

MEASURES TO ENHANCE ACCESS TO MEDICAL TECHNOLOGIES, AND NEW METHODS OF STIMULATING MEDICAL R&D¹

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1. Introduction

The TRIPS agreement is now more than a decade old, and developing countries are still struggling to reconcile TRIPS requirements with policy objectives concerning access to medicine. A new round of bilateral trade agreements are imposing also a number of TRIPS plus and TRIPS extra obligations on developing countries.

At the same time, developed economies, including those in North America and Europe, are also finding it difficult to pay for high prices on new medicines, including those for severe illnesses like cancer.

¹ Parts of this paper are an elaboration of, James Love, "Four Practical Measures to Enhance Access to Medical Technologies," a chapter in *Negotiating Health*, Earthscan, Edited by Pedro Roffe, Geoff Tansey and David Vivas-Eugui, 2006.

This paper begins with four methods of managing a traditional patent system, in order to more effectively manage limitations and exceptions, and patent quality and transparency issues. It ends with two new ideas which are relevant to more fundamental changes in the methods we use to support medical R&D.

Managing the traditional patent system better

- i. National governments need to enact in domestic law appropriate grounds for non-voluntary authorizations to use patents, expressing clear policy objectives, and consistent with TRIPS, streamlined procedural rules.
- ii. Governments should adopt guidelines for remuneration for non-voluntary authorizations, with the aim of increased transparency and predictability, and outcomes that are reasonably related to the policy objectives.
- iii. There should be greater use of patent pools and other approaches to the collective management of intellectual property rights, in order to better implement policies promoting access.
- iv. Manage the identification of relevant patents and the elimination of inappropriate patent grants – focus on resources and incentives.

New approaches to stimulating medical R&D

- i. Use the Medical Innovation Prize Approach to rewarding successful medical R&D
- ii. Change the global trade framework, to focus on the sharing on the costs of R&D

2. Managing the traditional patent system better

2.1. Grounds and procedures for non-voluntary authorizations to use patents under Article 31 of the TRIPS.

The November 2001 Doha Declaration on TRIPS and public health said:

- each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted,²
- the TRIPS Agreement “can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all,”³ and

² Paragraph 5(b)

³ Paragraph 4.

- in order to give practical effect to this statement, WTO members have the “right” to use “to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”⁴

It is clear from these statements that countries have both the ability and the *duty* to promote access to all. Should countries modify existing statutes to comply with the Doha Declaration?

For many countries, the answer is yes. Few developing countries have anything remotely close to the resources necessary to provide “access to medicine for all” even at generic prices, let alone at the prices typically charged by patent owners under exclusive rights regimes. Existing compulsory licensing laws are often a barrier to access. The standards for issuing compulsory licenses may rely excessively on narrow grounds such as non-working or difficult to establish abuses, exhibit a lack of clarity regarding public policy objectives, or invite litigation over factual issues or legal standards. This has caused some governments to delay or reject requests for compulsory licenses, despite enormous problems relating to access to patented medicines.

Countries also often do not have other basic TRIPS flexibilities in national laws, such as exceptions to patent rights relating to the early working of patents, the use of diagnostic, therapeutic and surgical methods for the treatment of humans or animals, non-profit or for-profit research, personal or compassionate use of patented inventions, or the exhaustion of rights associated with parallel trade. Nor do countries exercise the considerable TRIPS flexibilities regarding policies on patentability, such as the appropriate subject matter for patents, or the standards for novelty, utility or non-obviousness. All of these topics are important, and are addressed in many thoughtful papers and reports.⁵

This section focuses only on one area of TRIPS flexibilities -- the ability of governments to authorize non-voluntary uses of patented inventions under Article 31 of the TRIPS.

Because the TRIPS flexibilities are only recognized if they are a part of the national legal system, it is important to ensure that the statutory framework is both workable and working. In reviewing domestic laws, countries (*and public health experts and advocates*) should conduct the following review:

Grounds

1. Do the national statutes provide the government with an absolute right to use or have third parties use patents to promote access to health care inventions, subject only to adequate remuneration to patent owners, as permitted under Article 31.b of the TRIPS? While many countries make compulsory licensing subject to specific findings concerning abuses or public interests, this is not necessary. For example, the United States patent law has a “government use” provision that allows any federal

⁴ Paragraph 4.

⁵ Reference other works on other issues, including SC, ICSTD, TWN, WHO, etc.

employee to use any patent or copyright, subject only to remuneration to the right-owner. This right can be exercised without any finding of abuse or indeed without any proceeding or license whatsoever, and can be extended to third parties that use patents for a government purpose. Many other countries have similar “rights of the state,” “crown use,” or “*ex officio*” licensing provisions, but sometimes with more limited rights for the government to use patents.

2. Is the TRIPS requirement for prior negotiation on “reasonable commercial terms and conditions” appropriately limited only to cases *not* involving (a) public non-commercial use (b) national emergencies or *other circumstances* of extreme urgency, or (c) remedies to anticompetitive practices?
3. Does “public non-commercial use” permit the government to authorize third parties to supply medicines to the public, including not only through non-profit or government hospitals or clinics, but also when medicines are distributed through pharmacies or for-profit clinics in connection with national health systems?
4. Does the national statute recognize a lack of access to medicines or other medical inventions as the basis for a public health crisis, triggering the TRIPS waiver of prior negotiation with right-owners, when authorizing non-voluntary use of patents by generic suppliers?

Note: To eliminate the requirement for prior negotiation for use of patents in cases involving commercial transactions, such as non-state-subsidized pharmaceutical sales, countries can avoid using the specific reference to “national emergencies,” which may have a sensitive and off-putting legal meaning in some countries. Not only does the TRIPS itself provide for “other circumstances of extreme urgency,” which is fairly open, but more importantly, Paragraph 5(c) of the Doha Declaration on TRIPS and Public health provides that WTO members have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency,” and further, that it is “understood that public health crises, including [but not limited to] those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” It is thus possible to invoke the “emergencies or other circumstances of extreme urgency” provisions in the TRIPS by referencing a “public health crisis” in the statute or the administrative action implementing a statutory provision, including one that is related to a lack of access to medicine or treatment.

5. Do countries specify licensing practices or conditions that constitute abuses of intellectual property rights, pursuant to Article 40 of the TRIPS? This very important TRIPS flexibility, which is titled “Control of Anti Competitive Practices in Contractual Licenses,” provides that:

- Some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
- Nothing in the TRIPS Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.
- A Member may adopt appropriate measures to prevent or control such practices.

