

Patents and Essential Medicines: an Application of the Green Intellectual Property Project

Itaru Nitta*

Since 2001, the Doha Declaration and the August Decision in the World Trade Organization (WTO) as well as the price collapse of patent-protected HIV/AIDS medicines in developing countries have created the erosion of patent rights. While this erosion has functioned as a safeguard measure for developing nations to access those medicines, it has also resulted in the deterioration of pharmaceutical companies' incentives to further develop HIV/AIDS medicines. To simultaneously pursue the effective distribution and development of essential medicines for poverty-related diseases, including HIV/AIDS, this article argues a practical application of the Green Intellectual Patent (GIP) system. This system would create the GIP Trust Fund financed by reserves, taxes, and premiums in the patent system. The GIP reserve is a special budget for the GIP Trust Fund. The GIP tax is paid by successful patentees when they earn patent incomes including royalties and infringement compensations. The GIP premium is an insurance fee paid by patent beneficiaries to assure them of patent incomes. In return for this premium, when impoverished countries demand a safeguard measure for essential medicines, the GIP system would offer the GIP financial aid to such countries, including royalty assumption and the subsidy for purchasing needed medicines. Since this GIP financial aid would circumvent safeguard measures while allowing impoverished nations to access essential medicines and the GIP system would ensure patent incomes for patent beneficiaries, the system would increase pharmaceutical companies' incentives to develop medicines for poverty-related diseases even when the medicine's users do not have sufficient financial means. These mutual benefits for both patent users and owners would convince patent applicants and patentees of their financial burdens for the GIP Trust Fund, which could annually reach several tens of billions in US dollars at the highest amount.

* School of International Service, American University, Washington, D.C. and Wakabayashi Intellectual Property Law, Tokyo. The author can be reached at itaru100@yahoo.co.jp or +1-301-468-7353 (Phone / Facsimile).

INTRODUCTION

On June 27, 2005, Brazil announced that they were planning to exercise a compulsory license on the domestic production of the HIV/AIDS medicine, Kaletra, which is patented by a major US-based pharmaceutical company, Abbott Laboratories (Costa, 2005). This compulsory license would be an implementation of a public health safeguard that Article 31 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement stipulates as a flexibility of that agreement. Brazil's announcement symbolizes the heated debates about the tension between the TRIPS Agreement and the accessibility to essential medicines in developing countries, including least developed countries (LDCs) and advanced developing countries (ADCs).

To remove these tensions through the effective distribution of essential medicines while increasing companies' incentives, this article argues the feasibility for the "Green Intellectual Property (GIP)" system. The GIP system is a reformed patent system which the author has recently proposed (Nitta, 2005a and 2005b). This system would divert a part of the patent-related monetary flow toward a monetary pool for financial aid in developing countries. The next sections will review recent frictions concerning the TRIPS agreement and evaluate the GIP system from two sides: collecting and distributing patent-related money.

OBSTACLES TO DISTRIBUTION OF ESSENTIAL MEDICINES

Recent debates about the safeguard measures in the TRIPS agreement essentially include two issues: domestic manufacture and trade of generic copies for essential medicines. These safeguard measures are expected as a tool for developing countries to effectively access essential medicines, yet that is not what has happened.

Domestic Manufacture of Generic Copies

India and Brazil are the largest producers of generic medicines

(Homedes, 2005). These medicines have not been patented in these countries because the original applications were filed during a transition period when India and Brazil were not fully obligated to the TRIPS Agreement (Article 70.8). These countries have provided generic medicines at affordable prices, which has resulted in competition that demands a remarkable slashing of the original prices on branded medicines. For example, since the late 1990's, India and Brazil have been manufacturing generic copies including the World Health Organization (WHO)-recommended triple-cocktail medicine (d4T/3TC/NVP). In the year 2000, the lowest generic price of this cocktail was found in Brazil at \$2,765 per patient per year, and the lowest brand price was \$10,439. As of June, 2005, the lowest generic price of that cocktail was in India at \$152, and the lowest brand price was \$562, a result of sufficient price reduction since 2000 (MSF, 2005c). These generic copies and the competition they create enable not only India and Brazil themselves, but also LDCs in Africa to access essential medicines. While LDCs are not equipped to manufacture generic medicines in their countries, they can afford to purchase generic medicines at low prices from ADCs.

However, when the TRIPS transition period ended, India and Brazil were forced to comply with the full provisions of that agreement, which now demands that they implement patent protections for medicines in their countries. This implementation prevents them from domestic production of the generic medicines whose patent applications were filed after the transition period. Namely, the governments of India and Brazil introduced patent protection for medicines in 1995 and 1997, respectively. These countries now ban domestic production of the generic medicines that were applied and patented after those years by pharmaceutical companies in developed countries (MSF, 2004; MSF, 2005a). These patent protections significantly block access to newer HIV/AIDS medicines, especially for second-phase treatments. Due to the lack of competition between generic copies and original brands in LDCs of Africa, the prices of second-phase

medicines are approximately ten times higher than those of older first-phase medicines including the HIV/AIDS triple-cocktail (MSF, 2005b).

