

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

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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.

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%

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.

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:

$$\text{Royalty rate} = \text{value} * \text{utilization ratio} * \text{increase/decrease ratio} * \text{exploration ratio}$$

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:

$$\text{Royalty rate} = 0.04 * [(178) - \text{rank importing country}] / 177$$

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 United 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 @US\$ 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.