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REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES

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Executive summary

TRIPS FRAMEWORK

The 2001 Doha Declaration on the TRIPS Agreement and Public Health declared that WTO Members should implement intellectual property laws in a manner that promotes access to medicines for all, using to the full TRIPS flexibilities.

The TRIPS Agreement allows WTO Members to use a number of different limitations and exceptions to patent rights, including cases where governments can authorize persons to use patents, even when the patent owner does not give permission.

Although it establishes certain procedures that countries must follow in issuing compulsory licences, the TRIPS Agreement provides countries with broad discretion to establish the conditions under which they may issue compulsory licences. The Doha Declaration reiterated that countries have "the freedom to determine the grounds upon which such licences are granted".

In some cases, before a decision is made, WTO members must first require prior negotiation with patent holders on “reasonable commercial terms and conditions”. Normally this would involve an offer to license a patent for a “reasonable” royalty.

The terms “reasonable commercial terms” and “adequate remuneration” are not defined in the TRIPS Agreement. WTO Members are free to determine the appropriate method of implementing the TRIPS Agreement, within their own legal system and practice, and this extends to the standards they apply for “reasonable” royalties, or “adequate” remuneration.

STATE PRACTICE

State practice regarding the determination of “reasonable” royalties or “adequate” remuneration is extensive and highly varied. There is no single accepted approach. Not only do countries have very different practices from each other - practices also differ considerably within countries, depending upon the industry sector or the purpose of the authorization.

In recent years, a number of countries have issued compulsory licences on HIV/AIDS drugs. Malaysia set a royalty rate of 4% for such licences; Mozambique established a 2% royalty; Zambia set a 2.5% royalty; and Indonesia arrived at 0.5% royalty.

A number of royalty systems have been adopted or proposed in recent years, and establish useful frameworks for consideration. Royalty guidelines proposed by the Japanese Patent Office (1998) and UNDP (2001) set royalties from 0 to 6% of the price charged by the generic competitor. The 2005 Canadian royalty guidelines for the export of medicines to countries that lack manufacturing capacity set royalties at 0 to 4% of the generic price, depending upon the level of development of the importing county.

PRIVATE MARKET LICENSING RATES FOR PHARMACEUTICALS

There is extensive experience of voluntary technology licensing in the private sector. The evidence of compensation for private, market-based licence arrangements provides an important context for making determinations of royalty and remuneration arrangements in cases of compulsory licensing. There is some conflicting evidence on cross-industry licensing averages, but there seems to be agreement in reports from the pharmaceutical industry and others that licensing fees for the pharmaceutical industry congregate at 4-5%. The pharmaceutical industry has one of the higher licensing rates among all industries.

POLICY FRAMEWORK FOR REMUNERATION

When deciding on appropriate policies and practices for determining reasonable royalties or adequate remuneration for the manufacture or sale of a medicine, countries should consider approaches that address practical concerns regarding the administration of a system, as well as policy objectives.

Two issues should be paramount in establishing systems for determining remuneration in compulsory licensing cases.

First, the system of setting royalties should not be overly complex or difficult to administer, given the capacity of the government managing the system. Royalty guidelines will reduce complexity and provide guidance for adjudicators, as well as increase transparency and predictability. Royalty guidelines, or any system for setting remuneration for compulsory licensing, should anticipate and address the need to divide royalty payments among various patent holders when the product is subject to multiple patents.

Second, the amount of the royalty should not present a barrier for access to medicines. In most instances where a compulsory licence is issued on a consumer product, the purpose will be to lower price and improve access. Remuneration mechanisms should be designed so as to assist rather than defeat this purpose.

When countries are facing difficult resource constraints, and cannot provide access to medicines for all, royalty payments should normally not exceed a modest fraction of the generic price. The Canadian export royalty guidelines provide a useful benchmark for such countries, providing low royalty rates in poor countries and requiring only a single, straightforward calculation.

For countries able and willing to make somewhat more complex determinations of royalties, a range of appropriate factors should be assessed, though not all are required, and not all will apply in any given circumstance. These include but are not limited to:

- therapeutic value of the medicine, including the extent to which it represents an advance over other available products;
- the ability of the public to pay for the medicine;
- actual, documented expenditures on development of the medicine;
- the extent to which the invention benefited from publicly funded research;
- the need to respond to public health exigencies;

- the importance of the patented invention to the final product;
- cumulative global revenues and profitability of the invention;
- the need to address anti-competitive practices.

Particularly for middle- or high-income countries, it may be appropriate both to link royalty payments to therapeutic benefits of the product and other factors related to the medicine, and to adjust remuneration levels to the country's economic status and the population's ability to pay for pharmaceutical products. Such an approach may involve not basing royalties on the price of the generic product, since using the generic product as a base will generally result in very low royalty payments in absolute terms. Royalty-setting approaches that accommodate the ability of the licensing country to pay will be more economically rational, and may be more sustainable. In middle- or high-income countries, systems that result in royalty payments that are the same as they would be in the poorest countries are likely to be underutilized; adjudicators and policy makers will likely be uncomfortable with such outcomes, and thus will be deterred from issuing compulsory licences at all. Countries that invest significantly in R&D, and the home countries of brand-name pharmaceutical companies, are also likely to object to low remuneration in middle- and upper-income countries, and pressure from these sources will further inhibit countries from using compulsory licensing at all.

Approaches that take into account the economic situation of the licensing country may also be appropriate for global or regional patent pools that seek to provide a larger framework for remuneration to patent holders, including countries with very different incomes and burdens of disease.

RECOMMENDED APPROACHES FOR REMUNERATION

Different countries may prefer different approaches to remuneration, based upon administrative capacity, resource constraints, sensitivity to global norms concerning support for R&D, and policy objectives concerning access and innovation. The following approaches are reasonable and appropriate methods of setting remuneration.

2001/UNDP guidelines

The 2001 UNDP Human Development Report (HDR) proposed a simple system of royalty guidelines. The base royalty rate is 4% of the price of the generic product. This can be increased or decreased by 2%, depending upon such factors as the degree to which a medicine is particularly innovative, or the role of governments in paying for R&D.

The benefits of this approach include its simplicity, predictability, ease of administration and ability to incorporate certain factors particular to a licensed product (e.g. degree to which it is innovative).

1998/Japanese Patent Office (JPO) guidelines

In 1998, the JPO published guidelines for setting royalties on government-owned patents. The 1998/JPO guidelines allow for normal royalties of 2 to 4% of the price of the generic product, and can be increased or decreased by as much as 2%, for a range of 0 to 6%.

The 1998/JPO guidelines include a "utilization ratio" of 0 to 100%, which is used to allocate royalty payments among patent owners, when the product consists of a combination of multiple inventions. This is particularly useful when setting remuneration for fixed-dose combinations or other medicines that combine many different patented inventions. (The utilization ratio can be used independently with any of the other methods of setting royalties.)

The 1998/JPO guidelines are effectively a more elaborate version of the 2001/UNDP guidelines. As compared to the 2001/UNDP guidelines, they are somewhat more difficult to administer, because they incorporate a broader range of relevant factors into the royalty calculation. Additional precision is gained at the cost of some administrative complexity.

2005/Canadian export guidelines

In 2005, the Canadian Government adopted royalty guidelines for compulsory licensing of patents for export to countries that lack the capacity to manufacture medicines. These guidelines are a sliding scale of 0.02 to 4% of the price of the generic product, based upon the country rank in the UNDP Human Development Index (UNHDI). For most developing countries, the rates are less than 3%. For most countries in Africa, the rate is less than 1%.

The Canadian method can be thought of as a useful norm for those countries facing severe resource constraints in providing access to medicines for all. The rate is easy to calculate, and the rates are relatively low, thus avoiding large divergences from the marginal costs of medicines. The Canadian method is less useful for middle- or high-income countries that have both the capacity to pay more and the need for a remuneration system that will appeal for global norms concerning the sharing of R&D costs.

Tiered Royalty Method (TRM)

The TRM is different from the 2001/UNDP, 1998/JPO or 2005/Canadian methods in that the royalty rate is not based upon the price of the generic product. Instead, the royalty is based upon the price of the patented product in the high-income country. The base royalty is 4% of the high-income country price, which is then adjusted to account for relative income per capita or, for countries facing a particularly high burden of disease, relative income per person with the disease.

The TRM results in royalties that are considerably different from the other methods. Royalties are independent of manufacturing costs, and vary directly with proxies for therapeutic value (the high income price) and capacity to pay. The TRM provides a more rational framework for sharing the costs of R&D, and may be more sustainable for some middle- or high-income countries that are sensitive to global norms concerning the sharing of R&D costs. The TRM provides for much higher royalties in middle- and high-income countries with low burdens of disease, and the lowest royalties for countries that have the lowest incomes and the highest rates of disease burden. The TRM is particularly appropriate for global or regional patent pools that serve countries with very different circumstances in terms of income or disease burdens.

Medical Innovation Prize Fund (MIPF)

The MIPF approach involves making all medicines available to consumers at generic prices. With the MIPF approach, remuneration is not awarded to pharmaceutical innovators by a royalty or per-unit profit. Rather, they receive a portion of a national budget for rewarding medical innovation among owners of competing products. These payments are allocated according to each product's contribution to improved health outcomes. The MIPF approach provides the greatest rewards for products that are actually used and that provide incremental health care benefits. The MIPF can also be implemented to provide for remuneration for products that more closely address health care priorities, including products that are developed to address global neglected diseases, or medicines that are developed in anticipation of future needs, such as treatments for a disease like Severe Acute Respiratory Syndrome (SARS) that is currently contained, but which presents a important health care risk.

The MIPF approach can be implemented in countries of different levels of development, income and health care priorities. It is recommended that the overall level of funding for a MIPF approach increase with national income and the level of development.

1 Introduction

Article 31 of the WTO TRIPS Agreement requires that non-voluntary authorization to use patents include provisions for adequate remuneration to the patent owners, taking into account the economic value of the authorization. This paper addresses the following issues:

- WTO provisions regarding remuneration for non-voluntary use of patents
- Experience of royalty setting in voluntary and non-voluntary settings
- The policy framework for setting royalties on medicines in developing countries
- Proposed royalty guideline frameworks

2 WTO TRIPS provisions on remuneration for non-voluntary use of a patent

SECTION OVERVIEW

Two Articles of the WTO TRIPS Agreement, Articles 30 and 31, permit governments to authorize non-voluntary use of patents.

Article 30 permits non-voluntary uses where the "exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". In these limited situations, no remuneration to the patent holder is required.

Article 30 is sometimes used to authorize

* The manufacture, use, export and import of medicines used to prepare regulatory approval for medicines (the "Bolar exception");
* Research or experimental use (including reverse commercial engineering) of inventions;
* Personal or humanitarian uses of medicines.

Article 31 permits governments to authorize non-voluntary use in a much wider array of circumstances, with the requirement that patent holders be given "adequate remuneration" for such use. These Article 31 non-voluntary authorizations are generally characterized as compulsory licensing, a term that may encompass a range of particular kinds of non-voluntary authorizations. These include:

* Compulsory licensing for private use: a non-voluntary authorization by the government that a third, private party may use a patent;
* Government or Crown use: a non-voluntary authorization that a government entity - or its contractor - may use a patent;
* Remedies to anti-competitive practices: to repair the harm caused by anti-competitive practices, governments may authorize third parties to use a patent. Article 31(k) of the TRIPS Agreement stipulates that remuneration in such cases may be adjusted to take into account the need to remedy the anti-competitive practice.

The Doha Declaration on the TRIPS Agreement and Public Health, which WTO Members unanimously adopted in 2001, established that the TRIPS Agreement "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".

Although it establishes certain procedures that countries must follow in issuing compulsory licences, the TRIPS Agreement provides countries with broad discretion to establish the conditions under which they may issue compulsory licences. The Doha Declaration reiterated that countries have "the freedom to determine the grounds upon which such licences are granted".

One key requirement for compulsory licensing established by the TRIPS Agreement is that countries must provide for "adequate remuneration" of patent holders. The purpose of this paper is to consider appropriate options for "adequate remuneration" of patent holders in cases of compulsory licensing for medical technologies.

TRIPS AND NON-VOLUNTARY LICENSING OF PATENTS

For a variety of reasons, governments may determine that it is not acceptable to permit patent owners to exercise the unfettered right to exclude others from using an invention. There are three primary strategies for doing this.

Under Article 27 of the TRIPS Agreement, some inventions may be excluded from patentability.[1] Typical exclusions under Article 27 would be for inventions dealing with surgical procedures, the cloning of humans, or for agricultural inventions protected by *sui generis* plant breeder rights.

Under Article 30 of the TRIPS Agreement, Members "may provide limited exceptions to the exclusive rights conferred by a patent" provided that such exceptions meet a three-part test, namely that the uses authorized:

1. are limited,
2. do not unreasonably conflict with a normal exploitation of the patent, and
3. do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 30 is sometimes used to authorize (1) the manufacture, use, export and import of medicines used to prepare regulatory approval for medicines, (2) more general research or experimental use (including reverse commercial engineering) of inventions, or (3) personal or humanitarian uses of medicines. These uses are typically authorized without obligation to notify or compensate patent owners. While the exceptions under Article 30 are "limited" they can be economically important. For example, the "early working" exception permits generic drug manufactures to reduce, by 18 to 24 months, the time needed to register generic alternatives. The more rapid introduction of competition expedites price and market share reductions for the incumbent monopoly. This can reduce patent owner profits by billions of dollars for the best selling products.

[1] Under Article 27.2 of the TRIPS Agreement, "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." Under Article 27.3, "Members may also exclude from patentability (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes".

WTO Members also have broad authority to authorize third parties to use an invention without the permission of the patent owner, under Article 31 of the TRIPS Agreement. The Article 31 uses are subject to a number of procedural and substantive conditions, including those relating to remuneration for owners of rights on patents.

2.1 WTO rules for remuneration under Article 31 of the TRIPS Agreement

Article 31 contains more than 630 words in 12 paragraphs. The key provisions that relate to remuneration are as follows:

1. There is a general requirement that "authorization of such use shall be considered on its individual merits".[2] Thus, some decisions must be based upon the facts relevant to the patented invention.

2. There is a general requirement that efforts first be made to "to obtain authorization from the right holder on reasonable commercial terms and conditions".[3]

3. The requirement for prior negotiation on "reasonable commercial terms and conditions" is waived in three special cases:

   a. Public non-commercial use,[4]
   b. National emergency or other circumstances of extreme urgency,[5] or
   c. Where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.[6]

4. There is a general rule that when governments authorize non-voluntary use of a patent, they must provide patent owners "adequate remuneration" for the "circumstances of each case, taking into account the economic value of the authorization".[7]

5. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration.[8]

6. When a non-voluntary license is issued to allow the exploitation of a patent (the second patent) that cannot be exploited without use of another patent (the first patent), the owner of the first patent is entitled to a cross-licence to the second patent on "reasonable terms".[9]

[2] Article 31(a) of the TRIPS Agreement.
[3] Article 31(b) of the TRIPS Agreement.
[4] Ibid.
[5] Ibid.
[6] Article 31(k) of the TRIPS Agreement.
[7] Article 31(h) of the TRIPS Agreement.
[8] Article 31(k) of the TRIPS Agreement.
[9] Article 31(l)(ii) of the TRIPS Agreement.

7. Any decision relating to remuneration must be subject to judicial *or* other independent review by a distinct higher authority.[10]

The WTO leaves each Member considerable discretion in implementing the TRIPS Agreement. Article 1 of the TRIPS Agreement, on the Nature and Scope of Obligations, states, "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice". Article 7 on Objectives,[11] Article 8 on Principles[12] and Article 40 on the Control of Anti-Competitive Practices in Contractual Licences,[13] make it clear that Members are expected to protect the public interest in a wide range of areas including the protection of public health, the promotion of innovation, the transfer and diffusion of technology, the control of anti-competitive practices and other measures.

Article 31 of the TRIPS Agreement can be implemented in a variety of different ways.[14] If it so chooses, a WTO Member may create a system that effectively gives any third party the right to use a patent, subject only to the requirement of remuneration for right owners.[15] The procedural and substantive requirements of Article 31 are not difficult if a Member chooses the appropriate legislative framework. For example, an entirely administrative framework is permitted, and Members can curtail or eliminate judicial review or injunctive relief, and limit the remedies available against non-voluntary authorizations of use "to payment of remuneration in accordance with subparagraph (h) of Article 31".[16]

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[10] Article 31(j) of the TRIPS Agreement.

[11] Article 7 of the TRIPS Agreement, *Objectives*: "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."

[12] Article 8 of the TRIPS Agreement, *Principles:* "1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

[13] Article 40 of the TRIPS Agreement, Control of Anti-Competitive Practices In Contractual Licences: "1. Members agree 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. 2. Nothing in this 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. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member."

[14] Love J. Access to Medicine and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries. In: Drahos P, Mayne R, eds. *Global Intellectual Property Rights: Knowledge, Access and Development.* Palgrave, Macmillian, New York, 2002. Correa C. *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*. Geneva, South Centre, 1999.

[15] Such as, for example, the United States approach for government use under 28 USC 1498, or the case for follow-on innovators using patents on genetically modified plant varieties, under Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

[16] Article 44(2) of the TRIPS Agreement.

A WTO Member may also choose to adopt a patent law that provides few or no exceptions to the patent owner's exclusive rights. None of the exception provisions in the TRIPS Agreement are implemented except through national legislation.

2.2 The Doha Declaration on the TRIPS Agreement and Public Health

On 14 November 2002, the WTO issued the Doha Declaration on the TRIPS Agreement and Public Health.[17] The Declaration affirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".

> 4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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.
>
> In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Furthermore, paragraph 5(c) of the Declaration adopted a broad definition of what constitutes a national emergency or other circumstances of extreme urgency. These cases are not limited to situations where time is of the essence, but included more generally "public health crises".

> 5(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The interpretation from the Declaration is that the requirements in Article 31(b) of the TRIPS Agreement for prior negotiation with patent owners on reasonable commercial terms is waived if there is a public health crisis.

Paragraph 6 of the Declaration required the WTO Council for TRIPS to find a *solution* to the limitations of exports of medicines manufactured under a compulsory licence. The problem raised in negotiations over implementation of paragraph 6 was the provision in Article 31(f) of the TRIPS Agreement that normally limits exports to less than half of production when goods are produced under a compulsory licence. This restriction is waived when licences are issued as a remedy to anti-competitive practices. In 2003, the WTO agreed to additional flexibility for exports under a limited waiver of Article 31(f) of the TRIPS Agreement.[18] The 2003 Paragraph 6

[17] WTO Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, WT/MIN(01)/DEC/2, 20 November 2001.
[18] WT/L/540, 2 September 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Decision of the General Council of 30 August 2003.

Decision requires the exporting country to provide "adequate" remuneration to right owners, consistent with Article 31(h) of the TRIPS Agreement, "taking into account the economic value to the importing Member". In these cases, the importing country obligation to remunerate right owners is waived. In short, the right owner must receive remuneration, but the amount is set in the exporting country, which must consider the "economic value" of the product in the importing country.

2.3 Summary of TRIPS provisions that relate to remuneration

Term	**TRIPS Provision**	**Situation**
Do not unreasonably prejudice the legitimate interests of the patent owner	Article 30	Applies to cases where a compulsory licence is implemented under the general exceptions provision (rather than Article 31)
Prior negotiation on reasonable commercial terms	Article 31(b)	Applies to commercial non-emergency authorizations that are not remedies to anti-competitive practices
Adequate remuneration … taking into account the economic value of the authorization	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 at 0
The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration	Article 31(k)	Where such use is permitted to remedy a practice determined after judicial *or administrative process* to be anti-competitive
Reasonable terms	Article 31(l)	The owner of the first patent must offer a cross-licence on reasonable terms when obtaining a compulsory licence to use a dependent patent
Promote access to medicines for all	Doha Declaration, Para. 4	Applies to cases involving public health problems
Adequate remuneration … taking into account the economic value of the authorization in the importing country	30 August 2003 Decision of the General Council	Applies when exports are authorized under the system established by the 30 August 2003 Decision of the General Council, implementing paragraph 6 of the Doha Declaration

3 Examples of royalty setting

SECTION OVERVIEW

There is a rich global experience with royalty setting in compulsory licensing and related cases. This experience establishes that compulsory licensing is feasible and that establishing remuneration need not be overly complicated or bureaucratic; that countries may legitimately consider any of a wide range of factors in establishing royalties or remuneration for compulsory licences; and that countries may legitimately arrive at a broad range of royalties, depending on policy choices they make.

This diversity of options available to countries is evidenced by the examples presented in this section, among them:

* In a compulsory licensing case concerning patents on an ulcer drug, the United Kingdom of Great Britain and Northern Ireland awarded a 45% royalty for a compulsory licence for the drug, while the Philippines chose to issue a 2.5% royalty. Japan, in a related case, issued a 3.5% royalty on the same patents.

* In the 1970s and 1980s, Canada maintained the world's most active programme for compulsory licensing of medicines. It generally set royalties at 4%.

* The United States of America issues compulsory licences through a number of programmes and under a number of laws, including for government use of patents and to remedy anti-competitive practices. Historically, United States royalties for government use have ranged around 6% (but much lower in some important cases), though they have moved higher in recent years. Royalties for licences issued to remedy anti-competitive practices are typically low, and frequently zero.

* In recent years, a number of countries have issued compulsory licences on HIV/AIDS drugs. Malaysia set a royalty rate of 4% for such licences; Mozambique established a 2% royalty; Zambia set a 2.5% royalty; and Indonesia arrived at 0.5% royalty.

The TRIPS rules, when taken together with the Doha Declaration on the TRIPS Agreement and Public Health, present a challenge for policy makers. On the one hand, the TRIPS Agreement requires payment of "adequate" remuneration to right owners, taking into account the "economic value of the authorization" and, in some cases,[19] requires prior negotiation on "reasonable commercial terms and conditions". On the other hand, the Doha Declaration on the TRIPS Agreement and Public Health calls upon Members to implement their domestic laws in a manner that promotes "access to medicines for all".

[19] When the authorization is not for public non-commercial use, cases of national emergency or other circumstances of extreme urgency, or a remedy to anti-competitive practices.

In practice, governments may and do choose very different outcomes, each of which may be appropriate under their own legal traditions. For example, SmithKline French (SKF) held patents on cimetidine, the active ingredient for an ulcer drug marketed by SKF as Tagamet. Cimetidine was a best selling drug, and generic competitors initiated compulsory licensing proceedings in the Philippines, the Netherlands and the United Kingdom, and there was an infringement case in Japan. In the United Kingdom, SKF was granted a very high royalty - fixed in sterling at 45% of the patent owner's sales price. In the Philippines, the royalties were 2.5% of the generic competitor sales price.[20] The court in the Japanese infringement case awarded a 3.5% royalty. As noted earlier, the TRIPS Agreement provides that "[WTO]Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice".[21]

There are many different approaches that are used to determine what constitutes reasonable or adequate remuneration for the use of a patent, and each approach reflects a particular set of policy objectives.

3.1 Infringement

In cases involving patent infringement between commercial competitors, courts seek to achieve a variety of objectives, including (1) to compensate the patent owner for the commercial benefits of the patent, and (2) to deter others from infringing patents. The United States statute on damages in infringement cases sets as a floor on compensation "a reasonable royalty for the use made of the invention by the infringer" plus increases for interest and court costs.[22] Higher awards can take into account the profits lost by the patent owner. In cases involving willful infringement, the damages can be increased as much as three times to act as a deterrent, a punitive sanction that does not exist in most other jurisdictions.[23] In some countries, patent infringement can even result in criminal sanctions.

