

**EXPERT REPORT JL-R**

**COMPENSATION FOR NON-VOLUNTARY USE OF A PATENT ON  
MEDICAL TECHNOLOGIES**

James Love  
September 7, 2003

COMPENSATION FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES .....	1
1. Introduction.....	2
2. WTO TRIPS provisions on compensation for non-voluntary use of a patent .....	2
2.1 WTO Rules for compensation under TRIPS Article 31 .....	3
2.2 The Doha Declaration TRIPS and Public Health.....	5
2.3 Summary of TRIPS provisions that relate to compensation .....	6
3. Examples of Royalty Setting.....	7
3.1 Infringement .....	7
3.2 UK and US Licenses of right .....	9
3.3 US Government Use Cases .....	10
3.4 Special US Compulsory Licensing Programs .....	15
Civilian Nuclear Energy .....	15
Clean Air Act .....	16
Bayh-Dole March-In Rights.....	16
The Proposed Public Health Emergency Medicines Act,.....	16
3.5 US Experience With Compulsory Licenses Issued as a Remedy to Anticompetitive Practices.....	17
Microsoft.....	18
3.6 Canadian Compulsory Licenses for Pharmaceuticals.....	19
Frank Horner v Hoffmann-La Roche .....	20
Breast Cancer Gene Patents .....	22
3.7 The Philippines.....	24
3.8 Malaysia .....	26
The Malaysian Guidelines for the Approval of Technology Transfer Agreements on Intellectual Property.....	26
3.9 Singapore .....	27
3.10 Other evidence regarding norms for royalty rates.....	28
Consumer Electronics.....	31
IBM.....	31
The 3G Patent Platform Partnership and essential wireless patents.....	32
4. Policy Framework for Setting Compensation for Royalties on Medicines .....	32
4.1 Lost Profits with Willing Buyer-Willing Seller .....	33
4.2 Ramsey Pricing with Budget and Social Welfare Weights.....	34
4.3. Cost Based Economic Regulation .....	35
4.4 Reasonable Royalty Approach .....	36
4.5 Professor Reichman's seven factors for evaluating reasonable royalties in developing countries.....	36
4.6 Pharmacoeconomic Approach.....	38
4.7 Practical Issues .....	39
Precision versus Ease of Administration .....	39

Transparency .....	40
Multiple Patents.....	40
Exports with Parallel Patents in Import Market.....	41
Appropriate Compensation Base.....	41
4.8 The general level of compensation should not undermine access.....	43
5 Royalty Guidelines .....	46
5.1 UNDP Royalty Guidelines.....	46
5.2 Japan Royalty Guidelines.....	46
Value of working.....	47
Utilization Ratio .....	47
Increase or Decrease Ratio.....	47
Exploration Ratio.....	47
6. Recommended Royalty Guidelines .....	47
Guidelines for the value variable.....	48
Guidelines for the increase/decrease variable .....	48
7. Recommended Royalties .....	49
Standalone Royalties .....	49
Application of the guidelines for Three Fixed Dose Combinations (FDC).....	49

## 1. Introduction

The WTO TRIPS accord requires that non-voluntary authorization to use patents under Article 31 of the TRIPS accord include provisions for adequate compensation to the patent owners, taking into account the economic value of the authorization. This report reviews the WTO provisions regarding compensation, reviews royalty setting in a wide range of voluntary and non-voluntary settings, examines the policy framework for setting royalties on medicines in South Africa, and recommends both a royalty guideline framework for patents on medicines in South Africa and royalties for each standalone product in this case, plus royalties for three fixed dose combinations that would use in whole or in part those products. The recommended royalties for the relevant GSK and BI patents are as follows:

### Standalone products

- 2.5 percent for AZT by itself
- 5 percent for 3TC by itself
- 7.5 percent for Nevirapine by itself

### GSK and BI patents on Fixed Dose Combinations\*

- 3.875 percent for AZT+3TC\*
- 3.75 percent of d4T+3TC+Nevirapine\*
- 5.0 percent for AZT+3TC+Nevirapine

\* for relevant GSK and BI patents

## 2. WTO TRIPS provisions on compensation for non-voluntary use of a patent

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.

1. Under Article 27 of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property (the TRIPS Agreement), some inventions may be excluded from patentability.<sup>1</sup> Typical exclusions under Article 27 would be for inventions dealing with surgical procedures, the cloning of humans, or for agriculture inventions protected by *sui generis* plant breeder rights.
2. Under Article 30 of the TRIPS, 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:
  - a. are limited,
  - b. do not unreasonably conflict with a normal exploitation of the patent, and
  - c. 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 authorised 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 prices and market share reductions for the incumbent monopoly. This can reduce patent owner profits by billions of dollars for the best selling products.

3. WTO members also have broad authority to authorize third parties to use a invention without the permission of the patent owner, under Article 31 of the TRIPS. The Article 31 uses are subject to a number of procedural and substantive conditions, including those relating to compensation.

### ***2.1 WTO Rules for compensation under TRIPS Article 31***

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

---

<sup>1</sup> In TRIPS Article 27.2, "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." In 27.3, Members may also exclude from patentability (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (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.

1. There is a requirement that authorization of uses be based upon the individual merits.<sup>2</sup> Thus, some decisions must be particular to a patent.
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."<sup>3</sup>
3. The requirement for prior negotiation on "reasonable commercial terms and conditions" is waived in three special cases.
  - a. Public non-commercial use,<sup>4</sup>
  - b. National emergency or other circumstances of extreme urgency,<sup>5</sup> or
  - c. Where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.<sup>6</sup>
4. There is a general rule that when governments authorise 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."<sup>7</sup>
5. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration.<sup>8</sup>
6. When a non-voluntary licence 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-license to the second patent on "reasonable terms."<sup>9</sup>
7. Any decision relating to compensation must be subject to judicial *or* other independent review by a distinct higher authority."<sup>10</sup>

The WTO leaves each member considerable discretion in implementing the TRIPS agreement. Article 1 of the TRIPS, 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,<sup>11</sup> Article 8 on Principles<sup>12</sup>, and Article 40 on the Control of Anti-

---

<sup>2</sup> Article 31(a).

<sup>3</sup> Article 31(b).

<sup>4</sup> Article 31(b).

<sup>5</sup> Article 31(b).

<sup>6</sup> Article 31(k).

<sup>7</sup> Article 31(h).

<sup>8</sup> Article 31(k).

<sup>9</sup> Article 31(l)(ii).

<sup>10</sup> Article 31(j).

<sup>11</sup> *Article 7, 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."

<sup>12</sup> *Article 8, Principle.* "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

Competitive Practices in Contractual Licences,<sup>13</sup> 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 can be implemented in a variety of different ways.<sup>14</sup> If they so choose, a WTO Member may create a system that effectively gives any third party the right to use a patent, subject only to the requirement that the patent owner receive compensation.<sup>15</sup> 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."<sup>16</sup>

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 exceptions provisions in the TRIPS agreement are implemented except through national legislation.

## ***2.2 The Doha Declaration TRIPS and Public Health***

On November 14, 2002, the WTO issued the Doha Declaration on TRIPS and Public Health.<sup>17</sup> The Declaration affirmed that the TRIPS agreement "can and should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and, in particular, to promote access for all."

---

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."

<sup>13</sup> Section 8: Control of Anti-Competitive Practices In Contractual Licences, *Article 40*. 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.

<sup>14</sup> James Love, Access to Medicine and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries," in Peter Drahos and Ruth Mayne, Editors, *Global Intellectual Property Rights: Knowledge, Access and Development*. Palgrave, Macmillian, New York, 2002. Carlos Correa, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries. Geneva, South Centre, 1999.

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

<sup>16</sup> Article 44(2).

