

Patent Insurance (Green Intellectual Property) Scheme: A financial prescription for neglected diseases?

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CHAPTER I: EXECUTIVE SUMMARY

On November 19th, the World Health Organization appointed the expert working group as a response to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (IP) adopted at the World Health Assembly this May. One of the group's main tasks is to find new funding mechanisms fostering needed medical research on neglected diseases and ensuring unimpeded access to necessary medications irrespective of commercial profitability for developing nations.

The working group would likely find an answer with the "Patent Insurance" (or more generally referred to as the "Green IP") scheme that has been proposed by Geneva-based IP consulting group Green IP Project (all previous publications at www.greenip.org) to divert a part of the patent-related monetary flow for the sake both of driving research for the most necessary public interest, *e.g.*, "neglected" diseases and environmental technologies, and ensuring unimpeded access to such innovations for particularly developing nations.

The scheme is designed to impose an extra official fee on patent applicants and holders as a form of "insurance premium," and to establish a trust fund that would finance the compensation of technology transfer costs, particularly royalty assumption, and other subsidies for purchasing patented products in developing countries, as well as a wide variety of funding proposed for needed research, including medical grants, prizes, treaties, public-private partnerships, advance market commitments, market exclusivities (orphan drug schemes) and tax credits.

These financial assistances would convince society of the wisdom of patent, resulting in upholding the efficiency of the patent regime. In other words, the extra fee would serve as a "premium" for defending patent rights against the risk of compulsory license and other safeguard flexibilities which the worldwide anti-patent protest has increasingly justified, and resultant erosion of the entire patent system. Consequently, the dual benefit of the premium not only for developing nations in the financial aids but also for developed nations in ensuring patent rights would readily build consensus by developed nation patentees on their burden of paying the patent premium. This dual benefit would also attract any R&D oriented sectors in developed countries other than pharma industry because they all needs ensured patent.

Such premium would be an additional weight for patentees in the traditional balance of public interest (innovation disclosure) and private right (patent monopoly as a reward for the disclosure) in the patent legitimacy. In the sense of economics, the patent premium would serve as a combination of the "Tobin taxation" and "Pigovian taxation." From the Tobin's perspective, the premium is an international taxation imposed at a border when a knowledge asset is crossing. The Pigovian aspect of the patent premium is to facilitate market incorporating its failure that patent protections generate in society.

The scheme would also equip to prevent the burden of paying the premium from inflating the price of patented products by two measures: the translation waiver and reduced price of official fees.

- Translation waiver: Once patent applicants pay the premium, they would no longer need to file an application translation with a local patent office while their application enters a designated country or region, unless the office needs a faithful translation for a trial or litigation. This waiver of translation would compensate or even outweigh the financial load of the patent premium because application translation accounts for a significant proportion in the costs of obtaining a foreign patent (roughly speaking, the total cost for a single foreign application is US\$10,000 and its translation costs usually US\$3,000 or more). The translation waiver would be supported by considerable improvement in computer translation, allowing a patent office to examine an application without a human-conducted translation or even by utilizing such translation of limited portions (*e.g.*, only claims and relevant descriptions in a specification).
- Discounted fee: Another technical progress in examination of patent applications would offer a discounted price in official fees for those who have already paid the premium. This lowering would be brought about by streamlining examination by means of emerging technologies for identifying and measuring innovations. These tools would include information & communication technologies, highly-evolved patent-mappings and other intelligent methodologies.

Besides the scheme's original functionality of insuring patents, the financial advantage of the translation waiver and discounted official fees would further facilitate an agreement by patentees and industries in developed countries on paying the patent insurance premium.

Since the Patent Insurance scheme would be embedded in the existing patent system, the scheme would possess a substantive and sustainable financial scale (possible annual revenue: up to several tens of billions in US dollars) due to enormous amount of both quantity (*e.g.*, filing number) and quality (*e.g.*, subject matter) in the present patent system worldwide (source data at www.greenip.org) even within challenging economic conditions.

Once funds were established, the provision of financial assistance in a timely and structured manner would be of importance. A requestor, who needs the financial assistance, would submit a request to a deliberation commission, which would promptly and coherently decide whether to accept or deny the request. Importantly, in case of denial, the scheme should ensure opportunities for the requestor to consider an alternative measure, including the traditional flexibilities in the IP framework such as compulsory licensing. This deliberation process would avoid detrimental effects on unresolved IP disputes and mitigate the imbalance between stronger and weaker actors through an arbitration based on rules rather than power diplomacy.

The Patent Insurance scheme would no longer regard the patent as a mere innovation protector, but rather as more like a pro-active financial driver of funding for the largest overall benefit in society. This would herald the second coming of the Doha Declaration on the TRIPS Agreement (further progress in detail will appear on www.greenip.org).

CHAPTER II

Patent Insurance (Green Intellectual Property) Scheme:

A future legitimacy to protect intellectual property for knowledge liberalization

This chapter intends to develop an economic model, which allows the Expert Working Group to explore the Green IP scheme in depth.

Introduction

The expected function of protecting intellectual property (IP) is to enhance the total welfare in society through "knowledge liberalization." It might surprise the Group to know that the unexploited but genuine essence of the IP regime is not protection but liberalization of knowledge. This hypothesis is founded on a descriptive model of macroeconomics in that the knowledge liberalization contains two steps needed to be separately considered: the production and allocation of knowledge. Such model reveals that the current IP regime lacks the step of the knowledge allocation whereas the regime strongly accelerates the production of knowledge, which is the causation commonly underlying of enormous difficulties the current regime is encountering.

Based on such macroeconomic model for the knowledge liberalization, this chapter argues that the difficulties surrounding IP protection would be overcome by the "Green IP" scheme or more explicitly the "Patent Insurance" scheme, which has been proposed by Geneva-based IP consulting group Green IP Project to embed financial functionality of the knowledge allocation into the IP framework. Legitimacy of such framework is examined in economic aspects, particularly in conformity with the World Trade Organization (WTO) system, concluding that the patent insurance would serve as a "preferred tariff" and "preferred remedy" in analogy with the traditional tariff and trade remedies yet superior to these because the patent insurance would drive the knowledge liberalization while the traditional measures oppose free trade in the General Agreement on Tariffs and Trade (GATT).

