

WEALTH INEQUALITY AND “THE CASE OF THE PROBLEMATIC PATENT:” AN EXPERIENTIAL CLASSROOM EXERCISE

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ABSTRACT

As academic topics go, wealth inequality tends to be seen by students as relevant and interesting, whereas intellectual property is more inclined toward mixed reviews. Without a doubt, the study of intellectual property is extremely important, multifaceted, and replete with legal and ethical issues. Nevertheless, the classroom rollout of intellectual property can come off as exceedingly abstract, overly complex, and, yes, even boring. Regardless, the basics of intellectual property often need coverage in traditional business school courses, particularly those involving law and the regulatory environment. A powerful and engaging way to introduce both topics is with the experiential classroom exercise “The Case of the Problematic Patent,” which implicates issues of wealth disparities and intellectual property rights associated with the major players in the pharmaceutical industry – Big Pharma, NGOs (Non-Governmental Organizations), and Government (in the form of U.S. Congressional representation). These issues include high research costs, drug company profits, the cost of drugs to U.S. patients, U.S. law on negotiating drug prices, global access to life-saving drugs, generic drugs, evergreening, ethics, and more. This exercise works in classes involving business law, the regulatory environment, ethical decision-making, international business law, and organizational behavior. Debriefing the exercise may be tailored to emphasize key issues of the particular discipline being taught.

INTRODUCTION AND OVERVIEW OF THE EXERCISE

The general focus of this exercise is on how wealth inequality and intellectual property rights come together to determine—quite literally—life and death issues. It is loosely based on the events that occurred in India in 2001 when the price of HIV/AIDS treatments dropped by 96 percent when generic drug manufacturers began competing in the anti-retroviral drug market. India’s patent market excluded patents for life-saving drugs, ensuring that market competition would keep the prices down for India’s consumers. This approach was welcomed by many as a way to get life-saving drugs to citizens of developing countries through NGOs. As one might imagine, the larger American pharmaceutical companies became upset that their patents were not being recognized in India for these life-saving drugs. They argued that the higher prices were justified to recoup the large investment in research and development that is required before any new drug goes to market. Moreover, they believe that large returns on investment are needed to continue to spur new developments and innovations in the pharmaceutical industry. Meanwhile, the U.S. government was concerned about protecting the interests of American companies, organizations, and citizens, but not oblivious to humanitarian considerations, and how the United States appeared on the world stage.

Accordingly, the dynamics at play implicate and are replete with issues of ethics, law, power, rights, interests, and more. Students experience the different views and rationales of the various players (each group simulation includes one student (or more) assuming the role of one of the three major players). The students are put into groups of three and given a two-page description of the scenario and priorities of the role that each one of them is acting out. If the total number of participants does not divide evenly by three, or if the instructor wants to assign more than one student to represent any of the three major parties, then the total number of students in the group will of course exceed three people. The background (or setting) of each role is the same, while the confidential section of each role is very different (see Appendices 1 thru 4). The players are as follows: 1) an NGO that serves developing nations around the world and is in desperate need of the life-saving drug “Curalot;” 2) Big Pharma on behalf of the Pharmaceutical Research and Manufacturers of American; and 3) governmental involvement from the U.S. Congress House of Representatives. (If doubling up occurs for this role and thus more than one student is assigned to represent the U.S. Congress, one student may assume the role of being an actual elected member of Congress, while the other student serves as, say, the Congressperson’s very reliable and trusted Chief of Staff).

To reiterate, each role contains confidential information (see Appendices 2, 3, and 4). As a member of the World Trade Organization (WTO), the fictional country of “Guardia” (i.e., not the real world “India”) is legally obliged to respect U.S. patents. Guardia, however, is resistant to cooperating. The Congressperson is under intense pressure from the U.S. firms to push for enforcement of U.S. patents in other countries. At risk is the U.S.’s ability to lead the pharmaceutical industry, deliver drugs that are of the highest safety standards, and tackle many deadly diseases. The continued success of these U.S.

companies—known as Big Pharma—helps the U.S. economy and keeps the pipeline of innovation and new research and development (R&D) alive.

Big Pharma represents U.S. firms that are the leading global biopharmaceutical researchers and biotechnology companies in the world. Their four main objectives are 1) strong intellectual property protections, 2) patient access to safe and effective medicines through a free market, without price controls, 3) transparent and effective regulation with a free flow of information to patients, and 4) insistence that Guardia live up to its WTO obligation to respect U.S. patents. These companies spend billions of dollars each year to discover and develop new medicines. Only 12% of experimental compounds in development reach the marketplace, at a cost of approximately \$2.6 billion for each medicine approved (DiMasi et al., 2022)

Meanwhile, the NGOs represent organizations that provide medical services to individuals living in poverty. Their main goal is to provide care to as many people as possible and save lives in these suffering communities. The current prices of many patented, brand name drugs have limited their mission. Most of the drugs that NGOs provide to people are generics from Guardia. NGOs rely on the lower prices of generics in providing more and better services to those in need. These organizations have saved thousands of lives and continue to do so with generic medicines.