<sup>17</sup> Ministerial Conference, Fourth Session, Doha, 9 - 14 November 2001, WT/MIN(01)/DEC/2, 20 November 2001

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 Doha Declaration on TRIPS and Public Health adopted a broad definition of what constitutes a national emergency or other circumstance 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 that the TRIPS requirements in Article 31(b) for prior negotiation with patent owners on reasonable commercial terms is waived if there is a public health crisis.

### ***2.3 Summary of TRIPS provisions that relate to compensation***

Term	TRIPS Provision	Situation
<i>Prior negotiation on reasonable commercial terms</i>	Article 31(b)	Applies to commercial non-emergency authorisations that are not remedies to anticompetitive practices
<i>Adequate remuneration . . . taking into account the economic value of the authorization</i>	Article 31(h)	Applies to all authorisations, but the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration. In some competition cases, the remuneration is set to zero.
<i>reasonable terms</i>	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
<i>promote access to medicine for all</i>	Paragraph 4 of Doha Declaration	Applies to cases involving public health problems

### 3. Examples of Royalty Setting

The TRIPS rules, when taken together with the Doha Declaration on TRIPS and Public Health, present a challenge for policy makers. On the one hand, the TRIPS requires payment of "*adequate*" compensation to patent owners, taking into account the "*economic value of the authorization*," and in some cases,<sup>18</sup> requires prior negotiation on "*reasonable commercial terms and conditions*." On the other hand, the Doha Declaration on TRIPS and Public Health calls upon Members to implement their domestic laws in a manner that promotes "*access to medicine for all*."

In practice, governments may and do choose very different outcomes, each of which may be appropriate under their own legal traditions. For example, Smith Kline 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 UK, SKF was granted a very high royalty -- fixed in sterling at 45 percent of the patent owner's sales price. In the Philippines, the royalties were 2.5 percent of the generic competitor sales price.<sup>19</sup> The court in the Japanese infringement case awarded a 3.5 percent royalty. As noted earlier, the WTO TRIPS accord 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."<sup>20</sup>

There are many different approaches that are used to determine what constitutes *reasonable* or *adequate* compensation 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 US 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.<sup>21</sup> 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.<sup>22</sup> In some countries, patent infringement can even result in criminal sanctions.

---

<sup>18</sup> When the authorization is not for public non-commercial use, emergencies or cases of, urgency, or a remedy to anticompetitive practices.

<sup>19</sup> First Division, [G.R. No. 121267. October 23, 2001], Smith Kline & French Laboratories, LTD. plaintiff-appellee, vs. Court Of Appeals And Danlex Research Laboratories, INC., defendant-appellant.

<sup>20</sup> TRIPS, Article 1.1.

<sup>21</sup> 35 USC 284.

<sup>22</sup> <http://www.patent.gov.uk/news/patact3.htm>. UK Patents Bill Consultation. Proposed changes related to enforcement and post-grant issues, Report of open meeting held 11am, 17th 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

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 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 US Court in *Georgia Pacific v. United States Plywood Corp*, which identified 15 relevant factors for estimating the compensation that would have obtained from a hypothetical negotiation between parties.<sup>23</sup> Over the past 30 years a number of other methodologies have been

---

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.

<sup>23</sup> *Georgia-Pacific Corp. v. U.S. 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

promoted.<sup>24</sup> Methods used by courts and experts range from simple rules of thumb (5 percent of revenue, 25 percent 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 Cimetidine -- the active ingredient in a best selling ulcer drug -- was 3.5 percent of sales.<sup>25</sup> In a case involving a patent used in an AIDS test kit, a royalty of 1 percent was held to be reasonable, despite the patent owner's claims that a 15 percent 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."<sup>26</sup> In a case involving eye care product maker Alcon Inc. and Japan-based Nidek Co. Ltd., a US Court found that Nidek's excimer laser infringed on two of Summit's patents, and awarded a royalty of 5 percent of the infringer's sales.<sup>27</sup> Biocore, a Swedish firm, reported an infringement award based upon a royalty rate of 40 percent of the infringer's sales for a surface chemistry patent.<sup>28</sup> 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 UK and US Licenses 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 UK system for voluntary licenses of right, the patent owner declares the patent will be available for anyone to licence, and in return, the fees for patent renewal are reduced by 50 percent. Once a licence is so registered, the terms of the licence are either negotiated between the parties, or failing that, by the government.<sup>29</sup> There are also cases of non-voluntary licences of right. Of particular note in the UK are the licences of right created when the UK extended the term of patents from 16 to 20 years when the UK 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 World Trade

---

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.

<sup>24</sup> Roger D. Blair and Thomas F. Cotter, "Rethinking Patent Damages," TEXAS INTELLECTUAL PROPERTY LAW JOURNAL. VOL. 10:1.

<sup>25</sup> Toshiko Takenaka, Big Change in Measurement for Japanese Patent Infringement Damages? Tokyo District Court Awards \$23.5 Million in Lost Profits Damages, Smithkline & Beecham French Lab. Ltd. v. Fujimoto Seiyaku. CASRIP Newsletter. Autumn 1998, Vol 5, Issue 3.

<sup>26</sup> *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).

<sup>27</sup> September 25, 2002, Alcon wins patent suit, *Dallas Business Journal*.

<sup>28</sup> June 6, 2002, "Biacore Receives USD 2 million in Damages from Thermo BioAnalysis Corp Damages paid for infringement of Biacore US patent position." Press Release.

<sup>29</sup> In the UK system, the patent own can cancel the license of right endorsement at any time.

Organisation. The extended term (*the delta period*) was subject to a compulsory licence based upon equitable remuneration.<sup>30</sup>

The UK *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 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 licenses 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 UK 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 percent of the patent owners sales price.

### **3.3 US 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 US 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

---

<sup>30</sup> 35 USC section 154 (c)(2) (1994). Due of a technical inconsistency between the law and FDA regulatory statutes, the compulsory licenses were largely ineffective for pharmaceutical inventions. *Merck & Co., Inc., et al., v. David A. Kessler, M.D., Commissioner of Food and Drugs, et al.*, 903 F. Supp. 964; 1995 U.S. Dist. Richard DeLucia & Jeffrey Butler, "GATT Creates Conflict over Patent Terms," *N.J. Law Journal*, July 24, 1995.

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 US 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 percent, with 6 percent the more common award.<sup>31</sup>

Since the usual measure of damages in a 28 U.S.C. § 1498 action is a reasonable royalty,<sup>32</sup> 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%.<sup>33</sup> 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.<sup>34</sup> 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<sup>35</sup> 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.<sup>36</sup>

According to Professor Reichman:<sup>37</sup>

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.<sup>38</sup> In this respect, government use of patents and other intellectual property rights (including copyrights, plant breeders' rights, and semiconductor chip design rights)<sup>39</sup> under section 1498 is often understood to partake of the sovereign power of eminent domain, which inheres in every nation

---

<sup>31</sup> Richard J. McGrath, *The Unauthorized Use of Patents by the United States Government or Its Contractors*, 18 AIPLA Q.J. 349, 352 (1991).

<sup>32</sup> The criteria for determining reasonable royalties are set forth in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970); 446 F.2d 295 (2d Cir. 1971); cert. denied, 92 S.Ct. 105 (Oct. 12, 1971).

<sup>33</sup> *Tektronix, Inc. v. United States*, 552 F.2d 343, 351 (Ct. Cl. 1977).

<sup>34</sup> *Id.* at p. 345.

<sup>35</sup> *Carley Life Boat Co. v. United States*, 74 Cl. Ct. 682 (Ct. Cl. 1932); *Calhoun v. United States*, 453 F.2d at 1293.

<sup>36</sup> The royalty rates in the Claims Court tend to vary from 2%, *Pitcairn v. United States*, 547 F.2d 1106, 1119 (Ct. Cl. 1976), to 10%, *Tektronix v. United States*, 552 F.2d at 351, with 6% being typical. The determination of typical royalty rates are set forth in *Jamesway v. United States*, 207 U.S.P.Q. 131, 144 (Ct. Cl. 1980) (6-1/2% royalty rate); *Dynamics Corp. of America v. United States*, 5 Cl. Ct. 591, 609 (Cl. Ct. 1984), (6% royalty rate).

