36]

Patents and Biotechnology in Malaysia and Singapore

It is commendable that the two neighbouring countries, which are also the two most dynamic economies in the ASEAN region, have managed to resort to high technology to generate economic growth. However, the issue is whether the emphasis on this high technology such as biotechnology is to the benefit or to the detriment of the local (home-grown) scientific communities. Are the local scientific community able to use the patent system in the same way as foreigners? Or, are the patent systems in the two countries more for the benefit of foreign investors? The other issue is whether the local scientific community will be able to take advantage of the foreign patents by engaging in various collaborations for mutual benefits, such as, to achieve technology transfer to local experts. These issues require further research to find the ways to allow the local scientific continue to fully benefit from the patent system.

Nevertheless, patent is not a licence to commercial success. Many patented products or process are not commercialised. There are other factors that affect a failure or a success of a patented product or process. At the same time, commercialisation also depends on the intention of the patent owners. Some patent owners apply for patents to protect future research rather than seek commercialisation. Commercialisation of patented products or process depends on other factors, such as, marketing skills, viability of the products or process to meet market and consumer demand and expectation, viability of production, and the ability to translate the technology into commercially viable process. At the same time, some products such as pharmaceuticals require regulatory approvals from relevant authorities. The regulatory process can take much time and incur huge expenses.

In Malaysia, many researches are conducted at public universities, as the universities have access to expertise and grants. However, the results of the research, even if patented may not result in commercialisation. According to a study by Amran Md. Rasli, an associate professor at University Teknologi Malaysia, anticipated commercialisation activities of the university failed due, in part, to the lack of connectivity between the industry and academia. One of the contributing factors to the failure is that commercialisation of R&D has not been traditionally a high priority of university research.[37]

Another factor that leads to lower commercialisation in Malaysia is the fact that most researches are funded by the Government. Recent assessment by the Ministry of Science, Technology and Innovation (MOSTI) indicated that most academia research and development (R&D) activities are funded by the ministry and other governmental agencies with only 0.68% university R&D funding coming from the industry as compared to the more advanced countries, such as, Canada (11.8%), Germany (7.5%), UK (6.2%) and the USA (5.5%). Countries such as Canada, Britain, Australia and Germany exhibit strong university-industry linkage. [38] Md. Rasli also finds that one key reason for poor university-industry linkage in Malaysian, especially in the life sciences sector, is the lack of industry receptors due to the limited state of development of this industry in Malaysia. The Malaysian industrial sector 'prefers' to be labour intensive and not invest into R&D in technology to gain competitive advantage. As such, Md. Rasli states that Malaysia's commercialisation effort to date has been quite modest with low number of patents indicated by 8.8 patent applications per population million as compared to Australia (546), USA (623) and South Korea (1,561). Further, compounding the situation is the fact that, the commercialisation movement has not resulted in any significant licensing revenue for the Malaysian universities. No R&D output from Malaysian universities has been commercialised yet on a national scale. Only 5.1 % of 5,232 R & D projects implemented during 7th and 8th Malaysia Plans were considered as having commercialisation potential.[39]

Thus, one of the ways to promote commercialization is to encourage joint ventures or collaborations between local and foreign firms. Foreign firms may need the market and access to natural resources and at the same time local firms need access to the technology. Patents and the numbers of patents filed do not give the accurate picture of the situation. For example, certain foreign companies might have licensed out their patent to a domestic firm, or they are in a joint-venture and the registration largely driven by the interests of the experienced foreign firm. A joint-venture agreement/ partnership also enables the domestic firm to get full access to the protected knowledge of the foreign firm. Moreover, the equation is too simple because young Malaysian companies cannot churn out as many patents as foreign companies who are in business for many decades, and have expertise in getting patents for even minor innovations. Malaysian companies may use patents to attract investment, but foreign companies use patents to broaden their war arsenal in case they are sued by another company for patent infringement.

