

A Normative Model For Global Trade Negotiations

by

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Abstract

While the world sees increasing transnational activity with its attendant cross-border social and economic dependencies, we continue to cling to an aging Westphalian model of international relations. Free Trade Agreements are negotiated and struck between sovereign states with little regard to further-reaching implications. When we consider a proposed Agreement between the EU and India, and what that could potentially mean for Least Developed Countries dependent on Indian-produced pharmaceuticals, we become acutely aware of the need for a moral framework to guide such transnational interactions. Moving away from a state-centred approach to normative concerns on the global field, I propose that the morally relevant units be functionally delineated based on the spheres of influence of global institutional structures, such as the international trade regime. With this shift in focus, I argue that the existing dependency of impoverished nations on Indian pharmaceuticals places morally significant constraints on the EU-India Trade negotiations.

Keywords: global justice; free trade; access to medicines

Dedication

For my father who, while he would not fancy himself a philosopher, has always challenged me think critically, encouraged me to question the status quo, and taught me to never sacrifice my principles. His example has shown me what is possible with unrelenting dedication, a lot of hard work, and some good ol' fashioned stubbornness. Thank you for believing in me Dad.

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Chapter 1

An EU-India Free Trade Agreement

At the time of writing, negotiations are taking place between India and the European Union (EU) with respect to a proposed Free Trade Agreement (FTA). It is perhaps not surprising that no agreement has yet been reached despite many rounds of negotiations since 2007 and both parties' affirmation that a speedy conclusion is desirable. The two sides have developed politically and economically in vastly disparate ways, which means that the existing institutional structures are not necessarily well poised for straightforward integration of new regulations. Policies that are entirely appropriate, effective, and perhaps even necessary in developed nations like those of the EU may nonetheless have catastrophic outcomes when applied in India. Although there are many contentious aspects to this FTA, I would like to consider one that has potentially further reaching impact than the sphere of negotiations encompasses. A very important sticking point in this Agreement concerns the issue of Intellectual Property Rights (IPRs). IPR protection enters the equation in various sections of this FTA; I will focus on its implications regarding access to medicines.

Each year billions of dollars are spent on the research and development (R&D) of new drugs. The pharmaceutical companies that provide the personnel, resources, and capital for these efforts demand and expect that their accumulated knowledge, and the products born of it, will not be exploited by others for financial gain. Furthermore, it is generally accepted that this is a reasonable expectation, at least to some degree; so most countries have laws that offer protection for intellectual property, and these laws cover pharmaceutical innovations. I too think this is right and take no issue, in principle, with IP protections. But the acknowledged appropriateness of such protections does not itself specify their content, scope, or limits; and this is where I believe a one-size-fits-all approach is not the way to go. Protections for IPRs should be conceived and implemented with due concern for such factors as the unique industry and economic goals of the respective countries, as well as the types of goods covered by these protections. Once again, this is in keeping with standard

practice, as it is predominantly the role of sovereign states to determine the content of laws governing IPRs. I say ‘predominantly’ because, for those nations who are Member states of the World Trade Organization (WTO), there is an overarching set of transnational regulations covered by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement to be adhered to. Membership in the WTO is formally voluntary, although it is sometimes argued that it is not really so in practice. Nothing in what follows is dependent on the outcome of such arguments, and I will refrain from entering that debate. India and the countries of the EU are Members, responsive to the mandates of the WTO and the TRIPS Agreement, and yet we find them still at loggerheads in part because of differences in their domestic laws governing IPRs. IP laws in the EU tend to be more restrictive than the minimums mandated by TRIPS, whereas India has been in a transition phase since joining the WTO in 1995 in order to tighten its protections in accordance with TRIPS. Through this proposed FTA, the EU is asking India to tighten its protections even further to meet the higher protection standards that apply in the EU.

On a cursory first glance, it may seem right that if there is to be fair free trade between the nations, they should operate on a shared conception of how IPRs are to be cashed out. However, what this first glance fails to capture is the context under which the existing laws came to be in the first place. Much of the R&D in the pharmaceutical industry is conducted in the EU — just look at where some of the world’s largest pharmaceutical companies are located: Novartis in Switzerland, Roche in Switzerland, Sanofi-Aventis in France, Boehringer Ingelheim in Germany, Bayer in Germany, etc. It makes sense then that European countries would implement restrictive IPR policies in order to protect the interests of their industry. Conversely, very little pharmaceutical innovation takes place in India, as their pharmaceutical industry has traditionally focused on reverse engineering of generic drugs. So strong IPR protections do not provide the same benefit to the Indian industry as to the European industry. It appears quite likely that stronger IPR protections in India would actually have a detrimental effect on the existing generic drug industry. Stronger protection means manufacturers of generic drugs would have less access to the information and/or markets necessary to sustain them. Whether or not this would translate to an overall detrimental effect on the economic outlook for India, it would presumably have a significant impact on the existing consumers of Indian generic drugs.

Through a series of events discussed in greater detail in the next chapter, India has become a leading producer of generic medicines. Generics being cheaper than their brand name counterparts, India thus landed itself in the position of serving the markets of some of the poorest countries in the world earning the moniker ‘the pharmacy of the developing world’. Since disease tends to be endemic in poorer countries, the demand for affordable medicines is very high. The situation begins to look even more bleak when we consider the prevalence of life-threatening diseases like HIV with a high transmission rate and a complex treatment regimen. It is then that we begin to appreciate the importance of India’s

role in supplying the vast majority of medicines used in impoverished nations like those in Sub-Saharan Africa (SSA), where charity organizations and non-governmental organizations (NGOs) provide a good deal of aid. Estimates from Medecins Sans Frontieres (MSF) suggest that as much as 80% of the AIDS treatments purchased by them for use in Least Developed Countries (LDCs) are produced in India (Doctors Without Borders, 2010). Since 16 of the 48 LDCs are in SSA (United Nations, 2014), I will use that as the focus for this paper, but the argument does not rely critically on any special features of SSA that are not also present in other very low-income countries. So if 80% of the AIDS treatments for LDCs come from Indian manufacturers, a big concern emerges about what happens to those in need of treatment if and when their access to the drugs is diminished.

The point I argue for is that the circumstance of the needy in SSA is a morally salient consideration for what justice demands of these negotiations. It is not merely that we think it is terribly unfortunate that the lives of some should be adversely affected by the decisions of others. A large part of what we find so morally troubling about this FTA is the desperate situation of those being negatively impacted by it, particularly as they have no sway over its outcome. The production and effective distribution of affordable medicines to those with serious illness addresses a significant issue of human wellbeing. I am not proposing a new area of moral concern: extreme poverty and its associated influence on health outcomes, particularly in broadly circumscribed political/geographical regions, has long been a target of moral investigation. And it is within the context of that discussion that I point to this FTA and suggest that there is an appropriate role for it in the conversation. The relevant commodity is one that significantly impacts quality of life at a very fundamental level. Perhaps at least as disconcerting as the tremendous need for medicines felt in these impoverished nations is their relative lack of influence to do anything about it. Not only do they lack the purchasing power of more affluent nations, but the current state of affairs is such that they have little to no say in critical decisions that will impact the flow of medicines that are available to them. What I aim to show is that the nature of the relationship between SSA and India generates a moral imperative to factor in the cost to human welfare with respect to these FTA negotiations. This means that not only the interests of the negotiating parties are to be considered, but also the interests of those in SSA who have no part in the bargaining process.

I grant that from a moral perspective it is probably accidental that SSA has come to be so dependent on India for its provision of desperately needed medicines. I propose to make no contention that India's role in this exchange was ever an obligatory one. It is most likely that India developed its drug industry according to a plan that was thought to be best for India. It just so happened that this plan proved an immense benefit to the needy in SSA. But granting that no moral obligation previously existed requiring India to develop its drug industry in a manner conducive to the needs of those in very poor countries where

disease is extremely prevalent does not entail that no moral obligation presently exists¹. Regardless of the presence or absence of any explicit agreement between India and the African countries, it remains the case that the relationship between them is an extremely significant one. Without the drugs produced affordably in India, countless African lives would be lost or otherwise severely adversely affected. With an estimated 23.5M people in SSA suffering from HIV (The Joint United Nations Programme on HIV and AIDS, 2012) — not to mention a wide array of other life threatening and debilitating ailments — Indian-produced generic drugs are heavily relied upon to maintain important health initiatives for those who could not otherwise afford it. Intuitively, it seems flagrantly unjust to threaten the supply of these drugs and the effective distribution to those impoverished nations that require them². Indeed, the prevalence of demonstrations by advocacy groups, public outcry, op-ed articles, etc. adds momentum to this claim. However a troubling feature begins to reveal itself as one seeks to identify precisely what is unjust; our standard models of global justice fail to pick out a substantive moral imperative that is being violated.

The primary conceptions in this domain delineate the sphere of moral relevance either to the sovereign state or to the entire global community. These models tend to focus on the particular importance of certain types of relationship, typically highlighting some aspect of a cooperative scheme that is necessary for triggering obligations of justice. While I agree that social/political/economic relationships are what matter for ascribing duties of distributive justice, I think the complexity of these relationships is not well represented in the traditional dyadic approaches. The situation of a trade agreement between two sovereign parties that nonetheless has critical implications for others is not well represented by a moral conception that accepts ‘us’ and ‘them’ as basic constructs. Although other approaches to global justice are to be found, these are by and large on the fringes of the moral discussion. I will suggest that a promising way forward comes into relief by drawing our attention out to the fringes and highlighting a view that may best be summed up as a disaggregated approach to global distributive justice. Such a view acknowledges a plurality of different types of actors, relationships, and domains.

¹This should not be read as suggesting that any current moral obligation lies solely with India.

²Again, this is so far just a general observation rather than a judgment about the correctness of any particular party’s actions.

Chapter 2

Intellectual Property Rights and Generic Drugs

2.1 Early Indian Patent Law

A developing nation with the second largest population in the world (Central Intelligence Agency, 2011), India has built for itself a strong reputation as one of the world's leading exporters of generic drugs. This role has been facilitated in large part by a historical absence of pharmaceutical patents originating with the Patents Act, 1970 (Nair, 2003). By eliminating patents for pharmaceutical products and retaining patents only for processes, the Indian government hoped to stimulate competition amongst pharmaceutical companies to develop the most efficient and cost-effective processes for producing drugs. With these policies in place, India's pharmaceutical companies stepped up to the plate and developed a rapidly growing industry centred predominantly on the reverse engineering of molecules to produce generic versions of existing drugs (Sampat, 2010, p. 8). The weak patent system also provided little incentive for companies to develop new and innovative drugs, and so kept R&D from being a primary focus of pharmaceutical companies.

This emerging generics industry became prolific enough to supply not just its own population with inexpensive generic drugs, but also permitted India to export generic drugs to other countries — most notably to LDCs. For countries unable to afford the expensive, patented drugs to treat such pervasive health concerns as malaria, tuberculosis, and HIV/AIDS, the relatively inexpensive Indian produced generic drugs are heavily relied upon. A 2010 study looked at donor-funded purchases of antiretrovirals (ARVs) by low- and middle-income countries from 2003 to 2008, and published the following results (Waning et al., 2010).

Indian generic manufacturers dominate the ARV market, accounting for more than 80% of annual purchase volumes. Among paediatric ARV and adult nucleoside and non-nucleoside reverse transcriptase inhibitor markets, Indian-produced

generics accounted for 91% and 89% of 2008 global purchase volumes, respectively. From 2003 to 2008, the number of Indian generic manufactures supplying ARVs increased from four to 10 while the number of Indian-manufactured generic products increased from 14 to 53. Ninety-six of 100 countries purchased Indian generic ARVs in 2008, including high HIV-burden sub-Saharan African countries. Indian-produced generic ARVs used in first-line regimens were consistently and considerably less expensive than non-Indian generic and innovator ARVs. Key ARVs newly recommended by the World Health Organization are three to four times more expensive than older regimens.