Taken together, Articles 31.k and 40 of the TRIPS, and Paragraphs 4 and 5(b) of the Doha Declaration, allow a country to specify that refusals to license patents to competitors are illegal if the following conditions apply:

- i. The refusal to license the patent will impede the transfer and dissemination of technology that is essential for promoting access to medicine for all, or
 - ii. The patent is essential for the import, manufacture or sale of a medicine or medical technology that is placed on the market at an excessive price, defined as a price that is not affordable for most of the population.
6. Does the national law freely permit exports of medicines when compulsory licenses are issued as a remedy to anticompetitive practices, as is permitted under Article 31.k?
 7. Does the domestic law permit the importing of patented medical inventions?

Procedural issues

1. Does the law eliminate injunctive relief in cases involving non-voluntary authorizations to use patents, as is permitted under Article 44 of the TRIPS?⁶ Many believe this may be one of the most important procedural issues. The United States is among the countries that have eliminated injunctive relief for government use authorizations.⁷

⁶ TRIPS Article 44.2 on Injunctions states, “Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. . . .”

⁷ 28 USC 1498. Patent and copyright cases.

2. Do the laws regarding the decision to issue a compulsory license, and the setting of remuneration to the patent-owner provide for simplified and fast-track administrative procedures?
3. In particular, can a remedy to an anticompetitive practice be determined by an administrative rather than a judicial procedure, and by bodies such as the Minister of Health or Industry, as is permitted under Article 31.k?
4. Does the law create certain cases where the issuance of a compulsory license is mandatory? There are many advantages to a statutory framework that makes the authorization mandatory rather than discretionary. A law providing for mandatory licensing, with or without establishing a basis for qualifying for the mandatory provision, will:
 - a. lower transaction costs and reduce uncertainty regarding the availability of the license (often a rationale for statutory licenses available under copyright laws),
 - b. ensure that policy goals regarding access are implemented,
 - c. eliminate the opportunities for bilateral trade pressures, or inappropriate patent-owner lobbying of government officials, and
 - d. eliminate or at least greatly reduce the opportunities for corruption, either by generic firms seeking compulsory licenses or by patent owners who oppose the granting of compulsory licenses.

Illustrations of mandatory approaches include the mandatory compulsory licenses for genetically modified crops which are required by every member of the European Union under the European Biotechnology Directive, and the mandatory “licenses of right” that were used in the UK when it extended patent terms from 16 to 20 years, and also by the US when it extended patent terms from 17 to 20 years to comply with the TRIPS. The TRIPS requirement in Article 31(a) that the “authorization of such use shall be considered on its individual merits” can be satisfied by the consideration of the appropriate remuneration of the authorization, as was the case for the US licenses of right, and is today for the mandatory compulsory licenses under the biotechnology directive.⁸

⁸ An example of mandatory compulsory licenses outside of the patent area include the US approach to compensatory liability for uses of certain test data used to register agricultural products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which reads in part: "If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator." 7 USC Chapter 6, Subchapter II, § 136a. Registration of pesticides.

2.2. Remuneration guidelines⁹

Today several countries are using or considering Article 31 for non-voluntary authorizations to use patented medical inventions. After a grounds is selected for the authorization, the government or judicial authority authorizes the non-voluntary use of the patent must determine remuneration for the right-owner. The provisions in the TRIPS that relate to such remuneration are summarized below:

Summary of TRIPS provisions that relate to remuneration

Term	TRIPS Provision	Situation
<i>Do not unreasonably prejudice the legitimate interests of the patent owner</i>	Article 30	Applies to cases where a compulsory license is implemented under the general exceptions provision (rather than Article 31)
<i>Prior negotiation on reasonable commercial terms</i>	Article 31(b)	Applies to commercial non-emergency authorizations that are not remedies to anticompetitive practices
<i>Adequate remuneration . . . taking into account the economic value of the authorization</i>	Article 31(h)	Applies to all authorizations, but the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration. In some competition cases, the remuneration is set to zero.
<i>The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration</i>	Article 31(k)	Where such use is permitted to remedy a practice determined after judicial <i>or</i> administrative process to be anti-competitive.
<i>Reasonable terms</i>	Article 31(l)	The owner of the first patent must offer a cross license on reasonable terms when obtaining a compulsory license to use a dependent patent
<i>Promote access to medicine for all</i>	Doha Declaration, Paragraph 4	Applies to cases involving public health problems
<i>Adequate remuneration . . . taking into account the economic value of the authorization in the importing</i>	Doha Declaration, Paragraph 6	Applies when exports are authorized under the system established by the August 30, 2003 decision of the General Assembly, implementing paragraph 6 of the Doha Declaration

⁹ For an extensive discussion of these issues, see: James Love, *Remuneration guidelines for non-voluntary use of a patent on medical technologies*, TCM Series No. 18, published jointly by UNDP and the WHO, December 2005. On the WHO Web page here: http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf

<i>country</i>		
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In order to provide more transparency, greater predictability, and to make the process less costly and time consuming to administer, countries should consider the adoption of remuneration guidelines.

Any one of several existing remuneration guidelines may be appropriate, or a country may develop modified or new guidelines. The simplest are the royalty guidelines from the 2001 United National Development Program (UNDP) Human Development Report (HDR). These recommend a normal royalty of 4 percent of the generic price, with possible modifications up or down by 2 percent, based upon evidence regarding the therapeutic value of the product, or of a government role in financing R&D.

The 1998 Japanese Patent Office (JPO) royalty guidelines for government-owned inventions provided for a normal royalty of 2 to 4 percent, with the higher rates for inventions that generate higher profit margins. The 1998/JPO guidelines also had a number of factors which increased or decreased the rates, including most importantly the “utilization factor,” which takes into account the relative importance of the patented invention in the product. This approach is particularly well suited to the (common) case where there are multiple patents on the same pharmaceutical product, and specifically where the product is a fixed dose combination (FDC) of different drugs, and includes cases where some of the products are off-patent and others are on-patent. Examples of the latter case would include the AIDS fixed dose combinations (FDCs) LPV+RTV or d4T+3TC+NVP, which are combination products with very different patent coverage for the various component products. Depending upon the particular circumstances, the 1998/JPO guidelines provide for royalties of 0 to 6 percent of the price of the competitor’s generic product.