The U.S. government represents stakeholders that place great weight on the political and financial issues surrounding drug patents—more so than the medical benefits. The truth as seen by the U.S. Congressional Trade organizations, as sub-committees to both Houses of Congress, is that Guardia is not honoring existing trade treaties and international law. By using government as the instrument for bringing pressure for change, the trade committees can bring about a much more prolific public relations capability. The tactical strategy here is to sell the idea that instead of the pharmaceutical companies losing money they had spent in developing the drugs and other IP, Guardia's non-observance of the patent laws deprives the American (or international) investors of a fair-trade partnership. At the same time, the U.S. government does not want to look as though it does not care about those who are suffering and dying in some of the most impoverished regions of the world.

TEACHING NOTES

While the general topic of wealth inequality is present across disciplines, instructors are encouraged to introduce the course in a manner consistent with the specific discipline they are teaching. As an example, if used for an international law course, the focus might be on non-compliance with international law and/or treaties and conventions to which the fictional Guardia is a signatory. Used in a course on ethics, the focus changes to balancing the ability of companies to make a reasonable profit after spending billions of dollars on research versus the NGO's ability to save as many lives as possible. The professor, as the subject matter expert in their area, may adapt the debrief accordingly. Moreover, the professor could add an instructional note to the role sheet. For example, an ethics professor might consider instructing students to apply various ethical theories (e.g., teleology, deontology, virtue ethics, etc.) to back up their ideas on how the situation should be resolved). This slight "tweak" can easily be accomplished with no changes to the general or confidential information in the role sheets.

The introduction to the case should be brief and it should include a basic recitation of the facts (i.e., not revealing any confidential information). Students are then given one of the three role sheets (doubling up on any of the role sheets if necessary to make the numbers work) and instructed to prepare individually (this should take about 15 to 20 minutes). The role sheets should be numbered (for example, in a class of twenty-one students there will be seven separate groups, each containing three members: one for Big Pharma, one for the NGO, and one for the U.S. Congressional Representative). The three representatives will negotiate within their group. In a class of twenty-one students, you would have seven simultaneous negotiations going on. As the professor/facilitator, you will want to listen in for several minutes to each separate negotiation to gauge the following: 1) Are the students prepared and staying in their individual roles? 2) Which issue(s) are they focusing on? 3) Do they appear knowledgeable, engaged, and interested? The facilitator may wish to take notes on what is happening in the various groups and then incorporate those thoughts into the debrief.

In a longer class (80-90 minutes or more), students may be given the luxury of having 30-45 minutes to negotiate a resolution (though less time may be given in shorter classes, it works well, but typically with a less elaborate and robust debrief). You will find that the discussion issues are numerous (see Table 1 for a succinct "Chart of Issues, Priorities, Legal Focus, Realities, & Resolutions"). The participants likely will have neither the time nor the expertise to come up with everything. What the participants will have are new perspectives and a deeper understanding of important and relevant issues.

Finally, the name of this article is, "Wealth Inequality and the Case of the Problematic Patent: An Experiential Classroom Exercise." That being said, the name at the top of the page for the actual role sheets that are distributed to students should simply be, "The Case of the Problematic Patent." Why? It is interesting to see how many students identify wealth inequality as an issue when it is not identified for them in the title of the exercise.

**TABLE 1: THE PROBLEMATIC PATENT
CHART OF ISSUES, PRIORITIES, LEGAL FOCUS, REALITIES, & RESOLUTIONS**

| PARTY | ISSUE(S) | PRIORITIES | LEGAL FOCUS | REALITY | RESOLUTION(S) |
|--|---|---|---|--|---|
| BIG PHARMA | Existence depends on profits Restrictions on use of research funds Time restriction on patents | Must make a profit to continue to invest in research Continue to receive money for research from the U.S. government | Maintain and/or extend length of patent protection | Stop selling drugs in some countries (e.g., Guardia) | Negotiate some limited access to certain drugs in exchange for enforcement of patent laws |
| NON-GOVERNMENTAL ORGANIZATIONS | Doctors Without Borders mission to is care for and treat the poor Provide the greatest benefits to all those who need it Create publicity designed to protect access to affordable meds | Promote research re: neglected diseases Treat conditions of diseases neglected by drug companies Maintain relationships with government and Big Pharma | Prevent “ever-greening” of patents Allow for more generic drugs | Doctors Without Borders sources 80-90% of meds from countries like Guardia Defend against lawsuits from Big Pharma | Work with Big Pharma to provide access to some drugs (see above) Make public the wealth inequality that occurs from lengthy patent protection laws |
| U.S. CONGRESSIONAL REP/CHIEF OF STAFF | Protect IP of U.S. companies Enforce trade treaties and international laws re: fair trade partnerships Prevent drug companies from losing money after developing new drugs | Enforce agreements with other countries (e.g., with Guardia to have same patent law as U.S.) Continue to receive campaign contributions from Big Pharma Not appear callous by assisting NGOs in obtaining some discounted pharmaceuticals | Prevent other countries from designing generic versions of Big Pharma medications with active patents | Use diplomatic channels to force other countries to change their laws Discourage investment in drug companies in some other countries | Work to change perceptions (make it appear other countries are changing laws to be the same as U.S. law) |

To review the general “Background Information” received by all students, see Appendix 1. See Appendices 2, 3, and 4 for each role’s “Confidential Information.”

DEBRIEF

Questions to Ask Students During the Debrief

Students typically emerge from the exercise with an excitement about the learning. It is helpful to get their thoughts and ideas about the exercise before launching into the substance of the learning. Consider asking the following questions: 1) What was this exercise about? 2) What was the most important thing you learned during the exercise? 3) Did you feel comfortable in the role you were asked to play (e.g., sometimes students are asked to argue against their own beliefs about a topic).