It is important to keep in mind this set of background conditions when assessing the viability of developed world policies to India. With respect to its pharmaceutical industry, India is not well poised to benefit from strong IPRs on account of the relative absence of R&D in the field. Conversely, strong IPRs seem rather more likely to cripple the existing industry. Furthermore, many developing and Least Developed Countries rely on India's generic drug industry as a source of desperately needed life-saving medicines without the high price tag carried by patented drugs.

2.2 TRIPS Compliance

India's thriving generic drug industry met with a significant challenge in 1995, when India became a member state in the WTO. One of the most important obstacles India now faced in light of this membership was the obligation to conform to the WTO's TRIPS Agreement. Although it contains provisions dealing with multiple aspects of IPRs, those dealing with patents are the most directly applicable to India's generic drug industry and to the issue of access to medicines in general. Most notably, conformity with TRIPS required adding a provision for patentability of pharmaceutical products, not just processes, and the extension of patent terms to a minimum of 20 years from the 7 years granted under the 1970 Act (Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, Article 33).

The new regulations were written into India's Patents Act effective January 1, 1995; yet, as a developing nation with no previous patent protection for pharmaceutical products, India was granted until January 1, 2005 to achieve full compliance with TRIPS. What this meant is that patent applications for pharmaceutical products could be submitted as of the earlier date, but did not have to be reviewed until the later date — a practice referred to as the “mailbox provision”. However, if the product was allowed to be marketed during this time, the patent applicant was to be given exclusive marketing rights for 5 years, or until a determination was made on the application, whichever came first (Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, Article 70).

Understanding that the continued innovation and development of new technologies useful to society requires a measure of protection and incentive for companies to do so, TRIPS

aimed to establish a standardized set of principles by which to ensure that Member states enacted local regulations in accordance with WTO established goals. These objectives are laid down in TRIPS (1994) Article 7.

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Now presumably the invention of new technologies, like new medicines, is important to the health, wellbeing, and success of societies, and thereby warrants protection. Particularly in the case of drugs, the R&D costs can be so high that appropriate financial remuneration is necessary in order to ensure that companies are incentivized to undertake these costly endeavours. In this light, protections for intellectual property may be seen as beneficial to society. The process by which patents are granted also serves a social benefit because a patent application requires full disclosure of the invention, such that it is reproducible by one suitably trained in the area of specialty. And so the information about how to produce the invention becomes a matter of public knowledge available for use at the end of the patent term (World Trade Organization, 2006, p. 1-2).

Equally important as the need for IPR protections themselves, TRIPS recognizes the need to ensure that the technologies are appropriately disseminated. In order for new inventions to serve a social good, they must actually be available to society. It would seem to follow then that overly restrictive regulations that interfere with the dissemination of technology contravene the TRIPS objectives as set forth in Article 7. In order to achieve an appropriate balance between IPRs and other social goods, some areas of the Agreement are deliberately left open for interpretation by the Member states themselves. TRIPS Article 8 specifies that Member states may apply measures as they see fit in order to provide for public health and also to prevent the abuse of IPRs by right holders, abuse that may hinder trade or impede the transfer of technology.

Regarding patent protection, and particularly relevant for pharmaceuticals, TRIPS includes flexibilities — clarified and enhanced in the 2001 Doha Declaration on TRIPS and Public Health — to allow the limitation of patent holders' rights under certain circumstances, including national emergencies, the prevention of anti-competitive practices, and when the right holder fails to make the invention available (World Trade Organization, 2006, p. 2). What is more, the specification of these situations is one such area where the governments of the individual Members are granted the right to determine what activities or circumstances qualify. For instance, it would be left to the discretion of the Member to determine whether an HIV/AIDS epidemic constituted a national emergency, and so to limit IPRs in accordance with TRIPS flexibilities in order to meet the demands of the emer-

gency (World Trade Organization, 2001, §5c). These kinds of situations may be examples of cases where TRIPS permits the use of a patented technology without the authorization of the right holder.

One important such use included under TRIPS flexibilities is that of compulsory licensing. A compulsory patent license, like a voluntary license, is a permit allowing, for example, another drug company to produce a generic version of a drug currently on patent. The difference is that a voluntary license is one issued by the right holder in accordance with an agreement reached between the originator pharmaceutical company and the one to produce the generic drug. A compulsory license is one granted by the government of the Member state without the right holder's permission. A Member may issue a compulsory license under such situations as described above, although this is another one of those areas in which TRIPS is deliberately non-prescriptive. "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" (World Trade Organization, 2001, §5b). Compulsory licenses are subject to certain conditions outlined in Article 31 of the TRIPS Agreement. These conditions stipulate, amongst other things, that a compulsory license may only be issued where appropriate attempts to obtain a voluntary license have failed¹, and that "the right holder shall be paid adequate remuneration... taking into account the economic value of the authorization" (Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, Article 31h). The amount of the remuneration is subject to independent review by a higher authority in the Member state.

The ability to use TRIPS flexibilities such as compulsory licensing is important for the provision of essential medicines to those in need when the cost of on-patent medications puts them out of reach. The prevalence of HIV/AIDS has become an internationally recognized health concern in recent decades. This means that there is a large demand for effective treatments — a demand that drives the innovation of such treatments. For instance, the shift toward fixed-dose combination treatments can be extremely beneficial in places like SSA where medical resources are limited and patient compliance is an ever-present concern. It is an unfortunate fact that HIV treatments become less effective over time with increased viral resistance to treatment; so variation in treatment regimens is necessary for continued viral suppression. In order to effectively combat the disease, access to newer medicines is vital. First-line antiretroviral Therapy (ART) is the initial treatment recommended for a newly infected HIV patient². Once this treatment is no longer effective for the patient, it is recommended they be switched to Second-line ART, which is a different combination of ARVs (World Health Organization, 2007). The precise determination of which treatment option is preferred for a patient, and when to transition to next-line therapy, is complicated by many factors including the need for individual monitoring of adherence to treatment and

¹This condition is waived in situations of national emergency.

²First-line ART does not denote one particular combination of drugs; there are a few different options.

drug resistance. This type of advanced care is not typically available in resource-limited settings. However, a study published in the June 2013 issue of *The Journal of Infectious Diseases* found that resistance of HIV to first-line therapy is predictable at 12 months, at which time an immediate transition to second-line therapy is indicated (Hosseinipour et al., 2013). The problem is that, even though first-line ART is readily available and inexpensive, second-line ARVs are mostly still on patent and therefore expensive (Childs, 2010). Where life-saving second-line ARVs are patented, compulsory licensing is one avenue Members can pursue in securing access for those in need³.

The brief discussion of TRIPS given above is intended to illustrate the logistic framework that impacts India's production and distribution of generic drugs. In light of India's historically weak patent system, TRIPS mandates are particularly onerous. 20 year patent terms and the provision for patents of pharmaceutical products that were previously not patentable in India have certainly proved an extensive burden; one not easily met especially given the difficulties that nations face in actually making use of TRIPS flexibilities⁴. Against this set of background conditions, the proposed FTA presents a supra-regulatory dilemma in addition to the existing struggles with TRIPS. The TRIPS Agreement mandates minimum IP protections; however, bilateral and multi-lateral agreements between Member nations will often impose TRIPS Plus measures — IP protections in addition to those already imposed by TRIPS.

2.3 TRIPS Plus and Free Trade

Through a series of negotiations that began in 2007, India and the EU are in the process of negotiating a Free Trade Agreement that promises economic growth for both regions, as well as easing the barriers to trade with India. India's economy has grown in recent decades as it has embarked on a strategy of economic reform. But while India has been striving to bring its economy more in line with that of the developed world, existing regulations within India related to the trade of goods and services have been an obstacle to this development. Although the value of trade between India and the EU has increased substantially over the past decade, India retains significant tariff and non-tariff barriers that restrict trade (European Commission, nd). The EU's trade policy strategy envisions open markets with major trading partners, motivating a plan to help India with the removal of such structural impediments (European Parliament, 2013, p. 14). A trade agreement with India would give the EU access to a large, unsaturated market and would help pave the way for greater Foreign Direct Investment (FDI) in India. In order to assist India in its goal to "better

³I am not here aiming to give an argument for compulsory licensing of second-line ARVs; that is beyond the scope of this paper. I am merely trying to illustrate the kinds of situation in which TRIPS flexibilities may permit Members to limit IPRs in the interests of public health.

⁴For further information see Mitchell, Andrew D. and Voon, Tania. The TRIPS Waiver as a recognition of public health concerns in the WTO in *Incentives for Global Public Health*. Thomas Pogge, Matthew Rimmer, Kim Rubenstein (Eds.). Cambridge University Press. New York. 2010

integrate into the world economy with a view to further enhancing bilateral trade and investment ties, the EU is providing trade related technical assistance to India” (European Commission, nd). By aiding India in reforming its restrictive trade regulations, the EU proposes to help ease the difficulty of conducting business with India.

As part of this process of reforming trade regulations, however, the EU is asking that at the same time India is relaxing tariff and non-tariff barriers to trade — measures that are typically detrimental for local producers — it also strengthen its IP protections over and above what is already mandated by the TRIPS Agreement (Preliminary Consultation Draft on IPR Chapter of India EU Broad-based Trade and Investment Agreement, 2010, Article 17.3 and Article 18). Specifically, these TRIPS Plus measures are to include, in some cases, patent term extension up to an additional 5 years, as well as a supplementary market protection referred to as ‘data exclusivity’.

The issue of IPRs, specifically as pertaining to pharmaceuticals, has been a very controversial aspect of this FTA, and certainly one that has generated a great deal of public opposition⁵. All WTO Member states are bound by the TRIPS Agreement (with granted extensions until 2016 for LDCs) — an obligation that India fulfilled in the 2005 Amendment to the Patent Act, 1970 — and so Indian patent law now includes minimum 20-year patent protection for pharmaceuticals, as does patent law in the EU. However, in addition to the minimum patent protections allotted by TRIPS, the EU also grants data exclusivity for a period of 10 or 11 years, the purpose of which is that it “guarantees additional market protection for originator pharmaceuticals by preventing health authorities from accepting applications for generic medicines during the period of exclusivity” (Shargel and Kanfer, 2010, p. 135).

Data exclusivity is a separate kind of protection from patents, and one not specifically addressed by the TRIPS Agreement. It is perhaps simplest to consider a hypothetical scenario. If Bayer has a patent for Aspirin, that essentially means that they own the recipe to make Aspirin; and if some other pharmaceutical company, call it Company X, wanted to use that recipe to make a generic version of Aspirin, Company X would need Bayer’s permission in the form of a patent license. What is not covered in this exchange is approval for Company X to market its generic version of Aspirin. In order for Bayer to sell Aspirin in the USA, for example, it needs regulatory approval from the Food and Drug Administration (FDA)⁶, which will be granted only upon demonstration of the safety and efficacy of the drug. Likewise, Company X will also need FDA approval in order to sell its drug in the USA. Now since Company X used Bayer’s recipe to make essentially the same drug, the test data that demonstrate the safety and efficacy of Aspirin will also serve to demonstrate

⁵Large protests have been organized in large part by associations like the Asia Pacific Network of Positive People, the Delhi Network of Positive People, and the United Nations Special Rapporteur on the Right to Health, Anand Grover (Citizen News Service, 2011).