<sup>37</sup> Reichman, J. H., *Compulsory Licenses: History and Legal Principles (Expert Report JHR)*.

<sup>38</sup> Reichman with Hasenzahl, *Law and Practice of the U.S.*, *supra* note 88 at 89-100.

<sup>39</sup> See 28 U.S.C. §§1498(b), (d), (e) (2002). These provisions are beyond the scope of this study.

state.<sup>40</sup> 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."<sup>41</sup> 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.<sup>42</sup>

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.<sup>43</sup> 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,<sup>44</sup> governmental use represents a power reserved to the state when it initially grants the patent.<sup>45</sup> Because "the government cannot 'take' what it already possesses,"<sup>46</sup> section 1498 "grants the government the absolute power to take a compulsory, non-exclusive license to a patented invention at will."<sup>47</sup>

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 constitutional guarantees of "just compensation" under the Fifth Amendment.<sup>48</sup> . . .

---

<sup>40</sup> See, e.g., *Crozier v. Fried Krupp Aktiengesellschaft*, 224 U.S. 290, 307 (1912); see also Daniel R. Cahoy, *Treating the Legal Side Effects of CIPRO: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 Am. Bus. L. J. 125, 143-44 (2002) (stating that government use provision of §1498 "has generally been recognized as incorporating eminent domain principles"); Thomas F. Cotter, *Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?*, 50 Fla. L. Rev. 529, 571-72 (1998).

<sup>41</sup> See U.S. CONST., AMEND. V; *McKeever v. United States*, 14 Ct. Cl. 396 (1878); *Tektronix, Inc. v. United States*, 552 F.3d 343, 346 (Ct. Cl. 1977), cert. denied, 439 U.S. 1048 (1978); Lavenue, *supra* note 565, at 469 (stating that Supreme Court, Court of Claims, Federal Circuit, Claims Court, and Court of Federal Claims have at various times all interpreted patent infringement claims under §1498(a) "as suits in eminent domain").

<sup>42</sup> See *Crozier v. Fried Krupp Aktiengesellschaft*, 224 U.S. 290 (1912); Lavenue, *supra* note 565, at 453 (characterizing claims for "direct infringement" under §1498 as "more properly a compulsory nonexclusive license in eminent domain"); see also Richard J. McGrath, *The Unauthorized Use of Patents by the United States Government or Its Contractors*, 18 AIPLA Q.J. 349, 352 (1991).

<sup>43</sup> See *De Graffenried v. United States*, 29 Fed. Cl. 384, 388 (1993); *Brunswick Corp. v. United States*, 36 Fed. Cl. 204, 207-208 (1996).

<sup>44</sup> See Cahoy, *supra* note 92 at 147-53.

<sup>45</sup> See *Brunswick*, 36 Fed. Cl. at 207-08; *De Graffenried*, 29 Fed. Cl. at 387-88. This analysis deviates from most of the prior case law and has elicited scholarly criticism. See, e.g., Cahoy, *supra* note 92; Cotter, *supra* note 325.

<sup>46</sup> *De Graffenried*, 29 Fed. Cl. at 387-88.

<sup>47</sup> *Brunswick*, 36 Fed. Cl. at 207 (adding that "this exercise of the government's right is not a 'taking' in violation of the Fifth Amendment, for the government has the statutory right to use a patented devise").

<sup>48</sup> See *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 838 (2002) (stating that "the Federal Circuit has repeatedly stated that patent infringement by the government constitutes a government taking under an

Before the *Georgia Pacific* factors were applied in 1993, it appears that royalty rates of 6 per cent were commonly applied. . . . In one of the last important cases before 1993, *DeGraffenried v. United States*,<sup>49</sup> the court imposed an up-front payment of \$150,000 plus a 5 per cent 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.<sup>50</sup>

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 per cent on the bulk of the infringing articles and 50 per cent on a small portion of a government contract covering the development phase.<sup>51</sup> In 1999, the Court of Federal Claims awarded a 16.31 per cent royalty,<sup>52</sup> and in 2000, it approved an award of 15 per cent of the benefit conferred by use of the patent in view of the importance of the patent itself.<sup>53</sup> This award was subsequently challenged by the Federal Circuit.<sup>54</sup> The highest known percentage rate appears to have been awarded in *Brunswick Corp. v. United States*,<sup>55</sup> where the plaintiff obtained 17 per cent 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.<sup>56</sup>

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 per cent, which jumped another 4 per cent 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 per cent.<sup>57</sup>

It should also be noted that the government’s proposed royalty rates in these cases were generally quite low, often ranging from 0.5 per cent to

---

eminent domain theory”); *Wright v. United States*, 53 Fed. Cl. 466, 469 (2002) (“Compensation is premised on a Fifth Amendment taking of a nonexclusive license under the patent.”).

<sup>49</sup> *DeGraffenried v. United States*, 25 Ct. Cl. 209 (1992).

<sup>50</sup> See Reichman with Hasenzahl, *Law and Practice of the U.S.*, supra note 88, at 102.

<sup>51</sup> *Gargoyles, Inc. v. United States*, 113 F.3d 1572 (Fed.Cir. 1992).

<sup>52</sup> *Standard Manufacturing Co. v. United States*, 42 Fed. Cl. 748 (1999).

<sup>53</sup> *Dow Chemical Co. v. United States*, 36 Fed. Cl. 15 (1996), rev’d in part on other grounds, 226 F.3d 1334 (Fed. Cir. 2000).

<sup>54</sup> *Dow Chemical Co. v. United States*, 226 F.3d 1334, 1348 (Fed. Cir. 2000).

<sup>55</sup> 36 Fed. Cl. 204 (1996).

<sup>56</sup> *Schlitz & McGrath*, supra note 364 at 359.

<sup>57</sup> *Standard Manufacturing Co. v. United States*, 42 Fed. Cl. 748, 777 (1999).

5 per cent of the cost of the patented items.<sup>58</sup> The higher rates actually awarded, when compared to the pre-*Georgia Pacific* norm of 6 per cent, would thus seem to reflect a judicial shift toward fuller compensation.<sup>59</sup>

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 March 31, 1998 decision by the US Court of Appeals for the Federal Circuit, in *Brunswick Corporation v. the 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 US 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 license, 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.'"<sup>60</sup>

In some cases, the US government has set limits on the total royalties paid. In a famous case involving aircraft patents in 1917, the US government demanded that the Wright Brothers and others place the essential patents needed to build aircraft into a Manufacturers Aircraft Association (MAA) 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 the 1st World War, the US three times told the patent owners to lower royalties, eventually capping the Wright and Curtiss patents at \$2 million each. On March 8, 1918, the Secretary of the Navy wrote to the MAA patent pool to say:<sup>61</sup>

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

---

<sup>58</sup> See *Schlitz & McGrath*, *supra* note 364, at 359.

<sup>59</sup> *Cf. id.*, at 364 (stating that, under the *Georgia Pacific* factors, "the court has made very generous awards to plaintiffs").

<sup>60</sup> Quoting *Leesona* (599 F.2d at 969).

<sup>61</sup> 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, May 8, 1933.

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.

Professor Scherer provided additional examples of compensation for US government use of patents:<sup>62</sup>

For U.S. government use of Enrico Fermi's patent governing plutonium production, a payment of \$300,000 was made -- one percent 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 percent 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 percent 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 percent royalty in the U.S. Court of Claims.<sup>63</sup>

### ***3.4 Special US Compulsory Licensing Programs***

The United States has several special programs for compulsory licensing.

#### *Civilian Nuclear Energy*

The United States has two different statutes that provide for compulsory licenses of patents for civilian nuclear energy programs. Under 42 USC 2183, the US 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

---

<sup>62</sup> Scherer, F.M. In the Matter of Glaxosmithkline South Africa et al. (Expert Report FMS).