Partly because of the continual expansion of patent scope, the relative ease of obtaining a patent in the United States and other countries, the low quality of patent examination and the uncertainty over whether patents are even valid, patent infringement is a fairly common activity. As a consequence, there is an active

[20] *SmithKline & French Laboratories, Ltd. plaintiff-appellee, v. Court of Appeals and Danlex Research Laboratories, Inc., defendant-appellant*, First Division [G.R. No. 121267, 23 October 2001].
[21] Article 1.1 of the TRIPS Agreement.
[22] 35 USC 284.
[23] United Kingdom Patents Bill Consultation. Proposed changes related to enforcement and post-grant issues, Report of open meeting held 11am, 17 January 2003 at the Patent Office, London: "(16) A few users argued strongly that there should be a much stronger deterrent against patent infringement. An infringer only has to pay in damages what he would have paid in royalties as a licensee, and so is not perceived to have anything to lose by deliberately infringing and waiting to get caught. SME's in particular therefore have suffered as a result of the expense and time needed to undertake infringement proceedings. It was therefore suggested that exemplary damages be available as a strong deterrent against deliberate infringers. (17) Other users strongly opposed the suggestion, arguing that trying to prove deliberate infringement would hugely increase the cost and complexity of infringement proceedings – with the need for extensive disclosure etc. The punitive element to damages was resisted as blurring the distinction between civil law (namely, the tort of infringement), in which remedies should leave the parties as if the tort had not occurred, and criminal law, in which punitive measures are appropriate." (http://www.patent.gov.uk/news/patact3.htm)

industry of consultants and forensic royalty experts who battle each other over what royalties should be. One approach in determining a reasonable royalty is to approximate the outcome of a transaction between a willing seller and buyer. A particular framing of this approach was set out by a United States Court in *Georgia-Pacific Corp. v. United States Plywood Corp.*, which identified 15 relevant factors for estimating the compensation that would have obtained from a hypothetical negotiation between parties.[24] Over the past 30 years, a number of other methodologies have been promoted.[25] Methods used by courts and experts range from simple rules of thumb (5% of revenue, 25% of profits) to very elaborate cash flow simulations. There remains, however, a great deal of uncertainty as to how such rates should be calculated.

Actual awards under infringement doctrines vary considerably. As noted above, the Japanese decision in a case involving patents on processes for manufacturing

[24] *Georgia-Pacific Corp. v. United States Plywood-Champion Papers*, 318 F. Supp. 1116, 166 USPQ 235 (S.D.N.Y. 1970), modified, 446 F.2d 295, 170 USPQ 369 (2d Cir.), cert. denied, 404 U.S. 870 (1971). The fifteen factors were:

1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.
3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
4. The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by gaining licenses under special conditions designed to preserve that monopoly.
5. The commercial relationship between the licensor and the licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
6. The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.
7. The duration of the patent and the term of the license.
8. The established profitability of the product made under the patent; its commercial success; and its current popularity.
9. The utility and advantage of the patent property over the old modes or devices, if any, that had been used for working out similar results.
10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.
11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.
12. The portion of the profit or selling price that may be customary in the particular business to allow for the use of the invention or analogous inventions.
13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
14. The opinion testimony of qualified experts.
15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee - who desires, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention - would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

[25] Blair RD, Cotter, TF. Rethinking Patent Damages. *Texas Intellectual Property Law Journal*, 2001, Vol 10: 1.

cimetidine - the active ingredient in a best selling ulcer drug - was 3.5% of sales.[26] In a case involving a patent used in an AIDS test kit, a royalty of 1% was held to be reasonable, despite the patent owner's claims that a 15% royalty was appropriate. Here (and elsewhere) the Court noted "there is room for exercise of a common-sense estimation of what the evidence shows would be a 'reasonable' award".[27] In a case involving eye care product maker Alcon Inc. and Japan-based Nidek Co. Ltd., a United States Court found that Nidek's excimer laser infringed on two of Summit's patents, and awarded a royalty of 5% of the infringer's sales.[28] Biacore, a Swedish firm, reported an infringement award based upon a royalty rate of 40% of the infringer's sales for a surface chemistry patent.[29] Generally speaking, however, the cases involving compensation for patent infringement seek to restore or approximate market valuations of intellectual property, and not to change them.

3.2 United Kingdom and United States licences of right

A number of national patent systems have provisions for licences of right, and these systems are implemented in different ways, including both voluntary and non-voluntary approaches. In the United Kingdom system for voluntary licences of right, the patent owner declares that the patent will be available for anyone to license, and in return, the fees for patent renewal are reduced by 50%. Once a licence is so registered, the terms of the licence are either negotiated between the parties or, failing that, by the Government.[30] There are also cases of non-voluntary licences of right. Of particular note in the United Kingdom are the licences of right created when the United Kingdom extended the term of patents from 16 to 20 years when it joined the European Union. The four-year term extension included a non-voluntary (compulsory) licence of right obligation. The United States had a similar situation when it extended patents from 17 to 20 years to join the WTO. The extended term (the delta period) was subject to a compulsory licence based upon equitable remuneration.[31]

The United Kingdom *Manual of Patent Practice* section on licences of right and compulsory licences describes the general approach followed by the Comptroller to set compensation in such cases. One distinction the Manual makes is that the

[26] Toshiko Takenaka. Big Change in Measurement for Japanese Patent Infringement Damages? Tokyo District Court Awards US$23.5 million in Lost Profits Damages. Smithkline & Beecham French Laboratories Ltd. v. Fujimoto Seiyaku. *CASRIP Newsletter*, Autumn 1998, Vol 5, Issue 3.

[27] *Institut Pasteur and Genetic Systems Corporation v. Cambridge Biotech Corporation*, July 1999, United States Court of Appeals for the Federal Circuit, 98-1012. The CAFC noted: "When a 'reasonable royalty' is the measure, the amount may again be considered a factual inference from the evidence, yet there is room for exercise of a common-sense estimation of what the evidence shows would be a 'reasonable' award". *Lindemann Maschinenfabrik, GmbH v. American Hoist & Derrick Co., Harris Press & Shear Div.*, 895 F.2d 1403, 1406, 13 USPQ2d 1871, 1874 (Fed. Cir. 1990).

[28] Alcon wins patent suit. *Dallas Business Journal*, 25 September 2002.

[29] Biacore Receives USD 2 million in Damages from Thermo BioAnalysis Corp. Damages paid for infringement of Biacore US patent position. Press Release, 6 June 2002.

[30] In the United Kingdom system, the patent owner can cancel the licence of right endorsement at any time.

[31] 35 USC section 154 (c)(2) (1994). Due to a technical inconsistency between the law and FDA regulatory statutes, the compulsory licences were largely ineffective for pharmaceutical inventions. *Merck & Co. Inc. et al., v. David A. Kessler, MD, Commissioner of Food and Drugs, et al.*, 903 F. Supp. 964; 1995, U.S. Dist. DeLucia R, Butler J. GATT Creates Conflict over Patent Terms. *New Jersey Law Journal*, 24 July 1995.

compensation is for the invention, and does not extend to replacing all profits lost to competitors.

> 46.35.1 The royalty which would be agreed between a willing licensee and a willing licensor is a payment only for use of the invention and is not compensation for losses the patentee may suffer by grant of the licence. In particular, quoting Lord Justice Lloyd in the cimetidine case, "one of the effects of granting a licence in a limited market is that sales made by the licensee will necessarily reduce sales which would otherwise have been made by the licensor. It was held by a majority of the Court of Appeal in the salbutamol case that a patentee is not entitled to claim, as part of his royalty, compensation for loss of such sales. This was expressed by saying that the patentee's position as manufacturer is to be ignored. The licensee is to pay a proper sum for the use of the patentee's invention, as an invention. But he is not to pay for the patentee's loss of sales as manufacturer, or to make a contribution to the patentee's manufacturing overheads."

The Manual also indicates that considerable weight is generally given to royalties used in voluntary licences for similar products.

> 46.36 A variety of approaches have been used in determining the royalty that would be agreed between a willing licensor and a willing licensee. However, as the Court of Appeal confirmed in the cimetidine case, the best guide to what a willing licensor and a willing licensee would agree is what other licensors and licensees have in fact agreed in existing voluntary licences for the same or similar products. Where comparison between the licence sought and existing licences is not exact, the practice has been to adjust the royalty to take account of the differences.

When the United Kingdom was looking at mature pharmaceutical products for which the patent had already exceeded 16 years, it often awarded high rates of compensation, in some cases more than 40% of the patent owners sales price.

3.3 United States government use cases

Most national patent laws have special provisions for use of inventions by governments or contractors providing goods or services to the government. In the United States such use is provided under 28 USC 1498. Under this statute, the United States Government does not have to negotiate for the use of a patent or copyright. Any federal employee can use or authorize the use of *any* patent or copyright. Any contractor, subcontractor, person, firm, or corporation who receives authorization from the Federal Government to use patents or copyrights is construed as use by the Federal Government, and cannot be sued for infringement. In these cases, the only remedy for the patent or copyright owner is to seek compensation from the United States Government. Sometimes the patent or copyright holder seeks judicial review of the proffered compensation, and there is an extensive body of cases on "government use" cases. Richard J. McGrath reported in 1991 that royalties in such cases did not exceed 10%, with 6% the more common award.[32]

[32] McGrath RJ. The Unauthorized Use of Patents by the United States Government or its Contractors, *AIPLA Quarterly Journal*, 1991, 18: 349, 352.

> Since the usual measure of damages in a 28 U.S.C. § 1498 action is a reasonable royalty, a patent owner can estimate the value of a claim or lawsuit. Historically, the highest royalty rate that the United States Claims Court has awarded is 10%. In the Tektronix case, plaintiff asserted a substantial portfolio of patents, and the patents were recognized as pioneer inventions that had a major impact in their industry. Unless there is evidence of a higher established royalty rate, it is unlikely that the United States Claims Court will award more than a 10% royalty. If there is an established royalty rate or comparative royalty rate the Court is likely to use that rate. As a general rule the Claims Court is likely to find approximately a 6% royalty rate, unless one of the parties offers sufficient evidence to support either a higher or lower established royalty rate.

According to Professor Reichman:[33]

> When evaluating the workings of section 1498, one should understand that it does not empower the government to convert a patentee's exclusive rights into the kind of nonexclusive use rights available to private third parties under a typical compulsory licensing provision imposed for reasons of public interest. In this respect, government use of patents and other intellectual property rights (including copyrights, plant breeders' rights, and semiconductor chip design rights) under section 1498 is often understood to partake of the sovereign power of eminent domain, which inheres in every nation state. In the United States, the exercise of this power is subject to Constitutional guarantees of citizens' rights and they are entitled to "just compensation" whenever private property is "taken" for a "public purpose." Hence, courts and commentators often characterize section 1498 as "a compulsory license in eminent domain," and the government is not treated on the same footing as an ordinary infringer in cases arising under the statute.
>
> In the 1990s, however, the United States Court of Federal Claims twice rejected the notion that a section 1498 action constituted a "taking" under the government's eminent domain power. It reasoned that the patent law's grant of exclusive rights to inventors does not encompass the right to exclude the government from using a patented invention in the first place. On this approach, which is known as the "established statutory authority" theory of government appropriation, governmental use represents a power reserved to the state when it initially grants the patent. Because "the government cannot 'take' what it already possesses," section 1498 "grants the government the absolute power to take a compulsory, non-exclusive license to a patented invention at will."
>
> In its most recent pronouncements, the Federal Court of Claims has apparently retreated from this thesis. In two decisions handed down in 2002, this court has once more espoused the orthodox view that patent infringement by the government constitutes a government taking under an eminent domain theory, which arguably triggers the

[33] Reichman JH. Compulsory Licenses: History and Legal Principles. 2003.

> constitutional guarantees of "just compensation" under the Fifth Amendment. …
>
> Before the *Georgia Pacific* factors were applied in 1993, it appears that royalty rates of 6% were commonly applied. … In one of the last important cases before 1993, *DeGraffenried v. United States*, the court imposed an up-front payment of $150,000 plus a 5% royalty on each lathe delivered under the contract. It seems worth noting that this decision was one of two opinions that rejected the "eminent domain" rationale in favor of the "established statutory authority" theory of government appropriation.
>
> Since 1993, however, when courts began rigorously applying the *Georgia Pacific* factors under an "eminent domain" rationale, there has been a marked upward trend in the rates applied. For example, in a 1997 case that went to the Federal Circuit, the court upheld a royalty rate of 10% on the bulk of the infringing articles and 50% on a small portion of a government contract covering the development phase. In 1999, the Court of Federal Claims awarded a 16.31% royalty, and in 2000, it approved an award of 15% of the benefit conferred by use of the patent in view of the importance of the patent itself. This award was subsequently challenged by the Federal Circuit. The highest known percentage rate appears to have been awarded in *Brunswick Corp. v. United States*, where the plaintiff obtained 17% of the total cost of procurement, including closely related unpatented items under the "entire market value rule" discussed above. The value of this award totaled $17,325,000.
>
> One factor in these cases may be a greater willingness of the courts to consider lost profits and cost savings by the back door, i.e., by giving more weight to them as *Georgia Pacific* factors than in the past. For example, one court applying these factors started with a low baseline rate of 4.31%, which jumped another 4% when the court evaluated factor 11, *viz*, "the extent and value of the infringing use," which reflects cost savings. By the time all the factors were evaluated one by one, including factor 8, *viz*, lost profits, the royalty rate had climbed to 16.31%.
>
> It should also be noted that the government's proposed royalty rates in these cases were generally quite low, often ranging from 0.5% to 5% of the cost of the patented items. The higher rates actually awarded, when compared to the pre-*Georgia Pacific* norm of 6%, would thus seem to reflect a judicial shift toward fuller compensation.

The rationale for various awards varies. In some cases, a lower royalty rate is justified on the grounds of a particular purpose.

For example, a 31 March 1998 decision by the United States Court of Appeals for the Federal Circuit, in *Brunswick Corporation v. United States*, concerns the Government's purchase of camouflage screens, some of which were held to infringe on a Brunswick patent. Brunswick sought a large award based upon its analysis of "lost profits" from the sale of screens by competitors, while the court granted a lower award based upon

a "reasonable royalty." The court said the United States Congress directed the Army to "expand its industrial base for the production of camouflage screens in order to maintain a reliable industrial mobilization capacity" and noted "this type of outside policy making and political influence is peculiar to the federal government and is properly taken into account when considering whether a reasonable royalty would adequately compensate an aggrieved patentee". The court further indicated that the number of units purchased by the government was greater than would have been the case in the absence of the compulsory licence, and that this supported a lower amount of compensation than that sought by *Brunswick*.

In *Brunswick* and in many other cases, the courts note that the use should not be evaluated as a tort, and "because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained'".[34]

In some cases, the United States Government has set limits on the total royalties paid. In a famous case involving aircraft patents in 1917, the United States Government demanded that the Wright Brothers and others place the essential patents needed to build aircraft into a Manufacturers Aircraft Association patent pool. Some 60 firms, including Boeing, were allowed to participate in the patent pool, so they could freely manufacture aircraft for both civilian and military purposes. Faced with the expense of fighting World War I, the United States three times told the patent owners to lower royalties, eventually capping the Wright and Curtiss patents at US$ 2 million each. On 8 March 1918, the Secretary of the Navy wrote to the Manufacturers Aircraft Association patent pool to say:[35]

> It was contemplated that under the cross-license agreement between the manufacturers of aircraft and your association, royalties of $ 200 per plane would be paid over a term of years, with a possible maximum limit of $ 2,000,000 to each of two companies. It now appears, however, that owing to the great and growing requirements of the Government for airplanes, under the royalty of $ 200 per plane the limit of $ 4,000,000 would be paid by the Government alone during the next few months. I consider this excessive and inadmissible.
>
> The maximum payments which would in my opinion be at all acceptable under the cross-license agreement would be as follows:
>
> (a) On all planes shipped to the United States Government after December 31, 1917, the royalty be reduced to $ 100 per plane.
>
> (b) When the Wright-Martin and Curtiss Companies have together received royalties for machines bought by the Government not to exceed the aggregate amount of $ 2,000,000, no further royalties to be paid for the use of the patents controlled by the Manufacturers Aircraft Association by the United States Government during the period of the present war.

[34] Quoting *Leesona* (599 F.2d at 969).
[35] Letter published in *Manufacturers Aircraft Association, Inc, v. The United States*, No. J-569, United States Court Of Claims, 77 Ct. Cl. 481; 1933 U.S. Ct. Cl. LEXIS 277, 8 May 1933.

FM Scherer provided additional examples of compensation for United States Government use of patents:[36]

> For U.S. government use of Enrico Fermi's patent governing plutonium production, a payment of $300,000 was made - 1% of the government World War II investment in the Hanford plutonium extraction facilities. The heirs of Robert S. Goddard were paid $1 million for the government's use of Goddard's rocket engine patents - about 0.01% of the value of the liquid-propelled rockets produced by the U.S. government during the life of the patents.
>
> In what was initially described as the largest patent compensation case in history, Hughes Aircraft claimed a 15% royalty, or $3.3 billion in total, on the value of 81 government satellites using Hughes' geostationary orbit technology. The U.S. government argued for, and received, a 1% royalty in the U.S. Court of Claims.

3.4 Special United States compulsory licensing programmes

The United States has several special programmes for compulsory licensing.

3.4.1 Civilian Nuclear Energy

The United States has two different statutes that provide for compulsory licences of patents for civilian nuclear energy programmes. Under 42 USC 2183, the United States Government can "declare any patent to be affected with the public interest" if the invention or discovery covered by the patent "is of primary importance in the production or utilization of special nuclear material or atomic energy". Under 42 USC 2188, regarding "Monopolistic use of patents"

> Whenever the owner of any patent … is found … to have intentionally used such patent in a manner so as to violate any of the antitrust laws … there may be included in the judgment of the court, in its discretion and in addition to any other lawful sanctions, a requirement that such owner license such patent to any other licensee of the Commission who demonstrates a need therefor.

If a compulsory licence is ordered under either 42 USC 2183 or 42 USC 2188, and a voluntary agreement cannot be reached on royalties, compensation is determined by the Energy Research and Development Administration, according to standards set out in 42 USC 2187. This statute requires taking into consideration:

(1) the advice of the Patent Compensation Board;
(2) any defence, general or special, that might be pleaded by a defendant in an action for infringement;
(3) the extent to which, if any, such patent was developed through federally financed research;
(4) the degree of utility, novelty, and importance of the invention or discovery; and may consider

[36] Scherer, FM. Royalties for Compulsory Licenses. 2003.

(5) the cost to the owner of the patent of developing such invention or discovery or acquiring such patent.

3.4.2 Clean Air Act

Another United States compulsory licensing statute is 42 USC 7608, which provides for "Mandatory Licensing" of patents on inventions for clean air. Under this statute, the Administrator of the Environmental Protection Agency asks the Attorney General to certify that a patented invention is necessary to comply with certain provisions of the Clean Air Act and that the failure to license "may result in a substantial lessening of competition or tendency to create a monopoly *in any line of commerce in any section of the country*" (italics added). Once the Attorney General so certifies, a court may order the patent owner to license the invention "on such reasonable terms and conditions as the court, after hearing, may determine".

3.4.3 Bayh-Dole March-In Rights

Under the United States *Bayh-Dole Act*, any federal agency that funds research that leads to a patent, may issue so called *March-in Rights* to the invention, allowing third parties to use the invention on "terms that are reasonable under the circumstances" if the "action is necessary to alleviate health or safety needs" not reasonably satisfied by the patent owner.

3.4.4 The Proposed Public Health Emergency Medicines Act,

In the fall of 2001 the United States was confronted with an attack using anthrax. The United States Government did not have an adequate stockpile of ciprofloxacin to treat a larger population, in the event a new and broader attack was launched using a strain of anthrax that could not be treated with other antibiotics.[37] Ciprofloxacin was patented in the United States by Bayer - and priced at US$ 1.77 per pill. Bayer could not manufacture enough ciprofloxacin to supply the United States stockpile on a timely basis. Under pressure from domestic public health groups and the members of Congress, United States Secretary of Health, Tommy Thompson, threatened to override the Bayer patent and purchase ciprofloxacin from generic suppliers, unless Bayer lowered its prices.[38] Bayer then lowered its price to US$ 0.95 per pill. During the debate over the price and supply for Cipro (Bayer's brand name version of ciprofloxacin), Secretary Thompson expressed concerns that current United States laws on government use of patented inventions did not give the United States sufficient leverage when setting royalties. Partly in response, Representative Sherrod Brown introduced HR 3235, the Public Health Emergency Medicines Act, to empower the Secretary of Health and Human Services to issue compulsory licences for patents needed to address public health emergencies, and to provide for "reasonable remuneration for the use of the patent" based upon the following criteria:

[37] Bumiller E. Public Health or Public Relations. New York Times, 21 October 2001:
"The surgeon general, Dr. David Satcher, said in a White House briefing on Friday that a typical course of treatment against anthrax is to start with Cipro, determine if the anthrax strain is resistant to penicillin and doxycyline, then switch if indicated to the other drugs".

[38] Thompson: Cipro Price Must Be Lower. Associated Press, 23 October 2001: "Health and Human Services Secretary Tommy Thompson said Tuesday that he is prepared to go to Congress to seek a generic version of an antibiotic used to treat anthrax infection if the manufacturer does not lower its price. 'The price is the question, not the supply,' he told a congressional hearing."

(1) evidence of the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention;

(2) evidence of the efficacy and innovative nature and importance to public health of the invention or products using the invention;

(3) the degree to which the invention benefited from publicly funded research;

(4) the need for adequate incentives for the creation and commercialization of new inventions;

(5) the interests of the public as patients and payers for health care services;

(6) the public health benefits of expanded access to the invention;

(7) the benefits of making the invention available to working families and retired persons;

(8) the need to correct anti-competitive practices; or

(9) other public interest considerations.

3.5 US experience with compulsory licences issued as a remedy to anti-competitive practices.

FM Scherer notes the extensive use of compulsory licensing as a remedy to anti-competitive practices:[39]

> The United States has led the world in issuing compulsory licenses to restore competition when violations of the antitrust laws have been found, or in the negotiated settlement of antitrust cases before full adjudication has occurred. By the end of the 1950s, compulsory licenses had been issued in roughly 100 antitrust cases covering an estimated 40 to 50 thousand patents, including AT&T's basic transistor concept patents, IBM's computer and tabulating card machine patents, General Electric's fluorescent and incandescent lamp patents, Du Pont's nylon patents, and Eastman Kodak's color film processing patents. Additional cases since then have led to the licensing of Xerox's plain paper copying machine patents, the tranquilizer Meprobamate, synthetic steroids, the antibiotic Griseofulvin, Cytokine biopharmaceutical patents owned by Novartis and Chiron, and the 9-AC cancer drug patent rights assembled under the merger of Pharmacia AB with Upjohn. … Some of the U.S. antitrust decrees, such as those covering General Electric's incandescent lamp patents and many of the patents in AT&T's portfolio, required licensing at zero royalty rates. Most provided for "reasonable" royalties …

[39] Scherer, FM. Royalties for Compulsory Licenses. 2003.