These functions of the patent insurance would justify its introduction of a financial measure into the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which would compensate inefficiency in the TRIPS flexibilities in contrast to the existence of multiple financial measures in the GATT remedies. The resultant IP regime embracing the knowledge allocation with financial measures would successfully promote the knowledge liberalization and consequently expand society's welfare.

Knowledge liberalization

The knowledge liberalization is a macroeconomic model proposed to answer the most fundamental question for IP policymaking: "do we need to protect IP?" This challenging model would draw a sharp contrast between two phases of progress in knowledge: increasing the pie of human's knowledge and allocating the increased knowledge with an appropriate distribution. The increase in knowledge, *i.e.*, its production is concerned with creating, inventing and discovering anything by human kind. The knowledge allocation is involved in accessibility to knowledge (its distribution over users, *e.g.*, who can access to patented medicines) and incentive to knowledge (its distribution over producers, *e.g.*, no pharma industry is interested in neglected diseases). Both the production and allocation of knowledge should be promoted by wisely designing an ideal framework of IP protection to accelerate the knowledge liberalization and consequently build up wealthy society.

$$\begin{aligned} &\text{Knowledge liberalization} \\ &= f [\text{Knowledge production, Knowledge allocation (Producers, Users)}] \end{aligned}$$

Box 1: An expected role of the IP regime is to enhance wealth in society through the liberalization of knowledge, which is a function of knowledge production as well as its allocation over producers and users. One of the major defects in the current regime is lack of financial measures to promote the knowledge allocation over both producers (*e.g.*, research incentive) and users (*e.g.*, TRIPS flexibilities).

Knowledge production

The current IP regime, more specifically patent, has stimulated the knowledge production through innovation disclosure and capital concentration. These functionalities are two weights on the balance of public interest (innovation disclosure) and private right (capital concentration by patent monopoly as a reward for the disclosure) in the traditional patent legitimacy. The innovation disclosure not merely disseminates knowledge but also suppresses corporate secrecy and avoids duplicate research by different institutions. The capital concentration ensures inventors to collect the investment for research and reasonable benefit as well as facilitates the commercialization of their innovation, leading to further incremental and resulting radical innovations.

- Innovation disclosure:
Knowledge dissemination, Corporate secrecy, Duplicate research
- Capital concentration:
Investment, Benefit, Commercialization

Box 2: The traditional balance of public interest (innovation disclosure) and private right (capital concentration) stimulates only the production of knowledge in the existing IP regime.

Knowledge allocation

In contrast to the successful functions in the traditional IP regime to enhance the productivity of knowledge, the regime has entirely left the allocation of such enhanced knowledge to market. In other words, the knowledge distribution such as accessibility and research incentive obeys the market rule, with which the IP regime never interferes. Although the "flexibilities" in the patent system

can serve as a knowledge allocator for its users, these are all enforced to a limited extent and still more nonfinancial measures, as explored later in depth. Such nonfinancial flexibilities include compulsory licensing, parallel importing and generic producing under a certain condition (TRIPS 31) as well as the Bolar exemption for research tools (TRIPS 30), allowing unfavorable users to access to patented products of knowledge.

In addition to these distributors for users, patentability (TRIPS 27.1) and the scope of subject matter (TRIPS 27.2 and 27.3) can function as an allocator of knowledge for its producers (and eventually for users) because the range of patentable subject matter, typically including "order public or morality," influences the incentive and orientation of research. However, all these distributors for producers are again nonfinancial factors in the IP framework.

The lack of financial measures to allocate knowledge for both users and producers is dramatically becoming a major failure in the current IP framework. Such failure arises from the history of the IP regime: the traditional regime has not been required to introduce any financial mechanism to distribute knowledge because the framework has been shaped in wealthy societies of developed nations. The developed countries have possessed substantial market with enough scale of economy for the appropriate allocation of knowledge. Since, in such fertile market, users have had sufficient financial means to access to necessary products of knowledge, and resultant monetary flow has stimulated the production of needed knowledge, the traditional IP regime has not needed to contain its own allocator of knowledge with a financial measure.

Since, however, the creation of WTO in 1995, the IP regime has been increasingly compelled to contain its own financial allocator of knowledge due to expansion of the regime from developed to developing nations. This is an inevitable consequence from the integration of IP affairs, or the TRIPS agreement, into the WTO system despite the absence of sufficient market in developing countries. The TRIPS agreement is a result of strong demands by developed nations during the Uruguay Round, which was originally objected by developing nations. Developed nations pursued IP protection in developing countries by means of the dispute settlement mechanism in the WTO system and possible cross-retaliation over goods or services in the case of insufficient protection of IP. For these demands, developing countries eventually accepted the TRIPS agreement under the single undertaking of the WTO treaties (WTO Agreement, Article II) in return for other agreements in favor of developing nations to reduce tariff and non-tariff barriers against textiles and agricultural products, which were of particular interest to developing countries.

The TRIPS agreement, unless effective market exists, is the "White Elephant" merely blocking users from accessing to necessary products of knowledge because the agreement does not contain any financial measure to distribute knowledge. In such setting, the current IP regime by no means promotes appropriate allocation of knowledge irrespective of commercial profitability, resulting in adverse effects on increasing in society's welfare. This failure is a common root cause of a wide variety of the IP frictions and resultantly growing criticism and diminishing societal trust over the IP regime, relating to accessibility to patented essential innovations, typically medicines and green technologies, need-based research incentive, *e.g.*, "neglected" diseases, and patenting life and culture, including patentability, profit sharing and asset management over biological and cultural diversities (*e.g.*, genetic resources, traditional knowledge and folklore).

Patent Insurance scheme

One of the most straightforward solutions to address the global concerns about IP protection is the introduction of a financial measure into the framework in order to distribute knowledge with the best allocation in society for public benefit rather than profit motive. This idea would likely be realized by means of the "Patent Insurance" scheme, which is designed to impose an extra official fee on patent applicants and holders as a form of "insurance premium," and to establish a trust fund that would finance the knowledge allocation over both producers and users.