Teaching through role playing is not as direct as simply giving a lecture on the topic, but instead of learning a definition (e.g., what is evergreening?), the student experiences the effects of certain behaviors (e.g., if a company is evergreening, they learn the impact that action has on various stakeholders). Understanding the impact on individuals and society as a whole is likely to have a greater and more long-lasting effect on learning.

The professor/facilitator may want to assign a brief writing assignment (one to two pages, double-spaced) requesting that students reflect on how they believe that the issues should be resolved and their thoughts on the issues the group explored. It is not uncommon for students to admit to never having looked at various positions on the issue and afterwards demonstrating a more well-rounded understanding of the complexity of the problem.

Substance of the Debrief – Wealth Inequality and Patents on Pharmaceuticals

When it comes to wealth inequality, rich people getting medicine to live while poor people die is as unequal as it gets in the game of life. It is axiomatic that wealth, power, and influence seeks to perpetuate itself, and the legal protection afforded intellectual property rights is one of the ways that happens. When ownership and access is limited to a select few, the vast and expanding disparity between the small group of winners and the sizable group of losers is fueled and exacerbated.

Dean Baker, senior economist at the Center for Economic Policy and Research, has written a book arguing that over the last four decades, intellectual property laws have been important factors in the upward redistribution of income (Baker, 2016). Beginning in the 1980s, both U.S. and international laws increased the duration of patent rights. In 1980, the U.S. passed the Bayh-Dole Act allowing for patent protection on government-financed research. As an example, Moderna received close to a billion dollars from the U.S. government to develop the coronavirus vaccine. Fortunately, it was an effective drug, but if it had been ineffective, Moderna would still have been paid. Finally, in 1982, the U.S. established a patent-friendly appellate court to hear patent dispute cases. Internationally, the TRIPS provisions of the World Trade Organization, effective in 1995, extended the length of patent monopolies from 17 years from the date of issuance to 20 years from the date of filing.

In a subsequent working paper, Baker explains the upward redistribution of wealth. Very simply, there are not many low-income households who receive royalties from patents. He posits Bill Gates as exhibit 1—without patent and/or copyright protection, Gates would not have his current fortune. Baker says this is a result of policy decisions made by the government. The solution he offers is that governments weaken patent protection. While this may create some negative effect on growth, the same can be said of most tax and transfer policies. As such, he concludes we should be prepared to tolerate some negative effect from altering intellectual property rules if the distributional benefits are large enough (Baker, 2018).

This case focuses on determining whether greater weight should be placed on profits or on lives in situations where varying interests, rights, and power combine to pressure the parties into different viewpoints. We begin by looking at the approach each party utilized.

Non-Governmental Organization (N.G.O.)

Although no specific organizations are identified in the role sheet for the NGO representative, the real-world Doctors Without Borders provides independent, impartial medical humanitarian assistance throughout the world to the people who need it most. Accordingly, Doctors without Borders provides an excellent real-world frame of reference to bring up during the debrief. They take a humanitarian approach to healthcare, regardless of geopolitical boundaries. Their mission is to care for people affected by conflict, disease outbreaks, natural and human-made disasters, and exclusion from health care in more than seventy countries. (Home). They address the right to medical care regardless of gender, race, religion, or political affiliation, putting respect for human life first.

The leadership of Doctors Without Borders focuses on tactics that provide the greatest benefits to all those who need it. India has been an indispensable part of the process of providing affordable medicine worldwide. They are known as the “pharmacy of the developing world.” (Plahe & McArthur, 2021). Doctors Without Borders encourages the competition of pharmaceutical companies because it allows for innovation to occur, leading to new cures, and inexpensive medicine. They also use political and social campaigns to call out to India’s leaders “to resist pressure,” from the U.S. government, the European Union, Japan, and other countries with a strong pharmaceutical presence. (Ritchey, 2014).

Doctors Without Borders needs to maintain a healthy relationship with both Big Pharma and the U.S. and other governments to convince them to research neglected diseases. The Drugs for Neglected Diseases Initiative (DNDI) encourages research to treat diseases that are otherwise neglected by pharmaceutical companies (examples include several vaccination campaigns and AIDS treatments).

Currently, there is a global campaign, called “Hands Off!” urging India to protect access to affordable medicines. (MSF, 2015). This campaign is designed to prevent the Indian Government from changing any regulations or policies based on pressure from other countries. The Indian Patent Law is crucial to the pharmacy of the developing world. It was amended in 2005 to add Section 3(d):

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable.

The above amendment was added to prevent the “evergreening” of patents (Sharma, 2014). Evergreening occurs when a pharmaceutical company creates a different version of a patented drug without any considerable improvement in the

therapeutic benefits of the drug and patents the new version to expand the exclusivity period beyond the 20-year patent term. Novartis sued India in 2013, challenging the constitutionality of section 3. The Supreme Court of India held that when there is a conflict between international law (TRIPS) and municipal law, that municipal law prevails (Sharma, 2014).

Challenges to India's patent law remain. For example, the *Regional Comprehensive Economic Partnership* (RCEP) trade agreement could possibly stop the access of affordable medicine from India. The RCEP consists of 15 Asia-Pacific member countries accounting for 30% of the world's population and 30% of global GDP, making it the largest trade bloc in history. It was signed on November 15, 2021 and is effective as of January 2022. It is expected to eliminate about 90% of the tariffs on imports between its signatories within 20 years. (Mullin, 2022).