3.5.1 Microsoft

Among the more recent United States compulsory licences are those seeking remedies for Microsoft's anti-competitive conduct. Microsoft was ordered to provide non-discriminatory licensing of certain protocol technologies. In the first attempt by Microsoft to satisfy that order, it issued licensing terms that were widely criticized for being unreasonable. The United States Department of Justice and other parties forced Microsoft to lower its royalty payments and change other terms of its licences. On 1 August 2003, Microsoft issued this statement:

> **Microsoft Announces Additional Improvements To Protocol Licensing Program:** Changes Include Simplified, Low Cost Royalty Structure and New License Terms
>
> REDMOND, Wash. - Aug. 1, 2003 -* Microsoft Corporation today announced that improvements to its Communications Protocol Licensing Program are now available to existing and prospective licensees. *In response to industry and government feedback*, Microsoft has established a simplified, low-cost royalty structure and adopted new licensing terms that are more favorable to prospective licensees.
>
> A new royalty structure, calculated as a simple percentage of the licensee's revenues from products incorporating Microsoft's protocol technology. Depending on the functions they wish to enable, licensees can elect to license some or all of the protocols supported in Windows 2000 Professional and later client operating systems. For many functions, royalties are set at 1 per cent of the licensee's revenues from the software product incorporating the protocol technology. *All of the more than 100 protocols available under the MCPP can be licensed at a royalty of 5 per cent of the licensed product revenues.* Royalty rates on Microsoft protocol technology used in embedded hardware products range from 0.5 per cent to 2.5 per cent. [Italics added]

The Microsoft protocol royalties illustrate some important features of patent licensing when the final product is likely to involve combinations of several different inventions, and when it is perceived to appeal to consumers in a competitive market. The cap on stacked royalties of 5% for the MCPP is exactly the same as the voluntary cap on stacked royalties from IBM, and a common goal for voluntary patent pools. When all 100 protocols are used the Microsoft royalties are only 0.0005 (0.05%) per protocol, applied to the licensee's products, but many in the industry say that even this is too high.

3.6 Canadian compulsory licences for medical inventions

Canada, like many countries, has a variety of grounds under which compulsory licences can be issued, including failure to work the invention, government use, to remedy anti-competitive practices, as well as special provisions for issuing compulsory licences on medicines and food. The Canadian Government has issued more compulsory licences on medicines than any other government. The Canadian

decisions on medicines, particularly those issued from the late 1960's to the early 1990's, were motivated by a desire to promote the development of a domestic pharmaceutical industry, and to lower the price of medicines to consumers. Ironically, it was the decision to abandon the local working requirement for compulsory licensing that facilitated both the expansion of the use of compulsory licensing and the growth of a domestic manufacturing sector, since the requirement for local manufacturing was seen as an initial barrier to entry.[40] Section 41(4) of a 1969 modification to the compulsory licensing act provided clear policy guidance to promote public health goals:

> Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation or production of medicine ... the Commissioner shall grant to the applicant a license to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a license; and, in settling the terms of the license and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.

3.6.1 Frank Horner v. Hoffmann-La Roche

From 1969 to 1992, Canada issued more than 600 compulsory licences on medicines. In nearly every case, the compensation to the patent owner was a standard 4% royalty applied to the generic competitor's sale price.[41] The basis for this approach was set out by AM Laidlaw, the Commissioner of Patents, in *Frank Horner v. Hoffmann-La Roche*, on 20 January 1970:

> Royalty Considerations
>
> The changes in the legislation relating to royalty have not been changes in substance.
>
> The law in Canada differs from that applicable in England under the corresponding section of the Patent Act. The Canadian law does not give the patentee any guarantee that it shall derive a reasonable advantage from its patent rights.

[40] Reichman J, Hasenzahl C. *Non-voluntary licensing of patented inventions: the Canadian experience.* UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development, 2002*:* "The crux of the reform was to allow any person to apply for a compulsory license to import any medicines produced with patented processes, an activity that the 1923 Act had forbidden. The policy rationale was that allowing imports would effectively 'eliminate the largest barrier to entry: the manufacturing restriction'".

[41] Scherer FM. The Economics of Compulsory Drug Patent Licensing. May 2003. Reichman J, Hasenzahl C. *Non-voluntary licensing of patented inventions: the Canadian experience.* UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development, 2002. Lexchin J. Pharmaceuticals, patents and politics: Canada and Bill C-22. *International Journal of Health Services*, 1993, 23:147-60. Lexchin J. After compulsory licensing: coming issues in Canadian pharmaceutical policy and politics. *Health Policy*, 1997, 40: 69-80.

> In Canada the Commissioner must have regard to the desirability of making medicine available to the public at the lowest possible price consistent with giving the patentee due reward for the research leading to the invention. The Commissioner is not required to take into consideration such elements as the cost of obtaining and maintaining medical acceptance of the drug or a return on the capital employed in research and promotion.
>
> The royalty should take into account that it should be commensurate with an amount that will maintain research incentive and will reflect the importance of the medicine.
>
> The duty of the Commissioner is to fix a royalty in accordance with the provisions of the section. Voluntary licenses in respect of the same subject-matter are irrelevant.
>
> Royalty Award
>
> The royalty is fixed at 4% of the net selling price of the medicine by the applicant in its final dosage form as sold to purchasers at arm's length.

The decision was appealed and upheld by the Exchequer Court of Canada, which provided a more detailed discussion of the royalty issue. Hoffman-La Roche's appeal raised 17 technical objections to the royalty calculations, which at their core focused on the following:

> The … objection taken on the appeal was that the royalty so fixed was manifestly too low because at 4% of the sales price it was below the 11% which Roche companies spend on research and was therefore inadequate to maintain research incentive alone, besides affording no compensation for the expense of obtaining and maintaining medical acceptance of the drug and no return on the capital invested in research.

The court rejected this argument, noting:

> The submission of the appellant as to royalty springs from a misunderstanding of what a patentee is entitled to by way of remuneration on the grant of a license under s. 41(4) of the Act. A patentee, of a patent subject to license under the section, does not have an unassailable complete monopoly right. … The area of protection available for an invention falling under the section is considerably less than is obtainable for other inventions. The compensation to be paid to a patentee under the section is a reasonable sum for the value of the use of an invention having some intrinsic value. … The compensation upon the privilege of competing with the patentee and diversion to the licensee business of which the patentee might otherwise have had a monopoly. The compensation is not equivalent to damages for infringement nor the profits which the licensee may make through the use of the invention. It is not compensation for the interference with the business of the patentee if left with the market to himself. The

> principles applicable to the calculation of a royalty under the corresponding U.K. legislation differ from those applicable under s. 41(4) of the Canadian Act. The U.K. provision more closely approximates the measure of damages that might be recoverable in an infringement proceeding by the court.

Citing the Canadian Supreme Court in a related case, the Court noted[42]:

> No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary, Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may be 'available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention'.

In their detailed review of the Canadian compulsory licensing experience, Jerome Reichman and Catherine Hasenzahl note that royalties on compulsory licences for medicines were on average lower than were royalties for compulsory licences granted for other manufactured products under local working grounds.[43]

Canada abandoned the most important aspects of its compulsory licensing laws when it negotiated to join the United States-Canada Free Trade Agreement, a predecessor to the North American Free Trade Agreement (NAFTA), but the Canadian experience with compulsory licensing remained an important model, and the Canadian approach to setting remuneration was at the heart of royalty guidelines recommended to developing countries in the 2001 UNDP HDR.

Before Canada abandoned its compulsory licensing programme for medicines, the Minister of Science and Technology appointed a Royal Commission of Inquiry on the Pharmaceutical Industry, known as the Eastman Commission, which issued a report in 1985. The Eastman Commission gave the compulsory licensing programme high marks for generating substantial saving for Canadian consumers ($ 211 million in 1983), and noted that multinational pharmaceutical companies continued to have a major presence in the Canadian market where they had significant market shares, and that Canada had a positive rate of growth and investment in the pharmaceutical sector.[44] However, to address the criticism that the programme had an adverse

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[42] *Hoffmann-La Roche Ltd. v. L. D. Craig Ltd., Bell-Craig Pharmaceuticals Division*, 48 C.P.R. 137 at p. 140, 56 D.L.R. (2d)97, [1966] S.C.R. 313.

[43] Reichman J, Hazenzahl C. *Non-voluntary licensing of patented inventions: the Canadian experience*. UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development, 2002: "The royalty rates in these cases typically varied according to the facts. Examples include a per piece royalty of 10 cents on watch bracelets; 5% of cost on a machine and its component parts; between 6% and 10% on parts for a machine with a two cent per piece minimum; and 3½% of the net selling price of an article. However, these practices should not be confused with the Commissioner's duties pursuant to applications for compulsory licensing of pharmaceutical and agricultural inventions, where he was governed by guidelines, including a 4% "rule of thumb royalty," that were not contingent on a failure to work. … one should note that royalties tended to be higher in cases dealing with the working requirement than in cases of pharmaceutical and agricultural inventions."

[44] "An overall summary of the comparison of the growth and development of the pharmaceutical industry in Canada relative to that of the United States yields the straightforward conclusion that

impact on R&D, the report suggested a four year period of market exclusivity for the patent owner, combined with a higher royalty on a compulsory licence rate when the patent owner could demonstrate that it engaged in R&D of pharmaceutical products in Canada.

3.6.2 Breast cancer gene patents

In recent years, several Canadian provinces have revisited the issue of compulsory licensing of patents as it relates to patents on diagnostic tests for breast cancer. In a September 2001 Speech on the Myriad Gene Patent, the Ontario Health Minister said:[45]

> Some of you may have read that on May 31st of this year, Ontario was provided notice by the legal representatives of Utah-based Myriad Genetic Laboratories Inc. concerning the issue of that company's patent on two breast-cancer susceptibility genes (BRCA 1 and 2) and the exclusive rights to test for those genes. In essence, the company's request was that Ontario hospitals stop predictive genetic testing for the BRCA 1 and BRCA 2 gene for breast cancer. The position taken in Myriad's letters required Ontario, in effect, to route all genetic tests for breast cancer in Canada to the company's laboratory in Salt Lake City or through its designated licensees. Basically, Ontario was being told which test it could fund, and where and how the test could be performed. Implicitly, this is also about where and who controls and stores genetic data.
>
> Myriad maintains that continuing to perform ANY test, including the ones currently being used by our Ontario geneticist using the BRCA 1 or 2 gene - is an infringement of the company's patent. From our government's perspective, we are motivated not simply by the actions of one company, but by the assessment of what these actions mean for the thousands of patents that are in the process of being granted for other genes. All of which could potentially result in tests benefiting thousands upon thousands of Ontarians. Apart from the obvious moral concerns, the question we have asked ourselves is this: How can publicly-funded healthcare and equitable coverage be sustained when we add to the existing financial pressures on our health system the potential monopoly pricing of a whole new category of diagnostics over which Ontario - and indeed Canada's other provincial and territorial jurisdictions - have little or no control over approval or pricing. Ultimately this is ... about whether - in an evolving diagnostic field - new innovations, new knowledge, new tests can actually progress; and whether they can do so in a manner that is reasonably affordable for health systems around the world. We are therefore forced to ask ourselves the much larger question: Is the entire fruit of human genome project research and the mapping of the

growth has been more buoyant in Canada than it has been in the United States since 1967", page 65 of the report of the Royal Commission of Inquiry on the Pharmaceutical Industry.

[45] Speech Re: Myriad Gene Patent Issue by the Honourable Tony Clement Minister of Health and Long-Term Care, September 2001, (http://www.health.gov.on.ca/english/media/speeches/archives/sp_01/sp_091901_tc.html).

> human gene going to come down to a series of monopolies setting exclusive prices for tests which most of Canada - indeed most of the world, especially the poorer countries - cannot afford?

In January 2002, the Ontario Advisory Committee on New Predictive Genetic Technologies published the Ontario Report to Premiers: Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare.[46] One recommendation of the report was to revise the Canadian compulsory licensing system:

> The Ministerial Conference of the World Trade Organization in Doha, Qatar in November 2001 adopted a declaration dealing with international trade and public health. In that statement, the Ministers (including Canada's Minister of Foreign Affairs and International Trade) stated that nations should be able to take measures "to protect public health and, in particular, to promote access to medicines for all." The Ministers also stated that countries have the right to determine the grounds upon which they will grant compulsory licenses.
>
> In order to prevent the statement from providing a hollow right, the concept of promoting access to medicines for all must include providing access to the diagnostic procedures necessary to determine when and which medicines to provide. The federal government should, therefore, amend the Patent Act to specifically allow the potential for compulsory licensing of patents relating to the provision of genetic diagnostic and screening tests should this power be necessary. The compulsory license ought to be granted in return for a reasonable royalty established by the Commissioner of Patents. *This royalty should include an amount in respect of the use of the invention, and not profit gained by the patentee through the actual provision of the test.* The amendment should not obligate the provinces to first negotiate with patent holders for a license in respect of these patents. It should, however, require fair payment after determining the relevant factors. [italics added]

Aidan Hollis, an economist who works with Canadian Competition Commission, provided a further economic rationale for this a commentary in the *Canadian Medical Association Journal*[47]

> Compulsory licensing is essential in Canada in some cases in which the bargaining power of the state-funded medicare system has been enfeebled by the requirement to provide "medically necessary" patented treatments. An example of such a situation is testing for the *BRCA1* and *BRCA2* genes. Under a 1999 appeal ruling, the Ontario Health Insurance Plan is required to provide such testing as an "essential and timely medical service." Myriad Genetics, which holds a patent over such testing, is therefore in a position to charge any fee it wishes, because the government is constrained to purchase the service as being medically necessary. The combination of medical necessity and the patent right open up the possibility of unlimited exploitation of monopoly

[46] http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf
[47] Hollis A. Commentary: The link between publicly funded health care and compulsory licensing. *Canadian Medical Association Journal*, 1 October 2002, 167 (7).

power, which, I argue, can only be effectively combated through the use or threat of compulsory licensing.

3.6.3 Royalty for export under WTO waiver of Article 31(f) of the TRIPS Agreement

Canada was the first country to formally propose modifying its patent law to implement the 30 August 2003 WTO Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The implementing legislation, Bill C-9, also known as the Jean Chrétien Pledge to Africa Act, is considerably more restrictive than the 30 August 2003 WTO waiver of Article 31(f) of the TRIPS Agreement, placing a number of additional restrictions on the use (both as an exporter and an importer) of the system. The supporters of the Bill first proposed a fixed royalty of 2% of the value of the generic product. The 2% royalty was initially noted by developing countries, including for example Mozambique, which set a 2% royalty on its compulsory licence for the manufacture of a fixed-dose combination medicine for AIDS. But the 2% royalty was eventually eliminated from the Bill in favour of a more open-ended and flexible statutory provision. The Government has more recently proposed regulations to provide guidelines for setting royalties and, under the statute, the courts may also increase royalties. In both cases, the statute requires consideration of:

(a) the humanitarian and non-commercial reasons underlying the Issuance of the authorization; and

(b) the economic value of the use of the invention or inventions to the country or WTO Member.

The proposed regulations now provide for a sliding scale royalty, from 0.02 to 4%, which is based upon the rank of the country in the UNHDI, as is described in the regulatory analysis of the Act.[48]

Paragraph 3 of the 30 August 2003 WTO Decision calls for "adequate remuneration" to be paid to the patentee on a case-by-case basis, taking into account the economic value to the importing country of the use that has been authorized by the exporting country. The provisions in Bill C-9 which implement this obligation require that the royalty payable by the licencee to the patentee be determined in accordance with a formula to be prescribed by regulation. This regulatory formula must take into account the humanitarian and non-commercial reasons underlying the issuance of an export licence.

The regulatory formula calculates the royalty by multiplying the monetary value of the supply agreement between the licensee and the importing country by an amount which fluctuates on the basis of that country's standing on the UNHDI. The formula to determine the royalty rate is 1, plus the number of countries on the UNHDI, minus the importing country's rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04.

[48] Use of Patented Products for International Humanitarian Purposes, Regulations. Regulatory Impact Analysis Statement, *Canada Gazette*, Notice, Vol. 138, No. 40, 2 October 2004.

For example, Nigeria was ranked number 151 of the 177 countries listed on the UNHDI in 2004. Therefore, the royalty rate that would be applicable to exports of pharmaceutical products to Nigeria would be:

$$[(1+177-151)/177] * 0.04 = 0.0061 \text{ or } 0.61\%.$$

According to this formula, the royalty payable in respect of the lowest eligible country which currently appears on the UNHDI would be 0.02%, and the highest, 3.5%. Mathematically, the regulatory formula cannot result in a royalty rate in excess of 4%, a ceiling which is considered to be consistent with the humanitarian and non-commercial considerations which gave rise to the 30 August 2003 Decision and the Bill C-9 regime.

In the rare instance where a country is not listed on the UNHDI, the royalty is to be calculated by substituting the individual country's rank in the formula with the average rank of all countries appearing on the same schedule. However, an exception to this rule has been made in the case of non-WTO Member developing countries that are unranked. Although these countries appear on Schedule 4, their individual rank in the formula will be replaced by the average rank of all countries appearing on Schedule 3, as the latter is thought to better reflect the level of development of the countries in question.

Bill C-9 also provides that a licensee is required to pay royalties within the prescribed time, on the occurrence of a prescribed event. The proposed Regulations would make the royalty due and payable in full within 45 days of the export notice, which Bill C-9 requires the licensee provide to the patentee at least 15 days before the product is exported. Where there is more than one shipment of the product, the amount of payment that becomes due would be in proportion to the total quantity of product to be exported.

3.7 The Philippines

The Philippines adopted the Republic Act N° 165, known as the patent law, in 1947. The Act was amended in 1977 by Presidential Decree 1263. A section on voluntary licensing of patents provided that, for licences between an alien and a Filipino licensee, royalties should "not exceed five per cent (5%) of the net wholesale price … and shall be equally distributed to all the patentees in cases where more than one patent … are involved." [49] The Act also provided that compulsory licences "shall be granted to the petitioner" when any one of a number of conditions were met:

[49] Article One. Voluntary Licensing. Sec. 33-A. "Voluntary License Contracts. (1) All voluntary license contracts as well as renewals thereof involving payment of royalty for the use of patents, transfer of technology, or furnishing of services respecting patents of technology, or furnishing of services respecting patents shall, whenever entered into between residents and non-residents, be submitted to the Technology Resource center for prior approval and registration.
(2) The royalty to be granted in all license contracts involving manufacturing (including actual transfer of technology services such as secret formulate, processes, technical know-how and the like) shall, whenever entered into between an alien licensor and a Filipino licensee, not exceed five per cent (5%) of the net wholesale price of the articles manufactured under the royalty agreement and shall be equally distributed to all the patentees in cases where more than one patent similar to that contemplated in Section 34-C hereof are involved.

(a) If the patented invention is not being worked within the Philippines on a commercial scale, although capable of being so worked, without satisfactory reason;

(b) If the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms;

(c) If, by reason of refusal of the patentee to grant a licence or licences on reasonable terms, or by reason of the conditions attached by the patentee to article or working of the patented process or machine for production, the establishment of any new trade or industry in the Philippines is prevented, or the trade or industry therein is unduly restrained;

(d) If the working of the invention within the country is being prevented or hindered by the importation of the patented article.

The 1977 Presidential Decree also provided that the fast track procedures for compulsory licensing would obtain for certain categories of products declared to be of "vital importance to the country's defense or economy or to public health" by the National Economic Development Authority. This extended to "all products or substances and/or processes involved in any industrial project approved by the Board of Investments under the Investment Incentives Act."

Remuneration for the compulsory licence was set out in Section 35-B (3) of the Act:

> 3) A compulsory license shall only be granted subject to the payment of adequate royalties commensurate with the extent to which the invention is worked. However, royalty payments shall not exceed five per cent (5%) of the net wholesale price (as defined in Section 33-A) of the products manufactured under the license. If the product, substance, or process subject of the compulsory license is involved in an industrial project approved by the Board of Investments, the royalty payable to the patentee or patentees shall not exceed three per cent (3%) of the net wholesale price (as defined in Section 33-A) of the patented commodity and/or commodity manufactured under the patented process; the same rate of royalty shall be paid whenever two or more patents are involved; which royalty shall be distributed to the patentees in rates proportional to the extent of commercial use by the licensee giving preferential values to the holder of the oldest subsisting product patent.

In a series of compulsory licensing decisions, the Director of Patents fixed the royalty rate at 2.5% of the net sales, although in some cases the royalty was set higher.[50] The Courts repeatedly found the 2.5% royalty rate reasonable,[51] noting it only covered

(3) The term "net wholesale price" means the gross amount billed for the patented product subject to royalty less;
(a) Trade, quality, or cash discounts, and broker's or agent's commission, if any, allowed or paid;
(b) Credits or allowances, if any, given or made on account of rejection or return of the patented product previously delivered; and
(c) Any tax, excise or other government charge, included in such amount, on, or measured by, the production, sale, use or delivery of the patented product."

[50] An 8% royalty was awarded in *Parke, Davis & Company, petitioner, v. Doctor's Pharmaceuticals, Inc.*, G.R. No. L-27004, 16 August 1983.

[51] *United Laboratories, Inc. v. Boehringer Ingelhelm, GMBH*, IPC 929, 27 July 1981; *United Laboratories, Inc. v. Bristol-Myers Company*, IPC 1179, 20 August 1981; *United Laboratories, Inc. v.*

"the bare right to use the patented chemical compound in the manufacture of a special product without any technical assistance" and that the generic product would only be used, distributed and disposed of, locally. In some cases, the courts noted that "liberal treatment in trade relations should be afforded to local industry … it is so difficult to compete with industrial giants of the drug industry … that it always is necessary that the local drug companies should sell at much lower [than] the prices of said foreign drug entities".

On 6 April 1993, the United States Trade Representative and the Philippines Department of Trade and Industry signed an agreement (the Kantor-Navarro Agreement) that set out a number of changes in the Philippine intellectual property laws.[52] The Agreement provided that "within 90 days after the signing of the Understanding, consultations will be held with the aim of specifying when a patent compulsory license may be granted." This led to a number of changes in the procedures for obtaining a compulsory licence, in a new patent law that took effect on 1 January 1998.

3.8 Malaysia

3.8.1 Malaysian guidelines for the approval of technology transfer agreements on intellectual property.

Manufacturing projects licensed under the 1975 Malaysian Industrial Coordination Act are required to obtain the approval of the Ministry of International Trade and Industry before entering into any technology transfer agreement involving foreign partners. This is to ensure that the agreement (a) does not impose unfair and unjustifiable restrictions or handicaps on the local party, (b) is not prejudicial to the national interest, and (c) provides for the payment of fees commensurate with the level of technology to be transferred.