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| <ul style="list-style-type: none">● Revenue: insurance premium● Expenditure: financial measures to facilitate knowledge allocation<ul style="list-style-type: none">For producers, <i>e.g.</i>, needed research, exploiting and protecting biological and cultural diversitiesFor users, <i>e.g.</i>, unimpeded accessibility, profit sharing over the protected diversities |
|--|

Box 3: Monetary flow in the Patent Insurance scheme.

The allocation over users would include fostering true innovations for the most necessary public interest such as neglected diseases and environmental technologies, and a wide variety of funding proposed for needed research such as medical grants, prizes, treaties, public-private partnerships, advance market commitments, market exclusivities (orphan drug schemes) and tax credits. The knowledge allocation over users would furthermore encompass patentability and subject matter over biological and cultural diversities, specifically financial supports to exploit and protect genetic resources, traditional knowledge and folklore.

The knowledge allocation over users would contain ensuring unimpeded access to essential innovations, in particular the compensation of technology transfer costs, in particular royalty assumption, and other subsidies for purchasing patented products. The allocation over users would also include financial assistances for profit sharing and asset management over patented life and culture.

These financial measures to distribute knowledge would convince society of the wisdom of the IP regime, resulting in upholding the efficiency of the regime. In other words, the extra fee would serve as an "insurance premium" for defending patent rights against the risk of compulsory license and other safeguard flexibilities which the worldwide anti-patent protest has increasingly justified, and resultant erosion of the entire patent system. Consequently, the dual benefit of the premium not only for users in the financial aids but also for patentees in ensuring patent rights would readily build consensus by the patentees on their burden of paying the insurance premium.

Such premium would be an additional weight for patentees in the traditional balance of public interest and private right in the patent legitimacy. In the sense of economics, the patent premium would serve as a combination of the "Tobin taxation" and "Pigovian taxation." From the Tobin's perspective, the premium is an international taxation imposed at a border when a commodity, service or asset is crossing. The Pigovian aspect of the patent premium is to facilitate market incorporating its failure that patent protections generate in society.

The scheme would also equip to prevent the burden of paying the premium from inflating the price of patented products by two measures: the translation waiver and reduced price of official fees (see CAPTHER I).

Besides the scheme's original functionality of insuring patents, the financial advantage of the translation waiver and discounted official fees would further facilitate an agreement by patentees and industries on paying the patent insurance premium.

Since the Patent Insurance scheme would be embedded in the existing patent system, the scheme would possess a substantive and sustainable financial scale (possible annual revenue: up to several tens of billions in US dollars) due to enormous amount of both quantity (e.g., filing number) and quality (e.g., subject matter) in the present patent system worldwide.

- Readily consensus between patentees and users (in conformity to "*the mutual advantage of producers and users*" in TRIPS 7)
 - For patentees: ensuring the regime as whole and consequently individual IP rights
 - For users: financial assistances to allocate knowledge
- Combination of the Tobin and Pigovian taxations (additional weight over applicants and patentees in the traditional balance)
- Price-uncoupled by translation waiver and discounted official fees
- Substantive and sustainable financial scale

Box 4: Features in the Patent Insurance scheme.

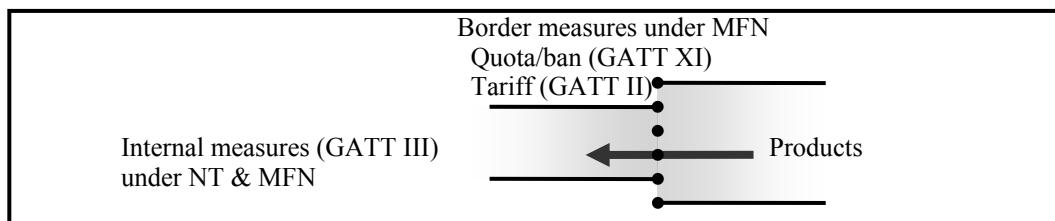
Patent insurance premium as preferred tariff

The descriptive model of macroeconomics, which the foregoing introduced to illustrate the production and allocation of knowledge for its liberalization, enables exploring over legitimacy of the patent insurance in three WTO pillars, i.e., GATT for products, the General Agreement on Trade in Services (GATS) for services and TRIPS for knowledge assets. A comparison of these treaties, as further discussed later, allows us to regard several factors of TRIPS as analogous to the border measures of GATT. For instance, the delimitation of patentable scope, including subject matter (TRIPS 27.2 and 27.3) and patentability (novelty and nonobviousness, TRIPS 27.1), and yet payment of the patent insurance premium have a similar function to the nonfinancial and financial border measures in GATT, respectively.

These views of the subject matter/patentability as "pseudo quota" and the insurance premium as "preferred tariff," as termed later, arise from a commonality of TRIPS and GATT, or knowledge assets and products, in that they are both tangible once knowledge asset becomes property by granting an intellectual property right to the knowledge.

In contrast to this commonality, however, the patent insurance premium in TRIPS differs very from the traditional tariff in GATT in that the premium is preferable in economics due to its functionality for promoting the knowledge liberalization while the tariff is an obstacle against the trade liberalization and reluctantly agreed as a tentative tool for peaceful transition to free trade. The advantage of the premium as the preferred tariff would strongly support inclusion of the patent insurance into TRIPS rather than the existing tariff in GATT, which has considerably diminished in a schedule and would be eventually abolished.

GATT



Box 5: GATT is a floodgate for restricting product flow to protect internal industries.

