# A Medical Patent System for Global Welfare

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#### Introduction

As society develops with new technology and innovations, the disparity in wealth continues to broaden. Consider that in 1998, the top 20% of the world's population earned 89% of the global income, up from 70.2% in 1960 [6]. This trend is an indication that the challenges in developing economies will only worsen in the future. Partly, due to this alarming disparity in wealth distribution, a global health crisis has developed in the last few decades.

This is a period in history where six treatable infectious diseases account for almost 90% of all deaths resulting from disease. Despite this, developed nations have done very little to create a solution. It is estimated that more than 40 million people will be living with HIV/AIDS by the end of this year, more than 82% in Africa alone [3]. There is essentially no financial capability for poorer countries to purchase effective medication. Even in developing countries, only 1 million people are receiving the life-saving HIV/AIDS drugs out of the 6.5 million people who need them [3].

The goal of this paper is to show that as the world leader in medical patents, the United States has the power and capability to amend the patent system in order to benefit global health. Further, the best approach in attempting to solve the global health crisis is to implement a more flexible patent system for drugs that treat epidemics in undeveloped nations.

## **Key Issues**

The United States is the driving force in pharmaceutical patents. The number of medical patents in the top ten developed countries accounts for over 75% of the world total, compared to less than 2% for the top ten developing countries [see Appendix 1].

Drastic changes would have to come from the developed countries for any significant changes. Moreover, since the United States account for about half of all medical patents [see Appendix 1]; we have the power to improve the current state of global welfare.

However, is a global welfare argument enough to justify a patent system that will allow poor countries to break the medical patents on drugs that can treat epidemics? With great power, comes with great responsibility; our government should feel a certain duty to be more active in a patent system that will benefit global health. The billions of dollars that the US donates in aid every year through PEPFAR, USAID, The Global Fund and UNICEF is only a short-term resolution. Changing policy is the best way to influence a sustained effect and revising our patent system on drugs would be a step in the right direction. The fear is that a more flexible patent system will decrease financial profits and lead to a recession in medical research. While these concerns are plausible, they are not as dire as the pharmaceutical companies have portrayed.

First, let us address the financial concern. Contrary to popular belief, the high drug prices are not a result of high production costs. Consider the following nine drug treatments for HIV. Production costs are far below the price at market (figure 1).

Figure 1 – Cost Analysis

Critics argue that the profits from these high prices are going into research and development; the data says otherwise (Figure 2). Out of the nine companies listed below, the most a single company has spent on R&D is 19%. While this is a significant chunk, these companies are still doing very well. Drug companies do in fact make a large profit and are not exhausting this profit on research and development of new drugs.

#### Figure 2 - Revenue Breakdown

Next, there is public concern that if we adopted a patent system that allowed generic companies in developing nations to produce cheaper drugs, the industry would collapse due to market efficiency. Although we would believe that the entire world is one giant market place, in reality there is a separation between the domestic market and the market of undeveloped countries. Generic drugs have been produced at very low costs in India for the last two decades, with very little harm in our domestic market. In fact, if we compared the performance of the Fortune 500 drug industry with all industries, we can observe that quite the opposite is true (Figure 3).

#### Figure 3 – Profitability of Fortune 500 Drug Industry

This trend shows that not only are the major drug companies profitable, but they are actually growing at a very rapid rate. These positive performance diagnostics leads to the question: why is the United States government requiring third-world countries to uphold first-world medical patents? Lobbying by the drug industry could be an explanation for our government's reluctance to amend our patent laws (Figure 4).

Industry Comparison of Political Spending 1999-2000

Figure 4 – Political Campaign Contributions by Industry

#### **Other Considerations**

If global welfare is the goal, there has actually been scientific support in allowing low-income economies to free ride on the patented inventions of developed nations. In Professor Scherer's paper [2], he assumes that the marginal utility of income is substantially higher in poor nations than in rich nations. Following from this assumption, he was able to argue that allowing advanced foreign technology to be obtained at a low cost initially can have a catalyst affect on a developing country. It follows that if the purpose of government legislature and global trade organizations is to promote economic growth and reverse the global health crisis, then we should consider allowing poor countries to break medical patents to fight epidemics. However, some poor countries are in such dire shape that they would not even have the capability to manufacture their own drugs even if we give them our intellectual property. Thus, we must consider other solutions to combat these diseases.