A compulsory license provides a safeguard measure that allows ADCs to manufacture patented medicines, such as second-phase medicines. However, it also provides a fierce conflict between patentees in developed countries and patent users in ADCs and LDCs. For example, as soon as Brazil announced their plan of implementing a compulsory license on Kaletra, American inventors reacted strongly. Abbott Laboratories denounced Brazil for the fact that they have the world's ninth largest economy and criticized that the objective of Brazil's action was to support their own pharmaceutical industries, which is inconsistent with the intent of the flexibility built into the TRIPS agreement to aid health emergencies in the poorest countries (Abbott, 2005). USA for Innovation also urged the United States Trade Representative to immediately issue a statement that their trade relations with Brazil would be adversely affected if Brazil actually seized their patents (USA for Innovation, 2005). Finally, Brazil and Abbott Laboratories reached an agreement on volume discounts for the purchase of Kaletra. While Abbott has agreed to cut their price to a level of a similar generic copy, Brazil must purchase a greater volume of the medicine. As a result of their negotiation, Abbott stated: "We're pleased to have reached an agreement that expanded access to Kaletra for Brazilian patients and preserved our intellectual property rights, which Abbott was not willing to negotiate" (Khalip, 2005). In the past, Brazil had successfully reached similar agreements with other pharmaceutical companies after threatening to wave their patents. These companies always proposed a price cut and never allowed Brazil to implement the compulsory license. Clearly, patent rights are invaluable assets for industries.

Trade of Generic Copies

The compulsory license that Article 31 of the TRIPS Agreement prescribes can function as a safeguard measure for ADCs which have the ability to manufacture patented generics. However, this license is completely useless for LDCs which are not equipped to produce generic medicines by themselves. This is because Article 31 allows domestic production of generic copies, yet Article 31(f) prohibits the exportation of such copies. In other words, although many of those who need HIV/AIDS medicines reside in LDCs in Africa, these countries cannot import generic medicines at affordable prices from ADCs such as India and Brazil.

This low flexibility on the trade of generic copies has provoked harsh criticism of the World Trade Organization (WTO) worldwide. This criticism led to a special ministerial declaration, the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), which was adopted on November 14, 2001 (Document #: WT/MIN(01)/DEC/W/2). Paragraph 6 of the Doha Declaration instructed the TRIPS Council to expeditiously establish a rule for waivers of Article 31(f), which allows LDCs without pharmaceutical manufacturing capacities to import generic copies. To this end, the TRIPS Council had to arbitrate a serious conflict between developed and developing countries. To protect their patents from being seized, developed countries, particularly the US, Switzerland and Japan, asserted a narrow rule available for limited medicines and countries. On the other hand, for sufficient access to medicines, ADCs and LDCs demanded a broad rule for comprehensive medicines and countries. As a

result of intensive and extended consultations, developed countries made a concession and agreed with a broad rule in the General Council Decision on August 30, 2003 (August Decision, Document #: WT/L/540). Paragraph 2 of the August Decision prescribes a procedure for waivers of the provision of Article 31(f) in the TRIPS agreement and the trade of the generic copies that are produced under a compulsory license.

However, the August Decision never brought about complete settlement of the controversy surrounding safeguard measures for essential medicines. For example, strong obstacles by developed countries have impeded further progress of the Decision. The August Decision is merely a temporary solution and African countries have insisted on the actual amendment of Article 31 in the TRIPS agreement as a replacement of that solution. Although the original deadline of that amendment was June, 2004, based on Paragraph 11 of the August Decision, no prospect has yet emerged because of developed countries' strong opposition to an amendment of Article 31 (South Center and CIEL, 2005).

DIMINISHED DEVELOPMENT OF ESSENTIAL MEDICINES

The Doha Declaration in 2001, the August Decision in 2003, and sharp cuts to patent-protected prices for HIV/AIDS medicines in developing countries since 2001 (Wall Street Journal, 2001 and MSF, 2005) have threatened the erosion of patent rights. This threat results in not only fierce arguments about TRIPS's safeguard measures but also a more serious consequence. That is to say, patent erosion leads to the deterioration of pharmaceutical companies' incentives to further develop HIV/AIDS medicines. If patent erosion more rapidly progressed in developing countries, -- for example, if ADCs and LDCs issued many compulsory licenses and traded a large quantity of generic medicines for the diseases from which they are suffering, -- research-intensive pharmaceutical enterprises would cut their ties with such poverty-related diseases including HIV/AIDS. Pharmaceutical firms would shift their emphasis of research and development to higher-profit medicines for affluence-related diseases such as rheumatism.