In 2004, Canada issued proposed royalty guidelines for medicines exported from Canada to developing countries under the 30 August 2003 WTO waiver of Article 31(f) of the TRIPS Agreement. The Canadian guidelines are a sliding scale from .02 to 4 percent, with the top rate of 4 percent assigned to the 1st country in the UNDP Human Development Report. The Canada formula is

$$.04 \times (178 - \text{HDR_RANK}) / 177$$

The Canadian guidelines are based upon a country’s rank in the UNDP Human Development Index (HDI), and correspond to the development of the country as measured by the ordinal HDI index, but are only weakly correlated with the actual affordability of medicines, particularly if applied to countries with high or middle incomes. Another element of the 2004/Canadian method is that it is tied directly to the cost of manufacturing the generic alternative, an approach also used by the 2001/UNDP/HDR, and the 1998/JPO methods.

Methods that base the royalty on the prices offered by the competitive generic manufacturers have the advantage of moving the price to the consumer closer to marginal costs in a predictable and transparent manner, which is particularly important for populations that face the largest barriers to access. The disadvantage is that there is a weak (2001/UNDP, 1998/JPO) or non-existent (2004/Canadian) link to

the therapeutic value of the invention, or the affordability of the royalty, particularly for higher income populations.

The 2004/Canadian method is particularly appropriate for countries with lower income, because on average, it is a sufficiently close approximation to an optimal/acceptable royalty rate, and the calculation only requires knowing a country's rank on the UNDP HDI.

A newer and somewhat more complex approach is the 2005/Tiered Royalty Method (TRM). The TRM begins with a base royalty, which is 4 percent¹⁰ of the price of a product in high-income markets. This base royalty is adjusted downward, to reflect relative capacity to pay, according to either the relative per capita income, or the relative GDP per patient population, for countries facing particularly high rates of disease burden. The TRM is considerably higher for countries with the highest incomes, and much lower for countries with both low incomes and high burdens of disease. The TRM is a potentially useful method for creating a more rational framework for royalty payments across different products and among countries of very different incomes and disease burdens.

Comparison of Remuneration under Four Royalty Methods

Annual Royalties in USD for AIDS drug Kaletra/LPV+RTV, with high-income price of \$7,766 and generic price of \$500

			2001/UNDP– 1998 JPO Methods @ 4 percent	2004 Canadian Export Method	Tiered Royalty Method
Country	2002 GDP/POP	HIV+ /POP	LPV+RTV @\$500	LPV+RTV @\$500	LPV+RTV @\$7766
United States	36,123	.31%	20.00	19.21	224.81
Germany	23,956	.05%	20.00	17.97	277.31
Chile	4,118	.13%	20.00	15.25	47.45
Brazil	2,593	.35%	20.00	11.98	14.45
Thailand	2,052	1.1%	20.00	11.57	3.69
Philippines	964	.01%	20.00	10.73	11.24
Indonesia	817	.06%	20.00	7.57	9.42
India	491	.38%	20.00	5.76	2.50
Swaziland	1,082	15.63%	20.00	4.63	.14
Zambia	352	11.47%	20.00	1.58	.06
Mozambique	213	5.97%	20.00	.79	.06
Sierra Leone	151	3.25%	20.00	.11	.09

¹⁰ Approximately the average pharmaceutical royalty in the US.

2.3. Use of non-voluntary patent pools for the collective management of intellectual property rights

One of the problems with the use of compulsory licensing is the daunting prospect of separate administrative or legal proceedings for large numbers of patents and medicines, in many different countries. Some of these concerns are mitigated if countries adopt good grounds and procedures for compulsory licensing. Another more pro-active approach is to borrow from experiences in the copyright sector, and embrace tools for the collective management of intellectual property rights, including approaches that involve non-voluntary authorizations to use patented inventions.

In 1917, the US government faced a crisis that involved patents and aircraft. The Wright Brothers were using their patents on key elements of aircraft design to suppress competition, and the increasingly costly and aggressive patent litigation was suppressing both competition and innovation in the aircraft industry—right as the US was preparing to enter the 1st World War. The US government created a patent pool for all of the essential patents related to the building of civilian or military aircraft. Patent owners were forced to join the pool or face government non-voluntary acquisition of patent rights.

The 1917 Manufactures Aircraft Association (MAA) patent pool, which was crated in just six months, was very successful in resolving patent disputes, led to the creation of the modern US aircraft industry. Today it serves as the model for a voluntary patent pool between Boeing and Airbus, which operates largely to resolve disputes over remuneration.

Today there are numerous situations where the complex landscape of patent rights and the high costs of obtaining licenses creates barriers for innovation or access, and there is considerable experience and interest in the use of patent pools to lower transaction costs and to facilitate innovation, including the many voluntary patent pools for consumer electronics, and proposed patent pools in the biotechnology and biomedical field. An approach more similar to the 1917 MAA was proposed by Essential Inventions, for an Essential Patent Pool for AIDS,¹¹ and a broader version covering a wider array of medicines has been discussed in the context of regional patent pools for Africa, Latin America or Asia. The use of patent pools to expand access to medicines has been endorsed in two recent regional consultations on TRIPS and public health held in Kuala Lumpur and Addis Ababa.

The Essential Inventions proposal would have a non-profit entity created to manage the patent pool. The pool would simultaneously seek voluntary licenses from owners of essential patents, and cooperative agreements with governments and donors. The governments that signed agreements would cooperate to issue compulsory licenses on patents in the event that voluntary negotiations were unsuccessful. Both the donors and the governments would negotiate policies concerning transparency, treatment of confidential information, remuneration, competition (open licenses), market access (including appropriate incentives for local production, or mechanisms to facilitate exports of medicines) and cooperation on the regulation of the quality of generic

¹¹ <http://www.essentialinventions.org/docs/eppa/>

products. The pool would also provide a number of services, including the licensing of patents to generic competitors, and the collection and distribute of royalties to patent owners, as well as resolving antitrust issues with national competition authorities. (See Attachment 3, “Proposal for Patent Pool for Essential Medicines.”)

2.4. Identification of relevant patents, and eliminating inappropriate patents.

Developing countries face three related problems. First, there is often too much uncertainty regarding which patents (if any) are relevant to the manufacture or sale of a particular medicine. Second, there is a need to make and enforce important policy decisions regarding what should be patented (the appropriate patentable subject matter, and standards for novelty or inventive step). Third, the patent examination system is highly imperfect, leads to many poor quality patents being issued, and very expensive and time consuming when challenging initial decisions granting patents. Possible measures to address these three problems include:

Transparency of relevant patents

In many countries, there is considerable uncertainty regarding the existence of patents on particular medicines. In some countries, patent searches are both costly and time consuming, particularly in cases where the records of the national or regional patent office are poorly organized or difficult to reach or search. There are many different ways that governments, regional or global organizations could facilitate more transparency of the status of patents on medicines.

