



Introduction

This book aims to provide a framework for analyzing the moral responsibilities of the global stakeholders in what I call the Global Health Crisis, with special attention devoted to the moral responsibilities of pharmaceutical companies. It defends the following claim: while all global stakeholders share certain responsibilities in remedying the negative effects of the Global Health Crisis, different degrees of responsibility apply to different stakeholders according to their relation to the Global Health Crisis and to those affected by it; in this regard, pharmaceutical firms have certain responsibilities that apply specifically to them as private owners of relevant medical knowledge.

An argument about responsibility for a common problem must first say something about the problem itself. What is the Global Health Crisis and what kind of moral and legal problems does it present? In order to answer this question, this Introduction first briefly explains what I mean by “Global Health Crisis.” Then, by providing some figures about its adverse effects on people’s health, this Introduction further discusses how these negative impacts are perpetuated by the current system of international law, notably the international intellectual property regime. In doing so, this Introduction makes explicit the factual premises of the normative analysis to be offered in this book, as well as their sources. The last section of this Introduction briefly outlines each chapter of the book and their respective relation to the problematic introduced here.

I.1 The Global Health Crisis

This book relies on the factual premise that the Global Health Crisis is fundamentally a crisis of research and development (R&D) in the area

that global health experts call “neglected diseases.”¹ The term “neglected diseases” is used widely in the relevant literature to denote the absence of market incentives that encourage the development of medicines for diseases that afflict mainly or exclusively the poorer populations. The factual premise that these diseases are neglected is not merely an empirical statement, though, given that the term “neglected” also carries an evaluative component, denoting a normative failure of some kind. This book will discuss these normative failures, which are attributable to different stakeholders.

The problem of neglected diseases is an issue driven by a lack of research and the unavailability of developed and patented medicines to those most afflicted.² This factual premise is widely accepted by scholars in the area and grounded in different expert analyses of the neglected diseases problem. There are three main international organizations specialized in dealing with the neglected diseases problem, namely, the World Health Organization (WHO), the World Trade Organization (WTO), and the World Intellectual Property Organization (WIPO). Recently, these three institutions published a joint report in which they analyze the neglected diseases problem on a global scale, and discuss the intellectual property and global health policy questions posed by the problem. The WHO, the WTO, and the WIPO all point to the lack of R&D in the area of neglected diseases as a major roadblock to improving global health conditions:

The unavailability of medical technologies to effectively address neglected diseases is one of the major problems associated with tackling this human health tragedy. The situation has been characterized by a chronic lack of investment in R&D to find effective treatments for neglected diseases. The innovation effort is starkly disproportionate to the public health challenge posed by such diseases. Since the diseases are concentrated in poor countries, and since poor people are affected the most, it is not just the diseases that are neglected; rather the problem is one of neglecting patients who die of these diseases.³

¹ The concept of neglected diseases is uncontroversial and widely accepted, as further discussed later in this Introduction.

² In this book, I will use the term “medicine” to refer to medical technologies/innovations in general, including medical products, such as pharmaceutical drugs and vaccines, for prophylactic and therapeutic uses, as well as medical procedures, treatments, and devices.

³ WHO/WTO/WIPO, *Promoting Access to Medical Technologies and Innovation – Intersections between Public Health, Intellectual Property and Trade*, 2013, p. 116.

This factual R&D imbalance as related to neglected diseases is agreed on not only by these international organizations, but also by global public health experts. Recently, a team of renowned experts in the field published a report in *The Lancet* – a medical reference journal – in which they concluded that, as per their empirical findings, minor progress has been made with respect to research and developments addressing neglected diseases, but that the chronic imbalance persists. As they put it: “Some progress has been made, but these advancements have not in large part redressed the R&D imbalance, reported more than a decade ago, in truly new therapeutic products for neglected diseases.”⁴

The Global Health Crisis, as I term it, refers precisely to this ongoing situation in which a deplorably large number of people, predominantly in poor countries, are dying of neglected diseases, and to the fact that solutions to this problem are impeded by a number of legal and knowledge-related barriers, in particular the rules of the current international intellectual property regime as expressed by the Trade-Related Aspects of Intellectual Property Rights (TRIPs) system.⁵ The remediation of the Global Health Crisis is complex and will require R&D, as well as other things, such as the competent delivery of appropriate health care goods and services. This will be addressed later. Before any good and service can be created and delivered, however, there must first be medical knowledge that is discovered and researched, and then developed into suitable medical technologies. It is in this sense that lack of access to medical knowledge (i.e., research and innovation) and lack of access to medical technologies (i.e., development of medicines) are both primary issues: without proper incentives and support for R&D, the death toll associated with neglected diseases will not and cannot decrease. This book is based on these empirical premises.