In fact, Figure 1 shows a recent decelerating trend in the number of HIV/AIDS-related patent applications in the US by American and foreign applicants. As is shown, the applications for rheumatic medicines, a typical example of high-profit goods related to affluence-related diseases, have been continuously increasing. However, the applications for HIV/AIDS medicines have been gradually decreasing since 2001, the year of the Doha Declaration. For example, 171 patents for HIV/AIDS medicines were granted after the USPTO's examination in two or three years from their applications in 2000 (Figure 1, open circle at the year 2000). In contrast, only 133 patents were granted among the applications filed in 2001 (Figure 1, open circle at the year 2001). These facts suggest that HIV/AIDS-related applications decreased from 2000 to 2001. In addition, 319 applications were filed for HIV/AIDS in 2002 (Figure 1, filled circle at the year 2002), whereas only 276 applications were filed in 2003 (Figure 1, filled circle at the year 2003), which means a 14% decrease of applications in 2003. Since the number of patent applications often reflects the level of research and development activities, the downward trend in HIV/AIDS-related applications would indicate the

deterioration of pharmaceutical companies' incentives to develop new HIV/AIDS medicines. In addition, such downward patent activity seems to correlate with the progress of patent threat and erosion since 2001. Therefore, we could conclude that threat and erosion of patent rights in developing countries actually have an adverse affect on the research and development for HIV/AIDS medicines in developed countries.

Companies' incentives for research and development of new medicines require adequate patent protections, which enable companies both to collect earlier investment for development of new medicines and to assure allowable profits as a price of their efforts for developing those medicines.

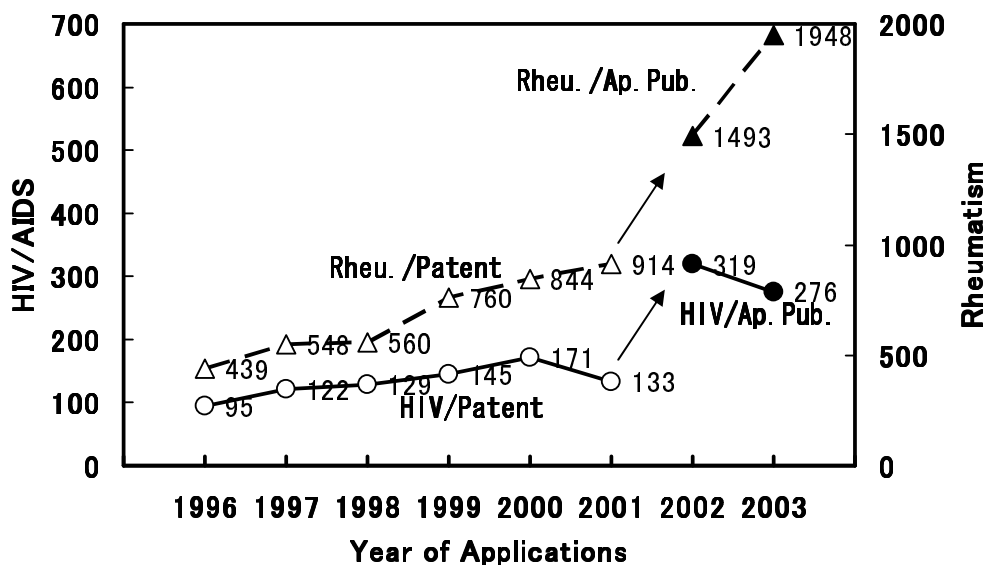


Figure 1. A downward trend of the number of patent applications for HIV/AIDS medicines in and toward the US since 2001. Since the Doha Declaration in 2001, the number of patent applications for HIV/AIDS has been decreasing in contrast to a continued increase in medicines for rheumatic medicines, a typical example of high-profit goods related with affluence-related diseases. The horizontal axis of the figure represents the year when a patent application was filed with the US Patent and Trademark Office (USPTO) by an American or foreign applicant. The left and right vertical axes represent the number of granted patents for HIV/AIDS and rheumatism, respectively when an application was filed in 2001 or earlier. In the middle of the figure, the left solid line (marker: open circle) and left dashed line (marker: open triangle) correspond to HIV/AIDS and rheumatism, respectively. For example, among HIV/AIDS-related applications filed in 2001, 133 patents were issued after examinations in usually two or three years from their application. However, when an application was filed in 2002 or 2003, a major percentage of applications is still under examination and not issued yet. For these later applications, two vertical axes indicate the number of application publications before examination, instead of the number of granted patents. In the figure, the right solid line (marker: filled circle) shows application publications for HIV/AIDS medicines and the right dashed line (marker: filled triangle) shows those for rheumatism medicines. The patent applications filed on or after November 29, 2000 have been disclosed in the form of application publications by the amended US patent law (35 U.S.C. §122(b)). For example, 319 applications for HIV/AIDS medicines were filed in 2002 and they are now available from application publications.

