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REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT

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 TRIPS and Public Health declared that WTO members should implement intellectual property laws in a manner that promotes access to medicine 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 licenses, TRIPS provides countries with broad discretion to establish the conditions under which they may issue compulsory licenses. The Doha Declaration reiterated that countries have "the freedom to determine the grounds upon which such licenses 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. WTO members are free to determine the appropriate method of implementing the TRIPS, 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 licenses on HIV/AIDS drugs. Malaysia set a royalty rate of 4 percent for such licenses; Mozambique established a 2 percent royalty; Zambia set a 2.5 percent royalty; and Indonesia arrived at 0.5 percent 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 Japan Patent Office (1998) and UNDP (2001) set royalties from 0 to 6 percent 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 percent 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 license arrangements provides 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 percent. The pharmaceutical industry has one of the higher licensing rates among all industries.

POLICY FRAMEWORK FOR REMUNERATION

In determining 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 medicine. In most instances where a compulsory license 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 medicine 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; it provides both low royalty rates in poor countries, and requires 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; and**
- **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 also 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 basing royalties not on the price of the generic product, since using the generic 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 licenses 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.

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/HDR GUIDELINES

The 2001 UNDP Human Development Report proposed a simple system of royalty guidelines. The base royalty rate is 4 percent of the price of the generic product. This can be increased or decreased by 2 percent, 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

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

The 1998/JPO guidelines include a "utilization factor," of 0 to 100 percent, 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/HDR guidelines. As compared to the 2001/UNDP/HDR 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.02 to 4 percent of the price of the generic product, based upon the country rank in the UNDP Human