Both Malaysia and Singapore are members of the World Trade Organisation ("WTO"). Both countries are also signatories of the Paris Convention for the Protection of Industrial Property 1883 ("Paris Convention") and the Washington Patent Cooperation Treaty 1970 ("PCT"). Being WTO members, both countries have to comply with the requirement of the Trade Related Intellectual Property Rights (TRIPs) Agreement. There is no doubt that both countries' patent laws are in compliance with TRIPs provisions. The main issue here is whether the existence and the implementation of the patent laws will benefit local innovations?

One of the ways to overcome this challenge is by the relevant country to introduce a *sui generis* system for certain innovation, such as, petty patent. Malaysia's Patent Act 1983 provides for utility innovation model,

generally known as utility model. Utility model may be defined as a second tier patent system, offering a cheap, no-examination protection regime for technical inventions which would not usually fulfil the strict patentability criteria. [40] The important factors identified by Suthersanen in relation to utility model are: utility model protection is accorded, cheaply and quickly, to inventions or innovations, many of which cannot gain protection under the patent regime.

Suthersanen identifies three traits common to all the national "utility model" laws from a global perspective: all utility model laws confer exclusive rights on the proprietor of the right (as opposed to an anti-copying right); novelty is a criterion in all utility model systems, though the standard of novelty varies widely; registration is a requirement but usually there is no substantive examination of applications; and most utility model laws protect the technical character of the invention, as opposed to the ornamental function or the appearance of the product. [41]

Simultaneously, the country may introduce sui generis registration system for traditional knowledge-based activities, as provided for under the CBD and discussed above. In this way, traditional knowledge-based activities may get protection in the form of proper registration and obtain rights, similar, to those obtained by patent holders.

The patent - dilemma with patents

Supporters of the patenting system argue that the rationale for a patent is to provide a long-term advantage to society as a whole by rewarding the development of new inventions. The counter argument is that the knowledge from the patents is not free and thus, the public may not fully benefit from the information provided in the patent disclosures. However, many innovations are not patented and remain trade secrets, meaning that a majority of new knowledge are not shared with the public.

It is also argued that patent promotes the advancement of technology and protects the inventor. The investors are rewarded by receiving exclusives over the inventions, which leads to financial rewards for their labour. Patent holders (most of which are the employers of the inventors) have the right to sell, transfer, assign or license the patented invention for free or for revenue. It is also argued that if there is no patent, individual inventors would not be encouraged to invent new products or share their inventions with the public. To obtain a patent, the inventor must eventually disclose to the public how to make and use the invention in the best way the inventor knows. The counter argument here is that inventors' motivation for obtaining a patent is for monetary gain rather than to share to knowledge with the public. The sharing of knowledge is by default of the system.

The Malaysian Patents Act 1983 and the Singaporean Patents Act 1995 provide that there are three elements to be satisfied before a patent is granted i.e. it must be new; involve inventive steps; and the invention must be industrially applicable. There are slight differences in the wordings of the laws.

Under the Malaysian Patent Act, an invention is patentable if it is new, involves an inventive step and is industrially applicable. [42] In Singapore a patentable invention is one that: (a) is new; (b) involves an inventive step; and (c) is capable of industrial application. [43]

The Malaysian Patents Act excludes from patentability discoveries- scientific theories, plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes and methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body other than to products used in any such methods. [44] This has direct implications for biotechnology. Singapore's patent law is more biotechnology friendly as it does not provide for such exclusion.

Countries such as Malaysia and Singapore are however wondering whether their patent systems are really used to reward development of new local and home grown inventions or whether they merely serve foreign patents to stake out their intellectual property rights area in the country? Does this mean foreign patent protection hinder local innovations? These two questions need further study so that not only Malaysia and Singapore will benefit from the answers but also other developing countries. This is because if local patents systems are just acting as mere agents to protect the interests of foreign inventions at the expense of local inventions, then there must be a rethink of the whole system, with a focus on how local inventions should be able to benefit more from the system.

Table 2 shows that, in Malaysia, between 1986 and 2006 there have been 82,008 foreign patent applications and only 4,603 local applications. Local applications are only about 5% of the total applications. Of the patents granted, local patents make up only 2.3%. The figure also shows that only 578 out of 4,603 or 12.5 % applications filed by locals are granted. The ratio for the foreign applications is higher, at about 30% of the total applications.