The book relies therefore on a widely accepted empirical and evaluative idea of neglected diseases. The general concept of neglected diseases is fairly uncontroversial, although the precise illnesses that are included by different authorities in their numerous lists may vary slightly according to their methodology and purpose. Yet, it is generally accepted

⁴ Belen Pedrique et al., “The Drug and Vaccine Landscape for Neglected Diseases (2000–11): A Systematic Assessment,” *Lancet Global Health*, Early Online Publication, 24 Oct 2013, p. e376. Available at: [www.thelancet.com/journals/langlo/article/PIIS2214-109X\(13\)70078-0/fulltext](http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(13)70078-0/fulltext).

⁵ The WTO’s agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) was negotiated between 1986 and 1994, during the Uruguay Round; the TRIPs introduced intellectual property rules into the multilateral trading system. See www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm.

that, as Paul Hunt – former UN Special Rapporteur for the Right to Health – puts it, neglected diseases are “those diseases understood to be primarily affecting people living in poverty in developing countries, in particular in rural areas.”⁶ Likewise, as defined in the *Lancet* publication, “neglected diseases, understood broadly as diseases affecting populations in mainly low-income countries, are a leading cause of mortality, chronic disability, and poverty.”⁷ The joint WHO/WTO/WIPO report provides the most thorough definition:

[Neglected diseases are] diseases that disproportionately affect poor people in developing countries as the market mechanisms, such as intellectual property right, do not work in this case. A key factor is the limited purchasing power of both governments and patients in the countries where such diseases predominate; unlike for other diseases targeted at more affluent markets.⁸

The Global Health Crisis therefore comes about from the unavailability of medicine, which is itself largely due to the lack of R&D. This unavailability of medicine is two-fold: (1) it is first an unavailability of *access to medical knowledge* on neglected diseases and (2) it is also an unavailability of *access to medicines that have been developed* to treat neglected diseases. These two unavailabilities result from market failures within the TRIPs regime: the first, a failure in the market for research of medical knowledge relevant for neglected diseases, and the other a failure in the subsequent market for the *development* of such medical knowledge into adequate medicines. These two market failures have catastrophic effects when combined. The Global Health Crisis thus emerges as a dual problem of medical knowledge *and* medical technologies for treating neglected diseases, both due to a lack of R&D. Before discussing how the TRIPs regime produces these two market failures, let us first examine their catastrophic effects.

I.2 The Catastrophic Effects of Lack of Access to Medical Knowledge and Lack of Access to Medicines for Neglected Diseases

It is said that 1.4 billion people worldwide are affected by so-called extremely neglected tropical diseases,⁹ for which there are very few

⁶ Paul Hunt, *Neglected Diseases: A Human Rights Analysis*, WHO, Special Topics in Social, Economic and Behavioral Research Report Series, No. 6, 2007, p. 1.

⁷ Pedrique et al., 2013, p. e371. ⁸ WHO/WTO/WIPO, 2013, p. 115.

⁹ Bill and Melinda Gates Foundation, *Private and Public Partners Unite to Combat 10 Neglected Tropical Diseases by 2020*, 2012.

innovation or ongoing research and no currently available adequate treatments. In other words, at least 1.4 billion people are affected by lack of access to medical knowledge, by which is meant access to medical research, and innovation on neglected diseases and especially those concentrated in the tropical zone. It is not possible to determine with certitude whether 1.4 billion is the total amount of people worldwide affected by lack of medical knowledge on neglected diseases per se, as neglected tropical diseases are a subset of neglected diseases. Nor is it possible to ascertain precisely which neglected tropical diseases have no existing treatment at all, and which ones have some treatment in phases of development and clinical trials. Nevertheless, in light of the above, it is sound to assert that at least 1.4 billion people worldwide are affected by lack of access to medical knowledge on neglected diseases, whether tropical or otherwise.