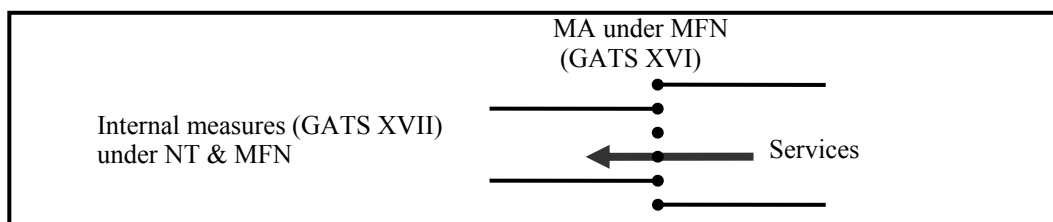
In the simplest description, GATT is a floodgate that is built by internal nationals for restricting the flow of inward products to protect internal industries. On the border gate, the volume of entering products is regulated by two measures: quota/ban (GATT XI) and tariff (GATT II) under the most favored nation (MFN) provision. The quota/ban is a nonfinancial determinant directly limiting the product flow, whereas the tariff is a financial burden imposed on external nationals to favor internal industries, which indirectly affects the product flow.

Once the products underwent these border measures, they are equally disciplined by internal measures (GATT III) under the principles of both the national treatment (NT) and MFN. These concepts of no-discrimination in internal measures are also applied to GATS (GATS XVII) and TRIPS (TRIPS 3).

GATS

While GATT exclusively deals with products, GATS is the floodgate of services to protect internal industries. Since services are not subject for tariff due to their intangibility and impossibility of regulation by tariff-type measures, GATS contains no financial measure on a border corresponding to tariff in GATT. The intangibility of services compels GATS to adopt its distinctive nonfinancial

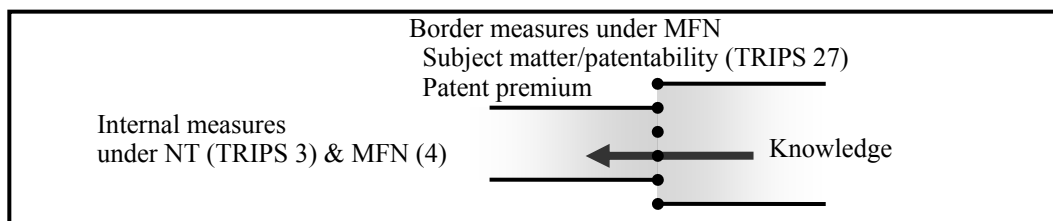
regulation, called market accessibility (MA, GATS XVI) under the MFN concept. The MA is the commitments in the GATS schedule, which is a matrix consisting of eleven different sectors and four modes for delivering services in the form of positive lists for each country to assume specific commitments relating to MA and NT (GATS XVII) in designated sectors. GATS NT is more limited in scope by the possible limitations than GATT NT, and the limitation of GATS NT is reduced by expanding the positive commitments, corresponding to decrease in tariff bound rates in GATT.



Box 6: GATS is a floodgate for restricting service flow to protect internal industries.

TRIPS

While the gates of both GATT and GATS are built by internal national, TRIPS is a floodgate built by external nationals to protect their knowledge, which restricts inward flow of knowledge assets to prevent internal nationals from acquiring the assets without permission. On a border, the TRIPS gate contains nonfinancial and financial measures here termed "pseudo quota" and "preferred tariff," respectively. The pseudo quota for patent is the subject matter and patentability (TRIPS 27) because these factors define the range of intellectual properties to be protected and consequently affect the volume of knowledge crossing the border as if by the ordinary quota in GATT without financial means.



Box 7: TRIPS is a floodgate for restricting knowledge flow to protect external industries.

Since the subject matter/patentability, however, has a more complex role than the traditional quota in GATT, such TRIPS version of quota is distinguished by wording of "pseudo." If the subject matter, for example, delimited the broader scope over product/method innovations, medical procedures and secrecy-ordered technologies, the production of knowledge would be enhanced with the wider extent whereas its allocation would be reduced, resulting in undetermined effects on the liberalization of knowledge as total. If the patentability, likewise, stipulated the stricter requirements, the knowledge allocation would be accelerated at the higher rate whereas the knowledge production would possibly be encouraged or discouraged.

Besides the subject matter/patentability in a form of the pseudo quota, TRIPS would be able to contain the patent insurance premium as a financial measure on a border, which would influence the flow of knowledge. Since the premium would act in a manner similar to the tariff in GATT, the patent insurance premium would be regarded as a certain tariff. Namely, the premium is the financial burden imposed on external nationals to favor internal nationals because the patent insurance would finance the knowledge allocation within a territory, which would provide economical advantages to internal nationals with correspondence to the traditional tariff in GATT.

In contrast to this correspondency, however, the patent insurance would prevail over the tariff because the insurance would encourage the knowledge liberalization whereas the tariff discourages the trade liberalization. Since, in addition, the patent insurance would financially boost the knowledge allocation and not adversely affect the knowledge production, the insurance would have more straightforward and definitive effect on the knowledge liberalization than the subject matter/patentability with the uncertainty mentioned above. To focus on these proactive effects of the patent insurance, its premium would be named the "preferred" tariff in TRIPS.

The capability of understanding the subject matter/patentability as the pseudo quota and the patent insurance premium as the preferred tariff would derives from the tangibility of intellectual property because this tangibility eliminates the necessity of classifying the knowledge flow in some modes like GATS and enables the financial measures on a border like GATT. This illustration would be one of the major sources for the advantages above mentioned over the patent insurance and legitimacy of its premium as a financial border measure in TRIPS.

Table 1: Common features in the border measures.

		GATT	GATS	TRIPS
Non-financial	Favoring internal nationals	Quota/Ban	MA	Subject matter/patentability (pseudo quota)
Financial burden on external nationals		Tariff	no	Patent premium (preferred tariff)

Patent insurance payment as preferred remedy

As with appreciation of the patent insurance premium in a sense of the preferred tariff, the payment of the patent insurance would be understood as "preferred remedy" in TRIPS, corresponding to the traditional "trade remedies" in GATT as generally recognized: the

safeguard measure (GATT XIX and the Agreement on Safeguard (SG)), the countervailing duties for subsidies (GATT III.8(b), VI and XVI, and the Agreement on Subsidies and Countervailing Measures (SCM)) and the anti-dumping measurement (GATT VI and the agreement of its implementation (AD)).