Big Pharma

Companies tend toward practicality when making decisions that have the potential to affect the quarterly margins. Since a company's continued existence depends upon earnings, the decision to focus on profits is not made lightly. Saving the lives of more people must also be considered by the pharmaceutical companies. The decision of how to proceed is complex. Big Pharma depends upon the earnings from the sale of their drugs to stay in business and continue funding research. While they do also receive research grants, these come with strings as to how the funds may be utilized. Even under patent protection, Big Pharma only receives a heightened return from a particular drug for 20 years. When the enforcement of patent law is non-existent, Big Pharma may potentially lose millions (or even billions) of dollars. Thus, for Big Pharma, the greatest weight is placed on profits. Accordingly, Big Pharma utilizes power tactics to pressure the parties to recognize their patents. Big Pharma's deep pockets are used to fund lobbyists, support groups, and politicians to push the smaller interest groups out of the way while pressuring governments to move in certain directions.

Big Pharma's aggressive pro-patent enforcement is seen by Big Pharma as an existential imperative. The influx of generics from India financially undermines Big Pharma during the patent period. If it continues, or worse yet, expands, then some companies may go bankrupt. At the very least, U.S. pharmaceutical companies may decide it is not worth doing business with India.

U.S. Government (represented by a Congressperson)

The governmental stakeholders in this case place their interests and greater weight on the political and legal positions of the United States. The United States Congressional Trade organizations, as sub-committees to both Houses of Congress, utilized the existing trade treaties and international laws to influence the government of India to follow the U.S. government's position on intellectual property laws (IP) and trade policies. Several powerful American lobbyist groups have brought pressure on U.S. congresspersons to look after the business aspect of both U.S. and international corporations. Their position is that India's trade policies and use of domestically produced generic drugs is harmful to U.S. interests and violates accepted international trade policies.

By using government as the instrument for bringing pressure for change, the trade committees are able to create a much more prolific public relations campaign. The tactical strategy is to sell the idea that instead of the pharmaceutical companies losing money they had spent in developing the drugs and other IP, India's non-observance of the patent laws deprives the American (and/or international) investors of a fair-trade partnership.

The U.S. trade committee's position is that when India joined the World Trade Organization (WTO) it agreed to abide by the *WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) Agreement. This position assumes that India's patent laws would be the same as the patent laws that are in effect in the U.S. India's patent laws are quite different and are the cause for many of the problems. India's domestic patent laws allow for generic reproduction of pharmaceuticals to avoid the high cost of many lifesaving drugs. It is precisely these practices that the large pharmaceutical companies via the U.S. government are trying to change.

Extreme Outcomes

In the worst-case scenario, what would happen if these three parties were unable to continue to satisfy their interests? If Doctors Without Borders ceased to exist, millions of people would die, now and in the future. If Big Pharma was threatened with bankruptcy due to ever-decreasing profits, they could choose to stop funding research for diseases found mostly in places like India that do not honor patents (again leading to more suffering and deaths). They might decide to focus solely on first-world diseases, like diabetes and heart disease, thus ignoring third world countries. Finally, the U.S. stakeholders might see the loss of patent protection as a direct challenge to trade equality. The repercussions could range from severe to negligible depending on other business interests and the political landscape at the time. Although the fates of all three are linked (at least to some extent), it is unlikely we will see a global agreement soon.

What is Happening in India Today?

According to the India Brand Equity Foundation (IBEF), India is the largest provider of generic drugs globally. The Indian pharmaceutical sector provides the U.S. with 40% of generic demand for various vaccines and provides the world with 80% of AIDS drugs (IBEF, 2022). The U.S. has concerns about India's reliance on China for active pharmaceutical ingredients (APIs) needed to produce the drugs, so India has begun the process of self-producing APIs in India (Buddharapu, 2022). Their goal is to self-supply 35% of their need for APIs by the end of the decade.

In 2020, the U.S. Food and Drug Administration entered its first bilateral enforcement operation with the Government of India to stop shipments of illicit, and potentially dangerous, unapproved prescription drugs (Commissioner, 2020). Unfortunately, there continues to be a lack of progress on long-standing IP concerns. India remains one of the world's most challenging economies with respect to protection and enforcement of IP. (USTR, 2022). In 2022, India remains on the Priority Watch list in the U.S.T.R.'s Special 301 report. Doctors Without Borders continues to source generic drugs from India.

CONCLUSION

This exercise is not designed with the expectation that the intractable conflicts built into it will be resolved. These tensions persist in the real world precisely because they do not lend themselves to easy or obvious solutions. Instead, the exercise is crafted as a platform for exploration of a wide variety of legal and ethical issues surrounding wealth inequality vis-à-vis the protection of intellectual property rights, international law, high research costs, drug company profits, the cost of drugs to U.S. patients, U.S. law on negotiating drug prices, global access to life-saving drugs,

Accordingly, this exercise works in a variety of courses and the professor/facilitator may select and explore the topics most suitable for a given discipline. As the authors of the exercise, we use it in a course called International Business Law & Ethics that explicitly takes up issues of both wealth inequality and intellectual property law. Students tended to enjoy studying the former while demonstrating less enthusiasm for the latter. Since we began using this exercise, students have been much more engaged in both topics. IP law can be a dry topic of discussion but the effect of IP law on individuals and society is impactful.