Technical assistance, licence and know-how agreements signed between Malaysian-owned/Malaysian joint-venture companies and any foreign party are automatically approved if the royalty payments are as follows: [53]

Running royalties not exceeding 3% of net sales

Lump sum payment not exceeding RM 500,000

E.R. Squibb & Sons, Inc., IPC 1349, 30 September 1981; *United Laboratories, Inc. v. Helmut Webe, et al.*, IPC 949, 13 December 1982; *Oceanic Pharmacal, Inc. v. Gruppo Lepetit S.A.* IPC 1549, 21 December 1982; *United Laboratories, Inc. v. Boehringer Ingelheim*, IPC 1185, 8 June 1983; *United Laboratories, Inc. v. Pfizer Corp.*, IPC 1184, 10 June 1983; *Doctors Pharmaceuticals, Inc. v. Maggi et al.*, 11 July 1983; *Drugmaker's Laboratories, Inc. v. Herningen et al.*, IPC 1679, 22 September 1983; *Superior Pharmacraft, Inc. v. Maggi et al.*, IPC 1759, 10 January 1984; *United Laboratories, Inc. v. Van Gelder et al.*, IPC 1627, 29 June 1984; *Drugmaker's Laboratories, Inc. v. Janssen Pharmaceutical N.V.* IPC 1555, 27 August 1984; *United Laboratories, Inc. v. Graham John Durant et al.*, IPC 1731, 14 August 1987; *United Laboratories Inc. v. Albert Anthony Carr*, IPC 1906, 31 August 1987. *Barry John Price v. United Laboratories, Inc.*, G.R. No. 82542, 29 September 1988.

[52] Understanding Between the Government of the Republic of the Philippines and the Government of the United States of America regarding the Protection and Enforcement of Intellectual Property Rights.

[53] http://e-directory.com.my/web/sw-investorinfo-technology.htm

Lump sum payment and running royalty in total not exceeding 3% of net sales.

Trademark and patent agreements signed between Malaysian owned/ Malaysian joint-venture companies and any foreign party involving royalty payments not exceeding 1% of net sales for each category.

3.8.2 2003 government use licence

In December 2003, the Ministry of Health authorized a generic drug manufacture to use patents owned by Glaxosmithkline in order to supply the Government with drugs to treat AIDS. The royalty offered by the Government was 4% of the generic price of the drugs. The Malaysian Government described this royalty as one that was consistent with the 2001 UNDP royalty guidelines for developing countries (see below).

3.9 Singapore

During the 1980s, Singapore imported medicines from generic suppliers under its government use exceptions clause in the compulsory licensing laws. Remuneration to patent owners was limited to 5% of the net ex-factory bulk cost of the drugs.[54] In the recently negotiated United States-Singapore bilateral free trade agreement, the United States now limits the grounds under which both the United States and Singapore may grant a compulsory licence, and introduced new trade rules for remuneration paid under the government use exceptions.

ARTICLE 16.7: PATENTS

6. Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:
    a. to remedy a practice determined after judicial or administrative process to be anticompetitive under the competition laws of the Party;
    b. in the case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that:
        i. such use is limited to use by the government or third parties authorized by the government;
        ii. *the patent owner is provided with reasonable and entire compensation for such use and manufacture*; and
        iii. the Party shall not require the patent owner to transfer undisclosed information or technical "know how" related to a patented invention that has been authorized for use without the consent of the patent owner pursuant to this paragraph. [italics added]

[54] Patent Protection for Pharmaceuticals in East Asia, United States Department of State, August 1987.

The term "reasonable and entire compensation" follows the language in the United States statute, 28 USC 1498, which requires compensation for United States Government use to be the "reasonable and entire compensation for such use and manufacture". As noted above in the discussion of the Anthrax/ciprofloxacin case, this standard was thought by some to present significant barriers to wider use of compulsory licensing in cases involving medicines, because of the possibility that a court would base the compensation upon the commercial value of the medicines prior to the government authorization. Certainly, if the objective of the compulsory licence is to overcome market outcomes, it is a problematic standard.

3.10 Mozambique

In Spring 2004, the Ministry of Commerce and Industry of the Republic of Mozambique granted a compulsory licence to patents for generic manufacture and sale of a fixed-dose combination AIDS drug which contains lamivudine+stavudine +nevirapine. The licence was issued to Pharco Moçambique Lda. The Mozambique Government set the royalty at 2% of the generic sales price - the same as was proposed in the initial debate in Canada over implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

3.11 Zambia

In September 2004, the Government of Zambia issued a compulsory licence for manufacture of fixed-dose combination AIDS medicines. The licence, which did not permit export outside of Zambia, set a royalty at 2.5% of the generic price.

3.12 Indonesia

On 5 October 2004, the Government of Indonesia issued a decree by the President authorizing compulsory licensing of patents for nevirapine and lamivudine, both drugs to treat AIDS. According to the decree, "The Government shall give a 0.5% compensation fee of the net selling value of Anti Retroviral Drugs to the Patent Holder."[55] The Indonesian rate was considerably lower than previous royalties, and only one third of the rate recommended for Indonesia under the new Canadian royalty guidelines.

[55] Decree of the president of the Republic of Indonesia, Megawati Soekarnoputri, Number 83, 2004, regarding Exploitation of Patent by the Government on Anti Retroviral Drugs, 5 October 2004.

Summary Table: Examples of royalty rates in compulsory licensing & related cases

Country	Case	Royalty rate/Remuneration
United Kingdom	cimetidine/Tagamet (ulcer drug)	45%
Philippines	cimetidine/Tagamet (ulcer drug)	2.5%
Japan	cimetidine/Tagamet (ulcer drug) (infringement case)	3.5%
United States	AIDS test kit (infringement case)	1%
United States	Eye-care related laser (infringement case)	5%
United States	Surface chemistry patent (infringement case)	40%
United States	Lathe	US$ 150 000 + 5% on each lathe
United States	Camouflage screens	17%
United States	Aircraft patents (date: 1917)	US$ 200 per plane, total compensation capped at US$ 2 million
United States	Rocket engine patents (World War II era)	US$ 1 million - 0.01%
United States	Geostationary orbit technology for satellites	1%
United States	Microsoft protocols	0.05-1%; maximum of 5% total for use of 100 protocols
Canada	Medicines - more than 600 cases from 1969-1992	4% standard
Canada	Medicine exports under WTO waiver of Article 31(f)	0.02-4%
Philippines	Various medicines, licenses issued in 1980s	2.5%, with some variation; statute capped royalties on voluntary licences at 5% and compulsory licences at 3%
Malaysia	Technology transfer agreements between Malaysian firms and foreign parties	Capped by statute at 3%
Malaysia	Certain HIV/AIDS drugs	4%
Singapore	Various medicines	5%
Mozambique	Certain HIV/AIDS drugs	2%
Zambia	Certain HIV/AIDS drugs	2.5%
Indonesia	Certain HIV/AIDS drugs	0.5%

Note: This table summarizes compensation schemes from various compulsory licensing and related arrangements from across the globe, and in various periods. The listing is drawn entirely from the examples included in this section of text; fuller descriptions of the cases and citations are included in the text.

4 Other evidence regarding norms for royalty rates

SECTION OVERVIEW

There is extensive experience of voluntary technology licensing in the private sector. The evidence of compensation for private, market-based licence arrangements provides an important context for making determinations of royalty and compensation arrangements in cases of compulsory licensing. There is some conflicting evidence on cross-industry licensing averages, but there seems to be agreement in reports from the pharmaceutical industry and others that licensing fees for the pharmaceutical industry congregate at 4-5%. The pharmaceutical industry has one of the highest licensing rates.

Evidence regarding voluntary practices for the setting of royalties suggests the following.

1. Average royalty rates for the pharmaceutical sector are approximately 5% of net sales, but have increased somewhat in recent years.
2. There is substantial variation in terms for individual licences, which can range from much less than 1% to more than 50% in exceptional cases.
3. The "stacking" of royalties is becoming more common as there continues to be a proliferation of patents issued in the biopharma field. A variety of methods are used to allocate payments to various patent owners in cases where stacked royalties are capped.
4. Many governments seek to oversee royalty payments between affiliated companies or between foreign and domestic firms, to address a variety of policy objectives, including those relating to capital controls or regulating tax evasion. A common threshold for automatic approval of royalty rates is 5%, the rate for example used by the South Africa Department of Trade and Industry.
5. Royalties for the competitive computer and consumer electronics sectors are somewhat lower than in the pharma sector.
6. Many standards-based patent pools seek to cap stacked royalty payments at 5% or less of net sales.

4.1 Miscellaneous evidence of normal royalty rates

In Table R-1 below, royalty rates for all United States industries are reported. The royalties reported to the Internal Revenue Service include payments for licence to use patents, copyrights, trademarks and know-how, as well as other items such as royalties on mineral development. For all industries, the average rate is 0.7%. The

average rate for pharmaceutical manufacturing sector was 4.9%. The only major industry sector close to the pharmaceutical sector is computer and electronic product manufacturing, at 4.5%.

Table R-1 **Average Royalty Rates as Reported to United States Income Tax Returns, 1999**	
Industry	**Royalty rate%**
All industries	0.65
Chemical manufacturing	2.96
Pharmaceutical manufacturing	**4.87**
Computer & electronic product manufacturing	4.52
Electrical equipment, appliance, and component manufacturing	0.75
Agriculture, forestry, fishing and hunting	0.13
Mining	0.94
Utilities	0.03
Construction	0.02
Manufacturing	0.48
Paper manufacturing	0.86
Food manufacturing	0.70
Beverage and tobacco product manufacturing	2.23
Accommodation and food services	1.31
Arts, entertainment and recreation	0.34
Information	1.44
Wholesale trade	0.14
Retail trade	0.20

In 1999, Rose Ann Dabek surveyed the (unweighted) distribution of royalty rates on pharmaceutical patents both for in-licensing and out-licensing, for company or university,[56] which is reported below in Table R-2. More than half of the respondents in her survey reported paying royalties of less than 5% for "in-licenced" patents, with higher royalties reported for "out-licenced" patents. 85 % of in-licensed and 89% of out-licenced patents were from 0 to 10%.

Table R-2 **Distribution of Royalty Rates on Pharmaceutical Patents** **(% of reported royalty rates for in-licensing or out-licensing, for company or university)**							
Rate (%)	**0-2**	**2-5**	**5-10**	**10-15**	**15-20**	**20-25**	**>25**
In-licence (%)	23.6	32.1	29.3	12.5	1.1	0.7	0.7
Out-licence (%)	1.3	20.7	67.0	8.7	1.3	0.7	0.3

In February 2000, the Pharmaceutical Research and Manufacturers of America (PhRMA) submitted a study prepared by Charles Rivers and Associates to the United States Trade Representative Office, which "assumed that licensed foreign

[56] Dabek RA (Proctor and Gamble). Valuation of a Technology. The University of Dayton School of Law, 18 February 1999.

production generates a 5% royalty stream for PhRMA's member" which they took to approximate the average pharmaceutical royalty rate.[57]

A 8 July 1999 statement from the United States Public Health Service, Centers for Disease Control and Prevention Policy, on Cooperative Research and Development Agreements and Intellectual Property Licensing[58] indicated that the agency seeks to license patents for royalty rates based on product sales at rates conventionally granted in the field for inventions with reasonably similar commercial potential. "Royalty rates generally will not exceed a rate within the range of 5-8% for exclusive commercialization licenses. Contingent royalty schemes based on, e.g., patent issuance or non-issuance, and clauses treating the stacking of royalties or packaging of other inventions developed under the CRADA may be provided."

The German law relating to inventions made by employees determines that inventions made by employees normally belong to them, and only by a special act and in conjunction with a special remuneration can they become the property of the employer. The remuneration for the invention can be calculated by three methods. The most common method to calculate the inventor's remuneration is the so-called "licence analogy". The inventor receives a reasonable royalty, based on the net sales made by the employer. Number 10 of the remuneration guidelines (added to the law relating to inventions made by employees) provides examples for reasonable royalties: [59]

Electronics:	0.5-5%
Machinery:	0.33-10%
Chemicals:	2-5%
Pharmaceuticals:	2-10%

Various industry consultants offer a range of views regarding licensing norms.

Harold A. Meyer III, from the firm Novelint, offered this estimate of typical royalty rates in March 2001. [60]

> Royalty rates for technologies run the range. Typically, technologies are licensed, not sold. One reason may be for tax depreciation advantages, another is risk. It is extremely risky for a licensee to drop millions of dollars to buy a patent. It just doesn't happen very often. Besides, licensors make more money from royalties anyway. The more product is sold, the more money is made. … all parties benefit from royalties, where the licensee pays the licensor a percentage of gross sales, which usually range from 2-10% …
>
> - A raw idea is worth virtually nothing, due to an astronomical risk factor
> - A patent pending with a strong business plan may be worth 1%

[57] Boltuck RD, Riker DA, Charles Rivers and Associates. Estimating the Cost to PhRMA Member Companies of Inadequate Intellectual Property Protection: A Study of Five Priority Countries and 20 Drug Markets. February 2000.
[58] http://www.cdc.gov/od/ads/techtran/forms/cradaa.htm
[59] Gross M. Actual Royalty Rates in Patent, Know-how and Computer program-License Agreements. *CASRIP Newsletter*, 1998, 413. (http://www.law.washington.edu/casrip/newsletter/newsv4i3gross.html).
[60] http://novelint.com/royaltyrates.html

- An issued patent may be worth 2%
- A patent with a prototype, such as a pharmaceutical with pre-clinical testing may be worth 2-3%
- A pharmaceutical with clinical trials may be worth 3-4%
- A proven drug with FDA approval may be worth 5-7%
- A drug with market share, such as one pharma distributing through another, may be worth 8-10%.

Rob McInnes, a partner in the law firm Baldwin, Shelston, Waters, Vice-President of the Licensing Executives Society (LES) of Australia and New Zealand and Chair of the LES International Working Group on technology transfer from universities and government research institutes, presented these data in a presentation to an intellectual property management workshop in New Zealand. As a rule of thumb, the licensor should receive around 25% of the gain from the use of the patent. Median royalty rates from LES Surveys were as follows:[61]

Automotive 4.0%	Chemicals 3.6%	Computers 4.0%	Cons. Goods 5.0%
Electronics 4.0%	Energy 5.0%	Environment 5.0%	Food 2.8%
Healthcare 4.8%	Internet 7.5%	Machinery/tools 4.5%	Media/ent.8.0%
Pharma & Bio 5.1%	Semiconductors 3.2%	Software 6.8%	

Q. Todd Dickenson, former Director of the United States Patent and Trademark Office and a former Undersecretary of Commerce, at a October 2002 meeting of the Trans Atlantic Consumer Dialogue's Committee on Intellectual Property, said "a royalty payment of about 4% … is a very standard royalty across all industries. Most royalties run between 2 and 5%".

Jerry Thursby of Emory University and Marie Thursby of the Georgia Institute of Technology and the National Bureau of Economic Research, characterize university patents as follows:[62]

> For all university technologies, an average royalty rate of 2% is common. For pharmaceuticals the maximum rate one typically encounters for university technologies is 5%; however, the rates are usually closer to 1.5%.

4.2 Consumer electronics

4.2.1 IBM

IBM has the following information on its web page regarding licensing practices:[63]

[61] McInnes, R. Effective Strategies to Manage and Commercialise IP. August 2003. Compiled by LES Surveys, http://www.frst.govt.nz/business/articles/IPStrategyforNZ(generic)2003.pdf
[62] Thursby J, Thursby M. University Licensing under Bayh-Dole: What are the Issues and Evidence? May 2003.
[63] http://www.ibm.com/ibm/licensing/patents/practices.shtml

> *IBM Worldwide Patent Licensing Practices*
> IBM has an open approach to patent licensing for products in the Information Technology (IT) field, and is generally willing to grant nonexclusive licenses under reasonable and nondiscriminatory terms and conditions to those who in turn, respect IBM's intellectual property (IP) rights. An exception to this open licensing practice is for patents directed to ornamental designs. These address the "look" of a product and are not normally licensed. IBM also has patents relating to products outside of the IT field, such as apparatus patents that cover machinery used to manufacture IT products. These may be available for licensing at IBM's discretion.

For products in the IT field that practice an IBM patent, the royalty rate follows the guideline of 1% of the selling price of that product. If more than one patent is practiced in a product, the maximum rate is 5% of the selling price of that product.

4.2.2 3G Patent Platform Partnership and essential wireless patents

The concept of *essential patents* is fundamental to many standards-based patent pools. One example is the effort to obtain agreement on licensing terms for the 3G Patent Platform Partnership. [64]

> In November 2002, the European Commission (EC) gave telecom companies permission to establish five patent licensing and evaluation structures - referred to as patent platforms. According to the EC, these will "help streamline the licensing of *essential* patents, reduce license fees for the patents, and aid in the rapid introduction of third-generation wireless services". The patent platforms were implemented by the 3G Patent Platform Partnership (3G3P), which comprises eight operators and 11 manufacturers and began operating last month. 3G3P will identify, with a high degree of credibility within the industry, patents that are technologically essential for the manufacture of 3G products, such as terminals and base stations.
>
> Also last November, in another encouraging development for W-CDMA, industry-leaders NTT DoCoMo, Ericsson, Nokia and Siemens introduced licensing arrangements that mean essential patents for W-CDMA are licensed at rates proportional to how many essential patents are owned by each company. The aim is to set a benchmark for all holders of W-CDMA technology patents, to achieve fair and reasonable royalty rates and to keep the cumulative royalty rate below 5%.

[64] W-CDMA licensees join forces. Wireless Web. 14 February 2003 (http://wireless.iop.org/articles/news/4/2/4/1).

5 Policy framework for remuneration and non-voluntary use of patents on medicines

SECTION OVERVIEW

There are a wide variety of potential policy frameworks from which to draw in devising compulsory licensing remuneration guidelines or systems.

Some of these alternatives - such as ensuring no lost profits to the patent holder - ensure that remuneration rates will be high, thus undermining compulsory licensing's promise of lower prices and expanded access. Others, such as economic regulatory models and many formulations of pharmacoeconomic approaches, are so complicated that they are likely to deter countries from issuing licences for fear of the complexities of setting royalties.

Other approaches suggest case-by-case consideration of a range of factors - such as importance of the patented invention, per capita wealth, and the patent holder's actual research and development expenditures for the invention - that can be tuned to promote access and ease of administration.

Although ease of administration may require a trade off with precision, a system overly focused on precision is likely to be too cumbersome to be practical, particularly in developing countries with resource constraints.

Any compensation system will need to confront certain practical issues, beyond ease of administration. Transparency and predictability are important to ensure fairness and to facilitate voluntary licensing. The system must be configured to handle products that are covered by multiple patents, as is the norm with pharmaceutical products. The system should be designed to permit exports to the maximum extent possible consistent with international trade obligations - exports will increase economies of scale and reduce per-unit prices. The system must make a determination of whether royalty rates will be determined as a percentage of the cost of the generic product or the branded product, or whether both will be considered in certain circumstances.

An overriding consideration at all times should be that royalty obligations should not undermine access - the key goal sought from the exercise of compulsory licensing of pharmaceuticals. While one should be mindful of the real costs of R&D, developing country governments especially should be cognizant that the small size of developing country markets means remuneration in these markets will not have a first order effect on R&D. They should also recognize that governments have options to support R&D through a variety of mechanisms other than the patent system.

Government's may choose any number of different policy objectives and approaches when setting remuneration for non-voluntary use of a patent. The World Bank, in a meeting in Washington, DC, on 2 June 2003, reviewed some of them, as outlined hereafter.

5.1 Lost profits with willing buyer-willing seller

A view supportive of strong patent rights and high levels of remuneration based upon lost profits was presented by Professor Martin Adelman.[65]

> … the patent system is designed to require that each generation pay for research and development costs associated with the development of new drugs with the understanding that the next generation will get them free of those costs. … The TRIPS Agreement permits compulsory licensing, but only if the licensee pays a royalty equal to adequate damages. If those damages are the *actual damages*, which of course is the only type of damage award that would be adequate, then compulsory licensing is only useful when the patent owner is unwilling or unable to provide a sufficient supply of a needed drug. … If the patent owner is willing and able to supply the needed drug, there is no economic advantage to purchasing it elsewhere using the mechanism of a compulsory license or using the power of eminent domain possessed by governments such as ours. Of course it may turn out that even these low prices are too high for the low-income countries. In such a case there is the need for a subsidy, but that is that same situation as we have in the absence of patent protection and should be solved in the same way. If, of course, a pharmaceutical company refuses to sell its patented pharmaceutical in a low-income country at its profit maximizing price which would, of course, be a low price, then there should be a compulsory licensing remedy with damages based on the profit-maximizing low price.[66]

In the Adelman scenario, companies would always be made whole for lost profits that they would have earned if the compulsory licence had not been issued, with the remuneration based upon the company's profit maximizing price. His analysis assumes that if the patent owner can avoid parallel trade or reference pricing, the profit maximizing price will be considerably lower in poorer country, which is the same assumption offered by Patricia Danzon[67] and others. In practice, patent owners often see lower prices in any one country leading to demands for lower prices in other countries (a point acknowledged by Adelman and Danzon), and, as acknowledged by Adelman, unequal income distributions globally and also within countries will provide economic incentives to price goods for elites (defined either globally or locally). For example, the income distribution in South Africa is so unequal that, even without parallel trade or reference pricing, the domestic profit-maximizing prices for some essential goods will be prices that are only affordable to

[65] Adelman M. The role of patents in the quest for affordable access to drugs. Paper presented at the World Bank, 2 June 2003.

[66] Adelman notes the possibility that the prices would not be low because of "niche-pricing" strategies discussed by Scherer and Watal.

[67] Danzon PM, Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents. December 2001.

the top decile of wage earners, and outcome that is inconsistent with the Doha Declaration mandate to promote "access to medicines for all".

5.2 Ramsey pricing model with budget and social welfare weights

A quite different scenario was presented at the World Bank Seminar on 2 June 2003 by Professors William Jack and Jean Lanjouw.[68] Jack and Lanjouw presented a Ramsey pricing model[69]that included both a budget constraint (innovators were only compensated for appropriate risk adjusted costs) and weights to reflect social values regarding preferences to reduce inequality. With reasonable values assumed for the social weights, Jack and Lanjouw conclude that royalties would be very low or even negative in developing countries.

> In particular, we have considered how extreme inequality in the distribution of world income, coupled with a concern therefor, leads to adjustments to standard pricing prescriptions. With these adjustments, poor countries should not necessarily cover their own marginal costs of drug production and distribution. In particular, these countries should not necessarily share in any of the costs of R&D. Also, the pricing structure is not related to that which would be chosen by a monopolist in a simple (proportional) way. Both of these results are at odds with standard analyses which do not take explicit account of distributional concerns.

The presentation of the Ramsey pricing model by Jack and Lanjouw differed in important details from the presentations on Ramsey pricing by Danzon and others who promote the benefits of unfettered market pricing combined with price discrimination. Danzon states that pharmaceutical products protected by patent do not typically have monopoly power, since free entry for new products can lead to competition from therapeutically equivalent products. By making this convenient assumption, the Danzon-modified Ramsey rule becomes identical to the profit maximizing price charged by a monopolist - albeit now with an association with Ramsey that suggests the monopoly price is also the optimal price for society. While the Danzon assumption regarding the lack of monopoly power wielded by the patent owner is undoubtedly *true* for some medicines, it is without a doubt *untrue* for other medicines, including for example the antiretrovirals used in highly active antiretroviral therapy (HAART) treatment where there is ample evidence of market power and limited medical substitutability of products. Jack and Lanjouw not only restore the budget constraint, which was part of the original Ramsey model, but also add social welfare weights to reflect more realistically the social values that shape policy on access to medicines.

Ramsey pricing rules promise an abstract mechanism to achieve economic efficiency, but even in the early debates over optimal tax theory (the problem Ramsey was addressing), it was recognized that Ramsey pricing would have perverse results

[68] Jack W, Lanjouw JO. Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute? Center for Global Development Working Paper No. 28, 9 June 2003.