These remedies in GATT are to narrow or close a gate in flood of influent products by financial (*e.g.*, raising tariffs and extra duties) and nonfinancial (*e.g.*, quota, ban and non-tariff barriers) means providing economic advantage to internal nationals on a temporary basis. In drought of knowledge, on the other hand, the patent insurance would open a gate in TRIPS more widely to irrigate a territory with the knowledge internal users need. This irrigation would be achieved by promoting the allocation of needed knowledge through a wide variety of financial assistances. Since such assistances would lead to the economic advantage of internal nationals, the payment of patent insurance would be regarded as a financial "remedy" in TRIPS.

The patent insurance, however, would have superiority over the traditional trade remedies of GATT in that the insurance would contribute to the knowledge liberalization by financially driving the knowledge allocation whereas the remedies of GATT go against the global efforts toward the trade liberalization. Such superiority of the patent insurance would be emphasized by call it the "preferred" in TRIPS rather than the original remedies in GATT.

In contrast to the possible aspect over financial measures in the patent insurance, such measurements are outside the current outline of the existing remedies in TRIPS, or its flexibilities. More precisely, the design of TRIPS as a whole bears less financial flexibility even supposing that the flexibility includes the subject matter/patentability (TRIPS 27), which are equivalent to the exceptions in GATT XX and the separate agreements of Sanitary and Phytosanitary (SPS), and Technical Barriers to Trade (TBT) because these factors determine the scope of subjects both in TRIPS and GATT.

The scarcity of financial measure in the TRIPS flexibilities arises from still short history of TRIPS compared to the long period of GATT and negotiations over trading even before the GATT, during which a number of financial measures have formed. In other words, TRIPS contains several flexibilities; however, they are not sufficient, even after the creation of Article 31^{bis} as only amendment so far adopted in the WTO treaties, to respond to various disputes caused by expansion of IP protections in geographical area, *i.e.*, from north to south, and subjects because the TRIPS flexibilities are limited within nonfinancial means.

Table 2: Internal measures and remedies in GATT and TRIPS.

				Treaties	
Reason	Usual duration	Mode	Basic procedure	GATT	TRIPS
Non-economic	Long	Exemption, standard and regulation	Non-financial	XX (SPS and TBT) and other non-tariff barriers	Patentability and subject matter
Economic	Temporary	Remedy	Financial included	SG	Four flexibilities
				AD and SCM	Patent insurance payment for knowledge allocation

This immaturity in TRIPS would ripen with the financial measures by the patent insurance in the form of the preferred tariff and remedies, approaching the full compliance with the distinct principle over "balanced protections" in TRIPS 7, quoting

[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

In particular, the stipulation of "*the mutual advantage of producers and users*" in TRIPS 7 would be financially implemented with the dual benefit of the patent insurance scheme not only for users in the financial assistances but also for patentees in ensuring patent rights.

CHAPTER III

A Legal Modeling for Patent Insurance (Green Intellectual Property) Scheme:

The Second Road to the Doha Declaration on the TRIPS Agreement

This chapter aims at assisting governments possibly interested in legally formulating an amendment of the global regime for intellectual property, in particular the TRIPS Agreement, which would bring to the Agreement a new financial mechanism of knowledge allocation for the public interest.

Introduction

The best agreement on funding for the knowledge allocation would not be worth very much if requested funds were not provided in a timely and structured manner. To enhance the practical value of such funds, the Green IP scheme would embrace a deliberation/appellate process to decide whether to accept or deny a request of financial assistance for knowledge allocation. This process would be designed in the quasi judicial framework of the WTO dispute settlement system, in which a requestor government, who needs the financial assistance, would submit a request to a deliberation/appellate commission (or commission body in short), which would make a prompt and coherent decision for the request. Importantly, in case of denial, the scheme must ensure opportunities for the rejected Member to consider an alternative measure, including the traditional flexibilities in the TRIPS Agreement such as compulsory licensing, parallel importing, generic producing and the Bolar exemption. This deliberation/appellate process would avoid detrimental effects on unresolved IP disputes and mitigate the imbalance between stronger and weaker Members through an arbitration based on rules rather than power diplomacy.

Knowledge allocation as a possible part of the dispute settlement in WTO

If the TRIPS framework incorporated the financial mechanism to drive the knowledge allocation, the mechanism would become a new backbone within the evolved framework. Such mechanism would rely on the conviction that the knowledge allocation would effectively facilitate the settlement of IP disputes in TRIPS, and consequently the ensured respect and enforcement of the carefully negotiated rules to discipline intellectual properties. This enhanced stability of intellectual properties and promoted transfer of them would benefit both owners and users of properties in any industrial field of all Member states.

The financial mechanism to assist knowledge allocation would be one of the procedures to settle international disputes though it is tuned specifically for IP conflicts. Among such procedures, the WTO dispute settlement system would be one of the most appropriate procedures to embody the knowledge allocation mechanism due to system's promptness, coherence and proven performance. This embodiment would allow the knowledge allocation mechanism to bear several features unique to the WTO system, for instance, the state-to-state policy, prompt process and compulsory nature.

State-to-State Policy

Like the traditional dispute settlement system in WTO, the only participants in the knowledge allocation mechanism would be the Member governments of WTO. Other international organizations, regional or local governments, private individuals or industries would not be entitled to directly access to the mechanism even if they were most involved. However, these non-Member actors would be encouraged to exert indirect or even direct influence on the mechanism through a petition. In a similar version to the US Trade Act of 1974 §301 and the Trade Barriers Regulation of the EC, for example, private parties would be able to petition their governments to bring their request for the knowledge allocation to WTO. In addition, a non-governmental organization would be able to file a "friend of the court" or "*amicus curiae* brief" to WTO whereas there are divergent views for such submission among Members, and the deliberation/appellate commission has the discretion to accept or reject it without obligation to consider it.

Prompt Process

As emphasized in settling ordinary trade-relating disputes, prompt processing would be of importance if the financial mechanism for knowledge allocation was to function effectively. To this end, the mechanism would set out in considerable detail the procedures and the timetable to be followed with "negative" or "reverse" consensus decision.

