Opposing Viewpoints

In this new section, *TuftScope* presents two contrasting commentaries on a controversial issue: pharmaceutical patent laws. Article I, Section 8, Clause 8 of the U.S. Constitution states, "The Congress Shall Have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries...." The practical result of this stipulation is that creators of drugs have exclusive rights to produce and sell their products for 20 years. This effective monopoly, in theory, serves as an incentive to create new drugs. It also allows drug companies to recuperate the considerable costs associated with developing and testing a new drug or therapy. The problem, however, is that drugs are sold at a higher cost during this 20-year period than they would be as generics. This higher price puts new, life-saving medications out of the reach of many who cannot afford them. The two articles below describe further the two main "Opposing Viewpoints" on this vital issue.

CURRENT PATENT LAWS MUST REMAIN UNCHANGED IN ORDER TO INCENTIVIZE INNOVATION

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Nobody would argue that withholding life-saving drugs from deserving, underdeveloped nations is a good thing. The opposition to the current patent structure contends that patents slow the development of vital medications, and impede access to these drugs for poorer, developing nations. They claim, the right to health is more important than intellectual property rights, especially in the case of an emergency, such as the AIDS epidemic. While this is a reasonable argument, it is irrelevant, as the current system of international patent law protects the property rights of inventors and researchers while creating conditions where there are incentives to develop new drugs; drugs which are ultimately available to developing nations.[1] The twenty-year patents currently allotted by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement create incentives for pharmaceutical companies to develop new drugs by granting them temporary monopolies in the form of patents on new compounds (drugs). This allows the pharmaceutical corporation to recoup the large costs associated with the R&D of a new medications.[2] After a set time, patents expire, production rights are given to other companies while more efficient production becomes possible; drugs become dramatically cheaper, making them accessible to developing nations.[1] In certain cases, TRIPS mandates that production rights be extended before the patent expires. In a state of *national emergency* or *extreme urgency* the patent may be suspended. While TRIPS may be ambiguous in defining these terms, it also stipulates that developing nations may engage in parallel importation: commonly known as the grey market.[1] The current patent system, as contracted by the TRIPS agreement is the most socially just outcome, it creates strong incentives for drugs to efficiently and quickly be created, which then reach developing nations through trickle-down effect and government action.

The development of pharmaceutical drugs is an arduous process. The purpose of the patent system is to create incentive for investors, researchers, corporations, and entrepreneurs to devote their personal capital towards the development of new treatments.[1] Pharmaceutical corporations must be able to financially offset a lengthy development process including pre-clinical testing in animals, submitting a New Drug Application to the FDA, waiting for the application to be granted, three phases of clinical testing on humans, resubmission to the FDA, and continued testing and quality assurance measures. All-in-all the process takes an industry average of 500-800 million dollars, and about 10 years.[1] Because patents are typically submitted before this process begins, the pharmaceutical company is left with only 10 years to profit from a 20 year patent. Furthermore, in the United States, only a third of developed drugs prove to be profitable.[1] With these tremendous costs, and risks associated with gaining FDA approval and probability of profitability; the need for strong incentives is clear. While reducing the length of patents on medications would lead to a brief period of more equitable distribution, it would also lead to a dearth of new drugs in the long-term.[3] Incentives for future medical advancement must be maintained so that there are always new drugs to distribute to all nations, rich and poor.

Regardless of initial market price, chemical

formulas (drugs) tend to exhibit tremendous depreciation as production becomes for efficient, patents expire and more effective versions of existing drugs are developed. Temporary high price for patented drugs can be justified by the long-term benefits to society, including those for the least advantaged members.[1] While developing nations may not be able to initially afford new technology, the technology becomes more affordable over time. As an example, in 1941 there were only 200 doses of penicillin, by 1964 there were thousands of doses available, and the price of each dose fell from the modern equivalent of $7730 to $351.[1] Further, as a guard against opportunistic profiting from natural disasters, the TRIPS agreement allows the World Trade Organization (WTO) to suspend patent law in the case of emergency.[2]

With patents in place, pharmaceuticals still have incentive to provide life-saving drugs to developing nations at a loss. Being able to profit from a monopoly on a new drug in developed nations affords the company an opportunity to lose money in other markets, particularly developing nations. Positive P.R. from providing this service alone is usually worth the associated cost to these corporations. Bristol-Myers Squibb Co. announced they would sell ddI and d4T (new AIDS drugs) to all African nations at a loss to combat the current HIV/AIDS epidemic.[4] Continuing this trend, Merck & Co. have began to sell Crixivan and Stocrin to developing nations at well below their market price.[4] A reduction in patent length would mean these corporations would not be able to afford these charitable acts.

The current patent system, as stipulated by the TRIPS agreement is an optimal solution to the complex problem of balancing equitable drug distribution, the protection of intellectual property rights, and the creation of incentives for companies and inventors to develop new drugs. Pharmaceutical patents reimburse firms for undertaking the tremendous risk and cost association with the R&D of a new drug. These incentives create a large and competitive market to develop and produce effective drugs as quickly and efficiently as possible. Initial high cost for these drugs can ethically be offset by the long-term positive externalities associated from the drugs being available to all members of society. Drugs quickly depreciate, and become available to even the poorest of developing nations. Finally, the brief period of monopoly power allows pharmaceutical companies the opportunity to engage in charity as they profit from more wealthier markets. This market-based system of incentives balances efficiency and equity to create the best possible social outcome.