The United States maintains an “Orange Book” that lists patents that companies identify as relevant to medicines sold in the US market. The disclosures in the Orange Book are voluntary. The incentive to disclose is related to the patent enforcement mechanism linked to the Orange Book. The US FDA will not register a generic competitor so long as there are patents listed in the Orange Book. While the Orange Book improves transparency of patent filings, it is routinely misused. Companies often list patents of dubious merit and relevance. As a consequence, the improper listing of patents is often the subject of litigation and antitrust enforcement actions. The US FDA is needlessly embroiled in disputes over the listing of Orange Book patents, because of the link to drug registration. Unfortunately, the US government is promoting this flawed system in regional and bilateral Free Trade Agreements (FTAs). However, as flawed as the US Orange Book system is it could easily be modified to work better. In particular, a listing of patents could be required or encouraged in any of the following ways.

Drug registration authorities could require or encourage the disclosure, without linking the disclosure to drug registration, by providing that patent owners could not enforce non-disclosed patents against generic competitors. Although this approach would still likely result in the listing of patents of dubious quality or relevance, the drug registration authorities would not use the listing to block generic competitors. The patent owners would have to seek enforcements in national court systems, as is the case now in most countries, and everywhere for non-pharmaceutical inventions.

Regional or multilateral bodies concerned with health care, such as the African Union, the Pan American Health Organization (PAHO), the World Bank, UNAIDS, the Global Fund, regional patent pools or the World Health Organization could also play an important role. For example, donors for AIDS treatment could meet with the handful of companies that developed key AIDS drugs and insist that they disclose the relevant patent numbers and countries where the patents are approved, and publish the information on the Internet.

The task of disclosure could also be managed by local, regional or multilateral patent offices, including the Patent Cooperation Treaty (PCT), which is administered by WIPO. While patent offices have not played a traditional role in such disclosures, it is increasingly difficult to ignore the enormous problems presented by the lack of transparency of patent status.

One advantage of a global system would be the information about the differences in the patent landscape for the same drug sold in different countries. Countries that face a high number of patents may seek to understand why such patents are not listed for other jurisdictions. The global authority could also do a more efficient job of “delisting” patents that are not relevant.

Management of Policies on Patentability

There are many policy options for what constitutes a patentable invention. Some issues are well known – is it possible to patent a second use for an older drug (such as AZT for AIDS, sildenafil for erectile dysfunction, or ritonavir as a booster of protease inhibitors), combinations of existing drugs, the prescribed dose of a medicine, or common methods of buffering, coating or delivering medicines (e.g. an enteric coating of a pill, or the common use of a solvent in connection with a gel tab presentation)? These are only a few examples of controversies regarding patentability. Some involve explicit policies regarding patentable subject matter (the patentability of second uses, doses of drugs, etc), and in other cases judgments over the novelty, obviousness or utility of the innovation.

Increasingly, public health experts are asking to play a greater role in pre- or post-grant review of such matters. To this end, it will be useful to develop clear and practical guidelines on patentability of medicines. These guidelines could address both traditional issues of patent quality, as well as expressions of health care policy.

Some approach the issue of patentability within a narrow policy framework that takes as a given the wisdom of extending patents into every area of economic activity, focusing only on the traditional framework for evaluating novelty and inventive step. There is no reason to begin from this approach, which assumes, without evidence, that patents are always a welfare-improving innovation. The more fundamental policy analysis begins with the question, are patents a welfare-improving innovation? This “cost-benefit” approach, based upon practical real world empirical realities, will exclude patents in areas where the grant of the patent is an unimportant incentive, and the costs of imposing patents are high. This analysis first limits patentable subject matter, and then secondarily, provides practical guidance of how to interpret the novelty, utility and non-obviousness tests.

National policy is not harmonized on these issues. However, there is no obvious value in a quick global harmonization effort, given the paucity of state practice that is free from poor patent quality, anti-competitive practices and other abuses, and the relatively low level of current engagement on these issues by public health experts. For now, experimentation and innovation in state practice is fitting, although some level of organic harmonization among regions or blocks of like-minded or commonly situated countries will be appropriate as countries gain experience and confidence in such initiatives.

Global bodies like WIPO or the WHO could collect information on state practice on the patentability of medicines. National governments could experiment with and share information about patentability guidelines for medicines, including collaborative efforts involving both health and patent authorities. Such guidelines could list areas that would not be considered patentable inventions, such as second uses of medicines, doses, or enteric coatings of pills, would be useful for patent examiners, as well as generic competitors who were evaluating whether or not to challenge patents that had been registered in that country.

It is also important to evaluate the implementation of such policies and guidelines. If a country has indicated it will not patent doses, second uses, or other areas, are such patents nonetheless granted and registered?

Avoiding Unwarranted Encroachments on the Public Domain

Whatever the intended standards for patentability, the actual administration of a patent system depends on the evaluation of highly technical patent applications. Mistakes will be made -- lots of mistakes. Poor patent quality is a phrase used to describe the mistake of granting patents that do not meet property standards. WIPO describes such mistakes as “unwarranted encroachments on the public domain.”

It is important but difficult to address problems of poor quality patents. Resources (*and incentives*) are important, both on the front-end, before a patent is granted, and later, to resolve post grant disputes.

A patent examination requires access to expensive library and database resources to judge prior art, as well as trained personnel. The United States Patent and Trade Office (USPTO) employs more than five thousand patent examiners and spends more than a billion dollars a year, but still faces a crisis of public confidence of patent quality. It is increasingly doubtful that any government can be realistically expected to weed out applications that should never see the light of day.

Not every country seeks to examine patent applications on the front end. Many maintain registration systems, where every application is accepted. Unlike the examination approach, in a registration system, the initial grant of the patent does not imply the patent will be enforced when there is a dispute. For some countries, the examination system looks almost as automatic as a registration system.¹²

¹² The grant rate at the USPTO is typically reported to be in the range 62% to 68%, Quillen and Webster that provided an analysis of continuing applications (including continuations, divisionals, and continuations-in-part), that suggested the rate might be as high as 97% in some years. Clarke estimated

If it is not realistic or cost-effective to enforce polices on patentability before the patent grant, the burden of dealing with poor patent quality shifts to the post-grant mechanisms that resolve disputes over patentability. These include mechanisms, if any, for administrative challenges to patents, or litigation. Litigation over patentability is very expensive in most countries. According to a recent article in *Nature*, the US costs of litigating disputes over biotechnology or pharmaceutical patents is typically \$3 to \$10 million for each party.¹³ Even though costs are lower in developing countries, they are often still too high to justify the expense, given the smaller domestic markets. Litigation also takes time. For example, the challenge to a controversial ddI patent in Thailand took several years, and during that time, patients could not use generic ddI in pill form.¹⁴

WIPO has identified patent quality as a priority issue for the Standing Committee on Patents, but has proposed only harmonization of patentability laws. More useful would be a work program to look at the practical issues that lead to poor patent quality, and the most useful policy interventions to address anticompetitive practices and inappropriate encroachments on the public domain.