⁶The corresponding body in India is the Central Drugs Standard Control Organization (CDSCO), and the European Medicines Agency in the EU.

the same for the generic version. However, the patent license only granted permission to make the drug, not the permission to use Bayer's test data in order to obtain FDA approval to market the drug. Whereas the pharmaceutical patent is an IP protection acknowledging Bayer's right of ownership of the product, data exclusivity protects the test data needed to obtain regulatory approval.

What this period of data exclusivity means in the EU is that, irrespective of voluntary or compulsory patent licenses, no generic version of a drug can be marketed until a minimum of 10 years from the first marketing approval of the original drug; the application for regulatory approval of the generic cannot even be considered until 8 years from this date. The EU's positive spin on this protection is that, at the end of this term, the application for the generic can be evaluated in the light of the data submitted by the originator company since the generic drug contains known safe and effective compounds; and this eliminates the need to repeat clinical trials. This evaluation takes place internally by the regulatory authorities and the originator's research data is never revealed (European Generic and Biosimilar Medicines Association, nd).

The negative twist on data exclusivity is that the originator pharmaceutical company holds a monopoly over that drug market for either 10 or 11 years⁷. In order for a generic drug to be granted regulatory approval during the period of data exclusivity, it would have to be considered in its own right, independently of the original drug. Since the originator's data are effectively locked for this period of data exclusivity and applications submitted during this time cannot be considered with respect to this data, any generic drug manufacturer would have to supply its own research data. For generic drug manufacturers, this would mean repeating expensive and otherwise unnecessary clinical trials. An enormous amount of money is spent to bring a drug to market. A study reported in the March 2003 *Journal of Health Economics* claimed that an average of \$802M is spent by drug companies to bring a drug to market (DiMasi et al., 2003, p. 180)⁸. In addition to the tremendous financial burden, there is also the cost in terms of time; it takes approximately 90.3 months from beginning of clinical trials to market approval (DiMasi et al., 2003, p. 164)⁹. It is precisely because generic pharmaceutical companies typically do not repeat these processes that they are able to produce low-cost alternatives to brand name drugs. So data exclusivity further restricts the ability of generic pharmaceutical companies to produce and market affordable medicines to the LDCs that presently rely heavily on India as a source for low-cost medicines.

Even aside from the debilitating financial and time constraints, repeating clinical trials for generic versions of approved drugs raises important ethical considerations. Clinical trials to secure market approval for a new drug usually involve three phases and tens of thousands of subjects in order to achieve statistical significance. Additionally, these clinical

⁷The additional one year may be granted if, during the first 8 years of data exclusivity, the company registers a new therapeutic use for the drug.

⁸This figure has been hotly contested since. Other estimates have ranged from 100M to 1.7B.

⁹These figures are U.S. estimates.

trials generally include a placebo control group. But there are serious moral concerns about giving a placebo to a study subject when an approved drug is available and the test drug does not offer a better, or even different, outcome from the approved drug. Since the generic versions are, by assumption, bio-identical with the original drug, the anticipated outcomes will be equivalent¹⁰.

At present India does not make provisions for data exclusivity: a fact likely attributable to its preponderance of generic pharmaceutical companies and scant infrastructure for R&D of new drugs. Under the proposed terms of this FTA, the EU would see the introduction of data exclusivity in India¹¹. In many cases, this may not have any dire practical consequences; especially in light of the fact that during the period of data exclusivity, the originator pharmaceutical company will probably also have patent protection for the drug. However, the concern has to do with a Member's right to employ TRIPS flexibilities in extra-ordinary circumstances. Since the regulations providing for data exclusivity are enacted and enforced independently of patent legislation, many of the flexibilities TRIPS currently permits in order to mitigate the constraints of restrictive patent law will be rendered inapplicable. To return to the example discussed above, compulsory licensing is an especially important provision for the Indian generics industry. However, although issued by a government when a voluntary license cannot be obtained, it is still just a license to produce a generic version of a patented drug. It is an independent process by which regulatory approval is granted to market a drug.

Let us say that some Swiss pharmaceutical company develops a new and highly effective fixed-dose combination ARV for the treatment of HIV. Furthermore, let us also assume that this drug meets India's criteria for patentability and so the Swiss company obtains a 20-year patent for their drug in India. Now suppose this drug is so effective and easy to administer that the government deems it essential to the goal of eradicating the HIV virus altogether. However, as with many things highly efficacious and easy to use, it is outrageously expensive and far out of reach for most of India's HIV sufferers, let alone the poverty stricken in places like Sub-Saharan Africa¹². In the unfortunate event that the Swiss company's test data are also protected for a period of 10 years, then patent license notwithstanding, the generic company will not be able to obtain regulatory approval, without running its own clinical trials, for at least that duration. In such a case, compulsory licensing — an important flexibility for protecting public health measures — would be rendered ineffectual.

TRIPS flexibilities like compulsory licensing are vital to striking a balance between economic/trade objectives and the requirement that these objectives not impinge a nation's

¹⁰For a good discussion of these ethical considerations see Angell, Marcia. (1997, September 18). The Ethics of Clinical Research in the Third World. *New England Journal of Medicine*, 337(12), 847-9

¹¹By the time of publication, the EU has removed this condition. However, the FTA has not yet been ratified, so there remains the possibility of its reintroduction.

¹²I am trying to set up a fictitious scenario where it would be reasonably uncontentious that a compulsory license to produce a generic version is warranted. If one remains unmoved by this scenario, the details can be altered as needed.

public health initiatives. And this is not a novel, or even particularly controversial point. In light of lingering questions about how to interpret the TRIPS flexibilities, the Doha Ministerial Conference was held in November 2001. To further clarify the intention, scope, and protection of these flexibilities, in the 2001 Doha Declaration, Member states “agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health...affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (World Trade Organization, 2001, §4). Given the conclusions of this conference, it is evident that the WTO is committed, at least in principle, to ensuring that trade rules do not trump public health concerns. Additionally, as noted above, the WTO officially recognizes each nation’s freedom to enact public health measures in the promotion of the Right to Health (World Trade Organization, 2001, §5c).

This point is especially important in India’s case because of its strategic position in the global supply of relatively inexpensive medicines. 2005 UN estimates indicate that nearly 3% of the adult population (>15 years of age) of LDCs suffers from HIV; that is about 24 million people (United Nations Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, 2006, p. 25). As noted above, India produces most of the ARVs used to treat that population. Also noted above, the WTO explicitly recognizes the need to establish a balance between economic development and public health interests. Specifically, TRIPS flexibilities such as compulsory licensing reinforce the WTO’s stated commitment to the “economic and social welfare” of “both users and producers” (Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, Article 7). Access to medicines for developing nations is a serious concern that has received increasing attention over the years and is a top priority for the UN’s World Health Organization (WHO), as the UN recognizes the Right to Health as a fundamental human right (United Nations General Assembly Human Rights Council, 2009). It is worth noting here that all of the EU member states are also members of the UN; and, as such, are likewise committed to the WHO’s global health goals, including access to medicines. At the same time, however, multilateral and bilateral trade agreements, such as the proposed India-EU FTA, seek to undermine some of the hard won and essential provisions for improving the welfare of Developing and Least Developed Countries. There is something extremely confounding in this dichotomy. One might hope that a formal declaration of support for recognized global health concerns would be accompanied by suitably supportive actions rather than the converse.

While we can understand that pharmaceutical companies in the EU would lobby for stronger IP protections in India so as to ensure the viability of the market for their products, the ethical dilemma emerges once we consider the potential ramifications of such stringent protections for those whose lives depend on affordable access to medicines. The question is not merely how best to achieve economic reform, but whether such reforms can be morally

justified in light of the human welfare costs. This is a question worth asking. Since the delivery of healthcare in SSA has become heavily reliant on generic medicines produced in India, it can be reasonably conjectured that strengthening IP protections on pharmaceutical products in India will have a deleterious effect on this relationship. It is the contention of this paper that the relationship whereby hundreds of thousands of disadvantaged patients in SSA acquire medical treatment is significant enough to be a serious moral consideration in these negotiations.

Chapter 3

Global Distributive Justice

3.1 Dependency on Indian Pharmaceuticals

Either by purchasing medicines directly — Kenya and South Africa, for example, have passed bills permitting the purchase of generic drugs from abroad (AVERT, nd) — or through the assistance of NGOs, MSF and other aid organizations, LDCs like those in SSA are deriving an important benefit from the flow of generic medicines out of India. Where patented medicines are expensive and out of reach for the tremendous numbers of people afflicted with HIV and other serious illnesses, generics provide a life-saving alternative. But I think it is worth noting that the resulting relationship between India and the African countries is not specifically a charitable one. Even if the drugs are provided to LDCs by charitable organizations, they are still purchased by those charitable organizations; they are not simply donated by India. MSF, for example, selects suppliers for its Procurement Centres through a process whereby drug manufacturers submit expressions of interest to MSF. The manufacturer is then subject to the MSF Qualification Scheme, which assesses the manufacturing site for compliance with WHO Good Manufacturing Practices. Products that are qualified by MSF may be a product pre-qualified by the WHO, a product registered in a highly regulated country, or a product that has successfully passed the MSF evaluation (Doctors Without Borders, 2013). From a commercial standpoint, the African countries are a market just like any other, and India's generic drug industry is well adapted to servicing that market. The point is that it is not only the LDCs that benefit from this relationship; it is an extremely profitable industry for India¹. For reasons already discussed, India's generic drug industry is unique for its size and scope of distribution.

This supply of generic drugs has in turn fostered the situation whereby LDCs have become reliant on Indian drugs to help meet their significant demands. Although the major pharmaceutical labels often extend certain concessions to LDCs in terms of cost

¹At present, the market size of India's pharmaceutical industry is US\$20 billion and growing. <http://www.ibef.org/industry/pharmaceutical-india.aspx>

reduction (Boseley, 2009), these measures do not negate the need for affordable generic alternatives²; and so India plays a significant role in health initiatives beyond its borders. This is not to say the current system is without flaw — there remain challenges to meeting TRIPS requirements, decisions about innovative new drugs continue to lie with originator companies that have R&D capacities — but it seems fairly uncontentious that having some, or more, or better medicines to address public health concerns is preferable to not having these medicines. Yet the legislative changes proposed by the EU through the EU-India FTA are likely to have a negative impact on the production and distribution of Indian generic drugs. While we may acknowledge the EU’s interest in expanding and strengthening its market and investment relationship with India — or perhaps, more cynically, the interests of large corporations within the EU to expand their profit margins — it seems equally clear that Indian and European commerce is not all that is at stake. We must consider also that these commercial interests affect trade in goods that are crucial for the preservation of human life and well being.

3.2 Justice

To be sure, the conclusions of my argument are modest; I am arguing that the negotiation of particular trade deals ought not overlook morally significant considerations and relationships that may not be directly represented in the trade terms. I do not propose to make any argument about the priority of moral considerations in trade negotiations vis-a-vis the merits of economic development. However, I do wish to clarify that I mean these moral considerations to be specifically matters of social, or distributive justice, as opposed to some more broadly humanitarian morality. In focussing on concerns of justice I do not thereby negate the legitimacy of humanitarian grounds for opposing the FTA terms relating to IP protections; although my feeling is that demands of justice tend to be weightier moral obligations than general duties of beneficence or non-maleficence. I will not argue for this here but to say there seems to be a reasonable precedent for my assumption in the works of John Rawls, Thomas Nagel, Darrel Moellendorf, and others.

