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Incentives for Global Public Health: Patent Law and Access to Essential Medicines

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Book Review

INCENTIVES FOR GLOBAL PUBLIC HEALTH:

PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES

Editors: Thomas Pogge[*], *Matthew Rimmer*[**], *Kim Rubenstein*[***]

This portrait of the global debate over patent law and access to essential medicines focuses on public health concerns about HIV/AIDS, malaria, tuberculosis, the SARS virus, influenza and diseases of poverty. The essays explore the diplomatic negotiations and disputes in key international forums, such as the World Trade Organization (WTO), the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO).

Drawing upon international trade law, innovation policy, intellectual property law, health law, human rights and philosophy, the authors seek to canvass policy solutions that encourage and reward worthwhile pharmaceutical innovation while ensuring affordable access to advanced medicines. A number of creative policy options are critically assessed, including the development of a Health Impact Fund, prizes for medical innovation, the use of patent pools, Open Source drug development and forms of 'creative capitalism'.

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INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES

Reviewer: Stephanie Snyder[*]

I. INTRODUCTION

It is often claimed that only ten percent of global health research is devoted to conditions that account for ninety percent of the global disease burden.[1] When one notes the staggering profits made by pharmaceutical companies in developing the drugs that pertain to that smaller percentage of global diseases, the claim is perhaps less surprising.[2] Pharmaceutical researchers and patent advocates insist that without the financial incentive for undertaking the development of drugs for neglected diseases, the traditional drug process falls apart. The research and development system cannot sustain itself on mere goodwill. Human rights activists and healthcare supporters argue that the greed of the patent holding pharmaceutical companies cannot be allowed to dictate the health of vast numbers of the human population.

In May 2008, a workshop of this same title was held at the Australian National University. Aimed at a vigorous discussion on the intersection of international and public law with a focus on health, the workshop resulted in the presentation of twenty papers by researchers and more than ten other presentations. The book is a compilation of those papers outlining the patent/access debate and proposing solutions from four areas: international trade, innovation, intellectual property and healthcare. As discussed in Section III below, the compiled papers present a range of proposals that ultimately succeed only in illustrating the dire need for international coordination and cooperation in devising a solution.

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1. Sameera Al-Tuwaijri ET AL., *The 10/90 Report on Health Research*, GLOBAL FORUM FOR HEALTH RESEARCH, 2003-2004, *available at* www.globalforumhealth.org/Media-Publications/Publications/10-90-Report-2003-2004.

2. See *generally Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, DRUGS FOR NEGLECTED DISEASES WORKING GROUP, 2001, *available at* www.doctorswithoutborders.org/publications/reports/2001/fatal_imbalance_short.pdf.

II. SYNOPSIS

In introducing the essays that compile this book, the editors made note of three components that make up the overall "lack of access" issue:

(1) The medicines that could treat or cure the diseases concentrated in the world's poor are neglected by pharmaceutical researchers precisely because those who need them cannot afford them.[3] A poor consumer base does not an enviable profit make.

(2) The medicines that are currently available for neglected diseases are priced at a cost that no needful patient in a least developed country (LDC) could dream of paying.[4]

(3) In the countries where these neglected diseases and needful patients are located, the health infrastructure that would deliver essential medicines is virtually nonexistent. Without clinics, hospitals, or even doctors to administer the medication, the point of cost-related access nearly becomes moot.[5]

The essays compiled by the editors address all three components as well as the "three Ds" of the pharmaceutical process: discovery, development, and delivery of essential medicines. The book is structured into four viewpoints from which the issues are discussed. Analysis is provided through the lenses of international trade, innovation, intellectual property, and healthcare.

A. International Trade

The first four essays in the book address the access issue as viewed through international trade and public law. The trade section begins with an essay by Rochelle Dreyfuss[6] that lays out the background for understanding the rest of the book: an explanation of the TRIPS Agreement, the Doha Declaration, and their relationships to pharmaceutical drug patents in particular. Dreyfuss argues that TRIPS Council is not taking advantage of the expertise vested in the various available international institutions such as WIPO and WHO.[7] Without coordination of knowledge among these institutions, the access problem will simply continue to grow. Building on the background set out by

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3. Thomas Pogge, Matthew Rimmer, & Kim Rubenstein, *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* 4 (2010).

