Open Source Medicine: Lessons in Innovation From the Software Industry

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Writer's Comment: As an international relations major and pre-med student, my academic journey has been defined by the intersection of science and policy. Our fourth paper in UWP 104F gave me an opportunity to explore this intersection, as we were asked to discuss a social or political problem we see in the healthcare industry and to propose a solution. Intellectual property laws in the United States, while heralded for inspiring innovation, have also hindered the equitable distribution of life-saving medicine. Having found a problem to write about, I looked to the software industry for solutions, where increased access to trade tools and information drive R&D. I have no previous experience in computer science, and this paper allowed me to learn about a new field in a creative, interdisciplinary context. I hope that this paper can inspire others to look for innovative solutions in unlikely places.

Instructor's Comment: One happy feature of teaching in the University Writing Program is that we are often in a position to give our students learning experiences that are rare outside of our courses. I regularly teach Writing in the Professions: Health. My students are engaged in the (normally exhausting) business of gaining acceptance to graduate or professional school. They are neck-deep in very, very hard science. One option on the final assignment in my health writing course therefore invites the students to use their scientific expertise to express an opinion on a social or political issue affecting healthcare. While their support is drawn from the considerable knowledge they have of science, the stand they take is ethical or moral, the sort of thing they rarely get to do any more. Xander took the opportunity and ran with it. His

expertise is, if anything, wider than usual; he takes familiar problems in the pharmaceutical business and applies to them unfamiliar solutions from the world of software development. The result is an essay whose author is comfortable in many fields.

—Scott Herring, University Writing Program

The pharmaceutical industry brings drugs to market based on the manufacturer's ability to generate profit from their sale. Intellectual Property (IP) rights are at the core of this model, as this allows drug developers to obtain patents on novel treatments. Some argue that IP protection drives innovation. Yet, as drug companies monopolize life-saving treatments, inequities in access to drugs are being exacerbated and drug prices are soaring. The World Health Organization reported in 2017 that nearly two billion people lacked access to affordable medicine, a sign that the process by which drugs are developed and distributed is broken. The software development industry offers a potential solution to the imperfect model utilized today: open source R&D. This alternative could bring forth an era of collaborative innovation that improves access to life-saving drugs while working within the constraints of a capitalist system.

Theoretically, IP laws serve as motivation for pharmaceutical companies to invest in the development of new drugs. Aaron Kesselheim (2007), of Harvard Medical School, explains that R&D requires substantial up front spending, and that market exclusivity serves as a financial motivator for companies to invest in the development of novel therapies. Patents secure a temporary monopoly on innovative treatments, which guarantees return on investment when drugs hit the market. This conceptualization posits that pharmaceutical R&D is primarily motivated by the promise of market exclusivity.

This incentive system has led to inequities in the distribution of drugs, however, and insulin serves as a compelling case study for the failure of the current model to support those most in need. Despite being a life-saving treatment discovered a hundred years ago, insulin is scarce throughout the developing world and unaffordable for many in the developed world. Luo and Gellad (2020) found that in the United States, the price per milliliter of insulin rose over 300 percent from 2002 to 2013 and that one in four Americans with diabetes use less insulin

than prescribed because of high costs. The factors contributing to the ineffective distribution of insulin are complex, but the United States' IP model plays an important role in this process.

The insulin market is noncompetitive; three companies dominate the market and no generic alternatives to name-brand insulin exist. As a large-molecule biologic drug, the lack of alternatives to insulin is partially because it is an inherently difficult drug to manufacture (Greene & Riggs, 2015). This is exacerbated by a process called evergreening, where pharmaceutical companies incrementally change a product in order to extend its patent and retain market control. Kaplan and Beall (2016) explain that in the case of insulin, these changes have been significant enough that brands who would otherwise be interested in manufacturing generics have determined that it would be economically inexpedient to develop a previous version of the drug that is no longer under patent. These brands have little financial motivation to invest in the development of a generic insulin alternative when it will already be outdated upon release, even if older versions of the drug could save lives. While it is true that current iterations of insulin are safer and more effective than its previous versions, Greene and Riggs (2015) argue that the lack of generic alternatives to insulin is a death sentence for those who cannot afford this life-saving drug. Insulin offers staggering insight into the flaws of the United States' approach to IP and of the human cost associated with drug development that prioritizes corporate wealth over public health.

IP laws have long been lauded for inspiring innovation, but these claims should not be taken at face value. An experiment by the University of Göttingen found that intellectual property rights hinder sequential innovation, a discovery that inverts Western understandings of how to promote creativity. This experiment showed that IP laws lead to a reduction in welfare and the development of less valuable and creative products, compared to the levels recorded without IP protection (Brüggemann et al., 2016). While this experimental study may or may not translate perfectly to the real world, it is worth considering the drawbacks of relying on IP to stimulate innovation.

Open source software (OSS), a collaborative approach to innovation utilized in the software development industry, offers an enticing alternative to the extant incentive structure for pharmaceutical R&D. This approach enables users to freely view, edit, and share source code. OSS is a decentralized approach to problem solving, where individuals

around the world can contribute to, and learn from, other people's coding. Ubiquitous in software development, OSS has come to define how IP can be reimagined to benefit both private actors and the industry as a whole.

In practice, OSS enables computer programmers to easily and directly utilize the work of other contributors in their own projects. Andrew Guldman, CEO of ConfigureID, believes that open source coding streamlines the creative process. He explains that when foundational code is readily and freely available, engineers can "take an idea and riff on it" without having to build from the ground up. This leads to a "virtuous cycle of innovation," where one user's code can go on to be used by other developers in novel ways. OSS stimulates a snowball effect, enabling the development of vastly different products that originate from the same source code.