WIPO should start with collecting data on the costs of resolving patentability disputes in different countries, and the practical barriers to the reversal of an inappropriate patent grant. The Patent Cooperation Treaty or a new instrument or agreement could address some of the obvious issues concerning patent quality, such as the appropriate obligations on patent owners to inform the PCT of national challenges to patent claims, and the reporting of the resolution of such disputes. It would be useful to consider a policy of automatic reexamination of patentability if a patent claim was reversed in a foreign jurisdiction.

Administrative procedures for post-grant patent opposition can be greatly strengthened. Here WIPO could consider providing low-cost arbitration services to resolve disputes over patentability, such as it now provides for resolving disputes over trademark protection on domain names. This could be particularly useful in cases where foreign patent disputes have already created a record regarding prior art or inventive step. WIPO could also facilitate sharing of information on national programs for administrative patent opposition procedures, to see which approaches are effective in controlling anticompetitive practices or poor patent quality.

the corrected grant rate at less than 75%. See, Stephen A. Merrill, Richard C. Levin, and Mark B. Myers, Editors, Committee on Intellectual Property Rights in the Knowledge-Based Economy, National Research Council, *A Patent System for the 21st Century*, 2004, the National Academies Press, Board on Science, Technology, and Economic Policy (STEP), pages 52-52. Quillen, C. and O. Webster, 2001, "Continuing Patent Applications and Performance of the U.S. Patent Office," *Federal Circuit Bar Journal* 11(1):1-21. Robert A. Clarke, 2003, U.S. Continuity Law and its Impact on the Comparative Patenting Rates of the U.S., Japan, and European Patent Office, 85 *J. Pat. & Trademark Off. Soc'y*, 335.

¹³ Ted Apple, "The Coming US Patent Opposition," *Nature Biotechnology*, Volume 23, No 2, February 2005.

¹⁴ Nathan Ford, David Wilson, Onanong Bunjumong, Tido von Schoen Angerer, The role of civil society in protecting public health over commercial interests: lessons from Thailand, *Lancet* 2004; 363: 560-63

3. New Paradigms for Medical R&D

There is considerable dissatisfaction with the existing global system for financing medical R&D. One concern is that the current system relies too much on high drug prices to reward successful innovations, which leads to access barriers and rationing. Strong patent rights are also seen as limiting follow-on innovation. There are concerns that the patent system currently focuses investments in products that do not provide significant therapeutic benefits over existing medicines, or which do not address important health care priorities. There is also a concern that the patent system does not provide incentives to invest in public goods, such as basic research, public databases or clinical evaluations of existing medicines. These criticisms have led to some proposals for reform. Among the more important are the medical innovation prize fund approach to rewarding innovation, which has been proposed in the United States Congress, a system of competitive intermediaries for supporting public goods, and the medical R&D treaty approach to address the global issue of sharing the costs of medical R&D.

3.1. Medical Innovation Prize¹⁵

In January 2005, Representative Sanders introduced HR 417 in the US Congress. The legislation provides generic producers non-voluntary authorizations to use any and all patents (and *sui generis* IP, such as rights in registration data) relevant to the manufacture and sale of all prescription medicines in the US market. The bill provides for remuneration to the developers of new medicines, through a medical innovation prize fund (MIPF) with annual funding of .5 percent (50 basis points) of the US GDP.

The proposal seeks to radically change the way the US government supports R&D for new medicines, by separating the market for the product from the market for new innovations, so that products can be made available to public at generic prices, while innovators benefit from a separate remuneration system.

The size of the MIPF is fixed as a fraction of the US GDP. The remuneration is paid by the MIPF directly to the innovator, regardless of which firm actually sells a product to consumers. Innovators that register new medicines would compete against each other for the proceeds of the MIPF. Prize payments would be awarded for the first ten years a product is on the market, based upon evidence of the incremental health benefits of the product, when compared to existing medicines. There are also minimum levels of funding for (1) global public health priorities, including treatments for infectious diseases such as AIDS, vaccines, and medicines for responding to bio-terrorism, (2) diseases that qualify under the US Orphan Drug Act, and (3) neglected diseases primarily affecting the poor in developing countries.

¹⁵ The discussion the medical innovation prize fund is taken from: James Love, *Remuneration guidelines for non-voluntary use of a patent on medical technologies*, TCM Series No. 18, published jointly by UNDP and the WHO, December 2005. On the WHO Web page here: http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf

The MIPF also uses a novel approach to rewarding innovation in situations where a new product offers an improvement over an existing product. The new product is rewarded for the incremental health benefits it adds, while the older product will continue to receive MIPF payments, to the extent that the new product was based on or benefited from the original product. Thus, for example, in cases where an innovative product creates a new therapeutic class or method, but is replaced in the market by a similar but slightly better improvement, the developer of the newer product will be rewarded for the incremental benefits of the follow-on invention, but the developer of the first product will also continue to share in the MIPF payments, even in cases where the original product has a zero market share.

The US proposal is a potential model for other countries, although possibly with different and likely lower fractions of funding, to reflect different degrees of ability or willingness to pay for the development of new medicines. Globally, the United States is the single largest source of funding for medical R&D, including incentives from the large US market for new drugs and hefty public sector funding of agencies like the US National Institutes of Health (NIH). No developed country contributes as much toward medical R&D, and so the US proposed contribution may seem high for some countries, particularly those from developing countries that face greater resource constraints.