<sup>63</sup> See *Hughes Aircraft v. United States*, 86 F3d 1566 (Fed. Cir. 1996).

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 license 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 defense, 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
- (5) the cost to the owner of the patent of developing such invention or discovery or acquiring such patent,

#### *Clean Air Act*

Another US 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 (EPA) 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.*" 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."

#### *Bayh-Dole March-In Rights*

Under the US *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.

#### *The Proposed Public Health Emergency Medicines Act,*

In the fall of 2001 the United States was confronted with an attack using anthrax. The US 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.<sup>64</sup> Ciprofloxacin was patented in the United States by Bayer -- and priced at \$1.77 per pill. Bayer could not manufacture enough ciprofloxacin to supply the US stockpile on a timely basis.

---

<sup>64</sup> Elisabeth Bumiller, "Public Health or Public Relations," *New York Times*, October 21, 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 doxycycline, then switch if indicated to the other drugs.

Under pressure from domestic public health groups and the members of Congress, US Secretary of Health Tommy Thompson threatened to override the Bayer patent and purchase ciprofloxacin from generic suppliers, unless Bayer lowered its prices.<sup>65</sup> Bayer then lowered its price to \$.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 US 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 licenses 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:

- (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 the 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 Licenses Issued as a Remedy to Anticompetitive Practices.***

FM Scherer notes the extensive use of compulsory licensing as a remedy to anticompetitive practices:<sup>66</sup>

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.

---

<sup>65</sup> "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." October 23, 2001, Thompson: Cipro Price Must Be Lower, Associated Press.

<sup>66</sup> FM Scherer, In *The Matter Of Glaxosmithkline South Africa Et Al*, August 28, 2003.

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 Meproamate, 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.<sup>67</sup> Most provided for "reasonable" royalties. . .

### *Microsoft*

Among the more recent US compulsory licenses are those seeking remedies for Microsoft's anticompetitive 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 US Department of Justice and other parties forced Microsoft to lower its royalty payments and change other terms of its licenses. On August 1, 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.

---

<sup>67</sup> In *United States v. General Electric Co.*, 115 F. Supp. 835, 844 (1953), the court explained: General Electric and the other defendants are mounted upon an arsenal of a huge body of patents that can easily overwhelm and defeat competition by small firms desiring to stay in or gain a foothold in the industry. These operators may well be unequipped to engage in litigation on the validity of one patent after another at what could be incalculable expense. In order to avoid it they could be required to shoulder royalties which could prove to be the very factor that would push them out of the competitive circle of the market.

In the circumstances such as these it would appear that royalty free licensing of patents on lamps and lamp parts is an essential remedy as a preventive against a continuance of monopoly in this industry. It would appear to be no more objectionable as confiscatory than where compulsory licensing is ordered. In the latter case the owner admittedly is permitted to receive a royalty but he nevertheless loses a monopoly inherent in his ownership of the patent, and the royalty he is forced to accept at times is not one that he fixes. Royalty free licensing and dedication are but an extension of the same principle, not to be directed indiscriminately, of course, but well within the therapeutic measures to be administered under circumstances such as were made to appear in this case.

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 percent 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 percent of the licensed product revenues.* Royalty rates on Microsoft protocol technology used in embedded hardware products range from 0.5 percent to 2.5 percent. [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 percent 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 .0005 (.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 Licenses for Pharmaceuticals***

Canada, like many countries, has a variety of grounds under which compulsory licenses can be issued, including failures to work the invention, government use, to remedy anticompetitive practices, as well as special provisions for issuing compulsory licenses on medicines and food. The Canadian government has issued more compulsory licenses 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 prices 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.<sup>68</sup> 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 licence 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 licence; and, in settling the terms of the licence and fixing the amount of royalty or other consideration payable, the Commissioner shall have

---

<sup>68</sup> "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'" Jerome Reichman and Catherine Hasenzahl, *Non-voluntary licensing of patented inventions: the Canadian Experience*, 2002.

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.

*Frank Horner v Hoffmann-La Roche*

From 1969 to 1992, Canada issued more than 600 compulsory licenses on medicines. In nearly every case, the compensation to the patent owner was a standard 4 percent royalty applied to the generic competitors sale price.<sup>69</sup> The basis for this approach was set out by A.M. Laidlaw, the Commissioner of Patents, in *Frank Horner v Hoffmann-La Roche*, in January 20, 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.

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 licences 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.

---

<sup>69</sup> The Economics of Compulsory Drug Patent Licensing. F. M. Scherer, May 2003, Jerome Reichman and Catherine Hasenzahl, *Non-voluntary licensing of patented inventions: the Canadian Experience*, 2002. Joel Lexchin, "Pharmaceuticals, patents and politics: Canada and Bill C-22," *International Journal of Health Services* 1993;23:147-60, and Joel Lexchin, "After compulsory licensing: coming issues in Canadian pharmaceutical policy and politics." *Health Policy* 1997;40:69-80.

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 licence under s. 41(4) of the Act. A patentee, of a patent subject to licence 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<sup>70</sup>:

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'.

---

<sup>70</sup> *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 .

In their detailed review of the Canadian compulsory licensing experience, Jerome Reichman and Catherine Hasenzahl note that royalties on compulsory licenses for medicines were on average lower than were royalties for compulsory licenses granted for other manufactured products under local working grounds.<sup>71</sup>

Canada abandoned the most important aspects of its compulsory licensing laws when it negotiated to join the US-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 compensation was at the heart of royalty guidelines recommended to developing countries in the *2001 UNDP Human Development Report*.

Before Canada abandoned its compulsory licensing program 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 program 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.<sup>72</sup> However, to address the criticism that the program had an adverse 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 license rate when the patent owner could demonstrate that it engaged in research and development of pharmaceutical products in Canada.

### *Breast Cancer Gene Patents*

More recently, several Canadian providences have revisited the issue of compulsory licensing of patents as it relates to patents on diagnostic tests for breast cancer. In a September 21, 2001 Speech on the Myriad Gene Patent, the Ontario Health Minister said<sup>73</sup>:

Some of you may have read that on May 31<sup>st</sup> 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

---

<sup>71</sup> "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 3 ½ % 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." Jerome Reichman and Catherine Hasenzahl (2002).

<sup>72</sup> "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 growth has been more buoyant in Canada than it has been in the United States since 1967." Page 65.

<sup>73</sup> Speech Re: Myriad Gene Patent Issue by the Honourable Tony Clement Minister of Health and Long-Term Care, September 19, 2001.

[http://www.health.gov.on.ca/english/media/speeches/archives/sp\\_01/sp\\_091901\\_tc.html](http://www.health.gov.on.ca/english/media/speeches/archives/sp_01/sp_091901_tc.html)

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 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 of 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*<sup>74</sup>. One recommendation of the report was to revise the Canadian compulsory licensing system:

The Ministerial Conference of the World Trade Organisation 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

---

<sup>74</sup> [http://www.health.gov.on.ca/english/public/pub/ministry\\_reports/geneticsrep02/report\\_e.pdf](http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf)

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 licence in respect of these patents. It should, however, require fair payment after determining the relevant factors.

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*<sup>75</sup>

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

### **3.7 The Philippines**

The Philippines adopted the Republic Act No. 165, known as the patent law, in 1947. The Act was amended in 1977 by Presidential Degree 1263. A section on voluntary licensing of patents provided that for licenses 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."<sup>76</sup> The Act also provided that compulsory licenses "shall be granted to the petitioner," when any one of a number of conditions were met:

---

<sup>75</sup> Aidan Hollis, "Commentary: The link between publicly funded health care and compulsory licensing," *CMAJ* • October 1, 2002; 167 (7) (Canadian Medical Association Journal).

<sup>76</sup> "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

(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 license or licenses 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."

Compensation for the compulsory license 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 percent (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 percent (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

---

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.

(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.