Compulsory Nature

If the knowledge allocation mechanism was embodied in the WTO system, it would be compulsory under ratification of the WTO agreements as the "single undertaking" (WTO Agreement XII), which distinguishes it from some of other systems of international dispute resolution embracing the "early harvest." In this circumstance, there would be no need for the parties requesting the financial assistance to accept the jurisdiction of the deliberation/appellate commission in a separate declaration or agreement within the system.

Standing to request the financial assistance

In the deliberation/appeal of a request for the financial measure to assist knowledge allocation, one or more Members would take part as a "requestor" or third party. The requestor, corresponding to the complainant in the traditional trade dispute settlement, would bring the request to WTO. Similarly to the traditional trade dispute, such request would take place when a Member considered that "any benefit accruing to it directly or indirectly under the TRIPS Agreement is being nullified or impaired or not being achieved at all nor sufficiently, or that the attainment of any objective of the Agreement is being impeded or not being promoted at all nor sufficiently" (GATT XXIII.1 with modification). In such a case, any Member has the standing to invoke the mechanism of the financial support for knowledge allocation. The requestor is guaranteed a rules-based process in which the merits of its request will be deliberate by an independent commission in return for complying with the TRIPS' obligations in good faith and imposing the patent insurance premium on patent applicants and owners in conformity to the national treatment (TRIPS 3 and relevant clauses in GATT) and the most-favored-nation treatment (TRIPS 4 and relevant clauses in GATT).

In contrast, unlike the traditional trade disputes, the knowledge allocation mechanism would not contain a respondent or defendant because this mechanism is not genuine dispute settlement or arbitration, but deliberation. The IP conflicts between a certain complainant and respondent, in particular a violation complaint (GATT XXIII.1(a)) covered by the existing dispute settlement system in WTO, should be out of the scope of the knowledge allocation mechanism.

The condition constituting a valid ground for the request of financial assistance essentially contains not- or dis-advantage for the benefits or objectives expected in the TRIPS Agreement, all of which are ultimately caused by blocked or imperfectly-promoted allocation of knowledge through compliance with the obligations in the Agreement. The "not-advantaged condition" means a condition where the protection of intellectual property is of no effect to at least one Member state for the benefits or objectives of TRIPS. This condition would result from the nullification or impeded attainment as defined in GATT XXIII.1. The "disadvantaged condition" is a condition where the protection of intellectual property adversely affects one or more Members for the benefits or objectives of TRIPS, which would be a consequence from the nullification, impeded attainment or the impairment under GATT XXIII.1.

The benefits and objectives of the TRIPS Agreement are explicitly stated in Article 7 (Objectives) as:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

To approach this objective, the clause of TRIPS 67 underscores the importance of financial measures for knowledge allocation, as saying.

--- developed country Members shall provide --- financial cooperation in favour of developing and least-developed country Members.

These clauses evince that the Agreement inherently encompasses the legal grounds for the financial measure to assist the knowledge allocation. Therefore, the TRIPS Agreement would be able to contain an additional article, which more explicitly defines such measure such as,

Member shall be given a right to pursue the financial assistance to promote better allocation of knowledge over its producer or user.

A request for financial assistance would require a not- or dis-advantaged condition for the benefits or objects under the TRIPS Agreement, in particular Articles 7 and 67, due to blocked or imperfectly-promoted allocation of knowledge, which should not result from the "failure --- to carry out its obligations (GATT XXIII.1(a))" but a legitimate measure and its resultant situation in conformity with the obligations and stipulations of Agreement. Therefore, this mechanism would be rely on an analogy to the non-violation or situation complaint pursuant to GATT XXIII.1(b) or (c) whereas the most common trade disputes have arisen from the violation complaint stipulated in GATT XXIII.1(a). This admissibility of the "non-violation-based" and "situation-based" requests for the financial measure to allocate knowledge would allow the measure to embrace a broader scope than that of other disputes settlement systems than WTO and public international law regarding a breach such as the "Responsibility of States for Internationally Wrongful Acts" adopted by the International Law Commission in 2001. At the same time, the knowledge allocation mechanism is narrower than other legislations in the sense that obligations and stipulations must result in the not- or dis-advantaged condition for the benefits or objectives of the Agreement.

Non-Violation-Based Request

The non-violation-based request would take place when, due to the obligations of the TRIPS Agreement, one Member, possibly the Member requestor itself, has adopted an IP measure or several Members, possibly including the Member requestor itself, have done an equivalent or similar measure in their individual territories, that at least one Member requestor considered to conform with the Agreement but to nullify or impair or not to facilitate at all nor sufficiently the achievement of any benefit accruing to the Member requestor directly or indirectly under the Agreement, or to impede or not to promote at all nor sufficiently the attainment of any objective pursuant to the Agreement, in particular Articles 7 and 67.

The legitimacy of the non-violation-based request would be justified by the particularity of the WTO regime as whole, which is sustained in the negotiated balance of concessions and benefits between Members. In accordance with the Panel Report for EEC - *Oilseeds I*, para. 144, the benefits that a Member legitimately expects in return for accepting a concession can be frustrated by measures consistent with the WTO system under its multilateral regime, which must be given a right of redress. For example, therefore, the impeded accessibility to medicines caused by the introduction of patent protection complying with the TRIPS agreement can be redressed by requesting the financial measure to normalize such accessibility.

Like the original non-violation complaints in trade disputes, submission of the non-violation-based financial assistance would require the requestor to "present a detailed justification in support of any request relating to a measure which does not conflict with the TRIPS Agreement" (DSU 26.1 with modification). In addition, the existence of not- or dis-advantaged condition would not be presumed in the non-violation-based request while such presumption has been applied in the past violation complaints as evolved in GATT jurisprudence (Panel Report, *Uruguay - Recourse to Article XXIII*, para. 15) and today codified in SDU 3.8. In order to be successful with the non-violation-based request, therefore, the requestor must demonstrate (1) the application of a measure, (2) the consistency of the measure with the TRIPS agreement, (3) the existence of not- or dis-advantaged condition, and (4) causality between the measure and the not- or dis-advantaged condition. These criteria would be supported by the consensus built, for example, in the Panel Report, *EC - Asbestos*, para. 8.283.