Is there an optimal resolution to this dispute? If only. Health care is a perpetual basic human need. Doctors Without Borders continues to be an indispensable lifeline for many people in third world countries. Big Pharma, with their groundbreaking research and lifesaving drugs, is integral to global healthcare, yet their vast power and influence threatens to overwhelm other important competing interests. In addition to political polarization on what the correct policy approach should be, governments everywhere inevitably face the vexing multiple constituency problem, i.e., you can't please everyone--but of course well-financed lobbying can and often does tip the scales. The reach and protection of intellectual property rights in connection with issue of wealth inequality continues to be a source of intense debate. Accordingly, as the conflicts and tensions persist, society must continue its efforts toward addressing them as clear-eyed and effectively as possible. "The Case of the Problematic Patent" provides students with a powerful and eye-opening experience surrounding this ongoing and multi-faceted dispute.

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APPENDIX 1

THE PROBLEMATIC PATENT

(NOTE: "GUARDIA" IS A FICTIONAL COUNTRY
CREATED FOR PURPOSES OF THIS EXERCISE.)

BACKGROUND INFORMATION

(NOTE: THIS INFORMATION IS PROVIDED
ON THE ROLE SHEETS OF ALL PARTICIPANTS.)

The price of life saving drugs can be exorbitant and over the years the ability of local Guardian companies to make generic versions of these drugs has significantly brought down the prices. This has been very impactful as many in developing countries are able to afford the lower prices and many lives are consequently saved.

A good parallel example is the price of HIV/AIDS treatments that dropped by 96 percent when generic drug manufacturers in India began competing in the anti-retroviral drug market at the turn of the century. This "generic drug" approach was taken at that time pursuant to India's patent law that excluded patents for life-saving drugs, ensuring that market competition would keep the prices down for Indian consumers. More broadly, this was a welcomed avenue for getting life-saving drugs to the citizens of developing countries by non-profit organizations (NGOs) as it enabled them to provide aid for a greater number of people in many more countries.

In this scenario, the country of Guardia has just such a law as the Indian one described above, i.e., a law that excludes patents for live-saving drugs. As expected, the affected American pharmaceutical companies are upset that their patents are not being upheld in Guardia for these life-saving drugs. They see it as an infringement on their patents that lower their marginal returns, which they claim must be protected to recoup the investment in the research and development (R&D) efforts required to develop new drugs. They also believe that the higher marginal returns are needed to continue to spur new developments and innovations in the pharmaceutical industry overall, therefore any sustained long-term infringements that curtail their higher returns could have an increasingly severe impact for everyone. In this scenario a specific controversy has arisen surrounding the astronomical cost of the life-saving drug "Curalot." which has drawn intense media attention. Guardia, a member of the World Trade Organization (WTO), is in the process of producing a generic version of the drug "Curalot," but it is not yet available.

Given the foregoing, a meeting to address these matters has been arranged that includes representatives from:

1. NGOs serving developing countries in desperate need of the life-saving drug "Curalot."
2. Big Pharma on behalf of the Pharmaceutical Research and Manufacturers of America.
3. The United States Congress, the legislative arm of the U.S. government.

APPENDIX 2

ROLE OF BIG PHARMA REPRESENTATIVE CONFIDENTIAL INFORMATION

[Note: This role can be played by one person or more, i.e., as many representatives as one would like.]

As the Big Pharma representative, you represent Pharmaceutical Research and Manufacturers of America. These are the global leading biopharmaceutical researchers and biotechnology companies in the world, headquartered in the United States. Your organization's main mission is to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical and biotechnology research companies. You are dedicated to achieving these goals not just in Washington, D.C., but throughout the world. Your main objectives are 1) Strong intellectual property protections, 2) Patient access to safe and effective medicines, absent any profit-gouging price controls, 3) Overseeing and improving upon the unfairly tarnished reputation of Big Pharma, and 4) Insistence that the renegade Guardia live up to its WTO obligation to respect U.S. patents.

In order to continue to expand your reach and facilitate the development of new drugs it is important that the companies you represent are able to recoup their costly investments in research and development. Big Pharma member companies spend tens of billions of dollars year after year to discover and produce new medicines. If companies manufacturing generics keep offering copycat drugs at lower prices they will erode countless sales in the patent-protected 20-year exclusivity period.

Moreover, reportedly only 12% of experimental compounds in development actually reaches the marketplace at a cost of approximately \$2.6 billion for each medicine approved. Thus, pharmaceutical companies must try to recover costs for the thousands of molecules that fail from each successful molecule that makes it as a drug. As R&D expenses surge, pharmaceutical firms feel that even the 20-year patent period does not sufficiently protect innovation, and they are thus forced into renewing patents by making variations of the drugs such as single dosage, daily-use or slow-acting versions of the same drugs, also known as the wise business practice of "lifecycle management."

At this meeting with both U.S. Congressional and NGO representatives you must convince them that patent protection is vital to the continued development of drugs and that Big Pharma drug patents must be respected in Guardia. You do not want any agreement that lowers the profits of the Big Pharma companies unless it benefits the companies in other ways. If no resolution is reached the Guardian firms will continue to produce generics and counterfeits which in the long run may negatively affect the industry. Pressure must be applied to the U.S. government to take aggressive action to get Guardia firms to respect the patents.