In 2005 a group 162 public health experts, scientists, NGOs, government officials and parliamentarians proposed a treaty for medical R&D that proposes global obligations on funding medical R&D, as an alternative trade framework.¹⁶ The draft R&D treaty proposes alternatives for minimum levels of support for medical R&D, including:

ALTERNATIVE 1 (Based upon World Bank Income Classifications)

- i. High Income, 15 basis points (.0015)
- ii. High Middle Income, 10 basis points (.001)
- iii. Lower Middle Income, 5 basis points (.0005)
- iv. Low Income, 0 basis points of GDP (0)

ALTERNATIVE 2

- i. 1 basis point of GDP for the per capita income from \$300 to \$999,
- ii. 5 basis points of GDP for the per capita income between \$1,000 and \$4,999,
- iii. 10 basis points of GDP for the per capita income between \$5,000 and \$9,999,
- iv. 15 basis points of GDP for the per capita income between \$10,000 and \$19,999, and
- v. 20 basis points of GDP for the per capita income of \$20,000 or more.

Countries might consider an approach similar to HR 417 with the level of funding of the innovation prizes related to these or other norms, adjusted to reflect the amount of R&D the prize system is expected to induce.

For purposes of discussion, a sliding scale for national funding of a medical innovation prize fund is presented in the attached Table A-3. The fraction of GDP

¹⁶ <http://www.who.int/intellectualproperty/submissions/en/CPTech.pdf>

allocated to the fund begins with a top rate of 20 basis points of GDP, for the country ranked first in the UNDP HDI, and is adjusted downwards for a country's relative rank in the index. If every country participated at the recommended rate, the fund would have generated \$54.7 billion in prizes in 2002, including \$34.8 billion outside the US. If the top rate was 30 basis points, the 2002 prize payments would have been \$82 billion.

As noted, the fixed budget for remuneration is allocated among competing products, based upon the relative merits of their products in terms of health care benefits. The advantages of the innovation prize fund approach are (1) all medicines are available as generics, and patients face fewer barriers for access to medicines, and (2) the prize fund provides targeted incentives for innovators, including incentives to develop priority medicines. This last point is particularly important when one considers the fact that about 70 percent of new drugs are judged by the US FDA to be no better than existing drugs, and there is evidence that the non-priority medicines have clinical trials approximately twice as large as the priority products that offer incremental benefits.¹⁷ If the prize fund can shift investments into more useful products, the ultimate benefits from innovation could be substantially higher than the existing system, and for much less total outlays, given the savings from the greatly expanded use of generic drugs.

Developing countries implementing the prize fund could also consider placing a portion of the prize fund into an essential R&D fund, to be invested through local universities, research institutions, small businesses, or public/private/partnerships (PPPs). Some have proposed the essential R&D fund be invested in the development of appropriate technologies, such as heat stabilized insulin, or treatments for neglected diseases, with the patent owners receiving shares in the fund, so they would benefit from successful commercial projects.

By keeping up to half of the prize funds for investment in the domestic economy, developing countries could develop a knowledge-based innovation sector. The technology transfer and capacity building that would accompany such a fund would help achieve some of the development goals mentioned in the TRIPS agreement.

Possible Levels of Medical Innovation Prize Fund Remuneration, 20 basis points top rate, (millions USD).

	2002 GDP	Prize Fund paid directly to patent owners	Invested domestically in essential R&D fund	Total Prize Payments
New Zealand	58,600	105.9		105.9
Germany	1,984,100	3,564.7		3,564.7
Chile	64,200	49.0	49.0	97.9
Brazil	452,400	271.0	271.0	541.9
Philippines	78,000	41.9	41.9	83.7
India	510,00	147	147	294.0

¹⁷ James Love, Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines, September 22, 2003.

Swaziland	1,200	.3	.3	.6
South Africa	104,200	34.7	34.7	69.5
Kenya	12,300	2.1	2.1	4.2

For non-LDC members of the WTO, the types of medical innovation prize funds described above would have to be justified as consistent with *either* Article 30 of the TRIPS, or Article 31. Article 30 permits exceptions to exclusive rights in cases where the exceptions are (1) “limited,” (2) do not unreasonably conflict with a normal exploitation of the patent, and (3) and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. (Note that the “Bolar” exception to patent rights, which was successfully defended under Article 30, effectively reduces the exclusive rights of a pharmaceutical patent by up to two years, without remuneration.) With adequate funding, the medical innovation prize fund would seem to satisfy the Article 30 three-step test, particularly for countries that provide more funding in prizes than is now paid (on average) in royalties to patent owners (about 2 to 8 basis points of GDP for most countries).

An Article 31 approach presents certain procedural difficulties, but a country can correctly argue that it is a public sector acquisition of medical innovation to promote public health, and under Article 31(b), the requirement for prior negotiation is waived. This approach is strengthened greatly by the Doha Declaration on TRIPS and Public Health, particularly paragraphs 4 and 5.

3.2. Competitive Intermediaries

Not every development model for new medicines works best with a “pay for success” pull incentive. Small biotech companies complain about gaps in financing for certain transitional research that is important for commercialization, but so risky it is shunned by private investors. There are also many new ideas for various decentralized open source development models.

Hubbard and Love have proposed the creation of a system of “competitive Intermediaries” to invest in R&D projects on behalf of employers.¹⁸ Under this proposal, employers would be required to contribute to entities that funded medical R&D. The employer would choose which R&D fund managed its money. There are a variety of ways such a proposal could be implemented, including for example:

1. The competitive R&D funds could do R&D themselves, or be restricted to funding third party R&D.
2. The competitive R&D funds could be allowed to invest in priority research, or only research that entered the public domain.

¹⁸ James Love and Tim Hubbard, *Paying for Public Goods*, a chapter that Tim Hubbard and I wrote for *Code: Collaborative Ownership and the Digital Economy*. Edited by Rishab Aiyer Ghosh. MIT Press, Cambridge, 2005.

3. Intellectual property rights, if any, could be help by the investors, the R&D manager, the firms that conduct the R&D, or the government.
4. Licensing of intellectual property rights (if any) could involve public interest provisions, including those relating to follow-on innovation, reasonable pricing, or cross licensing obligations.
5. There could be free entry to manage the R&D funds, or the government could limit the number of entities that compete.
6. Employers could invest in the R&D funds directly, or through associations that were large enough to do due diligence and evaluation of R&D portfolios.
7. R&D portfolios could be transparent, with useful information on invest flows.

3.3. Global Framework for Essential Health Research and Development¹⁹

On 27 January, 2006, the World Health Organization Executive Board – a small group of states that prepares the program for the coming World Health Assembly in May – agreed to forward for debate a resolution concerning a new “Global Framework on Essential Health Research and Development.”²⁰

The debate over this resolution is an attempt to involve the WHO in a new role of pro-actively re-shaping global policies regarding the support for R&D for new medicines. It is controversial. First submitted by the governments of Kenya and Brazil, the original version of the resolution touched on a number of different aspects of the global system for supporting medical R&D, including topics such as the equitable sharing of the costs of R&D; the need for better priority setting (“needs-driven R&D”); the importance of both access and innovation, including follow-on innovation; various problems concerning intellectual property rights and trade agreements; and the promise of new “open models” for the development of medical science.