In addition to these criteria, the requestor would have to clarify (5) a reasonable estimation for the duration and scale of the financial assistance based on an appropriate assessment. Such estimation would be commensurate with requisite amount to improve the not- or dis-advantaged condition, which would have to be proven substantially and convincingly. The minimum level of such improvement would be defined so as to achieve the benefits and objectives accruing to the requestor directly or indirectly under the TRIPS Agreement with satisfaction of the requestor. This estimation would be assessed prospectively rather than retroactively in accordance with a general rule for not a public international law for breach (*e.g.*, Responsibility of States for Internationally Wrongful Acts 2001, Articles 35) but trade dispute cases in the WTO system. In this rule, in order to avoid an extortionate scale of financial assistance, the estimation would usually cover only the time-period after the beginning of financial assistance, not the whole period during which the not- or dis-advantaged condition has taken place.

Situation-Based Request

The situation-based request would arise when, regardless of adopting a specific measure conforming with the TRIPS Agreement, at least one Member felt that the situation surrounding IP affairs nullifies or impairs or does not facilitate at all nor sufficiently the achievement of any benefit accruing to the Member requestor directly or indirectly under the Agreement, or impedes or does not promote at all nor sufficiently the attainment of any objective pursuant to the Agreement, in particular Articles 7 and 67 even though the Member states carry out the obligations complying with the Agreement in good faith.

As indicated in the negotiating history for the original situation complaints in trade disputes, the situation-based request would allow for salvaging acute or chronic macroeconomic situation, which did not improve the not- or dis-advantaged condition. When, therefore, the WTO Members adopt and carry out measures obeying the obligations of the TRIPS Agreement, which provided no or insufficient incentive for research over, for example, the neglected diseases due to difficult economic situations, any Member needing the medicines for these diseases is entitled to submit the situation-based request to promote such research.

Instead of a causal relationship between a certain measure and the not- or dis-advantaged condition, the requestor for the situation-based financial assistance must prove that the salvage of such condition would result in the achievement of the benefits and objectives of the TRIPS Agreement. Therefore, the criteria for a legitimate situation-based request would include (1) the existence of situation, (2) the existence of not- or dis-advantaged condition, (3) causality between the situation and the not- or dis-advantaged condition and (4) the coherency between the target of the financial assistance and the benefits and objectives expected in the Agreement. Besides, as

with the non-violation-based request, (5) the reasonable estimation for the duration and scale of the financial assistance would be required.

These requests for the non-violation-based and situation-based financial measures can raise a new controversy over TRIPS 64.3, which mandated the TRIPS Council to examine the scope and modalities for the non-violation and situation complaints in the TRIPS Agreement during a moratorium of the first five years from the entry into force of the WTO Agreement. Until this five-year deadline on the end of 1999, however, the TRIPS Council had failed to make any progress. At their fourth ministerial session in 2001, ministers of the WTO Members renewed the moratorium and directed the Council to make a recommendation for the fifth session of the Ministerial Conference, on which the fifth session was concluded without any action. This prolonged moratorium must be terminated to realize the non-violation-based and situation-based financial assistance in the TRIPS Agreement.

Measures objected by the financial assistance

As established for the scope of the possible objects in trade-relating complaints, a request for financial assistance to allocate knowledge would rely on a wide variety of legislative acts covered by the TRIPS Agreement, including binding and non-binding acts and obligations to take a positive and negative action as well as administrative authorities with an action and inaction.

Measures by Private Sectors

In addition to these governmental measures, behaviors of private sectors would be objected if such behaviors had a strong tie to some governmental action. This involvement of non-governmental actors can play an important role in the non-violation-based and situation-based requests, in both which governmental measures would be out of the scope of violation because they must comply with the obligations in the TRIPS Agreement. In some cases of the ordinary trade non-violation complaints, private actions with governmental connection or endorsement have been involved. For example, the Panel Report of *Japan - Film*, para 10.56 defines "sufficient governmental involvement" as the decisive criterion as to whether a private action may be deemed to be governmental measure.

Measures by Subdivisions

For the same reason, the request based on both non-violation and situation would be invoked in respect of measures taken by regional or local governments or authorities within their territory. This involvement of subdivisions is well supported by public international law, in which States are responsible for the activities of all branches of their government under their governance, and also for all regional levels or other subdivisions of their government.

Law as such and applied

Since the possible measures objected by the financial assistance for knowledge allocation would include Member's acts, laws, regulations and administrative procedures (law as such), a Member would be able to submit a request independently of, or without waiting for the application of such law (law as applied) though the Member can also rely on an application when the law was actually enforced. As a result of extrapolation from this argument, a request for financial assistance would take place based on not only on-going but also presume legislation even when the law has been adopted in its final form, but has not yet entered into force and it will be effective only from a future date.

Jurisdiction of the commission body

Jurisdiction: Covered Agreement for Claim

Since the "covered agreement" for the financial measure of knowledge allocation is solely the TRIPS Agreement, the deliberation/apellate commission would have its jurisdiction only over TRIPS in order to make a decision on the "claim" or the request for the financial assistance. In contrast to this limited scope, the range of the "applicable law" and "interpretation" must be much broader to decide whether to accept or deny the request for financial measure due to the wider scope of the essential criteria for such request, *i.e.*, regardless of the consistency of measures with the Agreement, the presence of the not- or dis-advantaged condition surrounding the IP issues covered by the TRIPS Agreement. Since, in addition, the TRIPS Agreement involves a wide variety of technical disciplines, for example from arts to sciences, the sources of applicable laws and interpretation for the jurisdiction by the deliberation/apellate commission can encompass a number of individual international laws, regulations and rules stipulating each technical discipline covered by the TRIPS Agreement.