One of the possible explanations for this situation is that the majority of foreign applications are priority applications, meaning that their applications are based on approved patents issued elsewhere. The Malaysian Patent Office will normally approve patents already granted by the European Patent Office (EPO) or those meeting EPO standards. The lower ratio of approvals issued to local applications also explains the standard of advice they get from local practitioners. In Malaysia, there are about 150 patent agents and the majority of them are lawyers without technical or scientific background. This means that the advice they can offer to their clients are based on the interpretation of the law rather than assisting client with the scientific technicalities of the application.

Table 2: Patents Application in Malaysia

Year	Patent applications			Patents granted		
	Local	Foreign	Total	Local	Foreign	Total
1986	29	233	262	-	-	-
1987	71	3,195	3,266	-	-	-
1988	73	1,547	1,620	-	6	6
1989	84	1,803	1,887	11	121	132
1990	92	2,213	2,305	20	498	518
1991	106	2,321	2,427	29	1,021	1,050
1992	151	2,259	2,410	10	1,124	1,134
1993	198	2,684	2,882	14	1,270	1,284
1994	223	3,364	3,587	21	1,608	1,629
1995	185	3,992	4,177	29	1,724	1,753
1996	221	5,354	5,575	79	1,722	1,801
1997	179	6,273	6,452	52	737	789
1998	193	5,770	5,963	21	545	566
1999	218	5,621	5,839	39	682	721
2000	206	6,021	6,227	24	381	405
2001	271	5,663	5,934	18	1,452	1,470
2002	322	4,615	4,937	32	1,460	1,492
2003	376	4,686	5,056	31	1,547	1,578
2004	522	4,920	5,442	24	2,323	2,347
2005	522	5,764	6,286	37	2,471	2,508
2006	361	3,710	4,071	87	4,162	4,249
Total	4,603	82,008	86,605	578	24,854	25,432

Source: Malaysian Intellectual Property Corporation.

Table 3 : Patent Applications in Singapore 1990 to 2005

Year	Re Registration Applications	Direct National Filings and PCT Applications entering national phase	Total
1990	1028	-	1028
1991	1104	-	1104
1992	1354	-	1354
1993	1426	-	1426
1994	1818	-	1818
1995	2329	2412	4741
1996	2802	12357	15159
1997	2140	6048	8188
1998	-	6367	6367
1999	-	6679	6679
2000	-	7720	7720
2001	-	8133	8133
2002	-	8070	8070
2003	-	7908	7908
2004	-	7951	7951
2005	-	8605	8605

Source: Intellectual Property Office of Singapore

A check with the patent statistics in Malaysia and Singapore fails to reveal how many of those patents are biotechnology-based invention. Patent offices in both countries do not reveal how many patents are still in force. At the same time, there is no clear figure of how many patents are commercialised. Probably the Government should commission a study to find out how many of these patents are commercialised. The study is important to ascertain the effectiveness of patent system and its contribution to the local economy.

Table 3 above shows number of patent applications filed in Singapore from 1990 to 2005. Singapore has 96251 patent applications by way of registration, direct national filings, and PCT applications entering national phase. The figures from 1990 to 1995 in the second column refer to the re-registration application or priority application under the Paris Convention. The figures are applicable to those applications before the introduction of the new Patents Act 1995, which enforce the PCT into Singapore.

The third column refers to PCT applications in Singapore which designates Singapore as the applicable country where the patents will be enforced. Thus, these figures refer to foreign applications. Compared to Malaysian figures in Table 2 above, Singapore received more foreign applications than Malaysia. However, Malaysia has not implemented the PCT and all foreign re-registration applications will have to go through priority application procedure under the Paris Convention.

As shown in Table 4 above, local applications in Singapore between 1995 and 2005 is 4844. This is about 6% of the total applications filed as shown in Table 2 above. This shows that, although Singapore is seen as more advanced in the biotechnology field as compared to Malaysia, Singapore also suffers from serious local patents deficit even when compared to Malaysia. It is unfortunate that the Intellectual Property Office of Singapore does not produce the numbers of patents approved to facilitate comparison of the figures of Singapore's approved patents with the figures in Malaysia.