Methodology: These data for HIV/AIDS were obtained by a retrieval formula, (SPEC/(((AIDS OR HIV) OR ((acquired AND immunodeficiency) AND syndrome)) OR ((human AND immunodeficiency) AND virus)) AND (retroviruses OR retrovirus)) AND (ICL/A61K031/\$ OR ICL/A61K047/\$)) AND APD/year\$\$, from the USPTO databases. The retrieval formula for rheumatism was (SPEC/((rheumatic OR rheumatism) OR rheumatoid) AND (ICL/A61K031/\$ OR ICL/A61K047/\$)) AND APD/year\$\$.

SIMULTANEOUS PURSUIT OF DISTRIBUTION AND DEVELOPMENT FOR ESSENTIAL MEDICINES

Recent deceleration of the development for HIV/AIDS medicines indicates that careful considerations are indispensable not only for patent users in developing countries, but also for patentees in developed countries. These considerations will allow for the sufficient distribution and development for essential medicines simultaneously. To this end, several proposals have suggested raising new funds to control patent-protected prices of medicines. For example, Sachs et al. (2002) proposed a vaccine-purchases fund and other scholars suggested similar funds (Barton, 2001; Subramanian, 2001). More recently, Ganslandt et al. (2005) proposed the Developing Economies' Fund for Essential New Drugs (DEFEND) to complement earlier suggestions. These proposals seek to inspire companies to develop medicines even

if their users do not have enough financial power to purchase them. The financial aid in these proposals aims to enable developing nations to purchase essential medicines with patent-protected prices, which would prevent compulsory licenses and trade in generic copies.

However, these previous ideas are based on financial resources outside the patent system, such as an international fund managed and funded by the Joint United Nations Program on HIV/AIDS (UNAIDS) or the World Health Organization (WHO) (Ganslandt, 2005), even though the objective of those ideas is to rectify the problems in the patent system. In other words, to address the problems of the patent system, these proposals advocate appropriating financial resources from other organizations rather than from the patent system. Since these organizations are financially over-burdened with their

own responsibilities, this financial burden shift from the patent system to other organization thwarts previous proposals.

The GIP System

In contrast, I have proposed the GIP system, which procures financial resources from inside the current intellectual property system (Nitta, 2005a and 2005b). Namely, the GIP system would collect a part of patent-related monetary flow in the form of budgetary reserves, taxes, and premiums. This collected money would be diverted to a monetary pool or a "GIP Trust Fund," from which the system would provide "GIP financial aid" (Nitta, 2005a and 2005b). When an institution needed a green technology, including essential medicines, and was unable to afford access to such technology because of a capital shortage, the GIP system would offer the necessary financial support. This support would come in the form of a soft loan or grant for purchasing that technology, or a royalty assumption for introducing that technology.

Establishing the GIP Trust Fund

The GIP Trust Fund would be established from three financial resources, which would be newly created inside the patent system: the GIP reserve, GIP tax, and GIP premium. Put simply, the GIP reserve would be a special budget to which revenues of the patent office are allocated. The GIP tax would be a kind of "green tax" collected from successful patentees when they earn license royalties and patent infringement compensations through the enforcement of their patent rights. The GIP premium would be a payment by patent applicants and holders as an insurance fee to guarantee royalties and financial rewards from their innovations. This guarantee would occur when the patent system assumed the royalty payment on behalf of patent users if they have no financial power to pay the royalty. The patent system would also subsidize the purchase of patent-protected technologies for their users who are without financial measures. This financial aid would prevent compulsory licenses and price collapses of medicines in developing countries, which assures the benefits of patentees.

The GIP reserve

If the patent system allocated a portion of its income to the GIP reserve, the system would create a financial resource to establish the GIP Trust Fund without soliciting additional revenue. In other words, the GIP reserve could be conceived as a product of socially responsible allocation of patent-related monetary flows.

Major players in the patent system are those who have enough financial power to create innovations and obtain their patent rights. To take legal actions such as filing applications and maintaining patent rights, patent applicants and holders pay various official fees that provide a large amount of revenue to the patent system. For example, the World Intellectual Property Organization (WIPO), a major patent office in the patent system, in 2004 produced revenue at \$226 million, including \$176 million (78%) of the official fees for the Patent Cooperation Treaty (PCT) applications (WIPO, 2005a). If the WIPO had allocated a portion of this income, even at a small portion, it would have helped to establish the GIP reserve. However, in 2002, the Assemblies of the Member States of the WIPO approved a plan to spend \$130 million for the construction of a new administrative building and \$30 million for the construction of a new conference hall (WIPO, 2005c). As shown in Table 1, the WIPO's expenditures in 2004 were

\$252 million, which included \$207 million in operation costs (82%) and \$45 million in non-operation costs (18%), including infrastructure construction costs (WIPO, 2005b). The WIPO also predicts that its expenditures will increase in the next five years due to an increase in income from PCT applications. These expenditures for non-operation of the patent system, if contributed to the GIP reserve, would have prevented the erosion of patent rights in developing countries while allowing them to obtain needed medicines.