[69] Ramsey F. A contribution to the theory of taxation. *Economic Journal*, 1927, 37:47-61. The Ramsey approach is often presented in regard to pricing of medicines without the budget constraint and without welfare weights, and when these elements are not considered, it simply becomes the pricing rule for a monopolist.

when goods such as medicines are involved. In the context of taxes, a Ramsey efficient tax system would place very high taxes on insulin and other essential medicines, since demand elasticities for such goods were considered to be low relative to less essential goods. Governments typically avoid levying the highest taxes on the most essential goods and indeed in many cases even exempt such goods from taxation. Jack and Lanjouw seek to remedy the undesirable distributional unfairness that would normally be associated with a plain Ramsey rule and, in doing so, present results that are consistent with very low *(*even zero or negative*)* royalties in lower income countries.

5.3 Cost-based economic regulation

Aidan Hollis has focused on the special market failures that obtain when a medicine is either essential for the treatment of an important illness and access to the medicine is required by national legislation, or when income inequalities provide incentives to price goods for elites.[70] When the patients have a *right* to treatment but a third party must pay, there is no true bargaining leverage, and the seller can exploit the party that pays for the medicine. In referring to cases where patent protection has very weak effects on stimulating innovation but large effects in terms of harming poor consumers, Hollis notes that: [71]

> In such a case, government-granted compulsory licenses can be used to mitigate the negative effects of government-granted patents. In the case of government-funded essential drugs, the government may find itself hostage to a combination of patent laws and constitutional imperatives which allows drug firms to charge virtually unlimited prices. The taxation required to fund expensive government-provided drugs will again create large deadweight losses. In this case, compulsory licensing can again be used to restore balance to negotiating positions, reasonableness to pricing, and a better trade-off between the incentive to innovate and current welfare losses.

In his presentation at the 2 June 2003 World Bank seminar on compensation on a compulsory licence, Hollis discussed models of remuneration for R&D investments that might be adopted from economic regulation of public utilities.[72] The Hollis paper can be read either as a roadmap for economic regulation of royalty payments or a sobering reminder of the difficulties and risks presented by economic regulation. Hollis notes that an economic regulation approach based upon the cost of developing and manufacturing medicines would have high informational requirements, require considerable resources to resolve disputes, and must contend with well documented cases of regulated firms seeking to manipulate or even corrupt regulatory regimes. Hollis also notes that Ramsey optimal pricing outcomes are rare in real regulatory settings, for a variety of reasons.

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[70] Hollis A. Commentary: The link between publicly funded health care and compulsory licensing. *Canadian Medical Association Journal*, 1 October 2002, 167 (7). Hollis A. Economic Analysis of the Need for a Compulsory License Remedy to Promote Access to Essential Medicines, 2003: "Whether essential medicines are state-provided or privately purchased, unusual characteristics of the demand for essential medicines provide a strong justification for the use of compulsory licensing."

[71] Hollis A. Royalties for Compulsory Licensing of AIDS drugs. 2003.

[72] Hollis A. Compulsory Licensing: Insights from Economic Regulation. Ottawa, May 2003.

5.4 Reasonable royalty approach

At the 2 June 2003 World Bank seminar, FM Scherer reviewed the historical experience with compulsory licensing of pharmaceutical patents in the United States, Canada, the United Kingdom and other countries:[73]

> To sum up, there is wide variation in the way responsible government agencies and courts have set the amount of remuneration awarded to patent holders when patents have been subjected to compulsory licensing. The United Kingdom has provided the most generous remuneration in its drug patent licensing decisions; the United States the least generous remuneration in key antitrust case orders. None of the royalty determinations on which information is available have established rates approaching those that would emerge under a "lost profits" criterion.
>
> There are important lessons here for nations that seek to apply the compulsory licensing provisions available under the TRIPS Agreement. High royalty rates, as in the British drug licensing experience, could undermine the objective of making drugs widely available to low-income consumers on competitive terms; low royalty rates, as in the Canadian experience, could provide the basis, assuming that other conditions are satisfied, for competitive drug supplies while compensating patent holders to at least some extent for their research and development contributions. The choices made in industrialized nations provide ample precedent for royalty-setting on the modest side of the range of possibilities.

5.5 Professor Reichman's seven factors for evaluating reasonable royalties in developing countries.

In a report studying the experience of the United States and Canada with royalty payments, Professor Jerome Reichman offered *(seven)* modifications to the United States Georgia-Pacific factors, to address important social and development objectives, and concludes that, with these changes, royalties for non-commercial use would normally range from 4 to 8% of the generic price.[74]

> In determining reasonable royalties for government use as well as in competition cases [a country] may find the *Georgia Pacific* factors of some relevance, but they should not be blindly applied. The *Georgia Pacific* factors tend to capture key aspects of the private rights holders interests, but they ignore equally key offsetting factors bearing on the public interest. For example, developing country evaluators would be advised to take account of the following additional factors:
>
> 1. Particular social impact of the invention such as the therapeutic value of a pharmaceutical product;

[73] Scherer FM. The Economics of Compulsory Drug Patent Licensing. Paper Presented at the World Bank, 2 June 2003.
[74] Reichman JH. Compulsory Licenses: History and Legal Principles. 2003.

2. Per capita GDP and the ability of the general population to pay for needed or essential products;
3. The existence of crises or emergency conditions, such as environmental disasters or epidemics threatening public health;
4. Vital needs of national economic development, national security, or the like;
5. The extent to which the underlying research and development was covered by public funds in either the country of origin or the importing country;
6. The extent to which the investment in research and development was directed at developing countries, or made in the country imposing the compulsory license, which would pull for a higher royalty;
7. The extent to which imposition of a compulsory license would broaden consumption beyond that likely to occur under an exclusive license, and this broadening of consumption (or of producers) could yield a multiplier or lottery effect that would translate into revenues beyond investment-backed expectations.

These and other public interest factors should be weighed against those of the *Georgia Pacific* factors to arrive at a reasonable royalty tailored to the different circumstances found in developing countries.

If the American experience is used as a base, reasonable royalties could range from a low of zero to 3% in antitrust cases to a high of 17% given in one recent government use case. The norm for government use prior to 1993 was, however, 6%, and even now, it seems hard to obtain more than 10% under the *Georgia Pacific* factors, although rates of 16 and 17% are reported. We believe that, if the offsetting factors listed above are applied, royalties in a government use context may range between 4 and 8% of the price the government charges the public, depending on the circumstances that motivated public noncommercial use in the first place.

5.6 Pharmacoeconomic approach

From the point of view of health care management, a more explicit economic model for setting remuneration would be one based upon modern pharmacoeconomic analysis. This would typically focus on the benefits of new inventions.[75]

Reimbursement policies by many national governments and insurance bodies increasingly rely upon systematic evaluation of the benefits of medicines. In a recent survey of 11 member countries of the Organisation for Economic Co-operation and Development (OECD), Michael Dickson, Jeremy Hurst and Stéphane Jacobzone note:[76]

[75] This is a different approach than the cost-based economic regulation referred to by Hollis.
[76] Dickson M, Hurst J, Jacobzone S. *Survey of Pharmacoeconomic Assessment Activity in Eleven Countries.* OECD Health Working Papers No. 4, DELSA/ELSA/WD/HEA (2003)4.

> Policy-makers responsible for publicly-funded drug programmes face continual pressures between the demand to accommodate a steady stream of new and more effective drugs and the ongoing requirement to control costs.
>
> In the face of these pressures, a growing number of OECD countries are applying 'pharmacoeconomic assessment' (health technology assessment for drugs) - to new drugs to guide decisions about accepting such products for reimbursement under their public programme, or to inform negotiations about pricing. …
>
> The most important motive for performing pharmacoeconomic assessments appears to be establishing the value-for-money of new drugs, to inform decisions on reimbursement and/or pricing. It appears to be viewed in some countries as a tool to assess the cost-effectiveness of new drugs against an implicit or explicit benchmark, and in other countries as a tool that can inform the pricing negotiation in a way that pursues cost-effectiveness.[77]

Australia pioneered the use of pharmacoeconomic analysis of reimbursement policies[78]and today most developed economies are increasing their capacity to make more rational allocations of scarce resources for medicine purchases. The approach originally developed in Australia is particularly interesting for developing countries, in that it optimized reimbursements within budget constraints. Products competed against each other for a share of the budget. In a similar model, a country might allocate a budget to fund R&D, and then allocate royalty payments among patent holders according the relative pharmacoeconomic benefits of each invention.

For example, a government might decide to allow widespread compulsory licensing in order to make prices of medicines more affordable, in support of the policy of "access to medicines for all" urged by the Doha Declaration on the TRIPS Agreement and Public Health. In order to support R&D on new products, the county could then target a percentage of its pharmaceutical or health care budget to compensate patent owners, with the royalties to each patent owner allocated on the basis of the relative benefits of each invention, possibly based upon transparent and periodically revised guidelines to evaluate benefits.

Another example of a pharmacoeconomic approach would be to set royalties so that the prices of the products were rationally related to both the capacity of the consumer or insurer to pay and the therapeutic value of the invention. An example of this approach is given below, in discussing the Tiered Royalty Method.

The disadvantages of pharmacoeconomic analysis primarily relate to the difficulty of conducting evaluations, including the resources needed for the evaluations, and

[77] Noting further: "The pharmaceutical industry expresses concern that the underlying purpose of assessment is cost-containment and that, as a result, it may stifle innovation. However, there is little evidence from this survey that cost-containment is the dominant aim of assessment or that the level or growth rate of drug expenditure has been reduced as a result of pharmacoeconomic assessment activities (although, strictly speaking, the counterfactual is unknown). There could be benefits to society if assessments led eventually to a rise in the quality of (value added by) innovation."

[78] Henry D. Economic Analysis as an aid to subsidisation decisions: The development of Australian guidelines for pharmaceuticals. *PharmacoEconomics*, 1992, 1:1, 54-67.

resolving disputes, since the evaluations are always subject to different interpretations. Dickson, Hurst and Jacobzone report that Australia has 14 full time persons who conduct the pharmacoeconomic assessments, and the United Kingdom has 23. Japan, Sweden and the United Kingdom all provide administrative appeals of staff decisions, and appeals to courts have occurred in several countries.

5.7 Practical issues

5.7.1 Precision versus ease of administration

According to the 2001 UNDP HDR, the practical mechanisms for compulsory licensing should be straightforward and not too complex.[79]

> Any system that is overly legalistic, expensive to administer or easily manipulated is of little use; the best option is an administrative approach that can be streamlined and procedural.

For developing countries, there are compelling reasons to reduce the complexity of setting remuneration, and there are also practical reasons why this is reasonable. The benefits of precise mapping of royalties to patent owners are small.

1. The scientific uncertainties of the R&D process are large and the process of invention is stochastic. Many of the most important medical discoveries have a very tenuous relationship to the original research programme. Drugs such as levamisole, zidovudine and even Viagra were originally developed for other indications.

2. The size of the market in developing countries is small. For example, without substantial donor support, the entire African market is too small to have a first order effect on R&D decisions for most products.

For these reasons, a system of "rough justice" is a reasonable method of funding R&D. The key macro issue is what the appropriate general level of support for R&D should be. To the degree that the pharmacoeconomic evidence is used, it should be to modify and fine-tune a general royalty guideline approach, without unduly seeking a level of precision in remuneration that is both impossible and unnecessary.

5.7.2 Transparency

There are several reasons to adopt a framework for remuneration that is transparent and predictable, including the following:

1. Predictable remuneration rules facilitate voluntary licensing. By providing predictable rules for remuneration, private parties will find it easier to negotiate voluntary licences. This was one of the main objectives of the Japanese *(discussed below)* and German royalty guidelines.

[79] http://www.undp.org/hdr2001/chapterfive.pdf, page 107.

2. Disclosure of evidence to support claims on remuneration improves policy making. Policy making about remuneration should be informed by information, including for example, evidence regarding:

    i. Actual industry practices on in-licensing and out-licensing of patents,
    ii. Remuneration paid in non-voluntary uses of the patent in other jurisdictions,
    iii. Actual R&D investments costs, by relevant stage of development (preclinical, phase I, II, III trials, post approval research),
    iv. Government support or subsidies for R&D,
    v. Global cumulative revenues and profitability of invention,
    vi. Evidence regarding novelty or utility of invention from foreign patent disputes, and
    vii. Evidence regarding the relative efficacy and innovative nature of the product.

There is ample evidence that patent owners will make unsupported claims regarding R&D investment costs, minimize the role of governments in supporting R&D, and overstate the novelty or efficacy of inventions. Information asymmetries can lead to weak bargaining positions of the uninformed parties, including both governments and consumers. The 2001 UNDP HDR recommends that, when a patent owner registers a dispute over remuneration:

> The onus should fall on the patent holder to back up claims that the royalty rate is inadequate. This will help promote transparency and discourage intimidating but unjustified claims.

5.7.3 Multiple patents

It is often the case that a single product will use several different patents. There are several approaches that can be used to resolve these issues. An overall royalty can be divided among individual patent owners on the basis the relative value of each patent (decided by negotiation or by arbitration), a simple allocation based upon the number of patents (used in some patent pools), or by another method. In some United Kingdom cases, Courts have required the division to be made before the compulsory licence can be used. This will in some cases delay the availability of the compulsory licence. A better system is to place the total royalty payments into an escrow account and have the money divided among the various patent owners when they can resolve the issue of the appropriate division of the royalties. It is recommended that the various patent owners be asked to negotiate between themselves and, in the event that they fail to reach a voluntary agreement upon the division, to enter into arbitration, with the cost of the arbitration paid by the various patent owners. Alternatively, the government could appoint a panel of experts to resolve the issue on behalf of the patent owners.

5.7.4 Exports with parallel patents in import market

Economies of scale are very important for some medical products, including in particular active pharmaceutical ingredients, vaccines, biologics, diagnostic and other medical devices, as well as for some finished pharmaceutical products.

Normally, exports of products should be permitted, to allow generic manufacturers to achieve more efficient scale economies, and also to serve the needs of countries that do not have a domestic source of affordable medicines. In some cases, there will be parallel patents in the export market. When there are patents in both the exporting and the importing country, the royalties in the exporting country should either be waived, or reduced by the amount of the royalties paid in the importing market.

In the 30 August 2003 Decision by the WTO on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the WTO decided to waive the obligation of the *importing* country to pay remuneration.[80]

> Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

This element of the WTO Decision was criticized on the grounds that it is more appropriate for the importing country to determine remuneration than the exporting country. The particular approach set out by the 30 August 2003 WTO Decision will only apply to compulsory licences issued under the "system" created for exports to countries that do not have the capacity to manufacture pharmaceuticals. It will not apply in general to "non-predominant" exports, or authorizations issued as a remedy to anti-competitive practices.

5.7.5 Appropriate base for royalty - brand or generic price?

The amount of a royalty will depend upon both the rate and the base. Many governments have considered two primary issues. First, should the royalty be based upon the price of the product sold by the patent owner, or the price of the generic competitor? In several United Kingdom licence of right cases involving pharmaceutical drugs, the Courts used the price of the patent owner's product to set the royalty. This approach is more appropriate if the policy objective is to protect the commercial interests of the patent owner (such is the objective in infringement cases) and the patent is used in an identical product, such as a drug. In Canada, Japan, the Philippines and the United States (government use and competition cases) and in many other jurisdictions, the competitor's price is often the basis for the royalty. The use of the competitor's price as a royalty base is more appropriate for cases where the policy objective is either to obtain lower prices (Canada, Malaysia Philippines, etc.), or create or approximate a competitive market structure (Japan, United States competition cases such as the Microsoft compulsory licence and United Kingdom cases involving electronics).

5.7.6 Appropriate royalty base – cost or value?

In some respects, the alternatives for the royalty base that are described above differ in that one is based upon the costs of manufacturing (the competitive generic price), while the other is based upon a notion of the value of the product to the patient (the sales price under a patent monopoly).

[80] WT/L/540, 2 September 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Decision of the General Council of 30 August 2003.

There are two considerable advantages of basing royalties on the competitive cost of the product. First, if the policy goal is to promote access to an invention, a royalty based upon the competitive cost is a transparent and understandable compromise between the lowest price possible and the need to finance innovation. A policy of granting open licences to all generic producers with a royalty of 2 to 5% will ensure that prices will only be slightly higher than the prices that would obtain in a free market without patents. The higher the percentage, the more access is compromised in favour of support for R&D. Secondly, it is often much easier to set royalties based upon the generic sales prices than to establish the correct "value" of the invention. A system that is easy to understand and administer has important advantages.

On the other hand, a cost-based system can lead to irrational results, particularly as applied to products that have far different manufacturing costs, but similar therapeutic value. One illustration of this concerns two important AIDS drugs. In 2004, the United States price for the drug efavirenz was US$ 4 781, and for the drug stavudine the United States price was US$ 3 795. In a market where drug prices more closely correspond to the perceived value of the products, efavirenz is about 25% more expensive than stavudine. But stavudine is much less expensive to manufacture. In markets where there was generic competition, efavirenz sold for US$ 329, while stavudine was selling for US$ 21. A 4% royalty on the best generic price would yield US$ 13.16 per year for efavirenz, but only US$ 0.84 for stavudine. Moreover, assuming efficient distribution networks, the royalty for both products would be roughly the same, no matter where the products were sold. Poor countries facing an AIDS crisis like Uganda would pay the same price as middle-income countries that have a lesser incidence of AIDS.

In general, the problems with a cost-based royalty system are clearer when higher income countries issue licences. For lower income countries, the administrative advantages of transparency and simplicity favour the cost-based approaches.

5.7.7 Appropriate royalty base – complex inventions

A second issue concerns situations where the patent is only a small part of a larger product. Professor Reichman discusses this issue as follows:[81]

> *(1) The Royalty Base*
>
> The problem here is that a patented invention may constitute only one component of a larger whole. When the government takes the patent, the patentee normally claims compensation for the ensemble, and the courts have been sympathetic to such claims. However, demarking the limits of the actionable ensemble may pose difficult questions.
>
> In principle, courts apply an "entire market value rule" to determine which, if any, unpatented components should be included in the compensation base. This method "allows the recovery of damages based on the value of an entire apparatus containing several features, even though only one feature is patented."

[81] Reichman JH. Compulsory Licenses: History and Legal Principles. 2003.

> However, to avoid overcompensation, the court must carefully evaluate how far outside of the patented invention the royalty base should extend. The least controversial results occur when courts include in the royalty base patented and unpatented components that function together to achieve the desired functional result.
>
> The Court of Claims, however, has experimented with a more controversial test of "financial and marketing dependence" rather than simple physical joinder of the components, as the test to determine whether an unpatented item should be included in the royalty base under the entire market value rule. This test focuses on the extent to which the expected financial returns depend on the marketing of the ensemble rather than of the patented article alone. If the courts wholeheartedly embrace this test, it could considerably expand the compensation base to which the percentage royalty rates ultimately apply.
>
> At present, according to Schlitz and McGrath, spare parts "are generally not considered to be part of the royalty base." Even here, however, there may be an exception for "first-time spare parts."

The 1998 Japanese royalty guidelines (discussed below) address this issue by assigning a "utilization ratio" to each patent, which takes into account the importance of the invention relative to the product. When the invention is the product, the ratio is 100%. Otherwise the ratio is the fraction that represents the value of the part compared to the value of the whole invention. (The utilization ratio can be no larger than 100%.)

5.8 The royalty obligation should not undermine access

As discussed above, for developing countries in general and, in particular, for those countries that have the fewest resources or which face public health crises, royalties should be relatively low. The primary reasons for this are as follows:

1. Royalties must be affordable to promote access to medicines.

2. When the market for medicines in developing countries is but a small fraction of the global market, remuneration will not have a first order impact on global R&D decisions.

3. The benefits of increased access to medicines in the poorest countries are greater than the benefits of higher contributions to global R&D that would obtain from high royalty payments.

4. Governments can support R&D though a variety of mechanisms, including some that are less restrictive in terms of access to medicines, or more efficient in terms of health care priorities.

Simply put, as royalties increase, prices rise. If the overriding policy objective is to increase access to the medicine, when access is constrained by the price the royalties have to be modest or the policy objective will be undermined.

It is important to note that when a patent right contributes to a lack of access to essential medicines, there is a very high level of dysfunction for an intellectual property regime. This is a more serious concern than in cases where prices are abusively high, but still affordable. When prices are so high that the poor go without access to a life-saving medicine, the social cost is unconscionably high. This view is at the core of the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which declared:

> 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.
>
> In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

The policy objective of promoting access to medicines is central to the decision regarding the general level of remuneration and proposals for royalties that undermine access goals should be rejected.

5.9 Remuneration for patents is only one aspect of the systems that provide economic incentives for invention and development of new products

As noted above, in the pre-NAFTA Canadian compulsory licensing regime, Roche objected to a compulsory licence royalty rate that was lower than the percentage of turnover the patent owner was investing in R&D. The Court rejected the Roche appeal on the grounds that the overriding policy objective of promoting competition and lower medicine prices was paramount. In addition, the Court noted that that the patented invention is only one aspect of the market for medicines.

According to DiMasi et al, approximately 30% of private R&D outlays are focused on preclinical discovery,[82] the research phase typically most closely associated with patent rights, while about 32% of R&D outlays are spent on the clinical trials used to support the product approval, and about 35% of total outlays are spent on post-approval clinical trials,[83] many of which are primarily designed to achieve marketing objectives.[84]

Investments in clinical trials are typically not considered sufficiently inventive to warrant an award of a patent. However, these investments often do qualify for other

[82] DiMasi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 2003, 22: 151-185.
[83] The annual PhRMA survey has somewhat different percentages.
[84] See, for more details, Love J. Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines. 22 September 2003.

non-patent types of protection. The TRIPS Agreement provides separate protections for undisclosed data from clinical trials under its Article 39.3. The United States has implemented Article 39.3 of the TRIPS Agreement by granting a five-year exclusive right to rely upon clinical trials that support the safety and efficacy of new chemical entities (and a three-year right for some other approvals). The European Union grants exclusive rights to rely upon clinical trial data for 6 to 10 years. Both the United States and the European Union have included similar protections in various bilateral trade agreements. The United States, Europe and several other OECD member countries also grant (7 to 10 year) exclusive rights to market orphan products that do not qualify for patent protection, and the United States grants six-month exclusive marketing extensions as a reward for clinical trials on pediatric uses of medicines.

Some analysts claim that *sui generis* regimes designed to protect investment should avoid exclusive rights models, in favour of non-exclusive *cost-sharing* approaches, such as the one used in the United States to protect non-patented investments in R&D needed for regulatory approvals of chemicals used in agriculture.[85]

Firms also make investments in R&D that are protected by copyright, trademarks, *sui generis* database regimes and trade secrets. Trade secret protection is particularly important in biotechnology, vaccines and in difficult to manufacture products, and know-how or data are often the subject of separate licensing and royalty agreements.

Thus, the patent is only one of several instruments to protect investments in R&D and, in some cases, not the most important one.

A final consideration is the evidence that the current private sector R&D agenda is highly focused on non-innovative products. The United States Food and Drug Administration reports that only 31% of new molecular entities are significantly better than existing medicines,[86]and only one sixth of the private R&D investments

[85] Federal Insecticide, Fungicide, and Rodenticide Act. This is an environmental protection law that requires firms to provide registration data to the US Federal Government. The firm has exclusive rights to the data, subject to procedures for a non-voluntary licences by third parties. The person seeking the non-voluntary license must first seek to negotiate a voluntary licence. That failing, a person can elect to begin binding arbitration. According to statute 7 USC Chapter 6, Subchapter II, § 136a. Registration of pesticides:

> 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.