It called for the creation of a group of member states to consider proposals to establish a global framework for supporting needs-driven research, consistent with appropriate public interest issues, and for a variety of other measures that were designed to promote access to medicines and a needs-driven R&D agenda.

The 1,200 word version of the resolution that emerged from the WHO EB (EB117.R13) contained most but not all of the original ideas, but also a number of proposed modifications, including several that would weaken or change the direction of the resolution. There are now 32 areas where the text of the resolution is bracketed, including even the words “Global Framework” in the title, indicating divisions among the WHO EB members on the most important issues.

¹⁹ This section is based on: James Love, "WHO to Debate Global R&D "Framework," Real Health News. No. 4, March 2006, page 14-16.

²⁰ WHO Executive Board draft resolution EB117.R13: [Global framework on] essential health research and development http://www.who.int/gb/ebwha/pdf_files/EB117/B117_R13-en.pdf

The existence of so many areas of disagreement raises questions about the degree to which the WHA members – the world’s governments, represented by their ministers of health – can reach consensus on the proposal at all, or if they do, what the final product of negotiations will look like.

Nevertheless it is a remarkable effort to fashion the landscape for financing R&D on new medicines, and if it is embraced, it could open the way for a new and important way of addressing medical R&D at the global level.

But what would a “global framework” for needs-driven health R&D actually look like? By definition, a framework is a “basic structure underlying a system.” This could take many different shapes.

Brazil and Kenya’s proposal for the creation of a working group of member states to consider the global framework would be a first step – a step toward multilateral negotiations, open to any interested country, to discuss and set norms about the appropriate level of support for medical R&D, and the creation of new mechanisms to address priority setting for R&D.

It could be a simple set of ‘soft’ norms, such as a suggestion, without enforcement, that a certain percentage of a country’s global GDP or health care budget supports essential medical R&D.

It could also be a more formal obligation, such as an agreement or treaty that required members to directly or indirectly support medical R&D.

It could also include new mechanisms to identify priority R&D in areas of greatest need, opportunity or benefit, and incentives or obligations to address these priorities.

It could address issues of technology transfer and capacity building in developing countries.

Such a framework could be completely outside of and separate from other frameworks that support medical R&D, like existing provisions in trade agreements such as the WTO’s TRIPS agreement or the many bilateral accords that touch on drug patents or drug prices.

But it could also be a model for an alternative and competing paradigm, based upon public health perspectives, that could eventually replace the older agreements, in terms of determining who will pay for the costs of R&D for new medicines. The choice of the word ‘framework’ is general enough that any of these outcomes are possible. The resolution simply opens the door for discussions on these topics to start. It does not say how they will conclude.

The need for a new framework to support innovation

The resolution notes a number of areas where medical R&D is inadequate. Much of the emphasis is on areas of particular relevance to persons living in poverty, singling out for example the need for new vaccines, diagnostics, and medicines, including

microbicides, for the treatment of AIDS, Tuberculosis and Malaria, as well as other illnesses that disproportionately affect persons living in poverty in developing countries.

But the resolution also addresses other concerns, such as the importance of the development of treatments for diseases that have small client populations (often referred to as ‘orphan’ diseases in the US or Europe), and more broadly, it notes that more than 70% of all new drug approvals are for medicines that do not provide incremental benefits over existing ones.

The resolution also makes reference to the importance of global public goods, such as the Human Genome Project, and other “open and accessible public research in advancing science and the transfer of technology.”

The resolution recognizes the importance of both public and private investment in the development of new medical technologies. It states that intellectual property rights are one of several important tools to promote innovation, creativity, and the transfer of technology, but also notes the importance of “providing for a proper balance between intellectual property rights and the public domain,” and “the need to implement intellectual property rules in a manner that is consistent with the fundamental right of every human being to the enjoyment of the highest attainable standard of health and the promotion of follow-on innovation.” Concerns about access to medicine are mentioned several times.

Reconciling access and innovation

The resolution notes the need to “reconcile the public interest in accessing the products derived from new knowledge, with the public interest in stimulating invention.”

Civil society supporters of the proposed resolution, which include a large number of public health, development and public interest NGOs, hundreds of well-known scientists, including several Nobel Prize winners, and many economists and other experts, see the resolution as a first step in a new approach to globalization that addresses the issue of R&D for new medicines as a public health matter, rather than strictly commercial concern.

The TRIPS accord of the WTO and the plethora of new bilateral and regional trade agreements that deal with drug patents and other measures that raise drug prices are seen as:

- raising barriers for access to medicine everywhere, and
- ineffective in promoting certain types of medical R&D, including investments in global public goods, or the development of medicines that are most relevant to persons living in poverty.

A new approach of focusing directly on the need to support R&D, with a realistic discussion of who will pay, is seen as a necessary step in addressing the legitimate

concerns that the globalization mechanisms provide sustainable sources of finance for R&D.

By recognizing the importance of both public and private sector investments, and the need to also address market failures and priority setting, the new framework can be a better mechanism – one that helps rather than hurts consumer interests.

In the January 2006 debate over the resolution, most developing countries on the WHO EB supported the resolution. Unfortunately, most countries with annual per-capita incomes greater than US\$ 10 000 were less supportive. The United States, Japan and the European Union (which acted on behalf of its member states) all sought a number of changes that would cumulatively reduce the resolution to a highly general appeal to provide more incentives for pharmaceutical companies to invest in neglected diseases.

These countries insisted on brackets on virtually every mention of global public goods, the public domain, open research projects, public sector financing of research, or market failures outside of infectious diseases, and they also put brackets around every mention of the need to provide for global mechanisms that would ensure equitable sharing of the costs of essential medical R&D.

Without support from the US, Japan and the EU, there will not be a new global framework – only an increasing emphasis on more and more bilateral and regional trade agreements that raise drug prices.

The high-income countries, particularly the United States, should reconsider their initial negative reaction to this important initiative. For years the United States government has claimed it is looking for new ways of getting its trading partners to share the costs of medical R&D. This is of course the rationale for the many new global trade agreements, such as the US/Australia Free Trade Agreement (FTA), or the many similar agreements recently negotiated with developing countries.

