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Patents on Life: Religious, Moral, and Social Justice Aspects of Biotechnology and Intellectual Property. Edited by Thomas C. Berg, Roman Cholij, and Simon Ravenscroft. Cambridge: Cambridge University Press, 2019. Pp. 313. $110.00 (cloth); $88.00 (digital). ISBN: 9781108659802.

As vaccine distribution continues to reveal the inequities between Western countries and those of the Global South, many have supported a proposal, headed by India and South Africa, to waive the World Trade Organization's intellectual property rules for COVID-19 vaccines. In October 2020, the two countries jointly submitted a proposal at the World Trade Organization to waive drug companies' intellectual property rights for COVID-19 vaccines under the Trade-Related Aspects of Intellectual Property Rights treaty. In mid-May 2021, President Biden announced that he endorsed a patent waiver for COVID vaccines and therapies. In support of the waiver, United States Trade Representative Katherine Tai wrote in a statement, "This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines."[1] Despite the support of more than one hundred countries, including the United States, however, the proposal is not guaranteed to be adopted. This is because World Trade Organization decisions are made by consensus, not through majority voting. That means that every member country must agree to the proposal,[2] and many countries are not willing to suspend intellectual property law. They perceive the solution as having greater economic and public health risks than potential benefit.

For example, Germany has refused to waive intellectual property rights on COVID-19 vaccines.[3] Canada, China, the United Kingdom, and the European Union are open to discussing the idea of an intellectual property protection waiver on COVID-19 vaccines, but they have not fully endorsed waiving patents.[4] Rather than simply waive patents, which will expropriate intellectual property from pharmaceutical companies, the United Kingdom and the European Union have suggested compulsory licensing agreements, whereby pharmaceutical companies would retain their intellectual property and could even be eligible for compensation, and, in return, they would share knowledge of how to manufacture the vaccines and oversee their production.

1 Office of the United States Trade Representative, "Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver," May 5, 2021, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver.

2 "Whose WTO Is It Anyway?, World Trade Organization, accessed May 20, 2021, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm.

3 Madeline Chambers and Andreas Rinke, "Germany Rejects U.S. Proposal to Waive Patents on COVID-19 Vaccines," *Reuters*, May 6, 2001, https://www.reuters.com/business/healthcare-pharmaceuticals/germany-opposes-us-plan-waive-patents-covid-19-vaccines-2021-05-06/.

4 David Ljunggren and Steve Scherer, "Canada Ready to Discuss COVID-19 Vaccine IP Waiver, 'Not Interfering or Blocking'—Trudeau," *Reuters*, May 7, 2021, https://www.reuters.com/world/americas/canada-willing-discuss-covid-19-vaccine-ip-waiver-statement-2021-05-07/; "China Backs Talks on Intellectual Property Waiver for COVID Vaccines," *Reuters*, May 13, 2021, https://www.reuters.com/world/china/china-backs-talks-intellectual-property-waiver-covid-vaccines-2021-05-13/; Silvia Amaro, "EU Is 'Ready' to Talk about Waiving Patent Protections on Covid Vaccines, after U.S. Backs Move," *CNBC*, May 6, 2021, https://www.cnbc.com/2021/05/06/covid-vaccine-eu-ready-to-talk-wave-of-ip-rights-after-us-backs-move.html.

One of the main concerns regarding the waiving of patents for vaccines is that the intellectual property of COVID vaccines is different from that of other pharmaceutical products. For example, generic drugs are created once a patent is lifted through a process of reverse engineering, called pharmaceutical deformulation. Drug companies discover the brand name's formula of active and inactive ingredients and then create something that has bioequivalence to the brand-name drug, which means that it works the same as the brand-name drug and is as safe and as effective. Waiving a patent on a drug, therefore, allows companies to skip the deformulation step so that they can create copies rather quickly.

COVID-19 vaccines, on the other hand, do not work in the same way as the types of drugs that can be copied through this deformulation process. Because the vaccines are biologics or biopharmaceuticals, the process of manufacture is part and parcel of the formula. A change in any part of the process, whether it be in cloning sequences, expression in host-cell systems, fermentation, or purification, can drastically change the safety or efficacy of the product.[5] Waiving patents therefore still does not provide all the knowledge necessary to replicate production. In a statement to CNN, Thomas Bollyky, director of the Global Health Program at the Council on Foreign Relations, stated, "It's very different for vaccines, where it's really a biological process as much as a product. It's hard to scale up manufacturing in this process for the original company, let alone another manufacturer trying to figure this out without assistance. . . . It requires a lot of knowledge that's not part of the IP [intellectual property]."[6]

Aside from how the World Trade Organization will ultimately decide on the proposal to waive intellectual property rights regarding the COVID-19 vaccines, the pandemic and the manner in which pharmaceutical companies created the vaccines to end it has demonstrated why it has become so important to question the current purpose and function of intellectual property laws. The public support for COVID vaccine research and development and the public need for the vaccines have shown that new ideas must be incorporated into discussions over the rights and benefits of intellectual property. As importantly, new and different models must be conceived to balance private incentives and social good, especially for products that rely on resources such as genetic materials, government funding, and the traditional knowledge of non-Western populations.