For a solution that takes more responsibility than merely lending out medical intellectual property, we turn to our neighbors from the North. A recent piece of legislature that we should consider adopting is Bill C-9, an amendment to the Canadian patent system. This Act will allow generic drug manufacturers to be able to sell specific pharmaceutical products (under patent protection in Canada) to eligible countries. To ensure that these discounted drugs do not leak onto the domestic market, Health Canada officials requires that these drugs be permanently marked with a unique identifier that the Minister of Health can track. Under this system, if large pharmaceutical giants do not want to sell their products at marginal profit to poor-countries, than the government will allow generic companies to break the patent protection for these contracts. Under their

new regulation, Canada will be the first country in the world to implement a patent system that will take proactive measures in the fight against the health crisis.

#### **Proposed Solution**

The proposed solution is that we adopt this bill of legislation from Canada with a three additional amendments. First, we should consider strengthening patent protection on drugs that are not prominent in poor countries. This would encourage/reassure pharmaceutical companies that the government is still interested in protecting their intellectual property and supporting their medical research. We would also have to carefully monitor generic drug companies to make sure they are not breaking any unauthorized medical patents.

Second, we should implement a strict quota on discounted drug exportation. The quota should be adequate to meet the needs of widespread epidemics in the poorest nations. The aim of this amendment is to prevent excess supply of discounted drugs in the foreign markets from affecting domestic prices. This will also encourage poor countries to investigate the extent of their health crisis and work with the US government for a solution.

Third, the entire process starting from the generic drug manufacturing to the actual distribution of these medical treatments should be tracked. It might even be a good idea to use health and human rights organizations such as The Red Cross, Amnesty International and Physicians for Human Rights as a means of distribution. These organizations have the motivation and a wealth of experience in the aid of diseased countries. Utilizing these existing organizations will also eliminate the need for additional costly government agencies.

#### **Conclusion**

The global health crisis can have serious economic implications. Millions of people dieing every year from maintainable, treatable diseases when there are affordable drugs that can allow them to contribute to society has immeasurable economic value.

More importantly, this issue on global health is about human compassion and our responsibility as a world leader.

As a nation, we cannot uphold a patent system that is profit centered.

Pharmaceutical companies will have incentive to continue their drug research and development regardless of whether or not they are patent protected in Africa. Africa only represents 1.3% of the pharmaceutical market [9]. The concern is not over sustainability and the growth of pharmaceutical giants, but about the drug industry's greed and selfishness. With an amendment in our patent laws, we would cut domestic drug company profits by a marginal amount, but we would benefit the rest of the human race. The responsibility lies in the hands of our legislatures and government officials to do the right thing.

There is no reason why one of the most advanced and educated countries in the world should not strive to be the leader in this war against infectious disease.

## Appendix 1 – Medical Patents Granted by USPTO, 1996 - 2000

TOP 10 DEVELOPED COUNTRIES (PCT MEMBERS)

|                   | Number | Percent of Sub-total | Percent of Total (Rank, 1-30) |
|-------------------|--------|----------------------|-------------------------------|
| 1. USA            | 18251  | 63.35%               | 47.97% (1)                    |
| 2. Japan          | 2877   | 9.99%                | 7.56% (2)                     |
| 3. Germany        | 2116   | 7.34%                | 5.56% (3)                     |
| 4. France         | 1775   | 6.16%                | 4.67% (4)                     |
| 5. United Kingdom | 1725   | 5.99%                | 4.53% (5)                     |
| 6. Canada         | 872    | 3.03%                | 2.29% (6)                     |
| 7. Switzerland    | 417    | 1.45%                | 1.10% (7)                     |
| 8. Sweden         | 349    | 1.21%                | 0.92% (8)                     |
| 9. Australia      | 216    | 0.75%                | 0.57% (10)                    |
| 10. Netherlands   | 213    | 0.74%                | 0.56% (11)                    |
| Sub-total         | 28811  | 100.00%              | 75.72%                        |