You would like to reach a resolution where NGOs and Guardia pay market prices for patent-protected drugs. NGOs live off the donations of wealthy donors who can certainly afford such prices, and Guardia should not be rewarded for stealing innovations from Big Pharma. From a public relations standpoint you would consider a substantial 20 to 25% discount on certain drugs with patents that are near expiration (say, 2 or 3 years of patent-protection left) if the NGOs could band together and buy in bulk.

As a complicating factor, a brutal (and you believe unfair) media assault has been launched against Big Pharma over the high cost of the very new and just brought to market drug called "**Curalot**," which is remarkably effective in combating a deadly global health crisis currently underway that is disproportionately ravaging the most impoverished regions of the world. Without much-needed patent protection, this drug would probably sell in the neighborhood of 5% of its patent-protected cost, but Big Pharma needs that kind of mark up in light of all the tested drugs that never make it to market, and whose R&D costs Big Pharma has to absorb. Even so, you know NGOs are looking to Big Pharma to discount the price of "Curalot." Given the magnitude of the current global health crisis, you are authorized to donate up to 10 million units of "Curalot" and offer a discount of no more than 50% on another 10 million units, all of which you consider to be extremely generous.

With regard to the broader range of patent-protected drugs beyond just the "Curalot," you want to zealously guard the 20 years of patent protection your drugs are afforded under the law. Accordingly, you may pretend you're open to some flexibility on the 20-year protection period, but you have no intention of ever actually budging in any significant way on this issue, i.e., it's something you can say you're open to, and you might even hint at considering it for some outdated drugs that are no longer viable—but that is as far as you are willing to go.

One very sensitive issue on which you know Big Pharma has some vulnerability is the "**evergreening**" of patent-protected drugs. [NOTE: "Evergreening" or "lifecycle management" (as referenced above) is achieved by seeking extra patents on variations of the original drug – new forms of release, new dosages, new combinations or variations, or new forms. From a pure business profitability perspective, even if the patent is challenged, companies can earn more from the higher prices than

they pay in legal fees to keep such patents alive.] This issue is very likely to arise and you will maintain that “evergreening” is a misleading term that falsely implies an “old” drug is being recycled when in fact patents are only being sought on what are really “new” drugs that are falsely perceived as re-treads. As far as you’re concerned, creating better drugs—or even better versions of existing drugs—is admirable and is nothing more than the prudent business practice of “life cycle management.”

If things do turn contentious, you may be threatened with a hyper-amplified social media campaign further aimed at discrediting “murderous” (!) Big Pharma (as the critics call you). In addition to the “evergreening” issue you already hear about endlessly, you expect an attack on the so-called “*bought-and-paid-for*” elected officials you rely upon for protection and support. You would prefer not to suffer additional reputational hits, especially if it resulted in political pressure for elected officials to “rein in” Big Pharma—when in reality, you know the real story should be about all the lives Big Pharma has saved and will continue to save if they are permitted to generate enough of a profit margin to reinvest in R&D.

Currently, you enjoy a highly beneficial symbiotic relationship with the U.S. government. Big Pharma generously donates to countless elected officials and lobbies Congress hard, and government, as it should, protects important intellectual property rights. You are counting on the government to continue to provide cover for you considering all the innovation and advanced medicines Big Pharma has been able to develop as a result of the patent protections Big Pharma has received and deserves. Moreover, you expect assistance from the government in persuading NGOs to dial back their harmful rhetoric, especially when it comes to NGOs defending renegade countries such as Guardia who flagrantly violate international law. Congress needs to impose strict sanctions on Guardia until they start respecting U.S. patents.

APPENDIX 3

ROLE OF NGO ASSOCIATION REPRESENTATIVE CONFIDENTIAL INFORMATION

[Note: This role can be played by one person or more, i.e., as many representatives as one would like.]

As a non-government organization (NGO) Association Representative, you represent the interest of the NGOs that serve around the world. Many of these organizations provide medical services to individuals living in poverty in developing countries. The main goal of these organizations is to be able to provide much needed care to as many people as possible and save lives in the process. The current prices of many patented brand name drugs have limited this mission. The majority of the drugs NGOs provide to indigent populations are generics mostly from Guardia. NGOs rely on the lower prices of generics in providing more and better services to those in need. These organizations have saved countless lives and continue to do so with affordable generic medicines.

In many developing countries, most people are uninsured, and the majority of the population pays for healthcare out-of-pocket. Several studies have shown healthcare costs are among the main reasons people throughout the world slide into poverty. You realize new drugs aren't developed in a vacuum. Their creation relies on generations of discoveries in order to be produced. Once produced, however, your organization would like to continue to provide the benefits of these drugs at an affordable cost so that you may save as many lives as possible.

It is undeniable that the United States pharmaceutical industry relies on government-granted patent monopolies that give them the exclusive right to sell their drugs. As a result, when they have a patent monopoly on a drug that can substantially extend life or improve its quality, drug companies can charge tens of thousands or even hundreds of thousands of dollars for drugs that may cost very little to produce. The fact that the drug might be relatively cheap to produce, however, is not necessarily a key factor—or *any* factor—in the market price at which it is offered. Accordingly, you find yourself weighing **(1)** the need to stimulate potentially life-saving innovation by rewarding it *versus* **(2)** the imperative of making life-saving drugs accessible in the here and now to those in need, and you decided to participate in this meeting in search of a viable path forward for the stakeholders involved.