Policy Reforms

Malaysia has taken few policy measures to address the problems of lack of local innovations. For example, one of the main thrusts of the National Biotechnology Policy is to develop an effective legislative and regulatory framework [45]. Under this thrust, Malaysia seeks to create an ena-

Table 4 . Local Applications in Singapore

Year	No. of applications
1995	145
1996	224
1997	288
1998	311
1999	374
2000	516
2001	523
2002	624
2003	626
2004	641
2005	572

Source: Intellectual Property Office of Singapore, as of February 2006.

bling environment through continuous reviews of the country's regulatory framework and procedures in line with global standards and best practices [46].

Under the 9th Malaysia Plan 2006-2010, Malaysia recognises the importance of a good regulatory environment in developing the biotechnology industry. One of the thrusts is the creation of regulatory framework to facilitate the build up of a strong and diversified biotechnology industry [47]. As stated in the 9th Malaysia Plan, Malaysia intends to improve the intellectual property (IP) policy and management framework. The main objectives of the IP plan are:

- ⇒ to conduct a comparative study on the best practices of IP policy and management;
- ⇒ to identify areas for the improvement in IP regulations and processes;
- ⇒ to introduce guidelines on IP sharing for researchers in public research institutions and in business collaborations as well as for local and foreign ventures;
- ⇒ to establish a referral centre that offers technical advice on issues such as IP and regulatory compliance;
- ⇒ to conduct capacity building and awareness programmes to encourage researchers to patent their findings and products;
- ⇒ to develop a comprehensive IP guide and management manual; and
- ⇒ to develop an adequate IP-related human resource base including patent specialists, technology evaluators, lawyers and examiners.

Singapore has also introduced measures to increase patent applications in the country. The EDB introduced the Patent Application Fund-Plus Scheme in 2002. This fund is to partially fund patent application costs. According to the EDB, up to 2006, this fund has supported a total of 348 applications, of which 209 are Singapore based businesses and 139 individual inventors.

Conclusion

The above discussion shows that they are more foreign applicants (including resident foreigners) and foreign granted patents in Malaysia and Singapore than locals. It is expected that this trend will continue in their near future.

The existence of foreign patents may have negative effects on local innovations if the patent claims are broad. However, the patent system alone should not be the main reason for lack of innovation. There are many other factors that affect innovations, such as, availability of fund for R&D, existence of capable human capital, an environment conducive for research, and, existence of suitable facilities.

There has to be a rethink of how the two countries address the issues relating to..... In addition to capacity building, grants of patent application funds and awareness programmes, local patents offices in the two countries may have to look at the possibility of revamping substantive provisions in their patent laws. One such provision is on research exemptions. There should be wider exemptions given to the local scientific community to conduct research in areas which may otherwise be in breach of existing patents.

Under Section 37 of the Malaysian Patents Act 1983, the rights under the patent do not extend to acts done only for scientific research. This is a broad research exemption. Nevertheless, this has to be explained to the scientific community. In Singapore, Section 66 (2) of Singapore's Patent Act 1995 provides for an exemption for experimental purposes relating to the subject-matter of the invention. The wordings between the Malaysian and the Singaporean provisions are different. Malaysia refers to scientific research and Singapore refers to experimental purposes. It is suggested that Malaysia's research exemption is wider than the Singapore's exemption.

Research exemption is important to encourage R&D and innovation within this biotechnology field. Without research exemptions or clear authorisation, activities falling within the scope of the patent owner's rights infringe on the patent holders' rights. Consequently, patent legislation in many countries states that research and/or experimentation on a patented invention is not an infringement of the patent holders' rights. This experimental use exception attempts to balance the interests of patent holders in commercialising their inventions with those of society in fostering further research. [48] This is because access to basic or platform technology such as DNA sequences, cell lines, plants and animals at reasonable cost is crucial to research.

Malaysia and Singapore may have to learn from the experience of more developed countries. For example in the United States, although the US Patent Act does not provide for statutory research exemption, the Waxman Hatch Act of 1984 provides exemptions to experiments carried out on drugs or medical devices for the purpose of obtaining Food and Drug Administration approval.