The US has also made several announcements at recent G8 meetings, calling for broader participation in global open source projects to develop new vaccines for AIDS and other public health threats, like SARS or avian influenza. If they reject this effort, it will appear as though they are more interested in getting higher prices for the products US companies sell, than on actually doing something constructive and positive with regard to the sharing of R&D costs. Europe should also reconsider its position on the new global framework. Like the US, Europe is facing a growing crisis of access to the newest medicines for severe illnesses, like cancer. If Europe continues to back only those globalization initiatives to boost drug prices at the expense of access, its own consumers, including in particular the new members of Europe, will face their own access problems.

The Kenya/Brazil proposal, which will be debated in May 2006, should not be seen as a North/South fight, but rather as a positive measure – one that takes a balanced look at the R&D issue, and calls for serious negotiations on the core issues of who will pay for R&D, and what type of R&D do we really need?

The draft text of an experts' proposal for a Medical R&D Treaty
<http://www.cptech.org/workingdrafts/rndtreaty.html>

A February 2005 experts letter to the EB, proposing evaluation of a Medical R&D Treaty

English <http://www.cptech.org/workingdrafts/24feb05WHOen.pdf>

Français <http://www.cptech.org/workingdrafts/24feb05OMSfr.pdf>

Español <http://www.cptech.org/workingdrafts/24feb05OMSes.pdf>

Open letter from scientists in support of World Health Organisation resolution proposed by Brazil and Kenya <http://www.whoscientistsletter.org/>

Neglected Diseases R&D Appeal
<http://www.researchappeal.org/>

Appendix 1: Examples of Grounds for Compulsory Licenses

Appendix 2: UNDP Rank, 2005/Canadian Export Royalty Guidelines, GDP per capita and persons living with HIV

Appendix 3: Patent Pool for Essential Medicines

Appendix 1: Examples of Grounds for Compulsory Licenses

The following are illustrative of the grounds for compulsory licensing that a country may include in national patent laws.

Government use

Whenever an invention described in and covered by a patent is used or manufactured by the government, or for the government by a contractor, subcontractor, or any person, firm or corporation who used the patent with the authorization and consent of the government to further a public purpose, the patent owner's only remedy shall be to seek adequate remuneration for the use of the patent.

Public Health Crisis

The Minister of Health may authorize third parties to use patented inventions without the permission of patent owners in order to expand access to medical inventions in situations involving a public health crisis. Lack of access to medicines needed to address morbidity or mortality constitutes a public health crisis.

Public Interest

The Minister of Health may authorize third parties to use patented inventions without the permission of the patent owners in order to promote or enhance,

- a. improved access to medicines,
- b. technological innovation,
- c. transfer and dissemination of technology, or
- d. social and economic welfare.

Access to Medicines (Mandatory approach)

The Minister of Health *shall* authorize third parties to use patented inventions without the permission of the patent owners when the use of the patents concerns the manufacture, sale or distribution of medicines or vaccines, which were originally placed on the market at prices that are not reasonably affordable for most persons.

Control of anticompetitive practices

The Minister of Health may issue compulsory licenses to remedy licensing practices or conditions which restrain competition if the practices:

- a. lead to prices that are higher than
 - i. prices charged in countries with acceptable levels of access, adjusted to reflect differences in per capita income, or
 - ii. prices that are not reasonably affordable for most people,
- b. impede the transfer and dissemination of technology, or
- c. otherwise constitute an abuse of intellectual property rights.

Appendix 2: Proposal for Patent Pool for Essential Medicines (PPEM)

Addis Ababa – 3 March 2005

The creation of a **Patent Pool for Essential Medicines (PPEM)** can facilitate the sustainable scaling up of treatment access, and provide a new and useful mechanism for countries to manage intellectual property rights.

A patent pool is an arrangement for the collective management of patent rights. The pools provide for systematic licensing of multiple patents. While most patent pools today are based upon voluntary agreements, including for example patent pools involving the manufacture of DVDs, radios and other consumer electronic products, or patent pools on agriculture products or SARS, there have also been cases where patent pools were mandated by government policy, such as the US experience in creating the Manufacturers Aircraft Association (MAA) patent pool to overcome barriers for the scaling up of aircraft manufacturing.

The rationale for creating a patent pool for essential medicines is as follows:

1. The high cost of patented medical products, when marketed by a monopoly, is a barrier to providing access to medicines for all.
2. Patents on essential medical inventions restrict innovation and adaptation of medicines and devices to fit the needs of patients such as different formulations, combinations, dosages and medicine forms. Innovation and adaptation is necessary to cope with the differing viral strains, changing immunities, related infectious diseases, local health system conditions and local patient customs, and to enhance patient compliance with treatment regimes.
3. Economies of scale and access to manufacturing know-how are important for efficient manufacturing of essential medical treatments and devices.
4. The multitude of patents, potential claims of infringement, variance of national laws, complexity of international treaties and national patent laws, and patent restrictions on the export of essential medical technologies, have presented barriers for access to medicines for all.

The PPEM would provide a framework for addressing these problems.

- a. A patent pool would be created as a non-profit entity.
- b. The PPEM would identify the patents relevant to manufacturing, importing, exporting and selling essential medicines.
- c. The PPEM would simultaneously negotiate agreements with patent holders and national governments.
- d. Patent owners would be asked to voluntarily license patents to the PPEM, for use in countries [in Africa] *or* [not designed as high income by the World Bank].
- e. In cases where the PPEM failed to obtain voluntary licenses, it would seek compulsory licenses.
- f. Licensing by the PPEM, under voluntary or non-voluntary arrangements, would follow “best practice” models, including:
 - i. Consistency with national patent laws and trade agreements on patents,
 - ii. Non-discriminatory “open” license to any qualified party,
 - iii. Rights to manufacture, export, import and sell,
 - iv. Adequate remuneration using transparent and predictable royalty guidelines,
 - v. Requirements that patent owners met appropriate standards of quality.

The PPEM would offer the following benefits to various parties:

- A. Patients. The PPEM would promote competition and lower prices, provide enhanced access to follow-on innovations, such as new FDCs, better heat stabilization, or other delivery mechanisms, and licenses would be tied to appropriate standards for product quality.
- B. National governments. The PPEM would provide technical assistance, a creditable and politically acceptable approach to the granting of compulsory licenses, acting together with other countries.
- C. Patent owners. The PPEM would provide a predictable and fair system for remuneration, and would comply with national patent laws and trade agreements on patent rights.
- D. Generic competitors. The PPEM would provide access to a larger generic market.
- E. Donors. The PPEM would ensure that the “solution” to the patent problem was focused on (a) the rule of law, (b) open competition, and (c) efficiency.