You would like to reach a resolution where NGOs can continue to channel life-saving drugs at affordable prices to individuals in developing countries who cannot possibly pay existing market prices for patent protected drugs. You calculate that realistically you need on average at least an 85% discount on the prices being charged by Big Pharma. In addition to an overall 85% discount for patented life-saving drugs for developing countries in general, more specifically you also desperately need 60 million units of newly developed drug called **“Curalot,”** which is remarkably effective in combating a deadly global health crisis currently underway that is disproportionately ravaging the most impoverished regions of the world.

Knowing concessions are inevitable, you intend to initially ask that Big Pharma to donate 50% of your 60 million units of total need (i.e., 30 million units of “Curalot”) and then give you a 90% discount on the other 50% of your need (i.e., the other 30 million units of “Curalot”). Acquiring 60 million units of “Curalot” will save innumerable lives and continue the mission of your organization. As you can surmise from the Guardian generic drugs market, without patent protection the market cost of a generic “Curalot” would be about 95% less than what Big Pharma is currently charging. In addition to your irrefutable humanitarian argument, you might also emphasize a practical benefit to Big Pharma, i.e., helping the suffering, the poor, and the sick in such a compassionate way would result in a public relations bonanza for them.

With regard to the broader range of patent-protected drugs beyond just “Curalot,” you want to persuade Big Pharma to lobby the government to reduce the time period of patent-protected, life-saving drugs from 20 years to, say, 3 years in developing countries, and to get Big Pharma to stop “evergreening” the drugs for which they currently have patents. [NOTE: “Evergreening” is achieved by seeking extra patents on variations of the original drug – new forms of release, new dosages, new combinations or variations, or new forms. Big pharma euphemistically refers to this as “lifecycle management.” Even if the patent is dubious, the company can earn more from the higher prices than it pays in legal fees to keep the dubious patent alive.]

If Big Pharma is not willing to at least come close to your initial request, a third approach would be to threaten Big Pharma with a highly aggressive social media campaign to further paint them as the cruel, greedy, and heartless behemoth it sometimes seems to be. You are also confident you can build a grass-roots movement to target and discredit politicians who, as recipients of exorbitant campaign contributions, are beholden to Big Pharma. In fact, it will be interesting to see just where the congressional representative you are meeting with stands, who many are alleging is a *“bought-and-paid-for”* elected official

buried deep in the pocket of Big Pharma. You know this member of Congress is locked in a tough re-election campaign against an opponent who is hammering them for all of the Big Pharma campaign contributions they have taken in.

Fourth, you can also continue to support political and social campaigns to encourage Guardia's leaders "to resist pressure," from the U.S government, the European Union, Japan, and other countries with a strong pharmaceutical presence. Currently, there is a global campaign, called "Hands Off!" urging Guardia to protect access to affordable medicines. This campaign is designed to prevent the Guardian government from surrendering to pressure to change any regulations or policies in a harmful way that might possibly stop or curtail access to affordable medicine.

A fifth possibility would be to try to lobby Congress for some type of a "carve-out" for specific patent protections in a manner similar to what Guardia has done for life-saving drugs. You intend to make this very suggestion to the Congressional representative attending the meeting.

Sixth, you want Big Pharma to stop protesting and challenging Guardia's law that excludes patents for life-saving drugs—a compassionate and humanitarian law that allows market competition to keep the prices down. Why is it that Big Pharma, with all their all their rhetoric in support of capitalism, hates or is afraid of competition? You find it outrageous and indefensible, if not downright "*murderous*" that they hide behind a government granted monopoly (which is what a patent really is) just so they can generate obscene profits at the expense of human life. So much for free and open markets.

You do understand that if a resolution is not reached, the patent laws in Guardia that preclude enforcement of patent protections may result in Big Pharma pressuring the U.S. government to take steps to stifle the accessibility of those generic drugs. You also are aware of the argument by Big Pharma that if companies are unable to afford necessary R&D costs to develop new innovative drugs then the world will be deprived of medicines to deal with many of the other deadly and terminal diseases that exist today, which is an argument that you find less than compelling. History is replete with invention and innovation brought about by decent people inspired by humanitarian concerns, not greedy people attracted only to flashing dollar signs. Yes, you may be considering playing hardball, but your conscience is clear. Rather than the Big Pharma model of hoarding and squatting on a mountain of money, you vastly prefer your perch atop the moral high ground.

APPENDIX 4

ROLE OF U.S. CONGRESSIONAL REPRESENTATIVE (& TEAM) CONFIDENTIAL INFORMATION

[Note: This role can be played by one person or more, i.e., as many participants as one would like. If, for example, more than person is representing the U.S. government, one person can be the actual member Congress and others can play such roles as the Congressperson's Chief of Staff, an involved spouse, or perhaps a Media Relations Specialist, any of whom can and should play an active role in the discussion.]