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.<sup>77</sup> The Courts repeatedly found the 2.5% royalty rate reasonable,<sup>78</sup> noting it only covered “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.”

In April 6, 1993, the United States Trade Representative (USTR) and the Philippines Department of Trade and Industry signed an agreement (the Kantor-Navarro agreement) the set out a number of changes in the Philippine intellectual property laws.<sup>79</sup> 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 license, in a new patent law that took effect on January 1, 1998.

### **3.8 Malaysia**

*The Malaysian Guidelines for the Approval of Technology Transfer Agreements on Intellectual Property.*

Manufacturing projects licensed under the Malaysian Industrial Coordination Act 1975 are required to obtain the approval of the Ministry of International Trade and Industry (MITI) 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, or (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.

---

<sup>77</sup> An eight percent royalty was awarded in G.R. No. L-27004 August 16, 1983, Parke, Davis & Company, petitioner, vs. Doctor's Pharmaceuticals, Inc.

<sup>78</sup> *United Laboratories, Inc. vs. Boehringer Ingelheim, GMBH*, IPC 929, July 27, 1981; *United Laboratories, Inc. vs. Bristol-Myers Company*, IPC 1179, Aug. 20, 1981; *United Laboratories, Inc. vs. E.R. Squibb & Sons, Inc.*, IPC 1349, Sept. 30, 1981; *United Laboratories, Inc. vs. Helmut Weber, et al.*, IPC 949, Dec. 13, 1982; *Oceanic Pharmacal Inc. vs. Gruppo Lepetit S.A.* IPC 1549, Dec. 21, 1982; *United Laboratories, Inc. vs. Boehringer Ingelheim*, IPC 1185, June 8, 1983; *United Laboratories, Inc. vs. Pfizer Corp.*, IPC 1184, June 10, 1983; *Doctors Pharmaceuticals, Inc. vs. Maggi, et al.*, July 11, 1983; *Drugmaker's Laboratories v. Heringen et al.*, IPC 1679, September 22, 1983; *Superior Pharmacraft Inc. vs. Maggi, et al.*, IPC 1759, January 10, 1984; *United Laboratories, Inc. vs. Van Gelder et al.*, IPC 1627, June 29, 1984; *Drugmaker's Laboratories, Inc. vs. Janssen Pharmaceutical N.V.* IPC 1555, August 27, 1984; *United Laboratories Inc. vs. Graham John Durant et al.*, IPC 1731, August 14, 1987; *United Laboratories, Inc. vs. Albert Anthony Carr*, IPC 1906, August 31, 1987). G.R. No. 82542 September 29, 1988, *Barry John Price vs. United Laboratories*.

<sup>79</sup> 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.

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:<sup>80</sup>

Running royalties not exceeding 3% of net sales

Lump sum payment not exceeding RM 500,000

*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.*

### ***3.9 Singapore***

During the 1980s, Singapore imported medicines from generic suppliers under its government use exceptions in the compulsory licensing laws. Compensation to patent owners was limited to 5 percent of the net ex-factory bulk cost of the drugs.<sup>81</sup> In the recently negotiated US/Singapore bilateral Free Trade Agreement (FTA), the United States now limits the grounds under which both the US and Singapore may grant a compulsory license, and introduced new trade rules for compensation 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.

---

<sup>80</sup> <http://e-directory.com.my/web/sw-investorinfo-technology.htm>

<sup>81</sup> August 1987, Patent Protection for Pharmaceuticals in East Asia, US Department of State.

The term "*reasonable and entire compensation*" follows the language in the US statute, 28 USC 1498, which requires compensation for US 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 authorisation. Certainly if the objective of the compulsory license is to overcome market outcomes, it is a problematic standard.

### ***3.10 Other evidence regarding norms for royalty rates***

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

1. Average royalty rates for the pharmaceutical sector are approximately five percent of net sales, but also have increased somewhat in recent years.
2. There is substantial variation in terms for individual licenses, which can range from much less than one percent to more than 50 percent 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 percent, 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 to 5 percent or less of net sales.

In Table R-1, royalty rates for all US industries are reported. The royalties reported to the IRS include payments for license 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 .7 percent. The average rate for pharmaceutical manufacturing sector was 4.9 percent. The only major industry sector close to the pharmaceutical sector is computer and electronic product manufacturing, at 4.5 percent.

**Table R-1**  
**Average Royalty Rates**  
**As Reported to US Income Tax Returns, 1999**

Industry	Royalty rate
All industries	0.65%
Chemical Manufacturing	2.96%
<b>Pharmaceutical Manufacturing</b>	<b>4.87%</b>
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,<sup>82</sup> which is reported below in Table R-2. More than half of the respondents in her survey reported paying royalties of less than 5 percent for "in-licensed" patents, with higher royalties reported for "out-licensed" patents. Ninety-five percent of in-licensed and eighty nine percent of out licensed patents were from 0 to 10 percent.

**Table R-2: Distribution of Royalty Rates on Pharmaceutical Patents**  
*(percent 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- license	23.6%	32.1%	29.3%	12.5%	1.1%	0.7%	0.7%
Out- license	1.3%	20.7%	67.0%	8.7%	1.3%	0.7%	0.3%

<sup>82</sup> Rose Ann Dabek (Proctor and Gamble), *Valuation of a Technology*, The University of Dayton School of Law, February 18, 1999.

In February 2000, PhRMA submitted a study prepared by Charles Rivers and Associates to the United States Trade Representative Office, which “assumed that licensed foreign production generates a five percent royalty stream for PhRMA's member,” which they took to approximate the average pharmaceutical royalty rate.<sup>83</sup>

A July 8, 1999 US Public Health Service, Centers for Disease Control and Prevention Policy, Statement on Cooperative Research and Development Agreements and Intellectual Property Licensing<sup>84</sup> 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 nonissuance, 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 "license 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:<sup>85</sup>

Electronics 0.5 - 5 %  
Machinery 0.33 - 10 %  
Chemical 2 - 5 %  
Pharmaceutical 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.<sup>86</sup>

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 they make.

---

<sup>83</sup> Richard D. Boltuck and David A. Riker, Charles River 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.

<sup>84</sup> <http://www.cdc.gov/od/ads/techtran/forms/cradaa.htm>

<sup>85</sup> Dr. Michael Gross, *Actual Royalty Rates in Patent, Know-How and Computer program-License Agreements*, CASRIP Newsletter (V413), 1998,

<http://www.law.washington.edu/casrip/newsletter/news4i3gross.html>

<sup>86</sup> <http://novelint.com/royaltyrates.html>

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 %
- 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 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 IP Management Workshop in New Zealand. As a rule of thumb, the licensor should receive around 25 percent of the gain from the use of the patent. Median royalty rates from LES Surveys were as follows:<sup>87</sup>

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, the former Director of the U.S. 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 two and five percent."

Jerry Thursby of Emory University and Marie Thursby of the Georgia Institute of Technology and the National Bureau of Economic Research (NBER), characterize university patents as follows:<sup>88</sup>

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%.<sup>89</sup>

### *Consumer Electronics*

#### *IBM*

---

<sup>87</sup> Rob McInnes, *Effective Strategies to Manage and Commercialise IP*, August 2003, Compiled by LES Surveys, [http://www.frst.govt.nz/business/articles/IPStrategyforNZ\(generic\)2003.pdf](http://www.frst.govt.nz/business/articles/IPStrategyforNZ(generic)2003.pdf)

<sup>88</sup> University Licensing under Bayh-Dole: What are the Issues and Evidence?, May 2003.

<sup>89</sup> Jerry Thursby, Emory University and Marie Thursby, Georgia Institute of Technology and NBER, *University Licensing under Bayh-Dole: What are the Issues and Evidence?* May 2003.

IBM has the following information on its web page regarding licensing practices<sup>90</sup>

*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 one percent of the selling price of that product. If more than one patent is practiced in a product, the maximum rate is five percent of the selling price of that product.

*The 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 (3G3P).