In specifying distributive justice as the focus, what I am concerned with is the allocation of resources (and I do mean this term to apply broadly to goods, services, opportunities, etc.) across a population. Contemporary usage is largely influenced by John Rawls’ work coining justice as “the first virtue of social institutions” (Rawls, 1971, pg. 3). Two key take-aways from this characterization are the idea that justice is socially circumscribed: there can be no obligations of justice to those with whom we have no social engagement; and the idea that justice is institutionalized: it is a concern for the effects of institutional regimes as opposed to individual actors. While these tenets are by no means universally accepted,

²Indeed a common argument for the benefit of generic pharmaceutical products is that, in addition to providing a lower cost alternative, they also help to drive down the market price of the brand name drugs.

they are held by the dominant competing conceptions in global distributive justice, roughly categorized as statism and cosmopolitanism.

By invoking Rawls here, I do not mean to suggest that the “basic structure”, as originally described, is straightforwardly translatable to alternative conceptions of justice. Rawls’ argument is explicitly intended to apply solely to domestic politics, and any appropriation of his terminology for other purposes must necessarily involve a somewhat relaxed interpretation of the concepts. But that is hardly a cause for concern. The statist argument for (or rather, against) global distributive justice owes much of its traction to its ability to piggyback on Rawlsian theory, but it yields implausible conclusions about duties to non-compatriots. The ‘basic structure’ terminology employed in my own argument reflects the idea that justice depends on relationships involving mutual expectations established through institutionalized patterns of trade in socially basic goods.

The constraints imposed by conceptions of distributive justice are constraints on the social, economic, and political institutions that have a significant impact over the course of people’s lives. The general idea is that people are to be treated in some sense equitably under these institutions, and resources distributed fairly. This general characterization leaves room for various ideas about what a just distribution of resources looks like, and I do not propose to solve any debates about the correctness of egalitarianism or communitarianism or social contract theories or any other. The general characterization also leaves room for different ideas about the scope of distributive justice; a point about which I must make substantially stronger commitments. While statist conceptions argue that the applicability of principles of social justice is restricted to the realm of domestic politics, cosmopolitans at the other end of the spectrum take the entire globe within justice’s purview. Both, I argue, are ill-suited to the task at hand.

Although it is not my aim here to develop a comprehensive account of international justice, I think it is worth taking a closer look at the theoretical models currently available for moral assessment in transnational affairs. Acknowledging the serious disagreement about the scope of social justice, I will consider each of the dominant conceptions in turn, with the aim of bringing to the foreground some of the more substantial impediments to progress in terms of justice in an increasingly integrated world. If the current models are found to be lacking the requisite mechanisms for gaining traction on the moral issues in these trade negotiations, there is strong motivation to revise the models. I will propose a moderate alternative conception that can account for our intuitions about these FTA proceedings and offers a more pragmatic approach in place of ideal theory.

3.2.1 Statism

In the discourse of global justice, the political, or statist, conception is the view that the sovereign state is the locus of political moral responsibility. Broadly speaking, statist believe that the morally significant relationship required to generate duties of justice is one

found solely within a sovereign state because the legal and political institutions therein do not exert power beyond state boundaries. There is, of course, a separate dilemma about what constitutes legitimacy for a state; and given that the government of a legitimate sovereign state is internationally recognized as having the authority to trade, invest, borrow, confer entitlements, etc. on behalf of the state, it is an extremely important question. However, for present purposes we will have to make do with the reasonable assumption that all countries involved in the present case are legitimate sovereign states, and bracket off the more contentious cases such as the present state of Syria.

The statist conception is a particular sub-species of associative views: those that take associations between agents to be the source of obligations of justice. The relationship plausibly generates special obligations in light of the cooperative nature of interactions that persist and iterate over time. The idea of society as an ongoing cooperative scheme is an important one for advancing the statist conception of justice. Interactions between individuals re-iterate and institutions, including legal and economic institutions, evolve to govern these interactions, maintaining the integrity of the process. It is the process — the entire system of integrated social and economic interactions — that can appropriately be regarded as just or unjust.

Because the notion of justice carries with it the idea of very strong moral obligations, there must also be very stringent criteria for what sorts of associations are relevant to the question of socio-economic, or distributive, justice. Although individuals routinely engage in voluntary, cooperative interactions, the majority of these localized personal associations are typically not regarded as being sufficient to trigger the heightened moral demands of justice. The statist view says that what elevates the moral demand to one of justice is the non-voluntary nature of the association amongst compatriots and with the state, along with the coercive authority of the state over fundamental aspects of citizens' lives. The incidence of birth is the default condition of citizenship and, emigration aside, determines the state of which one is a member. So membership is not voluntary, and yet the role of the state in the lives of its citizens is a coercive one, demanding conformity with state laws and policies. Legal institutions, for instance, proscribe sets of behaviours that are deemed impermissible, and delineate a range of punishments for offenders. In this respect, legal institutions impose significant restrictions on personal freedoms. Other fundamental aspects of life are governed by institutions that regulate property acquisition, lending and borrowing practices, taxation for public goods and services, etc. What is more, citizens can, and often do, hold one another accountable for conforming to these societal norms, thereby asserting an active role in the process. It is the nature of this relationship — that the state exerts a coercive influence over members whose participation in the collective enterprise is non-voluntary — that is the basis for special demands of justice. Because citizens adopt an implicit acceptance of the state's laws and policies, the argument goes, they are afforded

status to demand justification for them; including those policies that so crucially affect the allocation of goods within the state.

This model of distributive justice found probably its most popular expression in John Rawls's *A Theory of Justice* (1971). That work intended only to address the realm of domestic politics, and so the concept of justice employed there evolved in terms of the institutions that make up civil society within a nation state. Rawls' idea of Justice As Fairness incorporates a strong egalitarian component demanding equal basic liberties for all, and the caveat that any socio-economic inequalities be attached to positions open to all and that they be of the greatest benefit to the least advantaged members of society. The principles of justice are selected from the equalizing vantage point of universal ignorance about one's socio-economic status, so as to minimize the impact of pure chance on one's life prospects. As Thomas Nagel points out in his analysis, "What is objectionable is that we should be fellow participants in a collective enterprise of coercively imposed legal and political institutions that generates such arbitrary inequalities" (Nagel, 2005, p. 128). The focus on institutions is an important one because those are the features of domestic socio-political life that coercively shape the lives of citizens. Rawls originally conceived of this system of intertwined social institutions as the basic structure, and he argued that it was the only proper subject of social justice. Specifically, the basic structure of society refers to "the way in which the major social institutions fit together into one system, and how they assign fundamental rights and duties and shape the division of advantages that arises through social cooperation" (Rawls, 1977, p. 159). The type of structure Rawls had in mind is one that exists only under a single government because it requires enforceable authority to maintain. The social, political, and economic institutions of a democratic state are legitimized through the free participation of its citizens. This Rawlsian egalitarianism regards compatriots severally as members of an ongoing non-voluntary, co-operative scheme as each has an interest in the functioning of the state as a whole. "It is the nature of sovereign states, [Rawls] believes, and in particular their comprehensive control over the framework of their citizens' lives, that creates the special demands for justification and the special constraints on ends and means that constitute the requirements of justice." (Nagel, 2005, p. 123).

Statist thinkers such as Nagel have followed Rawls down this path and argued that because the relevant social cooperation necessary to trigger concerns of justice exists only at the level of the nation state, there is thereby no ground for claims of justice outside the relation of co-citizenship. In "The Problem of Global Justice" (2005), Nagel takes up this view that centralized authority is a necessary condition for the stability of the cooperative scheme and therefore also for the application of claims of justice. He goes on to argue that since there is no centralized authority at the global level that has the sort of coercive power domestic governments do, questions of global justice are without expression. This is because, on the statist view, it is only the complete, integrated system of institutions, what

Rawls calls the basic structure, that serves as an appropriate target for demands of justice. In the absence of this basic structure, there is no entity at which to direct discourse about distributive justice.

On the political conception, sovereign states are not merely instruments for realizing the pre-institutional value of justice among human beings. Instead, their existence is precisely what gives the value of justice its application, by putting the fellow citizens of a sovereign state into a relation that they do not have with the rest of humanity, an institutional relation which must then be evaluated by the special standards of fairness and equality that fill out the content of justice. (Nagel, 2005, p. 120)

Members of a state share with one another an institutionalized relationship they do not share with others, and it is only within this institutionalized relationship that questions of justice gain traction.

For Nagel, an important feature of this coercive relationship is that it is not *purely* coercive. State governments, he argues, act in the name of their citizens; the actions of the state are said to represent the collective will of the citizens. In international settings, for instance, state actors act on behalf of the citizenry. The attitudes they project are taken to be representative of the general feeling within the state. Because all members of the state are “putative joint authors of the coercively imposed system”, they are thereby complicit — even if not on an act-by-act basis — in the policies and actions of the state. This shared responsibility for actions of the state means that state members have grounds to demand justification for those policies. Global justice cannot be a real concern on this view because there is no equivalent in international politics to the institutionalized basic structure found domestically. Although the policies of a state may have significant impact for those in another state, as do immigration laws for instance, such laws are only enforced against non-nationals; the laws do not require their acceptance and so no justification is owed them for the policies (Nagel, 2005, p. 129-30).

On this view, then, the occurrence of bilateral and multi-lateral trade agreements between sovereign states is simply a matter of voluntary arrangements negotiated between self-interested parties. The members of one state are not beholden to the political community of any other state; they do not participate in its system of taxation, civil and criminal law, property acquisition, and are not held responsible for its actions. If, for example, Greece finds itself in economic dire straights requiring bail-out money from other countries, the austerity measures subsequently imposed within Greece do not extend also to its trade partners. The nature of trade agreements does not join the citizens of different countries in the strong way required to trigger obligations of distributive justice. Such voluntary associations are simply not appropriate targets for questions of justice. “Justice applies. . . only to a form of organization that claims political legitimacy and the right to impose decisions by

force, and not to a voluntary association or contract among independent parties concerned to advance their common interests.” (Nagel, 2005, p. 140)

It is certainly a compelling position that sovereign states have the moral authority — their legal authority is not questioned by anything I will say — to enter into trade agreements with other willing sovereign states, and those to whom the terms do not apply do not have a say in the matter. For instance, if Norway wants market access for selling steel in Algeria, and has an available market for buying inorganic chemicals from Algeria, it is no business of Canada’s if they set up a formal agreement to do so; even if Canada was previously or currently involved in either of these markets. Nagel would argue that if the terms do not call for Canada’s acceptance, then there is no obligation of justice to include Canadian interests in the deliberations (Nagel, 2005).

Some will be quick to point out here that the statist model can nonetheless acknowledge morally problematic aspects of the situation in LDCs. While this conception maintains that distributive justice is strictly an associative demand, there may be other morally germane considerations for caring about destitute populations that have nothing to do with justice. The statist view does not reject the existence of other kinds of moral rights that are not associative and do not depend on any sort of institutionalized political structure. These pre-political human rights are found at a lower moral baseline — because they apply more broadly than do associative moral demands — and exert influence across the spectrum of humanity irrespective of national identity.