[86] Love J. Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines. 22 September 2003.

are spent on the development of these new innovative products.[87] If one accepts the claim by pharmaceutical trade associations that 15% is the average reinvestment in R&D by the major research-based companies, the amount invested in innovative products is much lower - estimated at 2.5% of turnover and, as noted above, much of this is invested in non-patentable activity.

[87] About 25% is invested in R&D on existing products, and only 20% of the investment in new products is spent on the innovative medicines.

6 Royalty guidelines

SECTION OVERVIEW

Reasons of transparency, predictability and ease of administration, among others, argue strongly for countries to adopt royalty guidelines for compulsory licensing cases. Such guidelines establish a framework by which royalties may be set in individual cases, giving guidance to private parties and adjudicators alike about how remuneration will be set and the range of possible royalty rates.

This section presents and compares four models for royalty guidelines.

The 2001/UNDP guidelines recommended a standard 4% royalty, with variation up or down by 2% depending on therapeutic value and government contribution to the costs of R&D for the product.

The 1998/JPO royalty guidelines for licences of government-owned patents were set between 0 and 6%. Rates vary based on expected profits from the licensed product, the importance of the patented invention to the final product, the degree of additional research needed to bring the invention to market, the public interest in working of the patent, the novelty of the product, and other factors. Applying this model to medicines suggests looking at such factors as the extent to which the invention benefited from publicly funded research, the therapeutic value of the invention, and the need to respond to public health exigencies.

The 2005/Canadian guidelines for export of medicines pursuant to the waiver of Article 31(f) of the TRIPS Agreement establish 4% as the upper limit for royalties, and then diminish this rate based on the importing country's UNHDI position.

All these approaches have important advantages, but one important limitation is that they base royalty rates on the cost of the generic product. Except for the Canadian guidelines, this rate is determined without regard to the circumstances of the country issuing the licence - meaning royalties will not vary between Denmark and Uganda (there will be variance with the Canadian model, but not as much as the variance between national wealth).

A tiered royalty model (TRM) presented here determines a global base royalty based on the price of the product in rich countries such as the United States or in the European Union, and then adjusts the royalty relative to country capacity to pay for medicines. This capacity is based either on per capita income or national income per person needing treatment for a high-incidence disease. Royalty rates under this model are easily calculated and vary considerably between industrialized and developing countries.

As discussed above, a system of remuneration based upon royalty guidelines has advantages in terms of transparency and predictability. Three models for royalty guidelines are presented. The first was recommended in the 2001 UNDP HDR. The second is the 1998 JPO guidelines for determining royalty rates for licensing patents owned by the Japanese Government. The third approach, referred to as the TRM, is one that seeks to systematically relate royalties to economic measures of affordability and the economic value of the invention.

6.1 2001/UNDP royalty guidelines

In its 2001 HDR, the UNDP recommended that developing countries adopt royalty guidelines in order to provide greater transparency and predictability. UNDP specifically recommended that rates normally be set at 4%, and adjusted upwards as much as 2% for products of particular therapeutic value, or reduced as much as 2% when the development of the product had been partly supported with public funds, for a range of 2 to 6%.

For illustration purposes, the UNDP approach is applied to three important AIDS drugs.

Application of UNDP guidelines to zidovudine, lamivudine and nevirapine				
	Standard rate	**Therapeutic value**	**Government support**	**Total**
zidovudine	0.04	0.02	-0.02	0.04
lamivudine	0.04	0.02	-0.01	0.05
nevirapine	0.04	0.02	-0.01	0.05

6.2 1998/JPO royalty guidelines

Japan adopted patent royalty guidelines more than fifty years ago, and has long had broad authority to issue compulsory licences. During this time, Japan became a global power in high technology industries and has one of the highest living standards in the world.

On 29 June 1998, the JPO reported new guidelines for determining royalty rates for licensing patents owned by the Japanese Government. While the guidelines were officially for setting royalties on government-owned patents, they were considered by some a *de facto* standard, and were influential in the private sector. Previously the rates were 2 to 4% of net sales, and the guidelines had not changed for 50 years. Under the revised guidelines, the royalties were 0 to 6%, according to the following formula:

Royalty rate = value * utilization ratio * increase/decrease ratio * exploration ratio

6.2.1 JPO value of working variable

One of three standard rates are first assigned, on the basis of the value of working the invention:

High	4% (expected profits 30%)
Medium	3% (expected profits 20%)
Low	2% (expected profits 10%)

6.2.2 JPO utilization ratio

Next, a "utilization ratio" is applied, which takes into account the importance of the invention relative to the product. When the invention is the product, the ratio is 100%. Otherwise the ratio is the fraction that represents the value of the part compared to the value of the whole invention. (The utilization ratio can be no larger than 100%.)

For example, if patents on zidovudine were needed for a 3 drug fixed-dose combination, one might assign a utilization ratio of 1/3. If a patent was a relatively unimportant formulation or process patent, the ratio might be low, such as 5 to 15%.

6.2.3 JPO increase/decrease ratio

The increase/decrease ratio goes from 50 to 150%, and applies to the following cases:

(a) The working of the patent is particularly necessary for public interest,
(b) A royalty fee is particularly high or low,
(c) The patent is not particularly novel and other similar inventions exist,
(d) There are other special conditions.

6.2.4 JPO exploration ratio

This ratio goes from 50 to 100%. The lower ratio is used when

(a) A large sum is required to conduct research for the industrialization of an invention,
(b) A large sum is required to advertise and promote a product employing an invention.

6.3 Additional guidance for use of JPO royalty guidelines for pharmaceuticals

The following are recommendations for additional guidance on how one could use the JPO royalty guidelines for pharmaceutical products.

6.3.1 Additional guidance for value variable

The JPO value variable could be evaluated under the following criteria:

(a) 2% for a product that does not represent a significant advance in therapeutic benefits,
(b) 3 to 4% for a product that provides a significant advance in therapeutic benefits.

Independent evidence of (a) and (b) would be evaluations by regulatory bodies (United States Food and Drug Administration rankings for standard or priority approval status, similar designations in Australia, Canada or other countries) or *Prescrire International* evaluations.

6.3.2 Additional guidance for the increase/decrease ratio

Consider:

1. The degree to which the invention benefited from publicly funded research,
2. Evidence of particularly high therapeutic value (best in class),
3. Evidence the product was particularly innovative (first in class),
4. Evidence the private cost of development was relatively high or low,
5. Evidence that manufacturing costs are particularly low (increase royalty for products that are particularly inexpensive to manufacture),
6. The extent to which the investment in research and development was directed at developing countries, or conducted in [a country],
7. Evidence that the patent owner engages in R&D and technology transfer activities,
8. The need to correct anti-competitive practices,
9. Public health needs, including the benefits of increased access to medicines,
10. The need to respond to crises or emergency conditions, such as environmental disasters or epidemics threatening public health,
11. Other public interest considerations.

6.3.3 Illustration of 1998 JPO royalty guidelines for pharmaceuticals

Below the JPO royalty guidelines are applied to the patents on the three AIDS drugs, based upon the following factual conclusions:

> Zidovudine benefited from an extensive role by the government in development of the product. Zidovudine was first in its therapeutic class. The private cost of development through approval was low.
>
> Lamivudine benefited from some government-supported research. Lamivudine was fourth in its therapeutic class, and is one of the best products in its therapeutic class.
>
> Nevirapine benefited from some government supported trials upon which product approval was based. Nevirapine was first in its therapeutic class, and current second in market share in its therapeutic class in the United States. Nevirapine is the least expensive to manufacture "third drug" in HAART treatment.

Each product was awarded the highest value variable of 0.04. Zidovudine was given an increase/decrease ratio of 50%, based largely upon the extensive role of government support in the development of the product (including the discovery of the molecule), and the relatively low private cost of R&D for zidovudine approval. Lamivudine was given an increase/decrease ratio of 100%, based upon a decrease for government support but an increase for therapeutic benefit. Nevirapine was given an increase/decrease ratio of 150%, with the decrease in the role of government R&D

offset by innovative nature of the product (first in class) and low cost of manufacturing nevirapine (compared to other "third drugs" in HAART treatment). Since all three products are already successful in the market, the exploration ratio is set at the maximum of 100.

All three drugs are sold both as stand-alone products, and as part of fixed-dose combinations.

6.3.4 Stand-alone royalties

Patents	Value	Utilization ratio %	Increase/decrease ratio %	Exploration ratio %	Total
zidovudine	0.04	100	50	100	0.02
lamivudine	0.04	100	100	100	0.04
nevirapine	0.04	100	150	100	0.06

6.3.5 Application of the guidelines for fixed-dose combinations

In applying the modified Japanese guidelines to fixed-dose combinations, each patent is assigned a utilization ratio less than 100%. For purposes of division of royalties among patent owners, all patents owned by the same firm are considered together. Two cases are examined for illustration, both involving a fixed-dose combination for the AIDS HAART regime involving three drugs - zidovudine+lamivudine+nevirapine. The "invention" of combining the products is given a 10% utilization ratio. (This would include either the Glaxosmithkline zidovudine+lamivudine or CIPLA zidovudine+lamivudine+nevirapine patents). The patents for the three stand-alone products are each given a utilization ratio of 0.3. In the first case, all three drugs and the combinations are assumed to be under patent.

Fixed-dose combination zidovudine+lamivudine+nevirapine everything patented					
Patents	**Value**	**Utilization ratio %**	**Increase/decrease ratio %**	**Exploration ratio %**	**Total**
zidovudine+ lamivudine+ nevirapine/ zidovudine+ lamivudine	0.04	10	100	100	0.004
zidovudine	0.04	30	50	100	0.006
lamivudine	0.04	30	100	100	0.012
nevirapine	0.04	30	150	100	0.018
				Total	0.04

Fixed-dose combination zidovudine+lamivudine+nevirapine only lamivudine & nevirapine patented					
Patents	**Value**	**Utilization ratio %**	**Increase/decrease ratio %**	**Exploration ratio %**	**Total**
lamivudine	0.04	30	100	100	0.012
nevirapine	0.04	30	150	100	0.018
				Total	0.03

6.4 The Canadian royalty guidelines

In 2005, Canada proposed royalty guidelines for the export of medicines under the Jean Chrétien Pledge to Africa Act, which implements the WTO waiver of Article 31(f) of the TRIPS Agreement. The Canadian royalty guidelines are a sliding scale of the generic sales price. The rate depends entirely upon the location of the importing market and the rank of the importing country in the UNHDI. The formula is one, plus the number of countries on the UNHDI, minus the importing country's rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. The rate is then applied to the generic sales price.

With 177 countries currently in the UNHDI index, the royalty rate can be expressed as:

Royalty rate = 0.04 * [(178) – rank importing country]/177

The Canadian royalty guidelines result in relatively low royalties. The top rate is 4% of the generic sales price, and the lowest rate for 2004 was 0.02%, for Sierra Leone. Weighted by global population, the average rate is 1.9%. Weighted by global rates of HIV infection, the average rate is 1%. Selected royalty rates based upon the 2004 UNHDI rankings are presented in Table R-3. A complete list is given in Table A-1 of the appendix.

Table R-3: Royalty Rates under Canadian Royalty Guidelines - based upon UNDP 2004 HDI		
Country	**2004 HDI Rank**	**Royalty Rate**
Norway	1	4.0
United States	8	3.8
Chile	43	3.1
Brazil	72	2.4
Philippines	83	2.2
Indonesia	111	1.5
India	127	1.2
Swaziland	137	0.9
Zambia	164	0.3
Mozambique	171	0.2
Sierra Leone	177	0.02

6.5 Limits of the 2001/UNDP, 1998/JPO and 2005/Canadian methods

The 2001/UNDP, 1998/JPO and 2005/Canadian royalty guidelines all base the royalty payments on a percentage of the price of the competitor's product – in this case, a generic drug. In a competitive market, the royalty payment will depend upon the cost of manufacturing the generic product. The differences in manufacturing costs are sometimes large, and often unrelated to the benefits of using a product.

For the 2001/UNDP and 1998/JPO approaches the royalty rate is the same in high-, middle- or low-income countries. The Canadian guidelines vary royalty rates by country, but only hint at the differences of affordability between countries.

Consider the examples of stavudine and efavirenz, two important drugs for the treatment of AIDS, each selling for approximately US$ 3 800 and US$ 4 800 per year in the United States market. The cost of manufacturing stavudine is considerably lower than the cost of manufacturing efavirenz. A 4% royalty on stavudine, based upon the 2004 best generic price of US$ 21 per year, would be US$ 0.84 per year. A 4% royalty on efavirenz, based upon the 2004 best generic price of US$ 329, would be $13.16 per year. In both cases, the royalties would not vary by country. Whether the country was Brazil, Denmark, Germany, India, Korea, Thailand or Uganda, the royalty would be the same - US$ 0.84 per year for stavudine or US$ 13.16 per year for efavirenz.

The Canadian royalty guidelines vary the royalty rate by country, but not on the basis of a direct measure of affordability. For example, based upon the 2004 best generic price, the annual royalty for zidovudine, a drug that sold for US$ 3 915 per year in the Unted States, is US$ 5.03 in Germany, US$ 4.27 in Chile, US$ 3.35 in Brazil, and US$ 1.49 in Ghana. The royalties do vary, but not as much as the differences in income. As noted, the Canadian royalty method does not vary royalties according to the benefits of using the product, but rather based on the cost of manufacturing and the country rank in the UNHDI.

6.6 The Tiered Royalty Method (TRM)

The TRM is a proposed guideline for royalties that relies upon (1) a proxy for the therapeutic benefit of the products, and (2) a measure of affordability. It can be implemented without extensive data or analytical resources.

The TRM determines a global base royalty, which is then adjusted for different countries according to measures of affordability.

1. A base royalty is calculated from the price of the product in the United States or European market (where prices are assumed to be both affordable and related to the therapeutic benefits of the product), and a standard royalty rate. In the testing of the approach, a 4% royalty was used, a rate that approximates the average royalty payments for pharmaceutical products in the United States market.

2. The base royalty is adjusted for each country, according to the relative capacity to pay. The proxy for the relative capacity to pay is either the

relative per capita income or, where there is an unusually high incidence of a disease, the relative national income per person needing treatment.

The result is a royalty that varies directly with the therapeutic benefit of the invention and a direct measure of affordability.

6.7 Remuneration under 1998/JPO, 2001/UNDP, 2005/Canada and 2005/TRM methods

Table R-4 compares remuneration under the four different royalty methods. The comparison is for a single AIDS drug, the fixed-dose combination of lopinavir+ritonavir, marketed by Abbott as Kaletra. The high-income price for lopinavir+ritonavir is US$ 7 766. The generic price is difficult to estimate, because there is not yet a large generic market for lopinavir+ritonavir and the 2004 prices for active pharmaceutical ingredients are an order of magnitude higher for lopinavir+ritonavir than for a similar product like indinavir, which is widely available as a generic drug. For purposes of this analysis, the price of US$ 500 per year is assumed to be a realistic if generic producers benefit from larger economies of scale. The 1998/JPO and the 2001/UNDP methods both establish a percentage royalty, and apply this against the generic competitor's price. Assuming a US$ 500 generic price, and a 4% royalty, the remuneration is US$ 20, regardless of the country. The 2005/Canadian method is a sliding scale from 4 to 0.02%, depending upon the rank of the country in the UNHDI. The remuneration under the TRM is unrelated to the price of the generic product. Rather, it is based upon 4% of the average high-income price, adjusted upwards or downwards to reflect relative per capita income or, in cases of epidemics, relative income per patient needing treatment. Countries with high incomes or low disease rates pay more than countries with low incomes or low disease burdens. When compared to the 2005/Canadian method, the TRM provides for much greater variation. High- or middle-income countries pay considerably more than under the 2001/UNDP, 1998/JPO or 2005/Canadian methods, and countries with high disease burdens pay less than countries with low disease burdens.

Table R-4: Comparison of Remuneration under Four Royalty Methods Annual Royalties in US$ for AIDS drug lopinavir+ritonavir, with high income price of US$ 7 766 and generic price of US$ 500					
			2001/UNDP – 1998/JPO Methods @ 4%	2005/ Canadian Export Method	Tiered Royalty Method
Country	**2002 GDP/POP**	**HIV+/ POP %**	**lopinavir+ ritonavir @US$ 500**	**lopinavir+ ritonavir @US$ 500**	**lopinavir+ ritonavir @U$7 766**
United States	36,123	0.31	20	19.21	224.81
Germany	23,956	0.05	20	17.97	277.31
Chile	4,118	0.13	20	15.25	47.45
Brazil	2,593	0.35	20	11.98	14.45
Thailand	2,052	1.1	20	11.57	3.69
Philippines	964	0.01	20	10.73	11.24
Indonesia	817	0.06	20	7.57	9.42
India	491	0.38	20	5.76	2.50
Swaziland	1,082	15.63	20	4.63	0.14
Zambia	352	11.47	20	1.58	0.06
Mozambique	213	5.97	20	0.79	0.06
Sierra Leone	151	3.25	20	0.11	0.09

A more extensive comparison of the 2005/Canadian and the TRM method is presented in the Table A-2 of the Appendix, which reports remuneration for three antiretroviral drugs used in the treatment of AIDS, including zidovudine, stavudine and the fixed-dose combination lopinavir+ritonavir. The annual United States prices for zidovudine and stavudine were US$ 3 915 and US$ 3 795 in 2004. The products are similar in terms of therapeutic benefit, but have very different manufacturing costs. The 2004 best generic price for zidovudine was US$ 140. For stavudine the best generic price was US$ 21. As noted above, lopinavir+ritonavir does not enjoy a mature generic market, and prices for generic active pharmaceutical ingredients are currently quite high. Some generic versions of this product sell for US$ 2 000, while Abbott has reportedly discounted lopinavir+ritonavir to US$ 500 in some African countries. For purposes of the analysis in Table A-2, lopinavir+ritonavir is calculated for both the US$ 2 000 generic price, which is easily available today, and the US$ 500 generic price, which is thought to be easily achievable with larger economies of scale and more competition among generic suppliers.

Table A-2 provides insights from the inclusion of the head-to-head comparison of remuneration for zidovudine and stavudine. Methods that are based upon manufacturing costs will assign very different remuneration for these two products - generic zidovudine sells for more than six times the price of generic stavudine. For the 2005/Canadian method, annual remuneration for zidovudine runs from US$ 5.60 to US$ 0.03. For stavudine, the highest remuneration is just US$ 0.84, for exports to Norway, and for more than half the countries, the amount is less than US$ 0.50 per year. Under the 2005/Canadian method, the amount of remuneration for either product is low when compared to resources in the high- or middle-income countries and, in the case of stavudine, the remuneration is more symbolic than economically meaningful.

For the 124 countries for which there are data for the TRM, the remuneration is generally higher for the TRM when products are less expensive to manufacture, and lower for products that are more expensive to manufacture, when compared to the 2005/Canadian method. For stavudine, the least expensive drug to manufacture, the TRM royalties are higher for 101 countries, and lower for 23 countries, when compared to the 2005/Canadian method. For zidovudine, the TRM royalties are higher for 81 countries, and lower for 43 countries. For lopinavir+ritonavir, the TRM royalties are higher for 64 countries, and lower for 60 countries, when the generic price is US$ 500, but higher for just 30 countries, and lower for 94, when the generic price is US$ 2 000.

As noted, the TRM has higher royalties for countries with higher incomes, and lower disease burdens, and the differences are considerably larger than for the 2005/Canadian method. The United Kingdom would pay US$ 149 per year in remuneration for stavudine under the TRM, but only US$ 0.79 under the 2005/Canadian method. For Chile, the remuneration for stavudine would be US$ 23 under the TRM, but US$ 0.64 under the 2005/Canadian method. Under the TRM, countries with high incidence of HIV would pay much lower royalties. For example, Thailand has about twice the per capita income of the Philippines but, under the TRM, would pay less (for stavudine, US$ 1.80 compared to US$ 5.49 for the Philippines), due to Thailand's much higher disease burden. For 35 countries with high rates of HIV infection, TRM royalties are less than US$1 per year, for any of the three drugs in Table A-2.

7 Medical Innovation Prize Fund system of remuneration

SECTION OVERVIEW

The patent system is not the only means of promoting medical technology R&D and innovation. There is growing interest in approaches to support R&D that separate the markets for innovation from the markets for pharmaceutical products. Under such approaches, all pharmaceuticals would be sold as generic products, and pharmaceutical innovators would be compensated from a means other than the sale of final products.

One approach gaining increasing interest is a Medical Innovation Prize Fund (MIPF) system, where the government sets aside a fixed amount of money (established as a percentage of GDP, for example) and awards this money to pharmaceutical innovators on the basis of the demonstrated value of their products. Such an arrangement could actually increase the amount of funding available to R&D while dramatically reducing the price of pharmaceuticals to consumers.

A MIPF system may have special interest for developing countries, because they might specify that a percentage of the awarded money remain in the country to support domestic R&D efforts.

In January 2005, Representative Sanders introduced HR 417 in the United States Congress. The legislation provides generic producers non-voluntary authorizations to use any and all patents (and *sui generis* intellectual property, such as rights in registration data) relevant to the manufacture and sale of all prescription medicines in the United States market. The bill provides for remuneration to the developers of new medicines, through a MIPF with annual funding of 0.5% (50 basis points) of the United States GDP.

The proposal seeks to radically change the way the United States 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 the public at generic prices, while innovators benefit from a separate remuneration system.

The size of the MIPF is fixed as a fraction of the United States 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 bioterrorism, (2) diseases that qualify under the United States

Orphan Drug Act, and (3) neglected diseases primarily affecting the poor in developing countries.

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 brings, 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 improved product, 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 United States 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 United States market for new drugs and hefty public sector funding of agencies like the United States National Institutes of Health. No other developed country contributes as much towards medical R&D, and so the United States proposed contribution may seem high for some countries, particularly for developing countries that face greater resource constraints.

Recently a group 162 public health experts, scientists, nongovernmental organizations, 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.[88] 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 (0.0015)
ii. High Middle Income, 10 basis points (0.001)
iii. Lower Middle Income, 5 basis points (0.0005)
iv. Low Income, 0 basis points of GDP (0)

ALTERNATIVE 2

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

[88] http://www.who.int/intellectualproperty/submissions/en/CPTech.pdf

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 MIPF is presented in Table A-3 of the Appendix. The fraction of GDP allocated to the fund begins with a top rate of 20 basis points of GDP, for the country ranked first in the UNHDI, 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 US$ 54.7 billion in prizes in 2002, including US$ 34.8 billion outside the United States. If the top rate was 30 basis points, the 2002 prize payments would have been US$ 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 MIPF 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% of new drugs are judged by the United States Food and Drug Administration 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.[89] If the MIPF approach can shift investments into more useful products, the ultimate benefits from innovation could be substantially higher than with the existing system, and for much smaller total outlays, given the savings from the greatly expanded use of generic drugs.

Developing countries implementing the MIPF approach 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. 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.

[89] Love J. Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines. 22 September 2003.