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%.<sup>91</sup>

#### **4. Policy Framework for Setting Compensation for Royalties on Medicines**

---

<sup>90</sup> <http://www.ibm.com/ibm/licensing/patents/practices.shtml>

<sup>91</sup> Wireless Web, W-CDMA licensees join forces, February 14, 2003, <http://wireless.iop.org/articles/news/4/2/4/1>

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

#### **4.1 Lost Profits with Willing Buyer-Willing Seller**

A view supportive of strong patent rights and high levels of compensation based upon lost profits was presented by Professor Martin Adelman.<sup>92</sup>

. . . 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 need 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.<sup>93</sup>

In the Adelman scenario, companies would always be made whole for lost profits that they would have earned if the compulsory license had not been issued, with the compensation 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<sup>94</sup> and some others. In practice, patent owners often see lower prices in any 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). As noted by the Expert Reports by Hollis and Love (on excessive pricing), 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 the top decline of wage earners.

---

<sup>92</sup> Martin Adelman, "The role of patents in the quest for affordable access to drugs," June 2, 2003 presentation to World Bank, Washington, DC.

<sup>93</sup> Adelman notes the possibility that the prices would not be low because of "niche-pricing" strategies discussed by Scherer and Watal.

<sup>94</sup> Patricia M. Danzon, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, December 2001.

## 4.2 Ramsey Pricing with Budget and Social Welfare Weights

A quite different scenario was presented at the June 2, 2003 World Bank seminar by Professors William Jack and Jean Lanjouw.<sup>95</sup> Jack and Lanjouw presented a Ramsey Pricing model<sup>96</sup> 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 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 presented 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 ARV products used in 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 medicine.

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 when goods such as medicine 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

---

<sup>95</sup> William Jack and Jean O. Lanjouw, Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute? Center for Global Development Working Paper No. 28, June 9, 2003.

<sup>96</sup> Ramsey, Frank (1927): "A contribution to the theory of taxation," *Economic Journal*, 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.

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 unfairnesses 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.

Professor Jack expanded upon his earlier work with Lanjouw in an Expert Report examining prices and royalties for ARV in South Africa.<sup>97</sup> He concludes that:

Conditional on reaching some level of global profits from drug sales, the structure of royalty rates and prices should vary across countries in a way that balances the losses in consumer well-being from incremental, or marginal, price increases in each country: *countries that suffered a relatively high loss from such price increases would have lower royalty rates than others. . . .*

Reasonable royalty rates for licenses for ARV therapy in South Africa should be nominal – i.e. at or close to zero. If positive, the royalty rate should be calculated as the mark-up of price over the marginal cost of the most efficient producer of the drug.

#### **4.3. 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.<sup>98</sup> 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:

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.<sup>99</sup>

---

<sup>97</sup> William Jack. Expert Report: Economic Analysis of Prices and Royalties for ARVs in South Africa.

<sup>98</sup> Aidan Hollis, "Commentary: The link between publicly funded health care and compulsory licensing," *CMAJ* • October 1, 2002; 167 (7) (Canadian Medical Association Journal). Aidan Hollis, Expert Report: "Economic Analysis of the Need for a Compulsory License Remedy to Promote Access to Essential Medicines Under Section 8(C) of the South African Competition Act. "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."

<sup>99</sup> Hollis, Expert Report.

In his presentation at the June 2, 2003 World Bank Seminar on compensation on a compulsory license, Hollis discussed models of compensation for R&D investments that might be adopted from economic regulation of public utilities.<sup>100</sup> 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 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.

#### ***4.4 Reasonable Royalty Approach***

In the June 2, 2003 World Bank Seminar and in his Expert Report for this case, F.M. Scherer reviewed the historical experience with compulsory licensing of pharmaceutical patents in the United States, Canada, the UK and other countries.<sup>101</sup>

To sum up, there is wide variation in the way responsible government agencies and courts have set the amount of compensation awarded to patent holders when patents have been subjected to compulsory licensing. The United Kingdom has provided the most generous compensation in its drug patent licensing decisions; the United States the least generous compensation 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.<sup>102</sup>

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.<sup>103</sup>

#### ***4.5 Professor Reichman's seven factors for evaluating reasonable royalties in developing countries.***

---

<sup>100</sup> Compulsory Licensing: Insights from Economic Regulation Aidan Hollis, Department of Economics University of Calgary & Competition Bureau, Industry Canada, Ottawa, May 2003

<sup>101</sup> F. M. Scherer, The Economics of Compulsory Drug Patent Licensing. Paper Presented at the World Bank, June 2, 2003. F.M. Scherer, Expert Report In The Matter Of Glaxosmithkline South Africa Et Al.

<sup>102</sup> F. M. Scherer, The Economics of Compulsory Drug Patent Licensing. Paper Presented at the World Bank, June 2, 2003.

<sup>103</sup> F. M. Scherer, The Economics of Compulsory Drug Patent Licensing. Paper Presented at the World Bank, June 2, 2003.

In his Export Report, Professor Jerome Reichman examined the US and Canadian experience with royalty payments, and offered (*seven*) modifications to the US Georgia Pacific factors, to address important social and development objectives, and concludes with these changes, royalties for non-commercial use would normally range from 4 to 8 percent of the generic price.<sup>104</sup>

In determining reasonable royalties for government use as well as in competition cases, South Africa 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;
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 per cent in antitrust cases to a high of 17 per cent given in one recent government use case. The norm for government use prior to 1993 was, however, 6 percent, and even now, it seems hard to obtain more than 10 percent under the *Georgia Pacific* factors, although rates of 16 and 17 per cent are reported. We believe that, if the offsetting factors listed above are applied, royalties in a

---

<sup>104</sup> J.H. Reichman, Expert Report. Compulsory Licences: History and Legal Principles.

government use context may range between 4 and 8 per cent of the price the government charges the public, depending on the circumstances that motivated public noncommercial use in the first place.

#### **4.6 Pharmacoeconomic Approach**

From the point of view of public health, a more explicit economic model for setting compensation would be one based upon modern pharmacoeconomic analysis. This would typically focus on the benefits of new inventions.<sup>105</sup>

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 OECD member countries, Michael Dickson, Jeremy Hurst and Stéphane Jacobzone note:<sup>106</sup>

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.<sup>107</sup>

Australia pioneered the use of pharmacoeconomic analysis of reimbursement policies,<sup>108</sup> and today most developed economies are increasing their capacity to make more rational allocations of scarce resources for medicine purchases. The Australian approach is particularly interesting for developing countries, in that it optimizes reimbursements given a fixed budget constraint. Every product competes against

---

<sup>105</sup> This is a different approach than the cost based economic regulation referred to by Hollis.

<sup>106</sup> Michael Dickson, Jeremy Hurst and Stéphane Jacobzone, Survey of Pharmacoeconomic Assessment Activity in Eleven Countries, OECD Health Working Papers No. 4, DELSA/ELSA/WD/HEA (2003)4.

<sup>107</sup> 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."

<sup>108</sup> David Henry "Economic Analysis as an aid to subsidisation decisions: The development of Australian guidelines for pharmaceuticals", *PharmacoEconomics* 1:1, pp. 54-67. (1992).

every other project for a share of a fixed budget. In such a model, a country might allocate a fixed budget to fund R&D, and then allocate royalty payments among patent holders according the relative pharmacoeconomic benefits of each invention.

For example, South Africa might determine that five percent (*or a different percentage*) of its budget for pharmaceutical purchases would be allocated to royalty payments to fund R&D on new products, but allocate the royalties to each patent owner on the basis of the relative benefits of each invention, possibly based upon transparent and periodically revised guidelines to evaluate benefits.

The disadvantages of this approach primarily relate to the difficulty of conducting such pharmacoeconomic evaluations, including the resources needed for the evaluations and to resolve 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 UK has 23. Japan, Sweden and the UK all provide administrative appeals of staff decisions, and appeals to courts have occurred in several countries.