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THE FLAWS OF THE CURRENT PATENT SYSTEM MUST BE ADDRESSED TO EXPAND ACCESS TO NEW MEDICATIONS

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As pharmaceutical companies will attest, there is a reason that the United States strongly enforces patent laws. Inventing a new drug suitable for distribution to the general public requires considerable amounts of research and testing before any profit can be realized by the company. Firms argue that for this reason, they require the guarantee of a twenty-year monopoly over their product in order to even recover their initial investment. Yet the current system has several key flaws, and it is imperative that these shortcomings be addressed if the benefit from a drug therapy is to be maximized domestically, as well as internationally.

The present system for awarding patents to drug companies involves proving the superiority of the new drug through comparison with similar drugs. As a result, drug companies allocate much of their research funding towards the formulation of new drugs that are only slightly altered from the previous version. The FDA estimates that only one third of pharmaceutical patents are awarded to "qualitatively new" drugs.[1] The current system, therefore, provides an incentive not to develop innovative new drugs, but to modify existing formulas, thus slowing the overall progress of medicine.

An even more urgent problem resulting from current patent laws is that they both directly and indirectly prevent certain groups of people from receiving treatment for for life-threatening diseases. Patent laws prevent drugs from reaching populations in underdeveloped countries by allowing firms

in first world countries to export drugs at exorbitantly high prices, without the tempering effect of competition. The most commonly cited example of this is in the case of HIV/AIDS, where an estimated 77% of individuals in sub-Saharan Africa lack affordable access to drugs.[2] Treatments available for HIV/AIDS are relatively new, therefore most have at least ten years left on their patents. Affording medications is a huge burden for underdeveloped countries and two thirds of healthcare budgets in these countries goes towards the purchase of patented drugs.[3]

Furthermore, patent laws have the indirect effect of reducing the incentive for drug companies to research cures for diseases that are not prevalent in urbanized countries. Since a few U.S. and Western European firms disproportionately represent the pharmaceutical industry as a whole, most of the drugs that are invented are invented to treat "global diseases" such as heart disease, cancer, and diabetes. Even though these diseases also affect developing countries, the treatments produced by pharmaceutical companies are targeted towards wealthy nations and thus hard to implement without a high degree of financial, structural and technological resources. In contrast, because parasitic and infectious diseases such as malaria and tuberculosis are primarily a concern for less developed countries, there is much less interest in researching drugs for them.

When considering alternatives to the current system, it is important to refute the idea that private firms are by nature better suited than publicly funded projects in inventing new drug therapies. A few prominent examples, such as the invention of penicillin, the polio vaccine, AZT (an HIV/AIDS medication), and Taxol (a cancer drug), demonstrate the capability of the public sector in creating groundbreaking drugs.[1] Private foundations, universities, and organizations such as the NIH and CDC already have some involvement in the research phase of drug production, but private companies tend to take over during the refinement, manufacture, and approval phases.

One alternative to the current system suggests issuing conditional tax credits to pharmaceutical companies.[4] The idea behind this solution emphasizes that government should support innovation that benefits society as a whole, just as it supports other public goods such as national parks and education. With this policy prescription, tax credits would be issued to firms in proportion to how socially beneficial their new drugs were, providing a much clearer and more direct incentive for firms to produce cutting-edge solutions. Reciprocally, the companies would agree to price their drugs at "marginal cost," based on (but not necessarily equaling) the price of producing and distributing the medication. This market model stands in direct opposition to the current system of pricing.

Another proposed solution targets the global rather than domestic consequences of patent laws.[5] Assuming that the market for global diseases resides primarily in developed nations, and that the only market for infectious and parasitic diseases is in developing countries, this solution separates the two classes of medications. The proposal works around the issue of how pharmaceutical companies in the U.S. obtain foreign patents. If a firm gets a patent in the U.S., it can apply for a "foreign patent filing" allowing it to apply for patents in other countries, each patent being restricted to and enforced within certain political boundaries. If a U.S. firm has a patent in another country and a company within that country tries to sell the same drug, the U.S. company normally sues for patent infringement. The proposal states that in this when applying for the foreign patent filing, the U.S. drug company must also agree *not* to sue, with the penalty being forfeiting its patent in the U.S. In this situation, the American company would be forced to either withdraw from the specific foreign market, or lower its prices to compete with the "copycat" drug, hence reducing drug prices in poorer countries while allowing the firm to reap the same profits domestically. In contrast, if the drug were for a disease endemic to developing countries, the company would be willing to give up its U.S. patent in exchange for retaining patent rights in the foreign market. This policy would encourage the innovation of drugs for parasitic and infectious diseases while also keeping prices in underdeveloped countries reasonable.

Whether or not the best solution has been outlined thus far, it is clear that the current system promotes inequities and burdens the current medical system, and must be reformed.

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