Applicable Law

More specifically, the applicable law for the deliberation of the knowledge allocation would include the other covered agreements and case laws in the WTO system than the TRIPS Agreement, as well as relevant international laws and rules as suggested in DSU 7.2 by saying that "[p]anels shall address the relevant provisions in any covered agreement or agreements cited by the parties to the dispute." Especially in the TRIPS Agreement, Article 2 disciplines the relationship between the Agreement and external intellectual property conventions, *i.e.*, the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits. In addition to these conventions, other external legislations, for example, the Rio Declaration on Environment and Development in case of the financial assistance to promote the transfer of patented environmental technologies, would be applicable in a form of an exhaustive list of *e.g.*, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS 3 and its annex A.3) or a general provision of *e.g.*, the Agreement on Technical Barriers to Trade (TBT 1.1.1).

Interpretation

In addition to this wide resort of the applicable laws, the interpretation and clarification of the legal provisions in the knowledge allocation mechanism would take place pursuant to customary rules by following the fact that DSU 3.2 expressly states that the system is intended to clarify its provisions "in accordance with customary rules of interpretation of public international law." Although customary international law is usually unwritten, Articles 31, 32 and 33 of the Vienna Convention on the Law of Treaties codifies some of the customary rules of the interpretation of public international law. Making an analogy with these clauses, the legal provisions in the knowledge allocation mechanism would be interpreted according to the ordinary meaning of the words in the relevant provision from a view point of their context and the light of the benefits and objectives expected in the mechanism. This

ruling would be well consistence with the past practices by the Appellate Body in the traditional trade disputes (see, e.g., the Appellate Body Report, *EC - Customs Classification of Frozen Boneless Chicken Cuts*, paras. 170 - 176).

Proof and review

Burden of Proof

As stated in the Appellate Body Report, *US - Wool Shirts and Blouses*, p.335 for the ordinary trade-relating complaints, the burden of proof "would rest upon the party, whether a complainant or defendant, who asserts the affirmative of a particular claim or defence in line with the practice of various international tribunals." This means that, in the deliberation process over a request for the financial assistance, the party claiming the request, i.e., the requestor, would have to assert and prove its claim before a commission body. Unlike trade-relating complaints, however, the deliberation process would exclude a defendant. Therefore, the burden of proof would not be transferred from the requestor to a defendant.

Level of Proof

This absence of a defendant would allow the deliberation of the request for the financial assistance to embrace its unique procedure for the level of proof. The commission body would compel the party bearing the burden of proof, i.e., the requestor, to put forward evidence sufficient to make a *prima facie* case (a presumption) that what is claimed is true. In turn, notably, the onus would shift to not a defendant but the commission body when such *prima facie* case was established. Then, the commission body would fail to deny the request and have to accept it unless the body submitted sufficient evidence to disprove the claim, thus rebutting the presumption.

This transfer of the burden from the requestor to the commission body would entitle the commission to seek further information from any appropriate source in order to explore and establish facts (see DSU 13). This right of the commission body would be broad and comprehensive and its exercise would be left to the discretion of the commission as supported by, for example, the Appellate Body Report, *US - Shrimp*, paras. 104 and 106.

Standard of Review

By following the line of DSU 11, the commission body would be mandated not a *de novo* review (i.e., the complete repetition of the fact finding conducted by a Member) or "total deference" (i.e., the simple acceptance of the determination by a Member) but the "objective assessment" in order to establish the facts in a case.

More specifically, this would be considered to mean that the commission body must assess whether a Member have examined all the relevant facts and provided a reasoned explanations of how the facts support its determination. The commission would have to critically examine the Member's explanation as to whether it fully addressed the nature, and the complexities, of the data, and responds to other plausible interpretation of the data.

Flexibilities

Since the sole objective of the knowledge allocation is not to make a decision on a request for financial assistance but to improve circumstances unfavorable for a requestor who has not benefited sufficiently or at all, the mechanism would have to allow the requestor to resort to the traditional flexibilities recognized in intellectual property protection when the request was denied.

If, more specifically, the Member requestor received a rejection of financial assistance, the requestor would be entitled to invoke a remedy measure in the TRIPS Agreement (Articles 31 and 31^{bis} and relevant decisions following the Doha Declaration) or its exemption measure (Article 30), or to demand substantial enforcement of other Member states for an appropriate measure in order to improve circumstances in line with the benefits and objectives of the Agreement, in particular the implementation of TRIPS 7 and TRIPS 67. The remedy measures stipulated in Article 31 typically include generic producing or its importing under compulsory licensing, which are more serious consequence than that in other measures such as the Bolar exemption for a research tool (Article 30) and an action for TRIPS 7 or TRIPS 67.

The TRIPS 31 remedy is temporary and it would be applied at all times, i.e., even before or at the same time of the request for the financial assistance as long as the requirement was fulfilled, in particular "*in the case of a national emergency or other circumstances of extreme urgency*" (TRIPS 31(b)). The application would have to be revoked once the request was accepted for the financial assistance, which would reasonably redress the damage of legitimate benefit expected with protection for its holder. This compensation would not be prospective but retroactive in contrast to the general rule over the estimation of financial assistance because once the provision of the requested financial assistance began, the intellectual property right in question would resurge and the right holder would profit under a normal market rule in the territory, which the Member requestor would subsidized by means of the financial assistance.

In contrast, an exemption measure under TRIPS 30 or alternative financial measure under 67 would be a standing action rather than temporary depending on the nature and scope of the rejected request. These measures can be suggested in a form of recommendation which a deliberation/appellate commission would issue when they decided the rejection. Although this recommendation would not be a mandated function of the commission, such recommendation would be preferred if the deliberation/appellate commission was able to develop.

Concluding remarks

This chapter designs the deliberation/appellate process for a request of financial assistance by making an analogy to the quasi judicial framework in the WTO dispute settlement system. Some of characteristics well recognized in this framework are its compulsory and automatic nature by "reverse" or "negative" consensus with specific time-frames, which is a result from the history of diplomatic negotiations during the Uruguay Round, i.e., the concession of the US on its unilateral trade sanction under the Trade Act §301 and that of the EC on the veto in the settlement system. Such result also includes the mechanism to "rebalance benefits" based on interests and priorities of individual Members at the implementation phase after the Panel/Appellate Body issued their report. These results would be handed down to the TRIPS Agreement by possible second amendment of it following the Doha Declaration in 2001, the first amendment of the Agreement and even the solo amendment ever adopted in the WTO treaties as a whole.