The WHO also ascertains that some 2 billion people lack access to essential medicines.¹⁰ For these medicines that are considered to be “essential,” there are both medical knowledge and developed treatments available. Yet these medicines are not accessible for a number of different reasons: for example, medical knowledge might be kept secret under patent protections; existing medical treatments might be too expensive for certain afflicted populations; or they may be inadequately formulated for certain patients with specific requirements. However, the WHO’s emphasis on a figure of 2 billion people lacking access to medicines listed in its catalog as “essential” is in itself not sufficient to arrive at any conclusions about R&D on neglected diseases, as the WHO’s list goes beyond medicines for neglected diseases and includes various other diseases that are not generally considered “neglected.”¹¹ In fact, the WHO’s list of essential medicines focuses on the broader category of “infectious diseases affecting poor countries,” which may not necessarily correlate with its list of neglected diseases. Therefore, using data on lack of access to *essential* medicines has certain limitations when it comes to clarifying matters of R&D on neglected diseases. As the *Lancet* publication explains, “use of inclusion in the WHO Essential Medicines List as a proxy metric for medical innovation has its limits because the list favours infectious diseases affecting, and low-cost products for, low-income

¹⁰ UN.Doc.A/HRC/11/12, “Report of the Special Rapporteur on the Right to Health,” 2009, para. 13. WHO, *WHO Medicines Strategy: Countries at the Core 2004–2007*, 2004. See also <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html>.

¹¹ See <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html>.

countries.”¹² Nevertheless, despite not being the most adequate of sources for information regarding R&D on neglected diseases, the WHO Essential Medicine List allows us to make the following statement: at least 2 billion people worldwide are affected by lack of access to medicines that are *available* (meaning for which some treatment exists), but that are not *accessible* (for a number of reason, as set out below).

These figures on the lack of access to medical knowledge and the lack of access to medicine are not sufficient in themselves to show the precise impact of each component of the Global Health Crisis. However, the figures are sufficient to show that the Global Health Crisis is profoundly impacted and determined by economic factors, based primarily on the market value of medicines for neglected diseases. So the figures show that the Global Health Crisis is not only a humanitarian problem, but also a serious market problem in need of remediation.

The catastrophic consequences of the Global Health Crisis have arguably been perpetrated and exacerbated since 1994, when the TRIPs system came into effect.¹³ It has been argued that the TRIPs regime has worsened the already malign effects of historical severe poverty and ill-health in developing and least-developed countries (specified as the former colonies of developed countries).¹⁴ Scholars such as Thomas Pogge have argued that the TRIPs has magnified the harmful consequences of existing poverty in an unprecedented manner, in the same way that globalization (and the current global economic order, shaped by relatively recent legal instruments such as the TRIPs) has considerably aggravated “global poverty” – where global poverty is generally understood as the world population living under the severe deprivation of basic human needs, such as adequate nutrition, safe drinking water, basic sanitation, adequate shelter, literacy, and basic health care.¹⁵

This book focuses on one particular aspect of the current global economic order, namely, the TRIPs regime, and discusses the regime’s implications on one particular aspect of “global poverty,” namely, the severe deprivation of basic health needs amounting to what I am calling

¹² Pedrique et al., 2013, p. e376.

¹³ Thomas Pogge, *World Poverty and Human Rights*, Cambridge: Polity, 2008.

¹⁴ Ibid.

¹⁵ See *ibid.*, where Pogge fully explains his argument on how the current global economic order engenders global poverty. As he puts it: “Some 2.5 billion human beings live in severe poverty, deprived of such essentials as adequate nutrition, safe drinking water, basic sanitation, adequate shelter, literacy, and basic health care. One third of all human deaths are from poverty-related causes: 18 million annually, including over 10 million children under five.”

the Global Health Crisis. This is because both lack of access to medical knowledge and lack of access to medical technologies are related to the TRIPs. As Chapters 2 and 5 of this book rely on the argument set out above, that the TRIPs regime has exacerbated the adverse effects of global poverty and neglected diseases, it seems relevant to analyze further this claim by comparing the pre-TRIPs situation (before 1994) with the TRIPs status quo (after 1994), in relation to the main object of the Global Health Crisis, namely, R&D imbalance with respect to neglected diseases.