4. *Id.* at 5.

5. *Id.* at 6.

6. Rochelle C. Dreyfuss, *TRIPS and essential medicines: must one size fit all? Making the TWO responsive to the global health crisis*, in Pogge, *supra* note 3 at 35.

7. *Id.* at 46-55.

Dreyfuss, Andrew Mitchell and Tania Voon[8] continue by discussing the Doha Declaration in detail and presenting an argument that provisions similar to those therein should be formally implemented into the TRIPS Agreement by amendment. However, the authors argue that these provisions should only be made permanent after an evaluation by WTO members of their efficacy in light of regional patent systems and the "TRIPS-Plus" agreements made by many members.[9] Hitoshi Nasu's[10] essay is a natural follow-up to Mitchell and Voon; he argues fervently against TRIPS-Plus agreements precisely because they decrease the efficacy of the Doha provisions with respect to essential medicine access.[11] The fourth essay in the trade section finally addresses the true issue of the compilation: the battle between patent rights as protection for innovation and the need for assurances that essential medicines can still be made available. There, Elizabeth Siew-Kuan Ng[12] clearly lays out the debate at hand and intimates that the compulsory licensing provisions of TRIPS and Doha could be the appropriate answers.

B. Innovation

The second section of essays in the book addresses innovative proposals for solutions to the tug-of-war between patent rights and access to essential medicines. The first paper proposes Thomas Pogge's[13] Health Impact Fund – "an international agency that would provide a standing option to register any new medicine for health impact rewards."[14] Heralded throughout the rest of the book as at least the most unusual proposal, if not the most practical, Pogge describes a system that requires a minimum of $6 billion in seed money and a means of quantifying the "health impact" of each drug provided to LDCs by pharmaceutical companies who elect to participate.[15] The proposal begs many questions, some of which are addressed in the next article by Kathleen Liddell.[16]

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8. Andrew D. Mitchell and Tania Voon, *The TRIPS waiver as a recognition of public health concerns in the WTO*, in Pogge, *supra* note 3 at 56.

9. *Id.* at 68-69.

10. Hitoshi Nasu, *Public law challenges to the regulation of pharmaceutical patents in the US bilateral free trade agreements*, in Pogge, *supra* note 3 at 77.

11. *Id.* at 78-86.

12. Elizabeth Siew-Kuan Ng, *Global health and development: patents and public interest* in Pogge, *supra* note 3 at 101.

13. Thomas Pogge, *The Health Impact Fund: better pharmaceutical innovations at much lower prices*, in Pogge, *supra* note 3 at 135.

14. Pogge, *supra* note 3 at 25.

15. Pogge, *supra* note 13 at 151.

16. Kathleen Liddell, *The Health Impact Fund: A critique*, in Pogge, *supra* note 3 at 155.

Although her essay is based on a previous version of Pogge's proposal, many of the glaring holes still exist and warrant Liddell's discussion, including concerns about pharmaceutical companies' possible attempts at gaming the system. The next authors, William W. Fisher and Talha Syed,[17] propose another novel reorganization to the process of pharmaceutical research and development: a prize system. They define and illustrate the two different models of prize systems – "push" and "pull" – and engage in a discussion of whether either system is suited to the type of incentive that patent advocates say is required to drive research and development of drugs for neglected diseases. To round out the innovation section, Thomas Faunce[18] presents a chapter arguing for the implementation of both safety and sanitary measures on trade in health technologies. Faunce notes that regulations of this nature are necessary to explicitly protect the public interest that is ostensibly at the heart of these trade arrangements in the first place.