We typically understand humanitarian aid as called for when the human rights of some population are going unfulfilled. While there remain areas of dispute about the nature of rights and what sorts of things might properly be called human rights, it will serve our purposes to take something like the Universal Declaration of Human Rights³ as a workable starting point. It is pretty commonly accepted these days — and I will not attempt to recreate the argument here since my own argument does not depend either on its success or its failure — that there is a duty of rescue for those in very poor countries where basic health needs are not met; and further that this duty extends to wealthier nations who ought to meet the demand by providing humanitarian assistance. The nature of that assistance — whether it is best to provide financial aid or supplies or infrastructure or training, etc. — remains a topic of some substantial controversy, but the recognition of the humanitarian duty at least has achieved considerable acceptance. Many countries, including many in the EU, have specific budgets for international aid (European Commission, nd). They provide assistance in a variety of different ways to help alleviate the significant hardships faced by so many not graced with the fortune of living in a developed nation. This type of assistance is given not because of any specific relationship that binds one country to the well-being of another, but because of a universally shared respect for the sanctity of human life and the conditions of its fulfillment. So even if the political conception does not

³<http://www.un.org/en/documents/udhr/>

recognize any obligation of distributive justice across state boundaries, we may yet have moralist misgivings about the deplorable conditions found in many parts of the world on humanitarian grounds.

I do not wish to diminish the importance of pre-political humanitarian duties, and it is not my intention here to take up the issue of universal human rights. I think it is very plausible that there is a class of rights held by all persons, and that some of these rights are being denied some persons, and that most of us in wealthy countries ought to do more than we presently are to combat this problem. But none of these observations shed any light on the specific issues of this FTA. The humanitarian duties on offer are not associative; they pick out a very general duty and distribute the obligation across a non-specific set of capable agents. Perhaps all nations above some minimum Gross National Product (GNP) ought to contribute to the alleviation of abject poverty in those countries where it is so prevalent. Rawls offers an argument for something very much like this in *The Law of Peoples*⁴. Or perhaps the obligation extends also to any and all individuals sufficiently well off, whatever that might look like. But the statist view explicitly rejects any additional obligations of justice in such cases because the affected parties are not joined by the political relation of national citizenship. To be sure, the existence of humanitarian duties is quite compatible with the simultaneous existence of other, specifically associative, duties; it is, however, the position of the statist that the latter do not apply transnationally.

With respect to international trade, this approach regards the negotiating parties as voluntary participants in a mutually beneficial exchange, which does not trigger the heightened demands of social justice. State delegates to the negotiations are deemed responsible for protecting the interests of their own people so there is no moral requirement for either party to be concerned with the fairness of the resulting distribution. As long as the parties bargain in good faith; i.e., are not deceptive, and refrain from manipulation or bullying, there is no moral failing. So although this view can provide a moral assessment that recognizes a general problem with the lack of provisions for adequate healthcare in LDCs, it lacks moral explanation for the terms of this FTA that we deem to be problematic. The morally relevant features are not restricted to the happenstance of extreme poverty in parts of the world; there is also the matter of how countries interact with one another on the international stage that can play a contributory role in perpetuating circumstances detrimental to human flourishing. Humanitarian duties are tangential to the issue at hand. There may very well also be humanitarian duties owed, but if there are, they are so only in addition to matters of justice; not instead of. If I am right, there are matters of justice to be concerned with in these FTA negotiations, and these are independent of any existing humanitarian duties.

⁴Originally published as a short essay in 1993 and later as a book in 2001 (Rawls, 2001).

3.2.2 Cosmopolitanism

(Moral) Cosmopolitanism is often presented as the leading rival to statist conceptions of global justice; however the term ‘cosmopolitanism’ enjoys reign over such an expansive family of views in political theory that it does little to narrow the playing field. A central feature of moral cosmopolitanism is that “every human being has a global stature as the ultimate unit of moral concern” (Pogge, 2002, p. 169) as cited in (Beitz, 2005, p. 17); that is, it is the interests of individual human beings that matter morally. But this could be understood in a variety of different ways. Some cosmopolitans (e.g. Martha Nussbaum) argue that the ground of this moral stature is to be found in inherent qualities of human beings. Recalling the Stoics following Diogenes, Nussbaum recounts, “We should recognize humanity wherever it occurs, and give its fundamental ingredients, reason and moral capacity, our first allegiance and respect.” (Nussbaum, 1994). Her purpose is to encourage a feeling of fellowship with all mankind so that we may relate to one another first and foremost as human beings instead of approaching others always in the dress of particular affiliations like national identity. While I think there may be some worthwhile general moral themes embedded in this view, I think it is probably inadequate as an account of global distributive justice; but to be fair, it does not actually purport to be such. I introduce Nussbaum’s view here mainly to contrast it with another cosmopolitan stance that more directly addresses special obligations of social justice; what is typically referred to as the Global Basic Structure (GBS) approach. Such accounts argue that moral justification is owed to all persons because the global institutional order, with its intricately connected web of global finance, trade, and international law, constitutes a basic structure of the sort that critically impacts fundamental aspects of people’s lives. My focus on this set of views is not arbitrary, but I suppose it to represent some of the most common and compelling arguments in the literature of cosmopolitan justice.

GBS theories, like statist accounts but unlike Nussbaum’s cosmopolitanism, are associative in nature and share with statism a common denominator in Rawlsian theory. Building on the core principles developed in *A Theory of Justice* Rawls (1971), philosophers such as Charles Beitz, Thomas Pogge and Darrel Moellendorf have sought to bring Rawls’s insights to the realm of international politics. The irony of course, is that Rawls was most explicitly not a cosmopolitan philosopher. Rawls himself famously, or perhaps rather infamously, argued for a sharp distinction between moral principles for the domestic and the international domains in his later *The Law of Peoples* Rawls (2001); a work probably best known for the volumes of controversy it generated for failing to recommend any very robust moral principles for global politics. Some have even suggested that *The Law of Peoples* demonstrates an inconsistency with Rawls’s earlier writings. It is not my purpose to comment on what may or may not be an inconsistency in Rawlsian theory, but I will note here that those who think he should have been a cosmopolitan typically do so because they maintain that national

citizenship is one of those morally arbitrary factors that ought to be hidden behind the veil of ignorance in the original position. We would thereby end up with a global original position in which all persons were represented and so would take the worst off globally as the measure for applying the difference principle. It is argued that Rawls himself should endorse this approach in order to remain consistent with a liberalism that takes seriously the well-being of individuals⁵.

The GBS position is advanced from within the social contract tradition and Beitz specifically seeks to extend Rawls's argument in *A Theory of Justice* for the two principles of domestic justice:

1. The Egalitarian Principle - that every member of society is entitled to the most complete system of equal basic liberties compatible with the same liberties for all
2. (a) The Difference Principle - that any social/economic inequalities must be to the greatest benefit to the least advantaged members of society
(b) Equal Opportunity - that these inequalities be attached to positions open to all under conditions of fair equality of opportunity (Rawls, 1971)

It is a familiar argument and I will not attempt to reconstruct it here. As discussed above, Rawls takes the basic structure of society to be the subject of principles of justice, by which he means that moral principles be applied to those social, economic, and political institutions that have a pervasive and fundamental impact on citizens' life prospects. Recognizing this to be probably the most widely accepted view in domestic political theory, Beitz argues that the argument can be easily augmented to provide a similar argument for principles of distributive justice globally. Just as there exists a basic structure of social, economic, and political institutions within a nation, so too there exists a similar basic structure of global institutions.

In their shared appeal to a basic structure, GBS and statist conceptions agree that such institutions are enormously influential in determining outcomes for peoples' lives because of "how they assign fundamental rights and duties and shape the division of advantages that arises through social cooperation" (Rawls, 1977, p. 159). Furthermore, they agree that social justice can be an issue precisely *because* of this connection to a shared institutional framework; that such demands are broadly called associative because they simultaneously include all persons with whom we stand in the relevant relation and exclude the rest. But whereas statist maintain that the appropriate institutional setting is closed by state boundaries, cosmopolitans argue that while the global institutional order is of course different in certain respects from domestic ones, it nonetheless reflects a high degree of cooperation and interdependence amongst states. Pointing to such institutions as the International Monetary Fund (IMF), the World Bank, the WTO, and countless examples of multinational

⁵See for instance (Pogge, 2004).

cooperation in science, medicine, business, technology, etc., GBS theorists maintain that there is a global institutional order that exemplifies precisely this fundamental relation. So Beitz argues, “if evidence of global economic and political interdependence shows the existence of a global scheme of social cooperation, we should not view national boundaries as having fundamental moral significance. Since boundaries are not coextensive with the scope of social cooperation, they do not mark the limits of social obligation.” (Beitz, 1999, p. 151) And Moellendorf makes a similar point.

That principles of justice apply globally is, I argue, a contingent fact about the degree of integration, especially economic integration, or globalisation of the present world. In *Cosmopolitan Justice* I took duties of justice to be associative duties that arise when an association regularly affects the highest order moral interests of persons, and especially when the burdens of such associations are not easily avoidable. The globalising forces of the world economy, political and legal institutions have produced a global association. It is by virtue of this association that one can apply the constructivism delineated above, yielding principles of global justice. (Moellendorf, 2004, p. 204)

As the basic structure of society in the domestic case is the foundation upon which obligations of justice are owed to compatriots, it is argued that the fact of a similar basic structure of the global society must then show that obligations of justice are owed to all persons.

The concept of the basic structure incorporates the idea of society as a cooperative scheme of coordinated behaviour; and we have already looked at an example of how statisticians argue for limiting application of this conception to domestic society. Following a Hobbesian assumption that one only has reason to do a thing if so doing is in one’s interest, Nagel maintains that centralized, coercive authority is required in order to ensure compliance with moral norms that sometimes require people to act in ways that are not in their immediate interest. The cooperative scheme of coordinated behaviour provides the assurance that others will behave likewise, and so it is the state — the basic structure of domestic society — that prevents all from devolving to a state of war. Citizens are owed justification for the policies of their state because of their participation as both beholden to and co-authors of the coercive policies. In the absence of a coercive *global* authority, however, the Hobbesian state of nature prevails over the international setting, and the only rational course of action is for states to look out for their own interests and guard against those who would interfere. Without the guarantee, secured by centralized authority, that other states will cooperate with established norms, no state has a duty to any but itself and so the morality of states dominates the international arena.

But, as Beitz (1999, p. 36) observes, this Hobbesian analogy to international politics relies on the truth of 4 propositions (the international extensions of Hobbes’s own conditions in *Leviathan*); all of which, Beitz argues, are false.

1. The actors in international relations are states.
2. States have relatively equal power (the weakest can defeat the strongest).
3. States are independent of each other in the sense that they can order their internal (i.e., non security-related) affairs independently of the internal policies of other actors.
4. There are no reliable expectations of reciprocal compliance by the actors with rules of cooperation in the absence of a superior power capable of enforcing these rules.

For present purposes, I am particularly interested in Beitz’s arguments against the third and fourth conditions because they are specifically relevant to setting the stage for arguing that there is a global basic structure. It is easy to see why that third proposition is necessary for those who seek to advance the Hobbesian argument against an international morality; if states are strictly independent they will be in constant competition with one another for limited resources with an ever-present threat of violent conflict — the state of nature. But as an empirical claim about the actual world, this proposition appears to be simply false; states are not (at this time anyway) wholly self-sufficient entities. They rely on one another in significant ways that impact their own internal policies. States have common goals — such as assurance against wide-reaching potential disasters like nuclear confrontation, to take Beitz’s example, but also the destruction of Earth’s supply of fresh water and food-producing regions ⁶ — that justify a “measure of trust and predictability in their relations with one another” (Beitz, 1999, p. 42-3). And relatedly, domestic economies tend to be interconnected in increasingly complex ways involving commodities pricing, foreign investment, etc. With increased occurrence of cross-border transactions comes increased surveillance and regulation of these transactions (Beitz, 1999, p. 43). The World Bank and International Monetary Fund govern borrowing and lending practices, as well as the valuation of domestic currencies relative to one another; the World Trade Organization establishes and enforces rules for the practice of international trade; the World Health Organization researches and makes recommendations about the prevention and treatment of diseases that recognize no political boundaries. In short, then, it is reasonable to assert that states actually share a very high degree of interdependence.