As mentioned above, the neglected diseases' R&D imbalance has been "chronic."¹⁶ It has remained consistent over the last few decades despite great scientific progress in medical sciences and significant advancements for certain neglected diseases (such as HIV, TB, and malaria). In order to analyze the impact of the TRIPs regime on this imbalance, the situation before 1994 will now be compared with that after 1994.

According to the *Lancet* report cited above, from 1975 to 1999 (therefore mainly pre-TRIPs), 1,393 new therapeutic products were developed. Of these, only 16 (1.1%) were for neglected diseases, while such diseases accounted for 12% of the global burden of diseases.¹⁷ In the subsequent period from 2000 to 2011, of the 850 new therapeutic products registered, 37 (4%) were for neglected diseases, comprising of 29 products with a new formulation and 8 vaccines or biological products; and of the 336 new chemical entities approved during this study period, only 4 (1%) of them were for treatment of neglected diseases, consisting of 3 for malaria and one for diarrheal disease.¹⁸ The report concludes by saying:

Our findings show a persistent deficiency in product development for neglected diseases, although in the past 12 years positive advances have been seen for neglected-disease treatments, based mainly on the number of newly approved drug reformulations, repurposed products, and vaccines, as well as the number of ongoing clinical trials, especially for vaccines. Nevertheless, a major R&D gap remains in new chemical entities for neglected diseases, both in terms of new approvals and ongoing clinical development as shown by only 1% of existing clinical trials focused on this area. Malaria, tuberculosis, and diarrheal diseases remain

¹⁶ WHO/WTO/WIPO, 2013, p. 116. ¹⁷ Pedrique et al., 2013, p. e376.

¹⁸ *Ibid.*, p. e371. Pharmaceutical drugs can be generally classified as (1) traditional small molecule drugs (usually in the form of tablets and capsules, and usually derived from chemical synthesis) and (2) biopharmaceuticals, also known as bioengineered drugs or biotechnology drugs (which include recombinant proteins, vaccines, blood products used therapeutically, gene therapy, and cell therapy).

the main focus of product-development research, with little focus on other neglected diseases. Providing the required treatments to control and then eliminate neglected diseases is a crucial concern and will require investment efforts into R&D for neglected diseases on all fronts.¹⁹

The conclusions of the report are clear: despite some progress in the research and innovation of medicines for neglected diseases, the R&D imbalance persists. Furthermore, the little progress that has been made is not actually due to new research or innovation; rather, it is due to the reengineering of existing treatments. As the report further states: “of the 29 new products, few are truly innovative: most are based on the repurposing of existing treatments, namely reformulations, new indications, or fixed-dose combinations.”²⁰

Therefore, in both the pre-TRIPs period and the current status quo, the R&D imbalance on neglected diseases appears to have remained essentially the same, with modest progress on some fronts thanks to incentives and investments in the fight against certain neglected diseases such as HIV, tuberculosis, and malaria (the so-called big three). In this manner, the historical imbalance against neglected diseases persists under the TRIPs regime. And as further explained below, the existing R&D cycle nurtured by the TRIPs system will continue to perpetuate this imbalance, unless structural reforms are implemented in order to remedy specific institutional failures in the innovation and development phases of the R&D cycle.²¹

The rules of the TRIPs system are an important part of the dual access problems of the Global Health Crisis. Regarding the lack of access to medical knowledge, the TRIPs regime creates considerable difficulties in correcting the R&D imbalance related to neglected diseases, as explained above. As for the lack of access to medicine, the TRIPs rules may impose a major impediment on the provision of cheap generic medicines and the development of adequate formulations for the specific health needs of poor populations. It is particularly with regard to the latter that the TRIPs is considered by its critics as a clear step backward.²² The TRIPs, critics claim, has introduced, and continues to impose, obstacles to the

¹⁹ Ibid., p. e378. ²⁰ Ibid., p. e377.

²¹ I discuss various existing and proposed remedies to the different aspects of the Global Health Crisis in Chapter 5.