In representing the U.S. Congress, you represent the interests of the legislative arm of the U.S. government concerned with protecting U.S. companies, organizations, and citizens' interests. You are under pressure by U.S. pharmaceutical firms to push for enforcement of U.S. patents to be honored and protected by other countries. As a member of the World Trade Organization (WTO) Guardia is obliged to respect U.S. patents but there have been some issues with getting the Guardian government to cooperate. The continued success of these U.S. companies—known as Big Pharma—helps the U.S. economy and keeps the pipeline of innovation and new research and development alive. This in turn helps the U.S. continue to lead the pharmaceutical industry and deliver drugs that are of the highest safety standards and combat many deadly diseases.

The rising cost of drugs in the U.S., however, is a highly contentious political issue and an area of increasing concern raised by NGOs and private citizens. Many non-government organizations (NGOs) are not able to provide services that would save lives with the prices of the brand name drugs. Those same high costs are also consuming a significant part of the government's budget in funding social programs such as Medicare and Medicaid. In representing the U.S. Congress you would like affordable healthcare for the citizens of the U. S. as well, although that is not your primary concern at this time.

You have been invited to a meeting with representatives from both Big Pharma and from a healthcare-providing NGO to discuss and find solutions to these issues. Your two-pronged approach to this meeting is to find an amicable way, if possible, (a) to get the Guardian government to respect U.S. patents so Big Pharma can continue innovating and growing the industry in the United States while at the same time (b) to arrange to make the drugs available at an affordable rate to increase availability and accessibility in Guardia and other developing nations. If a resolution is not reached, many people will die without access to life-saving drugs. Moreover, Big Pharma will continue to draw even more adverse publicity, possibly resulting in 1) calls for lessening of patent protections, 2) calls for anti-price-gouging legislation, 3) demands for increased regulatory oversight, and 4) associated litigation, all which may cause Big Pharma to lose their edge in developing new drugs, which Big Pharma maintains would be bad for healthcare everywhere.

You are walking a tightrope.

NGOs provide medical services to individuals living in poverty in developing countries around the world. The main goal of these organizations is to be able to provide care for as many people as possible and save lives in these communities. The current prices of many patented brand name drugs have limited this mission. Conversely, Big Pharma maintains drug patents and their corresponding prices must be respected in Guardia and U.S. patent and price protection worldwide is vital to the continued development of innovative drugs.

The majority of the drugs NGOs provide to indigent populations are generics mostly from Guardia. NGOs rely on the lower prices of generics in providing more and better services to those in need. These organizations have saved thousands of lives and continue to do so with generic medicines. Big Pharma, however, maintains that NGOs live off the donations of wealthy donors who can certainly afford the prices of patent-protected, brand name pharmaceuticals, so punishing innovation and violating international law by using generics is entirely unacceptable.

It is undeniable that the United States pharmaceutical industry relies on government-granted patent **monopolies** that give them the exclusive right to sell their drugs. As a result, when they have a patent monopoly on a drug that can substantially extend life or improve its quality, drug companies can charge tens of thousands or even hundreds of thousands of dollars for drugs that may cost very little to produce. The fact that the drug might be relatively cheap to produce, however, is not necessarily a key factor—or *any* factor—in the market price at which it is offered. Accordingly, you are weighing **1)** the need to stimulate innovation by rewarding it *versus* **2)** the imperative of making life-saving drugs accessible to those in need, and you decided to participate in this meeting in search of a viable path forward for the stakeholders involved.

As a complicating factor, a brutal (and perhaps not entirely unfair) media assault has been launched against Big Pharma over the high cost of the very new and just brought to market drug called "Curalot," which is remarkably effective in combating a deadly global health crisis currently underway that is disproportionately ravaging the most impoverished regions of the world. Without patent protection, this drug would probably sell in the neighborhood of 5% of its patent-protected cost, but Big

Pharma contends it needs the full mark-up in light of all the tested drugs that never make it to market, i.e., failed drugs with R&D costs Big Pharma has to absorb. Even so, you know NGOs are looking to Big Pharma to discount the price of “Curalot,” so that is one area you will attempt to explore, especially given the current global health crisis.

One very sensitive issue is the “evergreening” of drugs for which Big Pharma currently has patents. [NOTE: “Evergreening” is achieved by seeking extra patents on variations of the original drug – new forms of release, new dosages, new combinations or variations, or new forms. Big Pharma refers to this as “lifecycle management.” Even if the patent is questionable, the harsh reality is that company can earn more from the higher prices than it pays in legal fees to keep the suspect patent alive.] NGOs believe “evergreening” is outrageous and an immediate stop must be put to it.

You know Big Pharma expects to receive a large measure of support from anyone representing the U.S. government. Big Pharma generously donates to countless elected officials and lobbies Congress hard. Big Pharma expects appreciation for all the innovation and advanced medicines Big Pharma has been able to develop as a result of the patent protection they have d. You are undeniably a recipient of sizable campaign contributions from Big Pharma.

Not surprisingly, from the other side of this debate you have heard rumblings of a grass-roots movement being organized to target and discredit you as too beholden to Big Pharma—pegging you as being a “*bought-and-paid-for*” elected official buried deep in the pocket of Big Pharma. To make matters worse, you are locked in a tough re-election campaign against an opponent who is hammering you for all of the Big Pharma campaign contributions you have taken in. On the other hand, Big Pharma has let you know in no uncertain terms that if you collapse in your support of them, the money spigot gets turned off and every possible measure to end your political career will be taken. The spotlight is upon you in your hotly contested battle for reelection, and all eyes are upon you. It’s up to you to produce a public relations win for everyone present. Failure is not an option.