The fourth proposition states that a central authority with enforcement capabilities is necessary in order to ensure that states can have reliable expectations of cooperative behaviour from other states. Recall that it is the expectations that are paramount here, making it reasonable for any particular state to abide by moral terms. But, again, we need only look to the institutions noted above to see that there is in fact a good deal of reliability in the expectations that states make of others. Although there is of course nothing akin to a global police force or central government, there are loci of significant influence/authority

⁶For example, as California is a significant producer/exporter of fruits, vegetables, tree nuts, rice, etc., the effects of their present drought will be felt well beyond the U.S. border. <http://www.ers.usda.gov/topics/in-the-news/california-drought-farm-and-food-impacts.aspx>

over circumscribed domains. The United Nations Security Council, for instance, has the authority to initiate aggressive intervention where some country's actions threaten the security of others. Other UN branches may at times authorize economic sanctions such as trade embargoes against a country whose behaviour falls short of the expected norms. One sort of example when this might be called for is when a state systematically violates the Human Rights of its people (or some sub-segment thereof). I find this example particularly illustrative because it highlights a specific moral norm — respect for Human Rights — that is intended to be universal in scope, but does not directly involve other nations, and yet is collectively enforced against all. States have a relatively high degree of confidence in the general compliance with, for example, UN doctrines. This is so in part because the costs of defection are quite high, but sanctions are collectively enforced by states themselves and not by a supreme government. What we have then is a pretty good empirical argument showing that there are at least some rules that do have normative force for states. Because states are not actually self-sufficient entities, but rather engage in regular interactions to incur benefits they could not achieve on their own, there are reasonable expectations of compliance with established norms even in the absence of a coercive central authority. And so the extension of the Hobbesian argument that the international order is a state of nature as opposed to a cooperative scheme ultimately fails.

The point of these empirical arguments is to show that the international landscape does resemble the domestic in sufficiently suitable ways as to recommend a corresponding application of principles of distributive justice. As should be clear by now, this is not an argument intended to advance a conception about cosmopolitan institutional design; in particular it does not argue for a centralized world government (Beitz, 1999, p. 199) (Beitz, 2005, p. 18). The empirical argument given above is designed to show that the absence of a world government need not interfere with the project of establishing moral principles for international relations. It is also not a view about one's political conception of the self as say, a 'citizen of the world', such as the view Nussbaum proposes. So it should not be seen to reject particular loyalties a person may have to kin and country (Beitz, 1999, p. 199). The *moral* cosmopolitanism presented here is a position about "the basis on which institutions and practices should be justified or criticized" (Beitz, 1999, p. 199); specifically that the interests of actual persons are what matter morally.

I would like to take this opportunity to be very clear about a particular point I think is often overlooked in these debates. The GBS argument does not by itself entail that there are no relevant distinctions between people living in different countries and it does not recommend a re-allotment of existing assets consonant with the difference principle — it is a wholly separate enterprise from that of moral arguments that appeal to the duty of assistance (Beitz, 1999, p. 49). The GBS account argues that the conclusions apply to the distributive outcomes of those transnational institutions comprising the global basic structure. The cooperative scheme produces collective benefits, so the conclusions

of any moral appeal to this cooperative scheme can only apply to those goods that derive from it. As Beitz remarks, “[i]nternational distributive principles establish the terms on which persons in distinct societies can fairly expect each other’s cooperation in common institutions and practices. These terms involve the distribution of the benefits gained from natural resources as well as those gained from social cooperation proper.” (Beitz, 1999, p. 180) But this is not at all the same as the redistributive conclusions of certain other moral arguments that demand massive transfers of wealth to the global poor indiscriminately of how that wealth came to be appropriated.⁷ It does, however, require a good deal more than the Hobbesian inspired arguments of the statist who maintain that no obligations of justice can exist across borders.

On the face of it, GBS might seem a very neat and tidy way of accounting for the moral obligations that I argue ought to factor into the negotiation of the EU-India FTA. Bilateral trade agreements are subsumed under a variety of international conventions established by the WTO, the World Bank, and other institutions. These institutions are partly constitutive of the global basic structure, and so particular trade deals must conform to the principles of justice. Accepting Beitz’s version of GBS, this FTA would be acceptable only insofar as it realized the difference principle. However, far from advantaging the worst off globally, we can reasonably conjecture that the FTA will actually have a negative impact on this segment of the global society. We might thus have the basis we were looking for in picking out what the moral failing is here; the EU-India FTA does not meet the moral standard for acceptability because it violates the global difference principle. The difficulty is that whether or not there is in fact something that could qualify as a GBS, such a thing would be a somewhat cumbersome entity at which to direct moral discourse. At the domestic level, those institutions comprising the basic structure of society are at least *prima facie* subject to the same standards; they operate within an established network of social and legal responsibilities. In the absence of a global government, the same does not apply globally. As a result, there is considerable ambiguity about the specific obligations of particular actors. Our problem in accounting for a presumed injustice in this FTA is a practical one; we want to be able to say whose conduct needs to be altered, and in what ways. As Helena de Bres points out, “[a] duty to alter the global basic structure as a whole is not a duty with which any agent we currently see, or would want to see, could feasibly comply” (de Bres, 2013, p. 422). Even if one rejects Nagel’s claim that a centralized coercive authority is required to ensure expectations of cooperation, it may nonetheless turn out to be the case that some sort of authority over a restricted domain is what makes possible effective reform at the level of the basic structure. Insofar as one’s only interest is in ideal theory, perhaps this is not a decisive blow to the GBS project; however, ours is a practical question. Any theory of global justice adequate to the task at hand must be able to make

⁷See for example Singer, P. (1972). Famine, affluence, and morality. *Philosophy & Public Affairs*, 1(3):229-243.

pragmatic recommendations about how to alleviate the injustice we perceive in the current proceedings.

3.2.3 A Moderate Alternative

The above survey of the dominant theories of global justice highlights a significant complexity about what it means to treat people equitably. While almost no one would deny the moral equality of all persons, distributive justice indicates an elevated moral standard for which an argument is owing when it is claimed. But the arguments considered thus far seem to miss elements that we think are an important part of justice in the actual world. If we are to trust our intuitions that the terms of this FTA raise moral concerns properly subsumed by principles of justice, we must look beyond the standard models of global justice to illuminate the path forward. What we need is a conception of social justice that grounds these moral claims in a framework that extends beyond national boundaries, and yet is not so structurally disunified that they have no practical expression.

There is a growing collection of more moderate variations on themes already indicated, and I propose that we will get some traction on the issue without having to deviate over far from the mainstream. As with the dominant views, I follow Rawls' lead in zeroing in on the moral significance of institutionalized relationships that are based on patterns of cooperative behaviour and thereby generate mutual expectations of future behaviour. It is on this understanding that I refer to a basic structure that I argue is not restricted to the domain of the sovereign state. At the most fundamental level, I agree that matters of social justice must be inherently social; that is, they are dependent upon relationships and interactions, coordinated patterns of conduct between human actors. Furthermore, I agree that principles of justice can only be properly applied in institutionalized settings, as justice is concerned with how people are treated systematically. There is a lot of appeal in the statist view that unifies citizens under the shared legal and political institutions of their country. However, the expansion of both public and private enterprises across national borders means that the relationship of co-citizenship may have dwindling significance with the rise of associations that cross-cut these boundaries. These associations comprise domain-specific institutional regimes that regulate particular sectors of fundamental human importance such as trade, energy, banking, science and technology; and each of these domains operates with an organized structure establishing rules of conduct, allocation of goods, and recompense. In this way they share with the institutions within a nation-state features of a constrained cooperative scheme for mutual advantage that significantly impacts the life-prospects of those in its purview. It is thereby fit to look at these domains as targets for principles of justice.

While these regimes fall short of encompassing the entire globe, they nonetheless have far greater reach than does any one state. The advantage for the present assessment of the EU-India FTA is two-fold: by rejecting statehood as the only governance structure with

distributive responsibilities, we are not hampered by the fact that some of the most pressing cries for justice emanate from, and on behalf of, groups not covered by state policies of either bargaining party. Further, if, as I have suggested, the cosmopolitan has cast the net too wide to produce practically efficacious recommendations, by narrowing the scope there is reasonable expectation of identifying responsible actors at whom demands for redress may constructively be directed. I contend that these functionally-delineated spheres — to coin a now familiar term of Michael Walzer’s — that cross-cut global political divisions are better suited to specifying the relevance of moral discourse in these FTA negotiations and providing constructive guidance.

In advocating this disaggregated approach, I follow the work of Aaron James and Helena de Bres, the former of whom has also argued specifically that the practice of international trade incorporates the appropriate institutionalized structure to ground claims of justice (James, 2005). The fundamental realization is that because the global terrain of political activity is non-uniform, the theoretical approach to moral questions on this terrain should be similarly varied. So in response to the empirical data that indicate strong forms of transnational governance practices, we adhere to a model that acknowledges the differences in integration and implementation of different social practices within the global political arena rather than a fully global model. Consider the cosmopolitan argument that constraining principles of justice to domestic politics is unjustified on account of the fact that suitable relations exist also across borders. While this does make a compelling case against the statist, it seems unlikely that the world is presently as fully integrated as would be a prerequisite for pitching principles of justice at the global order in its entirety. There is as yet no consensus about whether or not there is such a thing as a global basic structure, but the debate can be avoided altogether by sticking with the more modest assertion that we have achieved some success in certain areas of transnational governance within particular limited domains. This picture is less tidy than the alternative conceptions, but for that reason is arguably more reflective of the actual state of affairs. Assuming that we think our principles of justice should be applicable to the world in which we actually live, there is strong pragmatic appeal in targeting those principles at institutional regimes as we find them. Recalling a characteristically Rawlsian sentiment that the appropriate principle for a thing depends on the nature of that thing, a disaggregated approach differentiates particular spheres of social, political, and economic influence, recognizing that a variety of different contexts may all give rise to considerations of distributive justice, yet not be uniformly amenable to the same principles. So it is noteworthy that in advocating a disaggregated approach to distributive justice, I do not reject the plausible contention that justice will exert different demands within sovereign states than it does across borders. There is room here to accord status to the unique relationship that obtains amongst compatriots without drawing the further conclusion that justice is sensitive only to the relation of co-citizenship.

An additional advantage of addressing justice discourse to these socio-political spheres as opposed to a global structure, even if one does exist, is that the greater specificity enables better identification of culpable agents to whom it makes sense to address such demands. It remains an unsettled dispute whether the plausibility of the GBS view depends on the existence of a centralized global authority. As we have already seen, Beitz and Pogge pretty clearly think it does not; but insofar as they intend for principles of justice to be efficacious, they must then have in mind some other agent(s) that can achieve the required compliance of the institutional framework with the distributive principles. To be sure, the task would be an enormous undertaking, as securing the satisfaction of distributive principles “would require the manipulation and fine-tuning of each of the multiple parts of the global order to fit a single distributive pattern. Moreover, because the global order is an ongoing form of association, satisfying these principles would require not one-off but *continual periodic adjustment of the entire global system in accordance with the desired distribution*” (de Bres, 2013, p. 432).