TOP 10 DEVELOPING COUNTRIES (PCT MEMBERS)

|                 | Number | Percent of Sub-total | Percent of Total (Rank, 1-30) |
|-----------------|--------|----------------------|-------------------------------|
| 1. Israel*      | 280    | 43.55%               | 0.74% (9)                     |
| 2. South Korea  | 166    | 25.82%               | 0.44% (12)                    |
| 3. India        | 86     | 13.37%               | 0.23% (13)                    |
| 4. China        | 39     | 6.07%                | 0.10% (16)                    |
| 5. South Africa | 29     | 4.51%                | 0.08% (17)                    |
| 6. Mexico       | 15     | 2.33%                | 0.04% (18)                    |
| 7. Brazil       | 10     | 1.56%                | 0.03% (21)                    |
| 8. Cuba         | 8      | 1.24%                | 0.02% (23)                    |
| 9. Singapore*   | 6      | 0.93%                | 0.02% (25)                    |
| 10. Turkey      | 4      | 0.62%                | 0.01% (26)                    |
| Sub-total       | 643    | 100.00%              | 1.69%                         |

TOP 10 TRANSITION COUNTRIES (PCT MEMBERS)

|                   | Number | Percent of Sub-total | Percent of Total (Rank) |
|-------------------|--------|----------------------|-------------------------|
| 1. Russia         | 66     | 38.60%               | 0.17% (14)              |
| 2. Hungary        | 59     | 34.50%               | 0.16% (15)              |
| 3. Croatia        | 11     | 6.43%                | 0.03% (19)              |
| 4. Czech Republic | 11     | 6.43%                | 0.03% (19)              |
| 5. Poland         | 10     | 5.85%                | 0.03% (22)              |
| 6. Slovenia       | 8      | 4.68%                | 0.02% (23)              |
| 7. Ukraine        | 3      | 1.75%                | 0.01% (27)              |
| 8. Romania        | 1      | 0.58%                | 0.00% (28)              |
| 9. Slovakia       | 1      | 0.58%                | 0.00% (28)              |
| 10. Yugoslavia    | 1      | 0.58%                | 0.00% (28)              |
| Sub-total         | 171    | 100.00%              | 0.45%                   |

Source: Data obtained from the United States Patent and Trademark Office. Country-by-country data on medical patents comes from the set of tables compiled by the Information Products Division, Technology Assessment and Forecast (TAF) Branch, "Patenting by Geographic Region (State and Country), Breakout by Technology Class. Count of 1996-2000 Utility Patent Grants by Calendar Year of Grant," available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/clsstc/regions.htm (accessed April 28, 2002). Medical patents refer to class 424: Drug, Bio-Affecting and Body Treating Compositions (includes Class 514).

# References

- 1. World Health Organization: www.who.org
- 2. Schererer, F.M, Global Welfare in Pharmaceutical Patenting, <a href="http://www.iipi.org/Conferences/IP&Health/scherer\_paper.pdf">http://www.iipi.org/Conferences/IP&Health/scherer\_paper.pdf</a>
- 3. AVERT (AIDS Charity): <a href="http://www.avert.org/worldstats.htm">http://www.avert.org/worldstats.htm</a>
- 4. Website: <a href="http://www.himalmag.com/march2001/report.html">http://www.himalmag.com/march2001/report.html</a>
- 5. Website: <a href="http://poorcity.richcity.org/entundp.htm">http://poorcity.richcity.org/entundp.htm</a>
- 6. Figure 1: Doctors Without Borders, 2001
- 7. **Figure 2:** C.P. Chandrasekhar, J. Ghosh, "WTO Drugs Deal", *The Hindu Business Line*: www.thehindubusinessline.com.
- 8. Figure 3: Public Citizen, 2001
- 9. **Figure 4:** "TRIPS Teach-In", <u>www.yale.edu/aidsnetwork/TRIPS%20Teach-In.ppt</u>