Table R-5: Possible Levels of Medical Innovation Prize Fund Remuneration 20 basis points top rate (million US$)				
	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	510 000	147.0	147.0	294.0
Swaziland	1 200	0.3	0.3	0.6
South Africa	104 200	34.7	34.7	69.5
Kenya	12 300	2.1	2.1	4.2

For non-least developed country Members of the WTO, the types of MIPFs described above would have to be justified as consistent with *either* Article 30 or Article 31 of the TRIPS Agreement. 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 MIPF 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 the TRIPS Agreement and Public Health, particularly paragraphs 4 and 5 thereof.

8 Conclusion

SECTION OVERVIEW

Countries retain broad authority under the TRIPS Agreement to set royalties according to systems of their choosing. The Agreement's requirement that countries provide "adequate remuneration" to patent holders can be met by a broad range of royalties.

Different countries may prefer different approaches to remuneration, based upon administrative capacity, resource constraints and policy objectives concerning access and innovation, among other factors.

In general, it will be desirable for countries to adopt royalty guidelines to enhance transparency and predictability. The UNDP, JPO, Canadian and TRM approaches are all viable and appropriate options for establishing royalties in compulsory licensing cases.

The MIPF approach offers a viable, alternative mechanism for both funding medical R&D and facilitating access to affordable medicines.

8.1 WTO rules and state practice

Countries that authorize the use of patents without the consent of the patent owner under Article 31 of the TRIPS Agreement are required to provide for adequate remuneration to patent owners, and some authorizations under Article 30 of the TRIPS Agreement would require remuneration to patent owners.

WTO gives its Members very broad latitude in determining remuneration. The TRIPS Agreement does not require a country to make up the lost profits that the patent owner would have enjoyed with a monopoly and pricing freedom. Under Article 31, countries have discretion to consider private market licensing transactions, as well as other data, and to consider also a wide range of policy objectives in determining remuneration for use of patented inventions. Countries are not required to mimic market results, and indeed, may set royalties at levels that are plainly designed to change market outcomes, such as to lower market prices, and make medicines more affordable.

In medical technology cases, adoption of remuneration policies for compulsory licensing, like all other aspects of the TRIPS Agreement, should be informed by the Doha Declaration on the TRIPS Agreement and Public Health, and its provision that the TRIPS Agreement "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".

A determination of what is "adequate" remuneration may vary between countries. Very low royalty rates will be appropriate in cases of low income countries, especially for medical technologies that are used to treat diseases of high incidence, and/or when the cost of the treatment poses an economic hardship.

State practice regarding the determination of "reasonable" royalties or "adequate" remuneration is extensive and highly varied. There is no single accepted approach. Not only do countries have very different practices from each other - practices also differ considerably within countries, depending upon the industry sector or the purpose of the authorization.

In recent cases involving remuneration for the use of patents on medicines, governments have set royalties between 0.5 and 5% of the price of the generic product. Recent royalty guidelines proposed by the JPO and UNDP set royalties from 0 to 6% of the price charged by the generic competitor. The Canadian royalty guidelines for the export of medicines to countries that lack manufacturing capacity set royalties at 0 to 4% of the generic price, depending upon the level of development of the importing country.

Private market transactions vary considerably from product to product. The average rate of royalties in the United States pharmaceutical industry, including royalties for multiple patents, trademarks and know-how, is approximately 4 to 5% of sales.

8.2 Policy objectives

In deciding on appropriate policies and practices for determining reasonable royalties or adequate remuneration for the manufacture or sale of a medicine, countries should consider approaches that address practical concerns regarding the administration of a system, as well as policy objectives.

The following considerations should be taken into account in establishing systems for determining remuneration in compulsory licensing cases.

First, the system of setting royalties should not be overly complex or difficult to administer, given the capacity of the government managing the system. Royalty guidelines will reduce complexity and provide guidance for adjudicators, as well as increase transparency and predictability.

Second, royalty guidelines, or any system for setting remuneration for compulsory licensing, should anticipate and address the need to divide royalty payments among various patent holders when the product is subject to multiple patents. Normally this would be done either by determining the relative importance of each of the several patents, or by sharing a royalty for the product among each of the patent owners on an equal basis.

Third, the amount of the royalty should not present a barrier for access to medicines. In most instances where a compulsory licence is issued on a medicine, the policy goal will be to lower prices and improve access. Remuneration policies should assist rather than defeat this purpose.

When countries are facing difficult resource constraints, and cannot provide access to medicines for all, royalty payments should normally not exceed a modest fraction of the generic price. The Canadian export royalty guidelines provide a useful benchmark for such countries; they provide low royalty rates in poor countries and are easy to calculate.

For countries able and willing to make somewhat more complex determinations of remuneration, a range of appropriate factors may be considered, though not all are required, and not all will apply in any given circumstance. These include, but are not limited to, such factors as:

- therapeutic value of the medicine, including the extent to which it represents an advance over other available products;
- the ability of the public to pay for the medicine;
- actual, documented expenditures on development of the medicine;
- the extent to which the invention benefited from publicly funded research;
- the need to respond to public health exigencies;
- the importance of the patented invention to the final product;
- cumulative global revenues and profitability of the invention;
- the need to remedy anti-competitive practices.

For middle or high-income countries, it may be appropriate both to more directly link the amount of remuneration to the therapeutic benefits of the invention, and incorporate other factors such as the reasonableness of prices given relative incomes.

Such approaches may involve basing royalties on something other than the price of the generic product, since the manufacturing costs of generic products are generally not correlated with benefits or the ability to pay.

Royalty-setting approaches that are tied to the medical benefits of the invention and the relative ability to pay are more economically rational and may be more sustainable. In middle- or high-income countries, systems that result in royalty payments that are the same as they would be in the poorest countries are likely to be underutilized; adjudicators and policy makers will likely be uncomfortable with such outcomes, and thus will be deterred from issuing compulsory licences at all. Countries that invest significantly in R&D, and the home countries of brand-name pharmaceutical companies, are also likely to object to low remuneration in middle-income and upper-income countries, and pressure from these sources will further inhibit countries from using compulsory licensing at all.

Approaches that take into account the economic situation of the licensing country may also be appropriate for global or regional patent pools that seek to provide a larger framework for remuneration to patent holders, including countries with very different incomes and burdens of disease.

8.3 Recommended approaches for remuneration

Different countries may prefer different approaches to remuneration, based upon administrative capacity, resource constraints, sensitivity to global norms concerning support for R&D, and policy objectives concerning access and innovation. The

following approaches are reasonable and appropriate methods of setting remuneration.

8.3.1 2001/UNDP guidelines

The 2001 UNDP HDR proposed a simple system of royalty guidelines. The base royalty rate is 4% of the price of the generic product. This can be increased or decreased by 2%, depending upon such factors as the degree to which a medicine is particularly innovative or the role of governments in paying for R&D.

The benefits of this approach include its simplicity, predictability, ease of administration and ability to incorporate certain factors particular to a licensed product (e.g. degree to which it is innovative).

The 2001/UNDP guidelines do not accommodate all factors particular to a drug that a country may wish to consider in setting royalties. Nor do they take into account the country's ability to pay. Because royalty payments are based simply on the price of the generic product, and not adjusted otherwise to reflect country income, royalty outcomes under the guidelines will be the same in a rich country as in a poor one. Basing royalties on the price of the generic product also results in variation in the remuneration based on the cost of manufacturing a product, irrespective of the therapeutic value of the medicine.

Note, however, that the failure to take into account a country's ability to pay poses little problem in lower-income countries, where the policy objective should be to lower pharmaceutical prices as close as possible to marginal cost.

8.3.2 1998/JPO guidelines

In 1998, the JPO published guidelines for setting royalties on government-owned patents. The 1998/JPO guidelines allow for normal royalties of 2 to 4% of the price of the generic product, and can be increased or decreased by as much as 2%, for a range of 0 to 6%.

The 1998/JPO guidelines include a "utilization factor" of 0 to 100%, which is used to allocate royalty payments among patent owners, when the product consists of a combination of multiple inventions. This is particularly useful when setting remuneration for fixed-dose combinations or other medicines that combine many different patented inventions. (The utilization factor can be used independently with any of the other methods of setting royalties.)

The 1998/JPO guidelines are effectively a more elaborate version of the 2001/UNDP guidelines. As compared to the 2001/UNDP guidelines, they are somewhat more difficult to administer, because they incorporate a broader range of relevant factors into the royalty calculation. Additional flexibility is gained, at the cost of some administrative complexity.

Like the 2001/UNDP guidelines, the 1998/JPO guidelines set royalties based on the price of the generic product, and do not adjust for a country's ability to pay.

8.3.3 2005/Canadian guidelines

In 2005, the Canadian Government adopted royalty guidelines for compulsory licensing of patents for export to countries that lack the capacity to manufacture medicines. These guidelines establish a sliding scale of 0.02 to 4% of the price of the generic product, based upon the country rank in the UNHDI. For most developing countries, the royalty rate is less than 3%. For most countries in Africa, the rate is less than 1%.

The Canadian method can be thought of as a useful norm for those countries facing severe resource constraints in providing access to medicines for all. The rate is easy to calculate, and the rates are relatively low, thus avoiding divergences from the marginal cost of medicines. The Canadian method does not adjust for the therapeutic value of the medicine, or any factor particular to the medicine. Although it does adjust for countries' development status, because the royalty rate is based on the price of the generic product, remuneration under the Canadian method will always be low. This approach is therefore less useful for middle or high-income countries that have both the capacity to pay more, and the need for a remuneration system that is responsive to global norms concerning the sharing of R&D costs.

8.3.4 Tiered Royalty Method (TRM)

The TRM is different from the 2001/UNDP, 1998/JPO or 2005/Canadian methods in that the royalty rate is not based upon the price of the generic product. Instead, the royalty is based upon the price of the patented product in the high-income country. The base royalty is 4% of the high-income country price, which is then adjusted to account for relative income per capita or, for countries facing a particularly high burden of disease, relative income per person with the disease.

The TRM results in royalties that are considerably different from the other methods. Royalties are independent of manufacturing costs and vary directly with proxies for therapeutic value (the high income price) and capacity to pay. The TRM provides a more rational framework for sharing the costs of R&D and may be more sustainable for some middle- or high-income countries that are sensitive to global norms concerning the sharing of R&D costs. The TRM provides for much higher royalties in middle- and high-income countries with low burdens of disease, and the lowest royalties for countries that have the lowest incomes and the highest rates of disease burden. The TRM is particularly appropriate for global or regional patent pools that serve countries with very different circumstances in terms of incomes or disease burdens.

As presented here, the TRM is simple to administer, relying only on a determination of price in high-income countries, and an adjustment based on the ratio of high-income country income to licensing country income (or a similar adjustment if incidence of disease is to be taken into account). A somewhat more complex version of the TRM might adjust the 4% royalty rate to take into account factors particular to the invention to be licensed (such as those considered in the 1998/JPO approach), or consider alternative methods of determining the base for the therapeutic value of the invention. This more complex approach may seem especially desirable in cases where the price in the high-income countries is itself considered excessive, or is a poor proxy for therapeutic value of the invention.

8.3.5 Medical Innovation Prize Fund (MIPF)

The MIPF approach involves making all drugs available to consumers at generic prices.

With the MIPF approach, remuneration is not awarded to pharmaceutical innovators by a sales-based royalty. Rather, the developers of products compete, seeking to receive a portion of a national budget that rewards medical innovation. The payments from the government to the innovators are allocated according to each product's contribution to improved health outcomes. The MIPF approach provides the greatest rewards for products that are actually used, and that provide incremental health benefits. The MIPF can also be implemented to provide for remuneration for products that more closely address health care priorities, including products that are developed to address global neglected diseases, or medicines that are developed in anticipation of future needs, such as treatments for a disease like SARS that is currently contained, but which presents an important health care risk.

The MIPF approach can be implemented in countries of different levels of development, incomes and health care priorities. It is recommended that the overall level of funding for a MIPF approach increase with national income and the level of development.

Appendix

Table A-1: UNDP Rank, 2005/Canadian Export Royalty Guidelines, GDP per capita and persons living with HIV

UNDP 2004 HDI Rank	Country	Canada Rate	GDP/Pop 2002	HIV+
1	Norway	4.00%	41,974	1,800
2	Sweden	3.98%	26,929	3,300
3	Australia	3.95%	20,822	1,200
4	Canada	3.93%	22,777	55,000
5	Netherlands	3.91%	25,886	17,000
6	Belgium	3.89%	23,749	8,500
7	Iceland	3.86%	29,749	220
8	United States	3.84%	36,006	900,000
9	Japan	3.82%	31,407	12,000
10	Ireland	3.80%	30,982	2,400
11	Switzerland	3.77%	36,687	19,000
12	United Kingdom	3.75%	26,444	34,000
13	Finland	3.73%	25,295	1,200
14	Austria	3.71%	25,356	9,900
15	Luxembourg	3.68%	47,354	NA
16	France	3.66%	24,061	100,000
17	Denmark	3.64%	32,179	3,800
18	New Zealand	3.62%	14,872	1,200
19	Germany	3.59%	24,051	41,000
20	Spain	3.57%	15,961	130,000
21	Italy	3.55%	20,528	100,000
22	Israel	3.53%	15,792	NA
23	Hong Kong SAR	3.50%	23,800	2,600
24	Greece	3.48%	12,494	8,800
25	Singapore	3.46%	20,886	3,400
26	Portugal	3.44%	11,948	27,000
27	Slovenia	3.41%	11,181	280
28	Korea Rep. of	3.39%	10,006	4,000
29	Barbados	3.37%	9,423	NA
30	Cyprus	3.34%	13,210	NA
31	Malta	3.32%	9,748	NA
32	Czech Republic	3.30%	6,808	500
33	Brunei Darussalam	3.28%	NA	NA
34	Argentina	3.25%	2,797	130,000
35	Seychelles	3.23%	8,320	NA
36	Estonia	3.21%	4,792	7,700

UNDP 2004 HDI Rank	Country	Canada Rate	GDP/Pop 2002	HIV+
37	Poland	3.19%	4,894	NA
38	Hungary	3.16%	6,481	2,800
39	Saint Kitts and Nevis	3.14%	7,745	NA
40	Bahrain	3.12%	11,007	NA
41	Lithuania	3.10%	3,977	1,300
42	Slovakia	3.07%	4,403	NA
43	Chile	3.05%	4,115	20,000
44	Kuwait	3.03%	15,193	NA
45	Costa Rica	3.01%	4,271	11,000
46	Uruguay	2.98%	3,609	6,300
47	Qatar	2.96%	28,634	NA
48	Croatia	2.94%	5,025	200
49	United Arab Emirates	2.92%	22,051	NA
50	Latvia	2.89%	3,595	5,000
51	Bahamas	2.87%	15,797	6,200
52	Cuba	2.85%	NA	NA
53	Mexico	2.82%	6,320	150,000
54	Trinidad and Tobago	2.80%	7,384	17,000
55	Antigua and Barbuda	2.78%	10,449	NA
56	Bulgaria	2.76%	1,944	NA
57	Russian Federation	2.73%	2,405	700,000
58	Libyan Arab Jamahiriya	2.71%	3,512	7,000
59	Malaysia	2.69%	3,905	42,000
60	Macedonia TFYR	2.67%	1,860	NA
61	Panama	2.64%	4,182	25,000
62	Belarus	2.62%	1,441	15,000
63	Tonga	2.60%	1,347	NA
64	Mauritius	2.58%	3,740	700
65	Albania	2.55%	1,535	NA
66	Bosnia and Herzegovina	2.53%	1,362	NA
67	Suriname	2.51%	2,199	3,700
68	Venezuela	2.49%	3,760	NA
69	Romania	2.46%	2,052	6,500
70	Ukraine	2.44%	851	250,000
71	Saint Lucia	2.42%	4,124	NA
72	Brazil	2.40%	2,593	610,000
73	Colombia	2.37%	1,850	140,000
74	Oman	2.35%	8,002	1,300
75	Samoa Western	2.33%	1,484	NA
76	Thailand	2.31%	2,060	670,000
77	Saudi Arabia	2.28%	8,612	NA
78	Kazakhstan	2.26%	1,656	6,000
79	Jamaica	2.24%	3,008	20,000
80	Lebanon	2.21%	3,894	NA
81	Fiji	2.19%	2,281	300
82	Armenia	2.17%	771	2,400

UNDP 2004 HDI Rank	Country	Canada Rate	GDP/Pop 2002	HIV+
83	Philippines	2.15%	975	9,400
84	Maldives	2.12%	2,182	NA
85	Peru	2.10%	2,113	53,000
86	Turkmenistan	2.08%	1,601	NA
87	Saint Vincent & the Grenadines	2.06%	3,082	NA
88	Turkey	2.03%	2,638	NA
89	Paraguay	2.01%	1,000	NA
90	Jordan	1.99%	1,799	NA
91	Azerbaijan	1.97%	745	1,400
92	Tunisia	1.94%	2,149	NA
93	Grenada	1.92%	4,060	NA
94	China	1.90%	989	850,000
95	Dominica	1.88%	3,438	NA
96	Sri Lanka	1.85%	873	4,800
97	Georgia	1.83%	656	NA
98	Dominican Republic	1.81%	2,514	130,000
99	Belize	1.79%	3,332	2,500
100	Ecuador	1.76%	1,897	20,000
101	Iran	1.74%	1,652	20,000
102	Occupied Palestinian Territories	1.72%	1,051	NA
103	El Salvador	1.69%	2,226	24,000
104	Guyana	1.67%	937	18,000
105	Cape Verde	1.65%	1,345	NA
106	Syrian Arab Republic	1.63%	1,224	NA
107	Uzbekistan	1.60%	314	740
108	Algeria	1.58%	1,785	NA
109	Equatorial Guinea	1.56%	4,394	5,900
110	Kyrgyzstan	1.54%	320	500
111	Indonesia	1.51%	817	120,000
112	Vietnam	1.49%	436	130,000
113	Moldova	1.47%	382	5,500
114	Bolivia	1.45%	886	4,600
115	Honduras	1.42%	966	57,000
116	Tajikistan	1.40%	193	200
117	Mongolia	1.38%	457	NA
118	Nicaragua	1.36%	749	NA
119	South Africa	1.33%	2,299	5,000,000
120	Egypt	1.31%	1,354	8,000
121	Guatemala	1.29%	1,941	67,000
122	Gabon	1.27%	3,780	8,400
123	Sao Tome and Principe	1.24%	326	NA
124	Solomon Islands	1.22%	541	NA
125	Morocco	1.20%	1,218	13,000
126	Namibia	1.18%	1,463	230,000
127	India	1.15%	487	3,970,000
128	Botswana	1.13%	3,080	330,000

UNDP 2004 HDI Rank	Country	Canada Rate	GDP/Pop 2002	HIV+
129	Vanuatu	1.11%	1,138	NA
130	Cambodia	1.08%	321	170,000
131	Ghana	1.06%	304	360,000
132	Myanmar	1.04%	NA	NA
133	Papua New Guinea	1.02%	523	17,000
134	Bhutan	0.99%	695	NA
135	Lao Peoples Dem. Rep.	0.97%	304	1,400
136	Comoros	0.95%	437	NA
137	Swaziland	0.93%	1,091	170,000
138	Bangladesh	0.90%	351	13,000
139	Sudan	0.88%	412	450,000
140	Nepal	0.86%	230	58,000
141	Cameroon	0.84%	575	920,000
142	Pakistan	0.81%	408	78,000
143	Togo	0.79%	291	150,000
144	Congo	0.77%	825	110,000
145	Lesotho	0.75%	402	360,000
146	Uganda	0.72%	236	600,000
147	Zimbabwe	0.70%	639	2,300,000
148	Kenya	0.68%	393	2,500,000
149	Yemen	0.66%	537	9,900
150	Madagascar	0.63%	268	22,000
151	Nigeria	0.61%	328	3,500,000
152	Mauritania	0.59%	348	NA
153	Haiti	0.56%	415	250,000
154	Djibouti	0.54%	861	NA
155	Gambia	0.52%	257	900
156	Eritrea	0.50%	150	55,000
157	Senegal	0.47%	503	27,000
158	Timor Leste	0.45%	497	NA
159	Rwanda	0.43%	212	500,000
160	Guinea	0.41%	415	NA
161	Benin	0.38%	411	120,000
162	Tanzania	0.36%	267	1,500,000
163	Cote d Ivoire	0.34%	707	770,000
164	Zambia	0.32%	361	1,200,000
165	Malawi	0.29%	177	850,000
166	Angola	0.27%	857	350,000
167	Chad	0.25%	240	150,000
168	Congo Dem. Rep.	0.23%	111	1,300,000
169	Central African Republic	0.20%	274	250,000
170	Ethiopia	0.18%	90	2,100,000
171	Mozambique	0.16%	195	1,100,000
172	Guinea Bissau	0.14%	141	17,000
173	Burundi	0.11%	102	390,000
174	Mali	0.09%	296	110,000

UNDP 2004 HDI Rank	Country	Canada Rate	GDP/Pop 2002	HIV+
175	Burkina Faso	0.07%	264	440,000
176	Niger	0.05%	190	NA
177	Sierra Leone	0.02%	150	170,000

Table A-2: Comparison of remuneration for three drugs under the 2005/Canadian & 2005/Tiered Royalty Methods. The Canadian Export Royalty Guidelines are a sliding scale percentage of the generic price. The Tiered Royalty Method is 4% of the price of the patented product in high-income countries, adjusted for relative income (per population or per HIV+ incidence).