#### **4.7 Practical Issues**

##### *Precision versus Ease of Administration*

According to the *UNDP Human Development Report in 2001*, the practical mechanisms for compulsory licensing should be straightforward and not too complex.

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.<sup>109</sup>

For developing countries, there are compelling reasons to reduce the complexity of setting compensation, 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 program. Drugs such as levamisole, AZT and even Viagra were originally developed for other indications.
2. The size of the market in developing countries is small. As noted by many of the experts in this case, the entire African market is so small that it is unlikely to have a first order effect on R&D decisions.

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 compensation that is both impossible and unneeded.

---

<sup>109</sup> <http://www.undp.org/hdr2001/chapterfive.pdf>, page 107.

## *Transparency*

There are several reasons to adopt a framework for compensation that is transparent and predictable, including these two.

1. Predictable compensation rules facilitate voluntary licensing. By providing predictable rules for compensation, private parties will find it easier to negotiate voluntary licenses. This was one of the main objectives of the Japanese (*discussed below*) and German royalty guidelines.
2. Disclosure of evidence to support claims on compensation improves policy making. Policy making about compensation should be informed by information, including for example, evidence regarding:
  - i. Actual industry practices on in-licensing and out-licensing of patents,
  - ii. Compensation paid in non-voluntary uses of the patent in other jurisdictions,
  - iii. Actual R&D investments costs, by relevant stage of development (Pre-clinical, 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 by the uninformed parties, including both governments and consumers. The *2001 UNDP Human Development Report* recommends that when a patent owner registers a dispute over compensation:

*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.*

## *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 UK cases,

Courts have required the division to be made before the compulsory license can be used. This will in some cases delay the availability of the compulsory license. A better system is to place the total royalty payments into an escrow account and have the money be divided by the various patent owners until 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 failing 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 resolve the issue on behalf of the patent owners. In this case; a recommended allocation of royalties to different patent owners is presented (*below*) for two fixed dose combination ARV products that use patents from various parties.

#### *Exports with Parallel Patents in Import Market*

Economies of scale are very important for some medical products, including in particular Active Pharmaceutical Ingredients (APIs), vaccines, biologics, diagnostic and other medical devices, as well as for some finished pharmaceutical products. Normally, exports of products should be permitted, to allow South Africa manufacturers to achieve more efficient scale economies, and also to serve the needs to 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 August 30, 2003 action by the WTO to implement Paragraph 6 of the Doha Declaration on Public Health, the WTO decided to waive the obligation of the *importing* country to pay compensation.

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.<sup>110</sup>

This element of the WTO decision on Paragraph 6 of the Doha Declaration on TRIPS and Public Health was criticized on the grounds that it is more appropriate for the importing country to determine compensation than the exporting country. The particular approach set out the August 30, 2003 WTO decision will only apply to compulsory licenses issued under the "system" created for exports to a country that does not have the capacity to manufacture pharmaceuticals. It will not apply in general to authorizations issued as a remedy to anticompetitive practices.

#### *Appropriate Compensation Base*

The amount of compensation will depend both on the royalty *rate* and on the compensation base. There are two primary issues. First, should the compensation

---

<sup>110</sup> TRIPS: Council for TRIPS, Decision of 30 August 2003, WT/L/540, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health.

base be based upon the price of the product sold by the patent owner, or the price of the generic competitor? In several UK licence of right cases, 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 as the objective in infringement cases). In Canada, the Philippines, Japan, the United States (government use, 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 compensation base is more appropriate for cases where the policy objective is either to obtain lower prices (Canada, Philippines, etc), or create or approximate a competitive market structure (Japan, US competition cases, UK cases involving electronics).

A second issue concerns the situations where the patent is only a small part of a larger product. Professor Reichman discusses this issue as follows:<sup>111</sup>

(1) *The Compensation 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.<sup>112</sup> 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.”<sup>113</sup>

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.<sup>114</sup>

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.<sup>115</sup> This test focuses on the extent to

---

<sup>111</sup> Reichman, J. H. *Compulsory Licenses: History and Legal Principles* (Expert Report JHR).

<sup>112</sup> See *Lesona Corp. v. United States*, 220 Ct. Cl. 234, 262-264 (1979); *Brunswick Corp. v. United States*, 36 Fed. Cl. 204, 211 (1996).

<sup>113</sup> *Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 22 (Fed.Cir. 1984).

<sup>114</sup> See *Wright v. US*, 53 Fed. Cl. 466, 470 (2002); see also *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1549 (Fed. Cir. 1995).

<sup>115</sup> See *Lesona Corp. v. United States*, 220 Ct. Cl. 234, 262 (1979) (stating that the test for whether an unpatented item should be included in the royalty base should look beyond physical joinder to its “financial and marketing dependence on the patented item under standard marking procedures for the goods in question.”); see also *Brunswick Corp. v. United States*, 36 Fed.Cir. 204, 211 (1996); *Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 22-23 (1984).

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.”<sup>116</sup>

The new 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 percent. 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 percent.)

#### ***4.8 The general level of compensation should not undermine access.***

As discussed above, Scherer, Jack, Hollis, Reichman and Love all agree that for medicines in South Africa, royalties should be relatively low. The primary reasons for this are as follows:

1. The market for medicines in South Africa is a small fraction of the global market, and the compensation rates will not have a first order impact on global R&D decisions.
2. Royalties must be affordable to promote access to medicine.
3. The benefits of increased access to medicine in South Africa 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 through a variety of mechanisms, including some that are less restrictive in terms of access to medicine, or more efficient in terms of health care priorities.

Simply put, as royalties increase, prices rise (with the VAT and retail mark-ups, more than the royalty itself). 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 of essential medicines, there is a very high level of dysfunction for an intellectual property regime. This is a more serious concern than cases where prices are abusively high, but still affordable. When prices are so high that the poor go without access to a lifesaving medicine, the social cost is unconscionably high. This view is

---

<sup>116</sup> Schlitz & McGrath, *supra* note 364, at 365.

at the core of the 2001 Doha Declaration on TRIPS 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 medicine is central of the decision regarding the general level of compensation. Compensation rates which undermine access goals are rejected.

Professor Jack recommends royalty rates be set as low as zero or less. Professor Reichman suggests rates of 4 to 8 percent of the competitor's price may be appropriate. The Canadian pre-NAFTA compulsory licensing decisions required the "lowest possible price consistent with giving the patentee *due reward* for the research leading to the invention." The TRIPS simply requires "adequate" compensation be paid.

Normal rules of thumb (*5 percent or 25 percent of profits*), Pharmacia's new voluntary license for delavirdine, the average US royalty rate reported to the US IRS, the RSA Department of Trade and Industry royalty guidelines, and countless other comparisons indicate that five percent is a reasonable approximation for an acceptable royalty.

In the pre-NAFTA Canadian compulsory licensing regime, Roche objected to a compulsory license royalty rate that was lower than the percent 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, it is important to note that the patent itself is not the sole focus of the R&D investments.

According to DiMasi et al, approximately 30 percent of private R&D outlays are focused on pre-clinical discovery,<sup>117</sup> the research phase typically most closely associated with patent rights, while about 32 percent of R&D outlays are spent of the clinical trials used to support the product approval, and about 35 percent of total outlays are spent on post approval clinical trials,<sup>118</sup> many of which are primarily designed to achieve marketing objectives.<sup>119</sup>

Investments in clinical trials are typically not considered sufficiently inventive to warrant an award of a patent. However, these investments do often qualify for other non-patent types of protection. The WTO TRIPS accord provides separate

---

<sup>117</sup> Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, *Journal of Health Economics* 22 (2003) 151–185.

<sup>118</sup> The annual PhRMA survey has somewhat different percentages.