C. Intellectual Property

As a transition between the innovation and intellectual property sections of the book, the essay by Dianne Nicol and Jane Nielsen[19] fittingly considers a new "disease-specific" style of patent pools as an innovative option for fueling the "discovery, development, delivery" cycle of pharmaceutical products. Upon determining that a delivery-focused patent pool would reap the greatest results for the participants, the authors temper their hopes by noting that the anti-competitive effects of patents pools can be counterproductive.[20] Krishna Ravi Srinivas[21] continues the theme of inventive uses of relatively old tricks by discussing the possibility of an open source drug discovery program. Noting the success of open source software, he argues that new means of stimulating creative solutions could be quite successful. Switching gears from hypothetical solutions to actual case studies, Charles Lawson and Barbara Hocking's[22] article analyzes the

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17. William W. Fisher & Talha Syed, *A prize system as a partial solution to the health crisis in the developing world*, in Pogge, *supra* note 3 at 181.

18. Thomas Faunce, *Innovation and insufficient evidence: the case for a WTO-WHO Agreement on Health Technology Safety and Cost-Effectiveness Evaluation*, in Pogge, *supra* note 3 at 209.

19. Dianne Nicol & Jane Nielsen, *Opening the dam: patent pools, innovation and access to essential medicines*, in Pogge, *supra* note 3 at 235.

20. *Id.* at 254-59.

21. Krishna Ravi Srinivas, *Open Source drug discovery: a revolutionary paradigm or a Utopian model?*, in Pogge, *supra* note 3 at 263.

22. Charles Lawson & Barbara Ann Hocking, *Accessing and benefit sharing avian influenza viruses through the World Health Organization: a CBD and TRIPS compromise thanks to Indonesia's sovereignty claim?*, in Pogge, *supra* note 3 at 284.

conflict that arose between Indonesia and its obligations under the United Nations' Convention on Biological Diversity during the H5N1 outbreaks there. The authors use this case to illustrate the need they perceive for flexible international intellectual property protection obligations in less-developed countries. The final article in the intellectual property section is the only article in the book to address a form of IP other than patents – Matthew Rimmer[23] discusses the use of trademarks and celebrity endorsements in efforts to raise money for and lend awareness to the access issue. Drawing on themes of corporate social responsibility and "creative capitalism," Rimmer argues that these seemingly successful techniques can be detrimental to the causes they intend to promote, especially when challenged on the questions of transparency, accountability and sustainability.[24]

D. Healthcare

The final section of essays is focused on the issue of human rights and the right to health. This section continues with the format of discussions on specific cases instead of hypothetical policy proposals. Noah Novogrodsky's[25] article is unique to the volume in that it discusses actions taken by and available to non-state actors, specifically NGOs. He laments the current role of NGOs as advisors to international councils and delegations and is in favor of a less passive path for the organizations. Two examples of that less passive path are discussed by Katherine Young.[26] She compares two legal actions, one in South Africa[27] and one in Ghana,[28] where non-state actors succeeded in drawing the attention of the courts to the issue of a constitutional right to health. A third country with a constitutional right to health – India – is discussed in Rajshree Chandra's[29] article. Chandra outlines the landmark success of generic manufacturers over a patent owner for the leukemia drug Glivec.[30] The

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23. Matthew Rimmer, *The Lazarus Effect: the (RED) Campaign and creative capitalism*, in Pogge, *supra* note 3 at 313.

24. *Id.* at 336.

25. Noah Benjamin Novogrodsky, *Beyond TRIPS: the role of non-state actors and access to essential medicines*, in Pogge, *supra* note 3 at 343.

26. Katharine G. Young, *Securing health through rights*, in Pogge, *supra* note 3, at 357.

27. *Pharmaceutical Manufacturers' Association of South Africa v. President of the Republic of South Africa*, Case No. 4183/98 (High Court of South Africa).

28. Jeremy Perelman and Lucie White, *Stones of Hope: How African Activists Reclaim Human Rights to Challenge Global Poverty* (2010, forthcoming).

29. Rajshree Chandra, *The role of national laws in reconciling constitutional right to health with TRIPS obligations: an examination of the Glivec patent case in India*, in Pogge, *supra* note 3 at 381.