One natural suggestion is that states themselves could act in cooperation with one another to bring about the necessary changes in the global structure; after all, state governments are already tasked with the responsibility for distributive justice at the domestic level (at least insofar as each state recognizes principles of distributive justice as having purchase for them). There is also cause for optimism in the fact that some areas of transnational influence have already seen states achieve a measure of success in principle-driven cooperative action; inter alia environmental protections and trade. Indeed, the success of my own argument depends in large part on the ability of states to coordinate governance behaviour in these limited domains. But the practicability of wholesale coordination of governance action across all facets of human social, political, and economic life *worldwide* seems highly suspect. Adjustments to the global basic structure would plausibly require a unified authority capable of independently making complementary policy amendments in response to changing conditions. As de Bres (2013, p. 433) approvingly cites Freeman, “[t]he coordination problems of many nations separately trying to tailor their many decisions to affect peoples in distant lands over whom they have no political authority seem insurmountable” (Freeman, 2006, p. 289).

If state actors are inadequate for the task of ensuring the fulfilment of distributive principles aimed at the global order, that does not mean they are not suitable agents in any capacity (de Bres, 2013, p. 434). We can re-frame the issue by shifting attention to the target; so rather than lamenting that the agents we actually have on the global stage are incapable of managing the task of global distributive justice, we instead point out that the task itself is too big. It makes more sense to put to the agents a smaller task, one they are better suited to.

States acting internationally and nonstate agents lack [the features that make them effective domestically] and so need to employ alternative means for achiev-

ing specific distributions in relation to targets of justice. This fact restricts both the kinds of distributive aims that global actors can hope to have and the kinds of targets at which they can pitch their principles, but it doesn't rule them out as agents of global distributive justice. (de Bres, 2013, p. 434)

Securing compliance with principles of justice directed at the entire globe is not the sort of project we can reasonably expect state actors to take on, but responding to principled demands within smaller, more focused domains is just the sort of thing that state actors are equipped for. The examples we have of successful transnational governance functions show that states — along with non-governmental organizations, informal coalitions, etc. — do have effective tools for cooperatively organizing and re-organizing the institutional frameworks in which they operate; tools like diplomatic mediation and collective retributive actions like economic sanctions can be very effective at promoting compliance amongst parties with varying interests. The ability to shift the operational structure of their respective spheres lends hope for the prospect that these agents can also be successful in responding to principles of justice that are specifically targeted at these spheres. The point is brought into sharper relief when we recall that the functions of these spheres are what necessitate the call for directed principles of distributive justice in the first place. In the fora of these domains, state delegates act alongside other government and non-government agents to achieve common goals. It is the fact that the cooperative activities themselves generate specific advantages and burdens that yields the demand for equitable treatment of those affected by the practice.

3.3 In Defence of Disaggregating Distributive Justice

Statists, of course, reject any suggestion that state actors are responsible, either individually or collectively, for securing justice across borders; principles of distributive justice simply have no place outside the domestic politics of sovereign states. Nagel does address something like the disaggregated approach I defend here, but contends that these domains are inappropriate targets for claims of justice because, as he maintains, these transnational institutional enterprises are merely serving the mutual self interest of independent sovereign states. In Nagel (2005, p. 138 and p. 140) we find the two clearest statements of his objection: “[Current international rules and institutions] are not collectively enacted and coercively imposed in the name of all the individuals whose lives they affect; and they do not ask for the kind of authorization by individuals that carries with it a responsibility to treat all those individuals in some sense equally”, and “Justice applies. . . only to a form of organization that claims political legitimacy and the right to impose decisions by force, and not to a voluntary association or contract among independent parties concerned to advance their common interests.”

This seems absurd. If states are involved in political governance activities outside their own borders — as they most certainly are — it is surely a morally deficient view that fails to hold them accountable for the distributive consequences of these activities. In the first place, it is a bit of a mystery how we are supposed to understand the ‘in the name of’ relation that Nagel takes to be a critical element of the grounding condition. In the domestic case, state policies are said to be enacted in the name of all citizens because of their (non-voluntary) participation in the political life of the state. By remaining citizens of the state — an acknowledged default position — citizens give their tacit acceptance to the rules and policies governing them⁸. Because citizens ‘actively’ participate in their country’s structure of property and legislation, these policies must be reasonably justifiable to them and so can be said to be enacted in their name. But this is a pretty minimal construal of what it takes to regard a peoples’ engagement with a governance structure as active or wilful. The transnational institutions currently in place arguably also meet such minimal criteria. People all over the world participate in and are affected by such transnational activities as investment and commerce, production and sale of commodities, and telecommunications. Furthermore, it is pretty clearly part of the mandates of these transnational institutions to organize their activities in such a way that accounts for the needs, preferences, and other interests of the people affected by them. The motivation to expand telecommunication infrastructure, for example, comes from the demands of people across the world to be better connected. It is unclear what other sense could be made of a requirement that policies be enacted ‘in the name of’ some population, so it appears to be an illegitimate ground on which to limit the scope of distributive justice to sovereign states.

A further critique from the statist camp involves the charge that voluntary associations are not the right sorts of targets for distributive principles. Consider that objection directed at the international trade regime for instance.

[T]rade, however multilateral, does not constitute a cooperative scheme of the relevant kind. Trade, if freely undertaken, is (presumably) beneficial to the exchanging parties, but it is not, it seems to me, the kind of relationship giving rise to duties of fair play... Trade in pottery, ornamentation, and weapons can be traced back to prehistoric times, but we would hardly feel inclined to think of, say, the Beaker Folk as forming a single cooperative enterprise with their trading partners. No more did the spice trade unite East and West. (Barry, 1982, p. 233)

Such objections view trade deals as negotiations by sovereign governments acting solely in their own interests. In addition to membership in the relevant organizations, most notably the WTO, the agreements themselves are seen as lone-standing voluntary undertakings for

⁸I leave aside here the objection that Nagel’s argument is rather less compelling in the case of non-democratic states.

mutual advantage — the normative appraisal of which is restricted to considerations of coercion, exploitation, and manipulation of various sorts — as opposed to elements of an ongoing scheme of social cooperation⁹. Each party seeks to obtain something desirable from the other and agrees to give up something of value in return. So long as the bargaining parties engage fairly with one another without deceit, they are seen to have fulfilled any applicable moral obligations. Insofar as it makes sense to talk of any distributive demands arising from trade agreements, these concern only the internal distribution, within the state, of the advantages and costs of some particular trade deal.

The trouble is that this reckoning seems to fundamentally misconstrue the role of trade in contemporary international affairs. It is simply not the case that states are wholly independent, self-sufficient entities; and the goods traded are often of vital importance to the functioning of the state. The past several decades have seen an increase not only in global interaction, but in global interdependence¹⁰; and the international trade regime highlights this feature particularly aptly. Trade is generally touted as a means to promote specialization within states; they are encouraged to develop expertise in specific areas and to share this expertise within a cooperative system of global trade. This mechanism has the de facto effect of leaving each participating nation reliant on others to fill domestic gaps in various areas. Canada and Saudi Arabia, for example, are resource rich countries whose economies are strongly tied to oil exports. China and Taiwan have a strong market hold on manufacturing, while India and Malaysia are well known for textiles. In this way, national economies are built around particular sectors that then also have cascading effects on job creation/employment rates, migration of people within a country, infrastructure, taxation, etc.¹¹.

A suitably serious reflection on the extent of this global interdependence takes much of the sting out of Brian Barry's clever little quip about the Beaker Folk. Such comparisons fail to account for a pertinent evolution in the practice of international trade; that it is now very thoroughly institutionalized, regulated, and coercively enforced. Since the establishment of the General Agreement on Tariffs and Trade (GATT) in 1948 and its successor the WTO in 1995¹², global trade has been formally regulated both directly and indirectly through international as well as domestic laws in trade and such related areas as intellectual property, environmental protection, and labour. The WTO functions as a forum for trading nations to discuss and negotiate terms of agreements, as a set of rules to ensure that objectives are

⁹James (2005) characterizes this distinction as one between the morality of transactions versus the morality of practices.

¹⁰The General Agreement on Tariffs and Trade (GATT) was established following the Second World War.

¹¹For a telling example, one can look at Canada's current recession in the wake of falling oil prices globally and China's slowing economic growth rate, which reduces the demand for Canadian raw materials.

¹²For the sake of simplicity I will restrict the discussion to the WTO and its various councils and committees, as it is the most prominent institution with a unified governance role in the domain of international trade.

met and undesirable effects avoided or minimized, and as a dispute settlement mechanism¹³. It also has enforcement capabilities by which members may collectively impose punitive measures such as trade sanctions against offending countries¹⁴. WTO decisions are made by consensus of the full membership¹⁵, and trading nations subsequently enact domestic legislation commensurate with the agreed upon decisions of the formal bodies. Although the WTO is a voluntary organization, its membership boasts a large majority of the world's trading nations; and given the current extent of trade, non-membership carries a serious risk of omission from global markets. While it is true that the disaggregated approach targets institutional regimes that are, in some cases, formally voluntary, the advantages of membership and the costs of defection are often so significant as to render the voluntariness objection morally vacuous. It is a spurious oversight to neglect the significance of the institutionalized regimes within which international relations transpire.

To accept trade as an institutionalized social practice as I have suggested gives us *prima facie* grounds for regarding the international trade regime as an appropriate target for principles of distributive justice.

So long as the multilateral system is established and governed, and therefore *not* a state of nature in the relevant sense, trading nations bear certain collective responsibilities. The fair price of undertaking and maintaining a common practice of mutual market reliance is, for each trading nation, not only a responsibility of “fair play” to keep established rules in good faith, but also for each to use its bargaining powers in trade negotiations so that the system of trade itself treats those it affects equitably. (James, 2006, p. 716)

As previously acknowledged, demands of distributive justice represent a rise in moral concern above a humanitarian baseline. In the case of trade, the ongoing, cooperative efforts of trading nations have systematic consequences for people's lives such that those affected can demand justification. This is importantly different from Nagel's proposed counter-example that a nation's immigration policies do not call for justification to those they are imposed against (Nagel, 2005, p. 129-30). The underlying premise in this contention is that would-be immigrants are not party to the cooperative scheme that comprises the state's social, political, and economic infrastructure — even though they may be significantly impacted by it — and so they do not have equal standing to demand justification for the state's policies. But this premise does not hold where the institutional domain in question is the international trade regime, or other forms of transnational governance. It is not merely that citizens of trading nations are passive bystanders to the determinations of trade institutions; their

¹³https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm

¹⁴By way of emphasizing the potential magnitude of such measures, consider that after nearly a decade, international sanctions against Iran have just recently been lifted following a nuclear deal that ostensibly limits Iran's ability to produce a nuclear weapon.

¹⁵Under certain conditions, a vote may be taken. See https://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm

participation is embedded in the way international trade shapes the structure of their lives from the types of crops they grow to the technologies they possess. The difference between participation in the institutions of a state and the institutions of transnational regimes is at best a difference in degree, not a difference in kind. Properly regarded as a social practice, the international trade regime is morally accountable to those it encompasses. I leave it an open question whether there yet remains any inhabited region on Earth unaffected by global trade.

While I do recommend that a disaggregated approach to global distributive justice is superior to the dominant conceptions for its ability to explain our intuitions about the moral appraisal of transnational practices and make pragmatic recommendations for the satisfaction of principles of justice, I simultaneously acknowledge that accounts of this type are as yet undertheorized. It bears repeating that I am not proposing a defence of a full-blown account of global distributive justice, and leave untouched any attempt to provide a comprehensive mapping of the spheres to which I refer or the precise terms according to which they should be delineated. I suspect that a disaggregated approach is not actually amenable to the neat and clear boundaries that segregate concentration of political power into states; it is quite likely there will be a good deal of overlap such that the IMF or the World Bank, for example, are probably constitutive of the structure of several domains. Rather than supposing this to be a strike against a disaggregated approach, it may actually help in overcoming any challenges that could arise with respect to the compatibility of principles aimed at different spheres. Where some specific institution is partially responsible, say, for both principles targeting the international trade regime as well as for those directed at global economic structures, that institution will be uniquely positioned to provide constructive input that other institutions within each sphere may not otherwise have access to.