Fortunately, the book, *Patents on Life: Religious, Moral, and Social Justice Aspects of Biotechnology and Intellectual Property*, edited by Thomas C. Berg, Roman Cholij, and Simon Ravenscroft, begins to do just that. The collection of essays that comprise the book arose out of an international conference on this theme, "Patents on Life: Through the Lenses of Law, Religious Faith and Social Justice." The conference itself was inspired by a direct invitation from the papal representative, the apostolic nuncio, to the United Nations in Geneva to the Von Hügel Institute for Critical Catholic Inquiry at St. Edmund's College to produce a report for the Holy See on how the patent system could be used to achieve fair distribution of benefits and social good. Organized into three major sections, the book first gives the reader a strong foundation in patent law as it currently applies to biotechnology ("Life Patents, Law, and Morality," chapters 2–4). The next section, "Religious Perspectives on Life Patents" (chapters 5–10), then provides strong critique of current intellectual property law assumptions and offers alternative models for intellectual property rights. The final section, "Social Justice and Political Aspects" (chapters 11–16), focuses on questions of ethics and morality as it relates to the notion of intellectual property

5 Melisa J. Heinrichs and Gary M. Owens, "Where Generics and Biologics Meet," *American Health & Drug Benefits* 1, no. 5 (2008): 21–26, at 21.

6 Laura Smith-Spark, "Rich Nations Urged to Share Vaccine Knowledge as WTO Debates Waiving Patents," *CNN*, May 5, 2021, https://edition.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html.

and biotechnology. Roman Cholji offers an introductory chapter on the religious and political discourse on life patents, and Thomas Berg provides a concluding chapter that highlights key themes that emerge in the book.

One of the strongest themes that comes out of the book is that the classic Western conception of intellectual property—which is simply a practical application of the broader relationship between individuals in society and the society those individuals comprise—is insufficient. Western philosophical and ethical thinking frames social and moral issues predominantly as matters of rational self-interest, where the right balance of rights and duties will incentivize individuals to participate in bettering society, even if the motivation for doing so is indirect. For example, in this conception, the whole notion of intellectual property is a legal creation meant to spur creativity by virtue of the potential benefits accrued to an inventor. Social welfare is simply a fortunate by-product of the economic laws of supply and demand.

Yet, the reality of how the vaccines were created to stop the current pandemic does not fit the philosophical construction of reality that Western philosophy envisions. For example, the research scientists who developed the vaccines did not simply see a profitable endeavor on which to embark. Nor did the pharmaceutical companies who now hold the patents invest in research without public funding and support. Ending the pandemic for everyone in the world was a primary motivation for most who sought to create or fund the development of a vaccine. In this case, social good took primacy over individual self-interest.

While the current pandemic may be an aberration from the norm, it is not so far afield. Those who develop therapeutics and vaccines recognize that they are not simply creating commercial products, like the widget of economic theory. Many are medical professionals who have taken an oath to treat and heal the vulnerable or who engage in academic research for the sake of furthering knowledge for its own sake. Moreover, pharmaceutical research relies on greater social communities who serve as subjects to test the danger and efficacy of various products.

As the book as a whole so persuasively shows, once one recognizes the social and moral underpinning of biotechnology, one quickly sees the need for other voices to enter the conversation of what constitutes "social good" and how incentives should be utilized to complement it. The religious perspectives brought to some chapters of the book, ranging from various Christian denominations to Jewish and Muslim voices, each in their own way reframe the question of intellectual property from how to protect individuals' property rights to how to protect people against unfair competition and align public and private interests. This reframing concedes that an individual's efforts should be compensated, yet individual profit should not be set at odds with public benefit, especially with respect to products that arise from nature or are developed either through public engagement or for public purpose. The drawback of such a policy shift is that it lends itself to ambiguity—the devil is truly in the details. Yet, as the collection of authors for this wonderful book recognize, the book's conclusions are only meant to change the conversation from one that accepts the status quo to one that can imagine a more equitable balance between those who have the wherewithal to create new biotechnologies and the rest of us, who may benefit from them.

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