In another example, the United States Patent and Trademark Office (USPTO) earned a total of \$1.2 billion including \$1.0 billion from patent official fees in the fiscal year 2003 (USPTO, 2004a). Similar to the WIPO, the USPTO has annually spent \$15 million since 2001 to construct its new headquarters in Alexandria, Virginia (USPTO, 2001). Table 1 also shows that in fiscal year 2003, the USPTO spent a total of \$1.2 billion (USPTO, 2004a), and reports that non-operation costs traditionally comprise approximately one-third of its annual costs, or about \$400 million (USPTO, 2004b). Like the WIPO, the USPTO also predicts that its expenditure will increase over the next several years due to an increase in income from patent applications in and toward the U.S.

In addition to the WIPO and USPTO, Table 1 further shows that two other major offices, the European Patent Office (EPO) and Japan Patent Office (JPO), in 2004 spent respectively \$1.4 and \$1.3 billion, including \$484 and \$106 million for non-operation costs (EPO, 2004 and JPO, 2005). Taken together these non-operation costs, the total amount in 2004 was \$1.0 billion in only four patent offices. If even 1% of these expenditures had been allocated to the GIP reserve, the patent system would annually obtain at least \$10 million for the establishment of the GIP Trust Fund. Due to the large amount of total patent expenditures, if the patent system were to spend only a small fraction toward the GIP reserve, it would provide significant financial resources for the GIP Trust Fund.

The GIP tax

In addition to the revenue and expenditures in the patent offices, there are other patent-related monetary flows from which the patent system could potentially create the financial resources in the form of the GIP tax for the GIP Trust Fund. An example of such flows is royalty payments for a patent license from a patent user to owner. Another example is compensation payment for litigation from a patent infringer to owner. When a successful patentee earns patent incomes, including royalties and compensations gained through infringement actions, this patentee would pay the GIP tax from these patent incomes.

These patent-related monetary flows provide industrial corporations and research institutions a large amount of patent incomes. For example, in 2001, IBM earned \$1.5 billion in patent incomes, which are equal to 1.7% of their total income of \$90 billion (Nikkei, 2002). In twelve consecutive years, IBM has been the highest patent receiver from the USPTO in the world and they obtained 3,248 patents in 2004, including medical applications for the treatment of HIV/AIDS (USPTO, 2005). Based on these myriad patents, protection of their intellectual properties has grown into a business, which could provide over \$10 billion income to the company in the near future (Teresko, 2003). Similarly, Canon, a Japanese intellectual property giant, worldwide held 70,000 patents as of the end of 2001 and their patent income was \$22 million, 10%

of their total income (Nikkei, 2002). Their patents also include the products for medical treatments of HIV/AIDS. In addition to these commercial institutions, traditionally non-commercial research institutions have recently come into the "market of intellectual properties." For instance, the

national rankings for patent income in 2002 reported that the University of Cincinnati earned \$4 million in patent incomes for the first time (UC, 2002).

Table 1. Income/cost of major patent offices (US dollars in millions).

Year	WIPO 2004	EPO ³⁾ 2004	USPTO FY2003	JPO ⁶⁾ FY2004
Revenue	226 ¹⁾	1,398	1,162 ⁴⁾	1,268
Patent fee	176	1,215	1,005	983
Others	50	183	157	285
Expenditure	252 ²⁾	1,398	1,206 ⁴⁾	1,287
Operation	207	914	804 ⁵⁾	1,181
Non-operation	45	484	402	106

Sources and notes

¹ "Revised proposal for program and budget 2004-2005," WO/PBC/7/2. WIPO, 2005, Geneva, Switzerland, Table 20, the author converted the original value in Swiss franc to US dollar.

² *Id.*, Table 19.

³ "Annual report 2004," EPO, 2005, Munich, Germany, p.66, the author converted the original value in euro to US dollar.

⁴ "United States Patent and Trademark Office performance and accountability report, Fiscal year 2003," USPTO, 2004, Alexandria, Virginia, pp. 54-57.

⁵ *Id.*, p. 56, the third paragraph. This paragraph reports that USPTO's non-operation costs account for approximately one-third of the total expenditure. Based on this fact, the amount in the table was calculated by the author.

⁶ "Patent administration annual report (Japanese)," JPO, 2005, Tokyo, Japan, the author converted the original value in yen to US dollar.