<sup>119</sup> See for more details, Love, James. Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines (Expert Report JL(C)).

protections for investments in clinical trials under Article 39.3 of the TRIPS accord. The United States has implemented Article 39.3 of the TRIPS by granting a five-year exclusive right to rely upon clinical trials that support the safety and efficacy of new chemical entity (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. The US, Europe and several other OECD member countries also grant (7 to 10 year 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 favor 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.<sup>120</sup> Firms also make investments in R&D that are protected by copyright, trademarks, *sui generis* database regimes, and most important, as 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. As noted in the Expert Report on R&D,<sup>121</sup> the US FDA reports that only 31 percent of new molecular entities are significantly better than existing medicines, and only one sixth of the private R&D investments are spent on the development of these new innovative products.<sup>122</sup> If one

---

<sup>120</sup> 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 licenses by third parties. The person seeking the non-voluntary license must first seek to negotiate a voluntary license. That failing, a person can elect to begin binding arbitration. According to the 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.

<sup>121</sup> Love, James. Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines (Expert Report JL(C)).

<sup>122</sup> About 25 percent is invested in R&D on existing products, and only 20 percent of the investment in new products is spent on the innovative medicines.

accepts the big pharma claim that 15 percent is the average reinvestment in R&D by the major research based companies, the amount invested in innovative products is estimated at 2.5 percent of turnover, and as noted above, much of this is invested in non-patentable activity.

## 5 Royalty Guidelines

For the reasons presented above, a system of compensation based upon royalty guidelines is recommended. Three models for guidelines are presented. The first was recommended in the *UNDP 2001 Human Development Report*. The second is the Japanese Patent Office guidelines for determining royalty rates for licensing patents owned by the Japanese Government. The third and recommended approach is a modification of the Japanese Guidelines, incorporating specific factors relevant to South Africa policy goals.

### 5.1 UNDP Royalty Guidelines

In the 2001 Human Development Report, 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 percent, and adjusted upwards as much as 2 percent for products of particular therapeutic value, or reduced as much as 2 percent when the development of the product had been partly supported with public funds, for a range of 2 to 6 percent. If applied in this case, possible standalone royalty rates would be as follows:

#### Application of UNDP guidelines

	Standard Rate	Therapeutic Value	Government Support	Total
AZT	.04	.02	-.02	.04
3TC	.04	.02	-.01	.05
Nevirapine	.04	.02	-.01	.05

### 5.2 Japan Royalty Guidelines

Japan has had patent royalty guidelines for more than fifty years (and broad authority to issue compulsory licenses). During this time Japan became a global power in high technology industries and has one of the highest living standards in the world.

On June 29, 1998, the Japanese Patent Office (JPO) reported new guidelines for determining royalty rates for licensing patents owned by the Japanese Government. While the guidelines are officially for setting royalties on government owned patents, they are considered by some a *de facto* standard, and are influential in the private sector. Previously the rates were 2 to 4 percent of net sales, and the guidelines had not changed for 50 years. Under the revised guidelines, the royalties can range from 0 to 6 percent.

The formula for setting the royalties is as follows:

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

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

#### *Value of working*

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

#### *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 percent. 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 percent.)

For example, if patents on AZT were needed for a 3 drug fixed dose combination (FDC), one might assign a utilization of 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 percent.

#### *Increase or Decrease Ratio*

The increase or decrease ratio goes from 50 to 150 percent, 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.

#### *Exploration Ratio*

This ratio goes from 50 to 100 percent. 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. Recommended Royalty Guidelines**

The following is the recommendation for royalty guidelines that would be used for Medical inventions in South Africa. The guidelines follow the JPO guidelines for

government owned patents, with the following modifications and elaborations. First, the value variable is raised from .02 to .04 to .02 to .05, to provide a higher mean royalty rate, which is appropriate given the above average rate of royalties reported for pharmaceutical inventions. Second, the increase/decrease ratio is expanded from 50 to 150 to 25 to 175, to provide more flexibility in setting individual rates. As a consequence of these two adjustments, the possible royalties are 0 to 8.75 percent.

Variable	Range
Value	.02 to .05 percent
Utilization	0 to 100 percent
Increase/Decrease	25% to 175 percent
Exploration	50 to 100 percent

#### *Guidelines for the value variable*

##### Recommended Guidelines for value

- (a) two to three percent for a product that does not represent a significant advance in therapeutic benefits,
- (b) Up to five percent for a product that provides a significant advance in therapeutic benefits.

Independent evidence of (a) and (b) would be evaluations by regulatory bodies (US FDA rankings for Standard or Priority approval status, similar designations in South Africa, Canada or other countries) or *Prescrire International* evaluations.

#### *Guidelines for the increase/decrease variable*

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 South Africa,
7. Evidence that the patent owner engages in R&D and technology transfer activities in South Africa,
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, and
11. other public interest considerations.

## 7. Recommended Royalties

The royalty guidelines recommended above are now applied to the patents on the products in these cases. The evidence in this case supports the following factual conclusions:

AZT benefited from an extensive role by the government in development of the product. AZT was first in its therapeutic class. The private cost of development through approval was low.

3TC benefited from some government-supported research on 3TC. 3TC 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 the product's approval was based. Nevirapine was first in its therapeutic class, and is currently second in market share in its therapeutic class. Nevirapine is the least expensive to manufacture "third drug" in HAART therapy.

Each product is awarded the highest *value* variable of .05. AZT has an *increase/decrease* value of 50 percent, 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 AZT approval. 3TC has an *increase/decrease* value of 100 percent, based upon a decrease for government support but an increase for therapeutic benefit. Nevirapine has an *increase/decrease/value* of 150 percent, with the decrease in the role of government R&D offset by the innovative nature of the product (1st in class) and low cost of manufacturing nevirapine (compared to other "3rd drugs" in HAART treatment).

### *Standalone Royalties*

<i>Patents</i>	<i>Value</i>	<i>utilization</i>	<i>increase/ decrease</i>	<i>exploration</i>	<i>Total</i>
AZT	.05	100%	50%	100%	.025
3TC	.05	100%	100%	100%	.05
Nevirapine	.05	100%	150%	100%	.075

### *Application of the guidelines for Three Fixed Dose Combinations (FDC)*

In applying the guidelines to Fixed Dose Combinations (FDCs), each patent is assigned a utilization ratio less than 100 percent. For purposes of division of royalties among patent owners, all patents owned by GSK or GI for the standalone products are considered together. The first FDC examined is AZT+3TC+Nevirapine. The patents on the combination of AZT+3TC are given a 10 percent utilization ratio. The patents for the three standalone products are each given a utilization value of .3.

*Fixed Dose Combination (FDC) AZT+3TC+Nevirapine.*

<i>Patents</i>	<i>Value</i>	<i>utilization</i>	<i>increase/ decrease</i>	<i>exploration</i>	<i>Total</i>
AZT+3TC	.05	10%	100%	100%	.005
AZT	.05	30%	50%	100%	.0075
3TC	.05	30%	100%	100%	.015
Nevirapine	.05	30%	150%	100%	.0225
				Total	.05

The second FDC considered is d4T+3TC+Nevirapine. D4T was invented at Yale University of a government grant, and the patent on d4T is no longer enforced in South Africa. CIPLA holds a patent on combinations of d4T+3TC+Nevirapine. Only the GSK and BI patents are assigned values.

*Fixed Dose Combination (FDC) d4T+3TC+Nevirapine.*

<i>Patents</i>	<i>Value</i>	<i>utilization</i>	<i>increase/ decrease</i>	<i>exploration</i>	<i>Total</i>
3TC	.05	30%	100%	100%	.015
Nevirapine	.05	30%	150%	100%	.0225
				Total	.0375

The third FDC considered is 3TC+AZT, popularly known as Combivir.

<i>Patents</i>	<i>Value</i>	<i>utilization</i>	<i>increase/ decrease</i>	<i>exploration</i>	<i>Total</i>
AZT+3TC	.05	10%	100%	100%	.005
AZT	.05	45%	50%	100%	.01125
3TC	.05	45%	100%	100%	.0225
				Total	.03875