²² Joseph Stiglitz, recipient of the Nobel Memorial Prize in Economic Sciences in 2001, for example, claims that intellectual property rights “enable one person or company to have exclusive control of the use of a particular piece of knowledge, thereby creating monopoly power. Monopolies distort the economy. Restricting the use of medical knowledge not

development of affordable and adequate medicines for poor populations, obstacles that did not exist before the adoption of the TRIPs Agreement in 1994.²³ These obstacles are legal barriers established by the new international intellectual property laws passed under the TRIPs Agreement. Critics argue that the TRIPs regime (or at least its effects) is unjust because it has caused the poorest populations of the world to be even worse off.²⁴ Before 1994, the poor had better access to their basic health needs:

Before the TRIPs Agreement was adopted, most of the less developed countries had weak intellectual property protections or none at all, which enabled them to produce or import cheap generic versions of advanced medicines that were patented and thus much more expensive in the affluent countries. Relative to the Pre-TRIPs, status-quo thus imposes a serious loss on the poorer three quarters of the human population by pricing out of their reach new medicines that otherwise they could have obtained at generic prices.²⁵

As will be discussed in Chapters 2 and 5, critics argue that the TRIPs has contributed to the further deterioration of the health of the world's poorest populations inasmuch as these people must now pay much higher prices for certain medicines, without which they cannot live a minimally decent life. Surely, poverty has always existed. However, by comparing the pre-TRIPs situation with the current one, evidence shows, according to critics, that before 1994, the poor could more easily (meaning with fewer legal and economic restrictions) obtain new medicines at generic prices.²⁶ For example, the poorest countries, even if they did not have any production capacity to manufacture the generic versions themselves, could import these much-needed generic versions from developing countries such as Brazil, India, or Thailand, whose generic drug industries by 1994 had fairly good production capacities.

The current TRIPs regime does two things: (1) it makes effective medicines unaffordable – and thus inaccessible to most patients in poor

only affects economic efficiency, but also life itself" (J. Stiglitz, "Scrooge and Intellectual Property Rights," *British Medical Journal* 333, 27 December 2006, 1279–1280, p. 1279).

²³ This argument is set forth in Aidan Hollis and Thomas Pogge, *Health Impact Fund: Making New Medicines Accessible for All*, IGH, 2008, p. 53.

²⁴ Ibid.

²⁵ Hollis and Pogge, 2008, p. 53; and Peter Singer and Doris Schroeder, "Ethical Reasons for IPR Reform," in *A Report (D1.3) for Innova P2*, CAPPE, University of Melbourne, November 2009, p. 11.

²⁶ See Hollis and Pogge, 2008, p. 53.

countries – until the end of the patent term and (2) it gives no adequate market incentives for medical innovators (such as pharmaceutical companies) to invest their costly R&D efforts in formulations appropriate for the specific material and environmental conditions of the poorest populations. For example, tropical weather and remote rural areas may require changes in original formulations or specific conditions of delivery, transport, and storage to guarantee the effectiveness of the medicine. It is in this sense that critics of the TRIPs claim that the current patent protections over medical R&D *exacerbate* or *aggravate* the neglected status of certain diseases for large parts of the global population.

However, as Chapters 2 and 5 note, the TRIPs regime did come into being, in principle, to do justice to medical innovators, whose innovations were not properly protected in various countries before 1994. The TRIPs regime also allowed a legal harmonization among legal systems in different jurisdictions, and such harmonization was necessary in the wake of the dynamic cross-border interactions characterizing the new global economic order. The TRIPs regime therefore has reasonable purposes, and intellectual property rights certainly have to be protected so as to reward the efforts of innovators and to incentivize future researches and innovations. Chapter 4 provides a defense of intellectual property rights (and thus of the TRIPs regime), highlighting their importance for the global common good. The fact that intellectual property rights exist to do justice to innovators and to uphold the common good is important: this justifies the relevance and purpose of the TRIPs regime as a whole. The problem happens when the TRIPs' rules are abused (e.g., when an innovator makes a minimal modification to the drug formulation only then to be able to get another twenty years of monopoly), or when innovators, their respective countries, and other global stakeholders continuously overlook the evidences and grounds for legal exceptions within the TRIPs agreement.

This book argues that intellectual property rights are to be respected; yet they are not absolute rights, and reasonable exceptions do exist within the TRIPs. The greatest injustice, as Chapter 4 shows, is that the Global Health Crisis does qualify as a legal exception but that global stakeholders are failing to recognize it as such. The crucial point is this: it is unjust for innovators and other stakeholders to ignore the situation and continue to benefit from, impose, and maintain the TRIPs regime as it is.

Even if one is not convinced of Pogge's argument that the introduction of the TRIPs in 1994 was unjust because it put those suffering from neglected diseases in a worse position by *exacerbating* or *aggravating* the