Several surveys on the global market of intellectual properties reported that its size in 2002 hit \$100 billion despite almost only half of all patents in the world was enforced for patent licenses and litigations (e.g., Chesbrough, 2003). These surveys also predicted that the global size of the intellectual property market would expand to \$5 trillion until 2010 by virtue of the exploitation of unenforced patents (Nikkei, 2002). If the patent system collected a small portion, for example, even 1%, of this vast monetary flow from patent licenses and litigations, the system would annually obtain \$50 billion in the form of the GIP tax from successful patentees. This amount is comparable to the total of official development assistances (ODA) from the member countries in the Organization for Economic Cooperation and Development (OECD) in 2004 -- \$78.6 billion (DAC, 2005) -- and sufficient to raise the GIP Trust Fund.

GIP premium

In addition to the GIP reserve and tax, the third potential financial resource for the GIP Trust Fund is the GIP premium. The GIP premium could be regarded as the payment for a contract of "GIP insurance." As patent applicants pay application and examination fees for their patent applications and patentees pay maintenance fees for their granted patents, they would additionally pay the GIP premium. In return for this GIP premium, the GIP system would protect insured patentee's patent property from potential and actual damage or loss through safeguard measures or flexibilities of the patent system. Namely, in the event that impoverished nations give notice of the compulsory license for an essential technology or they demand a large price cut instead of that compulsory license, the GIP system would offer GIP financial aid, including royalty assumption and a subsidy for purchasing

such technology. This financial aid would circumvent compulsory licenses or price cuts in developing countries, which would result in the protection of patentee's intellectual property while allowing poor nations to obtain essential medicines.

A reasonable price for the GIP premium would sufficiently contribute to the establishment of the GIP Trust Fund and simultaneously realize the effective protection of patent rights and distribution of essential medicines in developing countries. Although the GIP premium increases the total expense to create and hold a patent, such a hike would be within an acceptable range. This is because, as long as the GIP premium costs less than 30% of an official fee, an additional payment for the GIP premium would be less than 10% of the total expense to obtain a patent. That is to say, the additional payment would not appear as a significant rise of the total expense due to low percentage of official fees in the total expense for a patent right. For example, one regular patent application in the US costs roughly \$4,800, which contains only \$1,300 in minimum official fees (application and examination fee) and \$3,500 that goes toward other expenditures such as attorney fees (based on the author's experiences). If the GIP premium is \$130 -- 10% of official fees --, this payment results in only a 3% increase in the total expense for obtaining a patent right. This 3% increase provides an applicant with a solid guarantee for patent royalties and patent-protected prices of an invented product and service. At a small fee, the GIP premium acts as an insurance policy and investment in the patent's future.

Even if the GIP premium amounts to less than 30% of official fees, the total incomes from the premium throughout the world

would be sufficient to create a financial resource for the GIP Trust Fund. For example, since the total amount of official fees paid for US patent applications and prosecutions in the fiscal year 2003 was \$1,005 million (see Table 1), the potential amount of the GIP premium would be \$100 million if the GIP premium was set to 10% of official fees. Similarly, the potential amounts in the WIPO, EPO and JPO would be \$18, \$122 and \$98 million, respectively, which means that the global amount of the GIP premium would be at least \$238 million annually.

As mentioned earlier, the current patent system runs on a large cash flow. By diverting a portion of this monetary flow, even at a small portion, the patent system would create the GIP reserve, tax, and premium, which is sufficient to establish the GIP Trust Fund. Specifically, 1% of non-operation expenditures in the patent offices, 1% of incomes in the patent market and a premium equivalent to 3% of the total cost for a patent would create worldwide \$10 million for the GIP reserve, \$50 billion for the GIP tax, and \$238 million for the GIP premium, respectively every year (see Table 2).

Table 2. Global financial resources for the GIP Trust Fund (US dollars).

	GIP Reserve	GIP Tax	GIP Premium
Source	Non-operational official costs	Patent market	Additional payments by applicants and patentees
Total amount	\$1 billion ¹⁾	\$5 trillion ²⁾	3% of the total cost to obtain a patent right ³⁾
Ratio for GIP	1%	1%	
Potential revenue	\$10 million	\$50 billion	\$238 million

Sources and Notes

¹ Annual reports of the year 2004 or fiscal year 2003 from WIPO, EPO, USPTO and JPO.

² Nikkei, 2002. Nihon Keizai Shimbun (Japanese newspaper), May 31, 2002, source: QED Intellectual Property, London.

³ Calculation based on a 10% of official fees.

Two Principles for Justify: Mutual Benefits and Compensation for Social Degradation

The GIP system would obey two principles that would convince patent applicants and owners of a payment for the GIP reserve, tax, and premium. The first is the principle of mutual benefits for both patent users and owners. While the GIP financial aid would enable impoverished countries, such as African nations, to access necessary technologies, including HIV/AIDS medicines, this aid would also provide benefits to patentees, i.e., pharmaceutical companies. This is because the GIP system would guarantee that patentees can collect early investments for developing new HIV/AIDS medicines and they can earn reasonable rewards for their efforts even when the medicines' users do not themselves have enough financial power to access these medicines. This two-sided benefit of the GIP system would provide reconciliation between patentees in developed countries and users in developing countries. As a result, the GIP system would shift inventors' incentives from higher-profit medicines for affluence-related diseases toward the medicines for poverty-related diseases even when the market for such medicines is not fertile. Since the GIP insurance would offer financial aid to patent users and the insurance would also offer patent grantee to patentees simultaneously, the GIP insurance would be compatible with the principle of mutual benefits. This principle would justify patent beneficiaries' payment for the GIP premium.