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
1	Norway	5.60	0.84	20.00	80.00		243.97	236.50	483.96
2	Sweden	5.57	0.84	19.89	79.55		156.52	151.73	310.49
3	Australia	5.54	0.83	19.77	79.10		121.03	117.32	240.08
4	Canada	5.51	0.83	19.66	78.64		127.58	123.67	253.08
5	Netherlands	5.47	0.82	19.55	78.19		150.46	145.85	298.46
6	Belgium	5.44	0.82	19.44	77.74		138.04	133.81	273.82
7	Iceland	5.41	0.81	19.32	77.29		172.92	167.62	343.00
8	United States	5.38	0.81	19.21	76.84		113.33	109.86	224.81
9	Japan	5.35	0.80	19.10	76.38		182.55	176.96	362.12
10	Ireland	5.32	0.80	18.98	75.93		180.08	174.56	357.22
11	Switzerland	5.28	0.79	18.87	75.48		138.25	134.02	274.25
12	United Kingdom	5.25	0.79	18.76	75.03		153.71	148.99	304.90
13	Finland	5.22	0.78	18.64	74.58		147.03	142.52	291.65
14	Austria	5.19	0.78	18.53	74.12		147.38	142.86	292.35
15	Luxembourg	5.16	0.77	18.42	73.67		NA	NA	NA
16	France	5.13	0.77	18.31	73.22		139.85	135.57	277.42
17	Denmark	5.09	0.76	18.19	72.77		187.04	181.31	371.02
18	New Zealand	5.06	0.76	18.08	72.32		86.44	83.79	171.47
19	Germany	5.03	0.75	17.97	71.86		139.80	135.51	277.31
20	Spain	5.00	0.75	17.85	71.41		49.35	47.84	97.90

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
21	Italy	4.97	0.75	17.74	70.96		116.34	112.77	230.78
22	Israel	4.94	0.74	17.63	70.51		NA	NA	NA
23	Hong Kong SAR	4.90	0.74	17.51	70.06		138.34	134.10	274.41
24	Greece	4.87	0.73	17.40	69.60		72.62	70.40	144.06
25	Singapore	4.84	0.73	17.29	69.15		121.40	117.68	240.81
26	Portugal	4.81	0.72	17.18	68.70		44.24	42.89	87.76
27	Slovenia	4.78	0.72	17.06	68.25		64.99	63.00	128.92
28	Korea Rep. of	4.75	0.71	16.95	67.80		58.16	56.38	115.37
29	Barbados	4.71	0.71	16.84	67.34		NA	NA	NA
30	Cyprus	4.68	0.70	16.72	66.89		NA	NA	NA
31	Malta	4.65	0.70	16.61	66.44		NA	NA	NA
32	Czech Republic	4.62	0.69	16.50	65.99		39.57	38.36	78.50
33	Brunei Darussalam	4.59	0.69	16.38	65.54		NA	NA	NA
34	Argentina	4.56	0.68	16.27	65.08		7.71	7.47	15.29
35	Seychelles	4.52	0.68	16.16	64.63		NA	NA	NA
36	Estonia	4.49	0.67	16.05	64.18		8.29	8.04	16.45
37	Poland	4.46	0.67	15.93	63.73		NA	NA	NA
38	Hungary	4.43	0.66	15.82	63.28		37.67	36.52	74.73
39	Saint Kitts and Nevis	4.40	0.66	15.71	62.82		NA	NA	NA
40	Bahrain	4.37	0.65	15.59	62.37		NA	NA	NA
41	Lithuania	4.33	0.65	15.48	61.92		23.12	22.41	45.85

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
42	Slovakia	4.30	0.65	15.37	61.47		NA	NA	NA
43	Chile	4.27	0.64	15.25	61.02		23.92	23.19	47.45
44	Kuwait	4.24	0.64	15.14	60.56		NA	NA	NA
45	Costa Rica	4.21	0.63	15.03	60.11		15.00	14.54	29.76
46	Uruguay	4.18	0.63	14.92	59.66		18.87	18.29	37.43
47	Qatar	4.14	0.62	14.80	59.21		NA	NA	NA
48	Croatia	4.11	0.62	14.69	58.76		29.21	28.31	57.94
49	United Arab Emirates	4.08	0.61	14.58	58.31		NA	NA	NA
50	Latvia	4.05	0.61	14.46	57.85		16.50	16.00	32.74
51	Bahamas	4.02	0.60	14.35	57.40		7.61	7.37	15.09
52	Cuba	3.99	0.60	14.24	56.95		NA	NA	NA
53	Mexico	3.95	0.59	14.12	56.50		36.73	35.61	72.87
54	Trinidad and Tobago	3.92	0.59	14.01	56.05		5.55	5.38	11.00
55	Antigua and Barbuda	3.89	0.58	13.90	55.59		NA	NA	NA
56	Bulgaria	3.86	0.58	13.79	55.14		NA	NA	NA
57	Russian Federation	3.83	0.57	13.67	54.69		4.86	4.71	9.65
58	Libyan Arab Jamahiriya	3.80	0.57	13.56	54.24		20.41	19.79	40.49
59	Malaysia	3.76	0.56	13.45	53.79		22.20	21.52	44.03
60	Macedonia TFYR	3.73	0.56	13.33	53.33		NA	NA	NA
61	Panama	3.70	0.56	13.22	52.88		4.83	4.69	9.59

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
62	Belarus	3.67	0.55	13.11	52.43		8.38	8.12	16.61
63	Tonga	3.64	0.55	12.99	51.98		NA	NA	NA
64	Mauritius	3.61	0.54	12.88	51.53		21.74	21.07	43.12
65	Albania	3.58	0.54	12.77	51.07		NA	NA	NA
66	Bosnia and Herzegovina	3.54	0.53	12.66	50.62		NA	NA	NA
67	Suriname	3.51	0.53	12.54	50.17		2.66	2.57	5.27
68	Venezuela	3.48	0.52	12.43	49.72		NA	NA	NA
69	Romania	3.45	0.52	12.32	49.27		11.93	11.56	23.66
70	Ukraine	3.42	0.51	12.20	48.81		1.63	1.58	3.23
71	Saint Lucia	3.39	0.51	12.09	48.36		NA	NA	NA
72	Brazil	3.35	0.50	11.98	47.91		7.29	7.06	14.45
73	Colombia	3.32	0.50	11.86	47.46		5.68	5.50	11.26
74	Oman	3.29	0.49	11.75	47.01		46.51	45.09	92.26
75	Samoa Western	3.26	0.49	11.64	46.55		NA	NA	NA
76	Thailand	3.23	0.48	11.53	46.10		1.86	1.80	3.69
77	Saudi Arabia	3.20	0.48	11.41	45.65		NA	NA	NA
78	Kazakhstan	3.16	0.47	11.30	45.20		9.63	9.33	19.09
79	Jamaica	3.13	0.47	11.19	44.75		3.88	3.76	7.70
80	Lebanon	3.10	0.47	11.07	44.29		NA	NA	NA
81	Fiji	3.07	0.46	10.96	43.84		13.26	12.85	26.30
82	Armenia	3.04	0.46	10.85	43.39		4.48	4.34	8.89
83	Philippines	3.01	0.45	10.73	42.94		5.67	5.49	11.24
84	Maldives	2.97	0.45	10.62	42.49		NA	NA	NA

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
85	Peru	2.94	0.44	10.51	42.03		10.47	10.15	20.77
86	Turkmenistan	2.91	0.44	10.40	41.58		NA	NA	NA
87	Saint Vincent and the Grenadines	2.88	0.43	10.28	41.13		NA	NA	NA
88	Turkey	2.85	0.43	10.17	40.68		NA	NA	NA
89	Paraguay	2.82	0.42	10.06	40.23		NA	NA	NA
90	Jordan	2.78	0.42	9.94	39.77		NA	NA	NA
91	Azerbaijan	2.75	0.41	9.83	39.32		4.33	4.20	8.59
92	Tunisia	2.72	0.41	9.72	38.87		NA	NA	NA
93	Grenada	2.69	0.40	9.60	38.42		NA	NA	NA
94	China	2.66	0.40	9.49	37.97		5.75	5.57	11.40
95	Dominica	2.63	0.39	9.38	37.51		NA	NA	NA
96	Sri Lanka	2.59	0.39	9.27	37.06		5.07	4.92	10.07
97	Georgia	2.56	0.38	9.15	36.61		NA	NA	NA
98	Dominican Republic	2.53	0.38	9.04	36.16		1.64	1.59	3.25
99	Belize	2.50	0.37	8.93	35.71		3.14	3.05	6.24
100	Ecuador	2.47	0.37	8.81	35.25		11.03	10.69	21.87
101	Iran	2.44	0.37	8.70	34.80		9.60	9.31	19.05
102	Occupied Palestinian Territories	2.40	0.36	8.59	34.35		NA	NA	NA
103	El Salvador	2.37	0.36	8.47	33.90		5.85	5.67	11.61
104	Guyana	2.34	0.35	8.36	33.45		0.38	0.37	0.76

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
105	Cape Verde	2.31	0.35	8.25	32.99		NA	NA	NA
106	Syrian Arab Republic	2.28	0.34	8.14	32.54		NA	NA	NA
107	Uzbekistan	2.25	0.34	8.02	32.09		1.83	1.77	3.62
108	Algeria	2.21	0.33	7.91	31.64		NA	NA	NA
109	Equatorial Guinea	2.18	0.33	7.80	31.19		3.50	3.39	6.94
110	Kyrgyzstan	2.15	0.32	7.68	30.73		1.86	1.80	3.69
111	Indonesia	2.12	0.32	7.57	30.28		4.75	4.60	9.42
112	Vietnam	2.09	0.31	7.46	29.83		2.53	2.46	5.03
113	Moldova	2.06	0.31	7.34	29.38		2.22	2.15	4.40
114	Bolivia	2.02	0.30	7.23	28.93		5.15	4.99	10.22
115	Honduras	1.99	0.30	7.12	28.47		1.14	1.10	2.26
116	Tajikistan	1.96	0.29	7.01	28.02		1.12	1.09	2.23
117	Mongolia	1.93	0.29	6.89	27.57		NA	NA	NA
118	Nicaragua	1.90	0.28	6.78	27.12		NA	NA	NA
119	South Africa	1.87	0.28	6.67	26.67		0.20	0.20	0.41
120	Egypt	1.84	0.28	6.55	26.21		7.87	7.63	15.61
121	Guatemala	1.80	0.27	6.44	25.76		3.42	3.31	6.78
122	Gabon	1.77	0.27	6.33	25.31		5.85	5.67	11.60
123	Sao Tome and Principe	1.74	0.26	6.21	24.86		NA	NA	NA
124	Solomon Islands	1.71	0.26	6.10	24.41		NA	NA	NA
125	Morocco	1.68	0.25	5.99	23.95		7.08	6.86	14.04

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
126	Namibia	1.65	0.25	5.88	23.50		0.12	0.12	0.25
127	India	1.61	0.24	5.76	23.05		1.26	1.22	2.50
128	Botswana	1.58	0.24	5.65	22.60		0.16	0.15	0.31
129	Vanuatu	1.55	0.23	5.54	22.15		NA	NA	NA
130	Cambodia	1.52	0.23	5.42	21.69		0.23	0.22	0.46
131	Ghana	1.49	0.22	5.31	21.24		0.17	0.16	0.34
132	Myanmar	1.46	0.22	5.20	20.79		NA	NA	NA
133	Papua New Guinea	1.42	0.21	5.08	20.34		1.62	1.57	3.21
134	Bhutan	1.39	0.21	4.97	19.89		NA	NA	NA
135	Lao Peoples Dem. Rep.	1.36	0.20	4.86	19.44		1.77	1.71	3.51
136	Comoros	1.33	0.20	4.75	18.98		NA	NA	NA
137	Swaziland	1.30	0.19	4.63	18.53		0.07	0.07	0.14
138	Bangladesh	1.27	0.19	4.52	18.08		2.04	1.98	4.05
139	Sudan	1.23	0.19	4.41	17.63		0.29	0.29	0.58
140	Nepal	1.20	0.18	4.29	17.18		0.93	0.90	1.85
141	Cameroon	1.17	0.18	4.18	16.72		0.10	0.09	0.19
142	Pakistan	1.14	0.17	4.07	16.27		2.37	2.30	4.70
143	Togo	1.11	0.17	3.95	15.82		0.09	0.09	0.18
144	Congo	1.08	0.16	3.84	15.37		0.27	0.26	0.53
145	Lesotho	1.04	0.16	3.73	14.92		0.02	0.02	0.04
146	Uganda	1.01	0.15	3.62	14.46		0.09	0.09	0.19
147	Zimbabwe	0.98	0.15	3.50	14.01		0.04	0.03	0.07
148	Kenya	0.95	0.14	3.39	13.56		0.05	0.05	0.10

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
149	Yemen	0.92	0.14	3.28	13.11		3.12	3.03	6.19
150	Madagascar	0.89	0.13	3.16	12.66		1.56	1.51	3.09
151	Nigeria	0.85	0.13	3.05	12.20		0.12	0.12	0.24
152	Mauritania	0.82	0.12	2.94	11.75		NA	NA	NA
153	Haiti	0.79	0.12	2.82	11.30		0.13	0.13	0.27
154	Djibouti	0.76	0.11	2.71	10.85		NA	NA	NA
155	Gambia	0.73	0.11	2.60	10.40		1.49	1.45	2.96
156	Eritrea	0.70	0.10	2.49	9.94		0.11	0.10	0.21
157	Senegal	0.66	0.10	2.37	9.49		1.82	1.76	3.61
158	Timor Leste	0.63	0.09	2.26	9.04		NA	NA	NA
159	Rwanda	0.60	0.09	2.15	8.59		0.03	0.03	0.07
160	Guinea	0.57	0.09	2.03	8.14		NA	NA	NA
161	Benin	0.54	0.08	1.92	7.68		0.22	0.21	0.44
162	Tanzania	0.51	0.08	1.81	7.23		0.06	0.06	0.12
163	Cote d Ivoire	0.47	0.07	1.69	6.78		0.15	0.14	0.30
164	Zambia	0.44	0.07	1.58	6.33		0.03	0.03	0.06
165	Malawi	0.41	0.06	1.47	5.88		0.02	0.02	0.04
166	Angola	0.38	0.06	1.36	5.42		0.31	0.30	0.62
167	Chad	0.35	0.05	1.24	4.97		0.13	0.13	0.26
168	Congo Dem. Rep.	0.32	0.05	1.13	4.52		0.04	0.04	0.09
169	Central African Republic	0.28	0.04	1.02	4.07		0.04	0.04	0.08
170	Ethiopia	0.25	0.04	0.90	3.62		0.03	0.03	0.06

UNDP HDI 2004 Rank	Country	Canadian Method					Tiered Royalty Method		
		zidovudine @US$140	stavudine @US$ 21	lopinavir+ ritonavir @US$ 500	lopinavir+ ritonavir@ US$2 000		ziduvudine @US$3 915	stavudine @US$3 795	lopinavir+ ritonavir @US$7 766
171	Mozambique	0.22	0.03	0.79	3.16		0.03	0.03	0.06
172	Guinea Bissau	0.19	0.03	0.68	2.71		0.12	0.11	0.23
173	Burundi	0.16	0.02	0.56	2.26		0.02	0.02	0.03
174	Mali	0.13	0.02	0.45	1.81		0.30	0.29	0.60
175	Burkina Faso	0.09	0.01	0.34	1.36		0.07	0.07	0.14
176	Niger	0.06	0.01	0.23	0.90		NA	NA	NA
177	Sierra Leone	0.03	0.00	0.11	0.45		0.05	0.04	0.09

Table A-3: Medical Innovation Prize Fund - sliding scale rate based upon a top rate of 20 basis points of GDP, adjusted downwards for relative rank in UNHDI

UNDP 2004 HDI Rank	Rate	Country	GDP 2002 *(billion US$)*	Prize @ 20 *(million US$)*
1	0.200%	Norway	190.5	381.0
2	0.199%	Sweden	240.3	477.9
3	0.198%	Australia	409.4	809.5
4	0.197%	Canada	714.3	1,404.4
5	0.195%	Netherlands	417.9	816.9
6	0.194%	Belgium	245.4	476.9
7	0.193%	Iceland	8.4	16.2
8	0.192%	United States	10,383.1	19,944.9
9	0.191%	Japan	3993.4	7,625.8
10	0.190%	Ireland	121.4	230.5
11	0.189%	Switzerland	267.4	504.6
12	0.188%	United Kingdom	1566.3	2,937.9
13	0.186%	Finland	131.5	245.2
14	0.185%	Austria	204.1	378.2
15	0.184%	Luxembourg	21	38.7
16	0.183%	France	1431.3	2,620.0
17	0.182%	Denmark	172.9	314.5
18	0.181%	New Zealand	58.6	105.9
19	0.180%	Germany	1984.1	3,564.7
20	0.179%	Spain	653.1	1,166.0
21	0.177%	Italy	1184.3	2,101.0
22	0.176%	Israel	103.7	182.8
23	0.175%	Hong Kong SAR	161.5	282.9
24	0.174%	Greece	132.8	231.1
25	0.173%	Singapore	87	150.4
26	0.172%	Portugal	121.6	208.8
27	0.171%	Slovenia	22	37.5
28	0.169%	Korea Rep. of	476.7	808.0
29	0.168%	Barbados	2.5	4.2
30	0.167%	Cyprus	10.1	16.9
31	0.166%	Malta	3.9	6.5
32	0.165%	Czech Republic	69.5	114.7
33	0.164%	Brunei Darussalam	NA	
34	0.163%	Argentina	102	166.0
35	0.162%	Seychelles	0.7	1.1
36	0.160%	Estonia	6.5	10.4
37	0.159%	Poland	189	301.1
38	0.158%	Hungary	65.8	104.1
39	0.157%	Saint Kitts and Nevis	0.4	0.6
40	0.156%	Bahrain	7.7	12.0
41	0.155%	Lithuania	13.8	21.4
42	0.154%	Slovakia	23.7	36.4
43	0.153%	Chile	64.2	97.9
44	0.151%	Kuwait	35.4	53.6

UNDP 2004 HDI Rank	**Rate**	**Country**	**GDP 2002** ***(billion US$)***	**Prize @ 20** ***(million US$)***
45	0.150%	Costa Rica	16.8	25.2
46	0.149%	Uruguay	12.1	18.0
47	0.148%	Qatar	17.5	25.9
48	0.147%	Croatia	22.4	32.9
49	0.146%	United Arab Emirates	71	103.5
50	0.145%	Latvia	8.4	12.1
51	0.144%	Bahamas	4.8	6.9
52	0.142%	Cuba	NA	
53	0.141%	Mexico	637.2	900.0
54	0.140%	Trinidad and Tobago	9.6	13.5
55	0.139%	Antigua and Barbuda	0.7	1.0
56	0.138%	Bulgaria	15.5	21.4
57	0.137%	Russian Federation	346.5	473.7
58	0.136%	Libyan Arab Jamahiriya	19.1	25.9
59	0.134%	Malaysia	94.9	127.6
60	0.133%	Macedonia TFYR	3.8	5.1
61	0.132%	Panama	12.3	16.3
62	0.131%	Belarus	14.3	18.7
63	0.130%	Tonga	0.1	0.1
64	0.129%	Mauritius	4.5	5.8
65	0.128%	Albania	4.8	6.1
66	0.127%	Bosnia and Herzegovina	5.6	7.1
67	0.125%	Suriname	1	1.3
68	0.124%	Venezuela	94.3	117.2
69	0.123%	Romania	45.7	56.3
70	0.122%	Ukraine	41.5	50.6
71	0.121%	Saint Lucia	0.7	0.8
72	0.120%	Brazil	452.4	541.9
73	0.119%	Colombia	80.9	96.0
74	0.118%	Oman	20.3	23.9
75	0.116%	Samoa Western	0.3	0.3
76	0.115%	Thailand	126.9	146.3
77	0.114%	Saudi Arabia	188.5	215.1
78	0.113%	Kazakhstan	24.6	27.8
79	0.112%	Jamaica	7.9	8.8
80	0.111%	Lebanon	17.3	19.2
81	0.110%	Fiji	1.9	2.1
82	0.108%	Armenia	2.4	2.6
83	0.107%	Philippines	78	83.7
84	0.106%	Maldives	0.6	0.6
85	0.105%	Peru	56.5	59.4
86	0.104%	Turkmenistan	7.7	8.0
87	0.103%	Saint Vincent & Grenadines	0.4	0.4
88	0.102%	Turkey	183.7	186.8
89	0.101%	Paraguay	5.5	5.5
90	0.099%	Jordan	9.3	9.2
91	0.098%	Azerbaijan	6.1	6.0

UNDP 2004 HDI Rank	Rate	Country	GDP 2002 *(billion US$)*	Prize @ 20 *(million US$)*
92	0.097%	Tunisia	21	20.4
93	0.096%	Grenada	0.4	0.4
94	0.095%	China	1266.1	1,201.7
95	0.094%	Dominica	0.2	0.2
96	0.093%	Sri Lanka	16.6	15.4
97	0.092%	Georgia	3.4	3.1
98	0.090%	Dominican Republic	21.7	19.6
99	0.089%	Belize	0.8	0.7
100	0.088%	Ecuador	24.3	21.4
101	0.087%	Iran	108.2	94.1
102	0.086%	Occupied Palestinian Terr.	3.4	2.9
103	0.085%	El Salvador	14.3	12.1
104	0.084%	Guyana	0.7	0.6
105	0.082%	Cape Verde	0.6	0.5
106	0.081%	Syrian Arab Republic	20.8	16.9
107	0.080%	Uzbekistan	7.9	6.3
108	0.079%	Algeria	55.9	44.2
109	0.078%	Equatorial Guinea	2.1	1.6
110	0.077%	Kyrgyzstan	1.6	1.2
111	0.076%	Indonesia	172.9	130.9
112	0.075%	Vietnam	35.1	26.2
113	0.073%	Moldova	1.6	1.2
114	0.072%	Bolivia	7.8	5.6
115	0.071%	Honduras	6.6	4.7
116	0.070%	Tajikistan	1.2	0.8
117	0.069%	Mongolia	1.1	0.8
118	0.068%	Nicaragua	4	2.7
119	0.067%	South Africa	104.2	69.5
120	0.066%	Egypt	89.9	58.9
121	0.064%	Guatemala	23.3	15.0
122	0.063%	Gabon	5	3.2
123	0.062%	Sao Tome and Principe	0.1	0.1
124	0.061%	Solomon Islands	0.2	0.1
125	0.060%	Morocco	36.1	21.6
126	0.059%	Namibia	2.9	1.7
127	0.058%	India	510.2	294.0
128	0.056%	Botswana	5.3	3.0
129	0.055%	Vanuatu	0.2	0.1
130	0.054%	Cambodia	4	2.2
131	0.053%	Ghana	6.2	3.3
132	0.052%	Myanmar	NA	
133	0.051%	Papua New Guinea	2.8	1.4
134	0.050%	Bhutan	0.6	0.3
135	0.049%	Lao Peoples Dem. Rep.	1.7	0.8
136	0.047%	Comoros	0.3	0.1
137	0.046%	Swaziland	1.2	0.6
138	0.045%	Bangladesh	47.6	21.5

UNDP 2004 HDI Rank	**Rate**	**Country**	**GDP 2002** ***(billion US$)***	**Prize @ 20** ***(million US$)***
139	0.044%	Sudan	13.5	5.9
140	0.043%	Nepal	5.5	2.4
141	0.042%	Cameroon	9.1	3.8
142	0.041%	Pakistan	59.1	24.0
143	0.040%	Togo	1.4	0.6
144	0.038%	Congo	3	1.2
145	0.037%	Lesotho	0.7	0.3
146	0.036%	Uganda	5.8	2.1
147	0.035%	Zimbabwe	8.3	2.9
148	0.034%	Kenya	12.3	4.2
149	0.033%	Yemen	10	3.3
150	0.032%	Madagascar	4.4	1.4
151	0.031%	Nigeria	43.5	13.3
152	0.029%	Mauritania	1	0.3
153	0.028%	Haiti	3.4	1.0
154	0.027%	Djibouti	0.6	0.2
155	0.026%	Gambia	0.4	0.1
156	0.025%	Eritrea	0.6	0.1
157	0.024%	Senegal	5	1.2
158	0.023%	Timor Leste	0.4	0.1
159	0.021%	Rwanda	1.7	0.4
160	0.020%	Guinea	3.2	0.7
161	0.019%	Benin	2.7	0.5
162	0.018%	Tanzania	9.4	1.7
163	0.017%	Cote d Ivoire	11.7	2.0
164	0.016%	Zambia	3.7	0.6
165	0.015%	Malawi	1.9	0.3
166	0.014%	Angola	11.2	1.5
167	0.012%	Chad	2	0.2
168	0.011%	Congo Dem. Rep.	5.7	0.6
169	0.010%	Central African Republic	1	0.1
170	0.009%	Ethiopia	6.1	0.6
171	0.008%	Mozambique	3.6	0.3
172	0.007%	Guinea Bissau	0.2	0.0
173	0.006%	Burundi	0.7	0.0
174	0.005%	Mali	3.4	0.2
175	0.003%	Burkina Faso	3.1	0.1
176	0.002%	Niger	2.2	0.0
177	0.001%	Sierra Leone	0.8	0.0
			31,780	54,738
				1.72%

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