In *Madey v. Duke University* [49] the Court of Appeals of the Federal Circuit that Duke University did not qualify for exemption because its use of the patented invention (a free electron laser) fell within normal "business" activities of the university, such as fulfilling government grants. Accordingly, in the US the research activities may not be shielded from patent infringement liability.

In Canada, the current Canadian experimental use exception is vague and dates from a 1971 decision of the Supreme Court of Canada in Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp. [50] decided in the context of research aimed at sustaining a compulsory licence. This situation was not remedied through the introduction of section 55.2 into the Patent Act. That section sets out a specific experimental use exception applicable only to regulated inventions such as pharmaceuticals.

The Canadian Biotechnology Advisory Committee (CBAC) recommends that the Patent Act should be amended to include an exemption from claims of infringement for research on a patented invention, as well as for certain research using a patented invention: [51]

It is not an infringement of a patent to use a patented process or product:

(a) privately and on a non-commercial scale or for a non-commercial purpose, provided that such purpose does not significantly prejudice the economic interests in the patent of its owner; and
(b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or to create a new (i.e., not incorporating the patented invention) product or process.

Most European countries have modelled their statutory provisions on Article 27 of the Community Patent Convention, even though it is not yet in force, the relevant portion reads: The rights conferred by a Community patent shall not extend to: (a) acts done privately and for non-commercial purposes; and (b) acts done for experimental purposes relating to the subject-matter of the patented invention.

The second part of the provision is similar to the provision in section 66(2) of the Singapore's Patent Act 1995.

The TRIPs Agreement provides exceptions to exclusive rights under certain conditions. It provides that

'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'[52]

Correa and Yusuf suggest that the following exceptions may be provided for within the scope of article 30: acts done privately and on a non-commercial scale, or for a non-commercial purpose; use of the invention for research; experimentation on the invention to test it or improve on it; use of the invention for teaching purposes; preparation of medicines under individual prescriptions; prior use; and experiments made for the purposes of seeking regulatory approval for marketing of a product after the expiration of the patent. [53]

In Switzerland, Thumm reports that there are asking for a broad research exemption, which is considered to be a more efficient strategy to resolve problems to those technologies of public interest. They also have asked for clarification for the "experimental use" exemption. [54]

Any reforms that the Governments of Singapore and Malaysia introduce may take into account several factors, such as, the need to attract and maintain foreign investments and at the same time the desire to encourage local domestic innovations.

The continued reliance on foreign technologies and foreign direct investment may have negative effects on the economy in the future as foreign companies may be more attracted to new markets which offer better returns for their investment.

Therefore, it is of crucial importance that governments in developing countries assist local innovators in all their efforts to file a patent. However, states cannot ensure the successful commercialization of the patent and for that purpose, foreign companies may still be of some importance (e.g. the local patent holder could license out the technology to a company (foreign or local) that has all the resources to commercialize it. The revenues from the royalty fees could then be reinvested into local private R&D in order to eventually obtain new patents. These would be genuine knowledge firms and they are likely to emerge also in countries such as Malaysia and Singapore, if the governments encourage such a development.

About the author

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45. Malaysian National Biotechnology Policy 2005, Thrust 7.

46. For discussions on development of biotechnology legal system in developing countries such as Malaysia, see Sufian Jusoh, Developing Biotechnology Legal System in Developing Countries, 3 Journal of International Biotechnology Law 4, 160-172.

47. See 9th Malaysia Plan, note 14 above, 162.

48. Canadian Biotechnology Advisory Committee (CBAC), Patenting of Higher Life Forms and Related Issues, June 2002, available at: http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00188e.html#sec2d3.

49. Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

50. (1971) 2 C.P.R. (2d) 193 (SCC).

51. See CBAC note 49 above.

52. TRIPs, article 30.

53. See C.M. Correa. And AA Yusuf , Intellectual Property and International Trade: The TRIPs Agreement, Kluwer Law International, 1998.

54. Thumm, N., Research and Patenting in Biotechnology, a Survey in Switzerland, Swiss Federal Institute of Intellectual Property, 2003, 67.