The second principle asks patent beneficiaries to consider the negative impacts on our society, which the current patent system has generated through patent monopolies. These negative impacts have been overlooked by society, which leads to "external costs." Patent monopoly concentrates capital or increases capital intensity for a patentee by blocking unauthorized access to a patented product and service. This

heightened capital intensity is the engine for technological progress because such capital resource enables a patentee to invest in further technological progress. However, while patent-driven technological progress has improved our living standards, such progress has also produced negative impacts on our society through haphazard economic growth. For example, such uneven economic growth has induced mass consumption in developed countries and increased gaps in economies between rich and poor nations, which has resulted in various social degradations. These results raise two demands for the current patent system. First, the patent system should consider neglected negative costs for social degradations. Second, developed countries carry the entire responsibility to pay such costs because developed countries have enough financial resources, which the patent system has provided in return for the global social degradations. These arguments lead to a clear conclusion; namely, the beneficiaries of the patent system -- patent applicants and holders in developed countries -- must contribute to the elimination of social inequalities that the current patent system produces. In accordance with this principle, the GIP system would allocate its revenue to the GIP revenue and collect the GIP tax from successful patent beneficiaries.

Distributing the GIP Financial Aid

Two principles of mutual benefits and compensation for social degradation would enable the GIP system to create financial resources ranging from several tens of millions to several tens of billions of dollars as the GIP reserve, tax, and premium. From these financial resources, the GIP system would establish the GIP Trust Fund and distribute the GIP financial aid to countries whose populations suffer from HIV/AIDS.

Despite a sign of recent progresses in the global response to

HIV/AIDS epidemic, it continues to spread especially in LDCs and ADCs. In those countries, almost 40 million people are living with HIV (see Table 3) and the number of HIV/AIDS patients is still on the rise. In 2004 alone, 4.9 million people in these countries became newly infected and this number was greater than any year since the first AIDS diagnosis in 1981. In addition to Sub-Saharan Africa, which has traditionally had the largest number of patients, new epidemics emerge in other areas. Specifically, Eastern Europe and Asia have experienced a faster increase in patients than any other region in these years (UNAIDS, 2004a).

Increased funding and political commitment have made considerable gains during past few years to calm those epidemics in virtue of scaling up access to HIV/AIDS treatments and preventions. For example, the "Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief" is supposed to enable 700,000 people to reach needed treatments by the end of 2005. In addition to this grant, the UN systems, national governments, and bilateral and international donors have pledged to provide grants of almost \$2 billion together to expand HIV/AIDS treatments in LDCs and ADCs (UNAIDS, 2004b). Among these, the WHO and UNAIDS in September, 2003 launched the "3 by 5" Initiative to provide HIV/AIDS drugs to three million people by the end of 2005. "Three million" is just an interim target and the program aims at functioning as a trigger to ultimately realize universal access to HIV/AIDS drugs and other measures against HIV/AIDS epidemic throughout the world (WHO, 2005).

However, these global responses to the HIV/AIDS epidemic remain extremely insufficient. Although the global spending on HIV/AIDS has increased 15-fold from \$300 million in 1996 to \$6.1 billion in 2004, this figure is still almost half of the \$12 billion needed in 2005 for developing countries (UNAIDS, 2004b). Specifically, Table 3 shows, among the total 37.6 million patients, 6.5 million people immediately need HIV/AIDS medicines in LDCs and ADCs. However, 5.5 million (85%) of them do not have access to required medicines. This circumstance means that four out of five people who urgently need HIV/AIDS treatments cannot reach necessary treatments and they will die in the next two years. Especially in Sub-Saharan Africa, 4.7 million patients need HIV/AIDS drugs and 4.2 million patients have not received any drug as of June, 2005 (see Table 3). In this area, the WHO recommends the triple-cocktail drug (d4T/3TC/NVP or its equivalent), which costs \$175 per person per year at the lowest price. This means that an additional \$735 million is needed to treat all patients in Sub-Saharan Africa. Similarly, Asia, Latin America and the Caribbean, Eastern Europe and Central Asia, and North Africa and the Middle East need \$144, \$44, \$59 and \$18 million, respectively. For all LDCs and ADCs, an additional \$1 billion is together needed every year for HIV/AIDS drugs.