The incentive system utilized in OSS technology actively encourages firms and employees to engage in collaborative innovation, while still driving profits. For individual software developers, open source platforms operate as work portfolios that inform hiring and recruitment. Guldman explains that Github, a popular OSS site that tracks contributions made by community members, "can provide a window into [one's] professional abilities." Contributions to open source code are resume builders, where developers can publicly display their aptitudes and advance their own careers. Guldman argues that under OSS, "people act in ways that are good for both themselves and the community." This system incentivizes individuals to work on collaborative projects through mechanisms grounded in capital gain.

Firms are similarly motivated to contribute to OSS. Dirk Homscheid (2020), of the University of Koblenz-Landau, emphasizes that the rich, creative landscape of a platform like Github can improve the quality of products that firms develop. Facebook React, a JavaScript library for building user interfaces, offers a compelling example for how contributing to OSS can improve a product. When Facebook made React's source code publicly available, users around the world quickly fine-tuned and implemented this technology into different contexts. Guldman explains that efforts by open source coders made React "more powerful and broadly useful," which transformed the market value of the product overnight. Guldman points out that Facebook did not have to fund the improvements to React, either. OSS enabled Facebook to

outsource the creative process behind React at no cost and with impressive results.

The reward system intrinsic to a platform like Github functions well within the context of a profit-driven system; the motivations for individuals and firms align with improving the knowledge base for the general public. OSS offers a model for innovation that could revolutionize the way in which drugs are brought to market. To translate the OSS model to the pharmaceutical industry, one must first acknowledge the differences between software and drugs. Primarily, code is private unless deliberately made public. Guldman explains that the intellectual property of software engineers is protected by default, and that action must be taken for code to enter the public sphere. Conversely, medical technology is tangible and can be reverse engineered in a laboratory, which leads drug manufacturers to rely on legal avenues to protect their work. Furthermore, the distribution of improperly manufactured drugs could negatively impact the health of patients. Safety concerns underscore the need for oversight and regulation within the medical industry.

With these caveats in mind, an open source approach to medicine should be introduced gradually and utilized for specific purposes at first. Perkel, a senior technology editor for Springer, details a case in which the medical world has already made use of open source technology. During West Africa's 2014 Ebola outbreak, Caitlin Rivers, a PhD student in computational epidemiology, tracked data on the spread of the disease which she shared on Github. Scientists around the world contributed to this database, which helped form a complete picture of the virus's spread (Perkel, 2016). This informed the public health response and enabled the medical community to predict the disease's progression. While this example does not involve IP, it demonstrates how open source technology can be utilized to improve medical practices.

Open source technology within the pharmaceutical industry could initially center on repurposing existing drugs. Balasegaram et al. (2017) explain that most drugs have the potential to be utilized in novel ways, and that pharmaceutical companies often sit on their clinical and experimental data rather than introducing it to the public domain. Ordinarily, drug repurposing is conducted by the same firm that holds the drug's patent, but an open source approach could support a more efficient process of innovation. Decentralized drug repurposing can improve the availability of technical information without threatening

existing patents, making it an effective way to introduce open source R&D to the medical world.

As drug prices continue to rise and billions of people lack access to crucial medication, it is time to reevaluate the extant model for pharmaceutical R&D. The open source model used by the software industry presents an enticing alternative to IP laws, but the differences between the software and pharmaceutical markets pose a logistical challenge to the adoption of open source principals in the medical world. For this transition to be realized, further research should be conducted to explore how open source strategies can be effectively implemented in the pharmaceutical industry. The medical world's model for drug development and distribution is in need of change, and open source R&D offers a promising future.

References

Balasegaram, M., Kolb, P., McKew, J., Menon, J., Olliaro, P., Sablinski, T., Thomas, Z., Todd, M. H., Torreele, E., & Wilbanks, J. (2017). An open source pharma roadmap. *PLoS Medicine*, *14*(4), Article e1002276. doi.org/10.1371/journal.pmed.1002276

Brüggemann, J., Crosetto, P., Meub, L., & Bizer, K. (2016). Intellectual Property Rights Hinder Sequential Innovation—Experimental Evidence. Research Policy. *Research Policy, 45*(10), 2054–2068. doi.org/10.1016/j.respol.2016.07.008

Greene, J. A, & Riggs, K. R. (2015). Why Is There No Generic Insulin? Historical Origins of a Modern Problem. *The New England Journal of Medicine, 372*(12), 1171–1175. doi.org/10.1056/nejmms1411398

Homscheid, D. (2020). Introduction. *Firm-Sponsored Developers in Open Source Software Projects. Innovation, Entrepreneurship und Digitalisierung,* 1–9. Wiesbaden, Germany: Springer. doi:10.1007/978-3-658-31478-1_1

Kaplan, W. A. & Beall, R. F. (2016). The global intellectual property ecosystem for insulin and its public health implications: an observational study. *Journal of Pharmaceutical Policy and Practice, 10*, Article 3. doi.org/10.1186/s40545-016-0072-8

Kesselheim, A. S. (2007). Intellectual property policy in the pharmaceutical sciences: the effect of inappropriate patents and market exclusivity extensions on the health care system. *The AAPS Journal, 9*(3), E306–E311. doi.org/10.1208/aapsj0903033

Luo, J., & Gellad, W. F. (2020). Origins of the Crisis in Insulin Affordability and Practical Advice for Clinicians on Using Human Insulin. *Current Diabetes Reports, 20*(1), 2. doi.org/10.1007/s11892-020-1286-3

Perkel, J. (2016). Democratic Databases: Science on Github. *Nature: London, 578*(7623), 127–128. doi.org/10.1038/538127a

World Health Organization. (2017, May 11). Access to medicines: making market forces serve the poor. *WHO: Medicines Selection, IP, and Affordability*. www.who.int/publications/10-year-review/chapter-medicines.pdf