Neither do I catalogue any concrete moral principles or a decision-making procedure a la Rawls' original position. The point is that neither statism nor cosmopolitanism provides a proper accounting of the moral landscape for principles of distributive justice to take hold; an inadequacy that I think can be remedied by carving up the world of social/political/economic interaction into spheres identified in terms of their functional roles. Although there remains much important work to be done regarding the specification of principles, the degree to which this account is underdeveloped should not be detrimental to my present argument, which aims only to show that concerns of justice have a real place in the negotiation of the EU-India FTA. The goal is to provide a framework that takes seriously the various forms of interaction that occur globally so as to enable a more careful assessment of global issues such as this FTA.

Chapter 4

Moral Constraints on Trade Negotiations

The task at hand is not particularly straightforward; and the moral waters are muddied by the fact that the population most vulnerable to a purported injustice is not represented in the trade negotiations. In some sense it would be simpler if SSA had a place at the bargaining table because the accepted practice of fair bargaining means that each parties' interests get equal representation. The difficulty arises because, even though the negotiating parties are well aware of the African interests, there is no established mechanism by which these interests have any credence in the negotiation of a trade deal between India and the EU. Negotiating parties are free to make whatever concessions and allowances they feel will best promote the advancement of their trade goals. So if India is pressed to concede stricter (than WTO imposed) IP protections in return for say freer mobility of Indian workers across EU state borders, then it is formally up to India to decide if that is a worthwhile concession for them. And if the EU suspects that mobility of workers is a key point for India, they are free to press the ultimatum even by threat of ending negotiations¹. But the particulars of these trade negotiations reveal a moral shortcoming in the understanding of current established practices. If there is at present no effective mechanism by which trading nations are required to account for consequences outside their borders, then there ought to be; but this will involve a shift in moral attitudes about global distributive justice. When trade deals are regarded as merely voluntary arrangements for mutual self-interest, bargaining parties are not constrained by higher moral principles, and trade practices risk producing severe collateral damage for their failure to account for broader social, economic, and political circumstances. In order to justify a broad level moral constraint in these negotiations, it is important to recognize that morally significant relationships, involving mutual expectations, arise through institutionalized patterns of trade in socially basic goods.

¹These are just hypothetical scenarios.

In making the case in the previous chapter for the global integration of transnational trade practices, I drew attention to the fact that a touted virtue of international trade is that it encourages states to develop areas of specialization they may be uniquely well-suited to. The special relevance of this fact for present purposes is that it helps to highlight how dependencies like that of SSA on India can arise. As earlier noted, India's pharmaceutical industry is quite a lucrative one for the country. India found a niche in the global market and directed its resources at servicing it. Recall the original motivation for the 1970 Patents Act that excluded patent protection for pharmaceutical products. The goal was quantity: make them fast, make them cheap, make lots of them, and sell them all over the world. The plan was successful, revenue grew and the industry expanded, as it continues to do now. The economic valuation of India's pharmaceutical industry helps to reinforce the stability of expectations about the continued supply of pharmaceutical products to its consumers, including the countries of SSA and other LDCs. So the dependency of those in need on this supply is not merely an accidental coincidence, but is in fact encouraged by the practice of international trade in generic drugs.

This is an important point as far as the moral argument goes because the moral relevance of SSA's interests to these trade negotiations rests on there being an institutionalized relationship which the LDCs, India, and others are all part of. Distributive justice, it is argued, is grounded in institutionalized relationships for which coordinated expectations are key. The system of both formal and informal practices in the international trade regime, such as India's development of a profitable export industry in generic drugs, means that SSA can reasonably come to expect continued supply of those drugs. Note also that this relationship involves no criterion that membership in the WTO is a necessary condition. Most LDCs are WTO Members, but many are not and this need not exclude them from the community whose interests are of moral relevance to the EU-India trade negotiations. The WTO is an institutional body with a formalized governance structure whose mandates reach even those who have not signed on. It sets the framework for a system of international trade that affects any and all countries that import or export goods. While the WTO is certainly an integral part of the international trade regime, it does not solely constitute it.

This brings me to a further point about the nature of the goods affected by the proposed EU-India FTA. The fact of a basic structure governing the international trade regime tells us that principles of distributive justice are properly applicable to trade practices. But the basic structure is morally relevant not just because it is a coercive institutionalized structure, but also because of its systemic impact on people's life prospects. So we need not suppose that all trade terms carry the same moral weight. It is specifically because the international trade regime governs, in part, global access to such basic goods as medicines that it is subject to distributive principles. I imagine I am not alone in assuming that moral outrage would be kept to a minimum if the worry had to do with a potential shortage of hula hoops. The EU-India FTA holds the reigns on a commodity of fundamental human

importance, and so must be accountable to principles that ensure that burdens of a trade deal are not unfairly borne by those least able to do so.

Having argued that the basic structure of the international trade regime is an appropriate target for principles of distributive justice, we are now in a position to see that the interests of those in SSA do have moral bearing on the EU-India trade negotiations. The long-standing situation whereby Indian-produced pharmaceuticals service the market of LDCs, including the countries of SSA, creates a morally significant dependency; one that cannot simply be unilaterally annulled. This dependency joins the impoverished countries of SSA with India in the community of international trade. That community has a basic structure inclusive of collectively imposed and enforced regulations and practices affecting the distribution of advantages and disadvantages across trading nations. Because the practice of international trade creates such a diverse community connected by the coercive force of the institutional basic structure, there is a requirement to accord equal moral status to all within that community². It is therefore fitting to ask whether some particular trade deal within the scheme places an unfair burden on any part of the trading community.

One reasonable response to this observation would be to ask whether this entails that India is under any moral obligation to continue the existing relationship with SSA, or if it is not free to negotiate a conflicting arrangement with the EU. After all, we surely do not mean to eclipse traditional principles of autonomy. Consider by way of contrast an example presented in Blake (2001) of two trading nations, Syldavia and Borduria, the former of which is relatively worse off than the latter. Blake does not echo my sentiments, but he does offer some illuminating commentary about the moral demands created by the trade relationship.

There was no presumptively wrongful proposal in the Bordurian offer to trade. Neither, I think, are the Bordurians under any obligation to continue trading with the Syldavians since the situation of the Syldavians without trade was morally acceptable. (This is, of course, assuming that the Syldavians have not adjusted their internal economy to render a threshold level of physical functioning impossible to achieve without foreign trade. This might well be a false assumption, in which case things are that much more complex.) (Blake, 2001, p. 292)

I am inclined to agree with Blake about the Bordurians and the Syldavians, but I wonder how well these hypothetical states represent any actual trading nations and what is meant by a “threshold level of physical functioning”. In the first place the situation of Blake’s

²Recall that I have deliberately left open the possibility that the international trade community encompasses the whole world. The key point is that the unifying force of the basic structure of the trade regime calls for principles of justice grounded in the trade relationship. There will of course be overlap with principles grounded in other kinds of relationships as well, such as the relation shared by co-citizens of a sovereign state.

Syldavians without trade is stipulated to be morally acceptable, even if relatively worse than that of the Bordurians. That caveat simply does not apply to the situation in SSA. The extent of poverty experienced in those countries puts the majority of the population well below any threshold of minimal subsistence. Mortality rates are disproportionately high, as are infection rates for diseases that are largely controlled if not outright eradicated in the developed world. Lack of access to clean water, adequate nutrition, and health care means that the situation of SSA without effective trade routes for the importation of Indian pharmaceuticals is far from morally acceptable³; and I cannot think of anyone who would argue this point. Blake's parenthetical remarks above are also worth exploring, as he does not actually address the moral impact of any situation in which "things are that much more complex". The trade patterns by which Indian pharmaceuticals are exported to SSA are so well established and entrenched, with no suitably effective alternative presently available, that it is fair to say that these countries have adjusted their internal economies to be dependent on this supply chain. Since death from treatable diseases diminishes peoples' capacity for physical functioning well below any conceivable threshold level, I suppose India's proposed retraction from the existing relationship would constitute a very much more complex moral situation.

So herein lies the crux of the matter. The terms of the EU-India FTA offer India various incentives to help strengthen its economy, but at the foreseeable cost of nullifying India's existing role as exporter of affordable medicines to the global poor. Although the situation draws out hints of exploitation, it is significantly different in that the would-be victims are not the ones being incentivized; so moral principles of fair-play do not straightforwardly apply. This is why I argue that a different moral framework is required in order to discuss how the dependency of SSA on Indian drug exports can morally constrain the autonomy of India and the EU to enter into a conflicting agreement. The institutionalized relationship that I argue encompass all the relevant agents secures the moral stature of the LDCs who are thus situated. By itself, of course, this does not resolve the question of whether India must continue the existing relationship, but it is a relevant limiting factor on state autonomy.

My primary aim has been to demonstrate a moral requirement that the pending EU-India FTA be sensitive to the fundamental interests of LDCs not party to the trade negotiations, in light of the fact that a new trade deal would disrupt the existing flow of pharmaceutical products to those in need. The moral requirement is quite general in form, claiming a need for specific institutional protections to guard against the misuse of vulnerable populations who have very few avenues for affecting trade outcomes. This is not to suggest, however, that the onus is solely on India to refrain from accepting terms that would compromise the integrity of the relationship with SSA. Inasmuch as the EU is part of the trade community, they share responsibility for ensuring that proposed terms do not

³Note that this does not imply that the existing relationship with India is sufficient for elevating the circumstances in SSA above the subsistence threshold. It is enough that it improves the situation.

violate moral principles. It is unjust to incentivize another with terms they cannot morally comply with. But the argument does not yield the conclusion that the moral demand is to be borne exclusively either by India or the EU. We must recognize also that trade is governed by institutions — most recognizably those of the WTO — tasked with coercively enforcing shared rules and settling disputes. So to maintain that both India and the EU have moral duties to account for the interests of those in SSA is to acknowledge as well that institutions like the WTO have a responsibility of oversight to ensure the application of moral principles. Because the basic structure of the international trade regime is the target of principles of justice, its institutions are collectively responsible for organizing themselves in such a way as to promote just distributions.

It is important to emphasize that I am not offering any one particular solution that is morally preferred. My conclusion is that the existing relationship between India and LDCs such as those in SSA is a feature that has moral relevance to the proceedings of trade negotiations between India and the EU, but not that these morally significant interests must necessarily trump the autonomy of India and the EU in seeking to achieve independent goals. One way to address the moral dilemma might be to remove trade terms requiring India to strengthen IP protections that would restrict the production and distribution of generic drugs. A possible alternative might be to substantially improve access to drugs produced by originator pharmaceutical companies. In collaboration with a group of like-minded colleagues, Thomas Pogge has suggested one such solution, the Health Impact Fund (Pogge, 2008). Very broadly speaking, the idea behind this proposal is to move away from the patent scheme, changing the way companies are incentivized and compensated for developing drugs. It is important to note, however, that because the relevant pharmaceutical companies are found in many different countries, this route is not something over which either India or the EU will have exclusive control. So an interim solution might be called for; something perhaps along the lines of the WTO-granted extensions for LDCs to achieve compliance with TRIPS. The evaluation of these potential solutions would be an important next step, but we must first acknowledge the deficit in current moral thinking about global trade. The institutionalized basic structure of the global trade regime has moral implications for trading nations, and the threat to LDCs of their supply of life-saving medicines places important moral constraints on the negotiations of the EU-India FTA.

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