With the inclusion of these costs for HIV/AIDS drugs, the UNAIDS estimates that approximately \$10 billion will be needed annually in the next several years for comprehensive HIV/AIDS programs, including treatment, prevention, counseling, education and care of orphans whose parents died of AIDS (UNAIDS, 2004a). Even if the GIP system cannot afford to cover the whole cost for these HIV/AIDS programs, the amount of revenue for the GIP Trust Fund would be sufficient for the GIP system to contribute to the achievement

of the universal access to HIV/AIDS drugs throughout the world. As estimated in Table 2, the GIP reserve and premium would provide the GIP Trust Fund almost \$250 million at the lowest revenue and the GIP tax would provide \$50 billion at the highest revenue. Even at the lowest revenue, i.e., \$250 million every year, it would account for one fourth of \$1 billion, the total cost for HIV/AIDS drugs annually required in LDCs and ADCs. As far as the author's experience with the pharmaceutical industry, regular royalty of one patent costs from 10% to 30% of the total sale amount of the medicines that the patent protects. This figure means even when the GIP Trust Fund is smallest, i.e., \$250 million, the GIP system could assume the royalty of patent-protected drugs, i.e., 25% of the total sales \$1 billion in LDCs and ADCs. On the other hand, if the GIP system could generate \$50 billion at the highest amount, which is five times as much as the total cost for HIV/AIDS drugs, the system would aid many HIV/AIDS programs effectively. In these ways, the GIP system would create the GIP Trust Fund with a sufficient amount to achieve universal access to essential medicines in developing countries while encouraging the research and development of new medicines in pharmaceutical companies in developed countries.

CONCLUDING REMARKS

Some opponents of the patent system depict it as impeding universal access to HIV/AIDS medicines in developing countries. This picture was especially emphasized by an HIV/AIDS lawsuit from 1998 to 2001 in South Africa. This lawsuit was fielded by a group of 39 pharmaceutical companies to strike down the Medicines and Related Substances Control Act in South Africa, which stipulates compulsory license and trade of generic medicines, and withdrawn by that group due to severe criticism by the international community (TAC, 2001).

Table 3. Required costs for HIV/AIDS medicines (US dollars).

	Sub-Saharan Africa	East, South and South-East Asia	Latin America and the Caribbean	Eastern Europe and Central Asia	North Africa and Middle East	Global Total
Number of patients						
Living with HIV ¹⁾	25.4 million	8.2 million	2.1 million	1.4 million	540,000	37.6 million
Newly infected ²⁾	3.1 million	1.2 million	293,000	210,000	92,000	4.9 million
Needing ³⁾	4.7 million	1.1 million	465,000	160,000	75,000	6.5 million
Untreated ³⁾ (%)	4.2 million (89%)	945,000 (86%)	175,000 (38%)	140,000 (87%)	71,000 (95%)	5.5 million (85%)
Lowest drug price ⁴⁾	\$175 ⁵⁾	\$152 ⁶⁾	\$250 ⁷⁾	\$423 ⁸⁾	\$250 ⁹⁾	
Total cost for drug needed	\$735 million	\$144 million	\$44 million	\$59 million	\$18 million	\$1 billion

Sources and notes

¹ As of the end of 2004, "AIDS epidemic update: 2004." UNAIDS, 2004, Geneva, Switzerland, p.77.

² During 2004, *Id.*, p.78.

³ As of June, 2005, "Progress on global access to HIV antiretroviral therapy: An update on «3 by 5»." WHO, 2005, Geneva, Switzerland, p.13.

⁴ Estimated lowest price in each region per patient per year for the WHO-recommended triple-cocktail medicine, such as Crixivan/AZI/3TC, d4T/3TC/NVP or equivalents.

⁵ "Untangling the web of price reductions: A pricing guide for the purchase of ARVs for developing countries, 8th Edition." MFS, 2005, Geneva, Switzerland, p. 13.

⁶ *Id.*, p. 10.

⁷ "Prices of AIDS medicines in developing countries still a concern." June 29, 2005 in Medical News Today.

⁸ "Price of retroviral drugs drops sharply." December 1, 2003 in Lexis-Nexis Academic Universe.

⁹ Assumed to a regular price in MSF due to no available data.

Since this defeat of pharmaceutical companies, many patent opponents have increasingly questioned the necessity of the patent system because of several successes in some technologies such as computer software and electronics that patent-free industrial-standard policies have strongly distributed (e.g., Bollier, 2003). However, patent-free industrial-standard policies usually function well only if the costs of research and development of new technologies are not too high. Conversely, pharmaceutical companies usually have to invest more than \$300 million in developing only one new medicine (Sachs, 2000), and they definitely need patent protections to recover such a huge amount of earlier investments (New York Times, 2001). Moreover, if the patent system did not exist, most firms would keep their technologies as trade secrets and people could not even learn about or manufacture generic copies. Although the current patent system has generated numerous undesirable outcomes and still has flaws, it is an undeniable fact that the patent system is an indispensable and powerful tool to promote technological progress. The GIP patent system would be an evolved patent system that can serve for not only patentees but also patent users.

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