30. *Novartis AG et. al v. Union of India et. al* (6 August 2007, High Court of Judicature at Madras for W.P.

unusual circumstances of that case lead to the drug being available in India, then removed from treatment plans of patients who couldn't afford it once Novartis was granted exclusive marketing rights.[31] Subsequently, generic manufactures succeeded in having Novartis' patent application rejected, opening the door for cost-effective generic versions of the drug to come back into the worldwide market.[32] Illustrating another avenue for the provision of inexpensive drugs in an LDC, Jonathon Burton-MacLeod[33] discusses the problems Thailand has had implementing the sections of TRIPS that allow for compulsory licensing of patented drugs. In its attempt to bring AIDS and heart disease drugs to its citizens, Burton-MacLeod argues that Thailand has exposed the grave inadequacies that still remain in the supposed flexibilities of TRIPS.

III. EVALUATION

The editors of this text have made noble overtures toward addressing the problem of essential medicine access. The diversity of the essays in the volume and the credentials of their respective authors both make clear the efforts being made towards finding a solution. Perhaps the best aspect of the book as a whole is the feeling that one has when coming away from it: a feeling that such an immense problem is, in fact, being addressed with seriousness and vigor. Similarly encouraging are the innovative proposed uses for existing aspects of the patent regime, such as patent pools. It is frequently suggested that the U.S. patent system may need to be almost completely dismantled to accommodate global health issues; the proposals in this book indicate that we should not be so rash. Unfortunately, a further look at the book reveals that the bold plans of the authors inside are not without flaws.

The primary defect in the volume is that many of the articles contain oversimplified assumptions of fact that are too glaring to ignore. For example, Pogge, in explaining his Health Impact Fund (HIF), notes that the six billion dollars in initial funding could be collected by taxing every citizen of the world 0.01 percent of his or her gross income and pooling that collection into the HIF. Although this is probably intended as a demonstration of the "drop in the bucket" of the world's wealth that could kick off the HIF, this example is not followed up by any kind of discussion

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Nos. 24759 and 24760 of 2006).

31. *Id.*

32. *Id.*

33. Pogge, *supra* note 3 at 406.

of where this funding could come from in reality. There is no acknowledgement of the extreme difficulty the U.S. government in particular has in enacting even tiny tax hikes. When one realizes that there is not even a superficial evaluation of possible funding sources, the hopeful proposal for HIF deflates almost instantaneously. Secondly, not all of the articles seem to truly belong in the volume. For example, Rimmer's article on trademarks and celebrity endorsements for foundations and fundraising makes only tenuous links between the main topic and the problem of access to medicine. In reading the book straight through, the Rimmer article jumps out as almost a commercial break – something to attract your attention away from the dark issues being discussed by waving names-like Bill Gates and Bono - in front of your eyes.

Many of these flaws, though, are somewhat inevitable when one considers the seriousness and complexity of the problem at hand. To suggest that workable solutions could be outlined in papers under thirty pages is certainly naïve. The so-called "blind spots" in many of the articles are understandable: the authors in each section are experts in their fields but cannot be expected to have mastered the intricacies of each of the other areas of law and policy this book attempts to cover. Because each of the four sections hosts its own experts, many of the holes in logic are filled by reference to other articles in other sections. However, this is not readily apparent as it can be cumbersome to read an entire compilation of essays straight through. If one is to read and digest each of the essays separately, this problem persists.

I would recommend this book, albeit with reservations, to anyone with an interest in solving the access to medicines issue. One must have a clear idea of what the book sets out to be, and perhaps more importantly, a clear idea of what the book is not. It is not a primer; coming in with little to no background knowledge of US and international patent regimes and global health issues is not advisable. Such an approach could easily leave a reader frustrated and disinterested. What the book does well is present preliminary proposals for alleviating this worldwide problem. With the right set of preexisting knowledge and goals, the framework in these essays is the perfect foundation upon which to build the eventual solution to this problem.

IV. CONCLUSION

This book is a useful resource as a compilation of discussions on the causes of the access to medicine issue, as well as proposals for and

critiques on potential solutions. In the end, most of the proposals presented are more precisely categorized as "pre-proposals." For a policymaker who endeavors to finally resolve the access issue, this book holds the germinations of several potentially viable solutions. It is most useful, then, as a jumping-off point for further research and policy development instead of as an anthology on existing policy and law on the issue.