

# Trade agreements and policy space for achieving universal health coverage (SDG target 3.8)

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## ABSTRACT

Achieving universal health coverage (UHC) is one of the core priorities of the Sustainable Development Goal health agenda, and much of the debates on the means to achieve this target has focused on financing and benefits models. However, little attention has been paid to the challenges related to the costs of providing UHC, such as the affordability of medicines. This paper explores the challenges countries face in negotiating trade and investment agreements that could restrict their ability to manage access to medicines and the public health systems more generally. The paper outlines the key provisions in recent trade agreements—strengthened intellectual property (TRIPS plus) requirements, government procurement, dispute settlement—that constrain policy space for implementing universal health coverage. These consequences can have particularly dramatic effects for countries that made effective use of medicines and intellectual property policies to expand access to medicines. The paper elaborates on the case of Bangladesh to illustrate these consequences.

**Keywords:** Universal Health Coverage, SDGs, integrated goals, policy space, Public health, trade and investment agreements, trade and health linkages

**JEL Classification:** F13, I14, I15

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Typesetter: *Nancy Settecasì*

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## 1 Introduction – trade as a health issue

Universal Health Coverage (UHC) has emerged in recent years as one of the top priorities in global health. It is a central priority for the new Director General of the World Health Organization (WHO), Dr. Tedros, who campaigned on the message ‘all roads lead to universal health coverage’, and who sees UHC as a human right and an ethical imperative in a world where 400 million have no access to health services, and millions more risk falling into financial ruin to cover catastrophic health bills. He goes on to argue that it is ‘ultimately a political choice. It is the responsibility of every country and national government to pursue it. Countries have unique needs, and tailored political negotiations will determine domestic resource mobilisation.’ Few would disagree with these points, but he omits to mention the constraints that lie outside of domestic policies and outside of the health sector. In today’s economic policy environment, the constraints to implementing UHC extend well beyond the need for domestic resource mobilisation. In fact, some of the critical policy choices for achieving UHC concern whether a country would join international trade and investment agreements that restrict national governments policy space in the range of policy measures that could be used. While the effect of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on restricting government ability to expand access to medicines are by now well-known and have persisted since 1994 (Commission on Intellectual Property Rights, 2002) (Commission on Intellectual Property Rights, Innovation and Public Health, 2006) (Global Commission on HIV and the Law, 2012) (for overview see t’Hoen 2016), new

models of plurilateral trade and investment agreements (21<sup>st</sup> century TIAs) that are being pursued include provisions that strengthen IP rights (‘TRIPS plus’ provisions), as well as other provisions in areas such as government procurement that have important consequences for national UHC policy (see for example: (Kapczynski, 2015), (McNeil, et al., 2017)). Governments face a dilemma of weighing such potential costs to public health policy against the potential gains in market access and other benefits in trade. Such dilemmas are particularly difficult in developing and least developed countries that have limited options for pursuing economic growth.

Yet health priorities continue to be neglected in standard analyses and debates about trade and investment policies, and vice versa. Dr. Tedros’s focus on domestic financing and neglect of global and non-health issues reflects current international debates about UHC implementation efforts that neglect the rising cost of medical services and products to consumers. How to pay for it and what to cover are the two core questions that dominate the policy reviews and guidelines on how best to design national UHC systems, generated by the most influential international bodies such as the World Bank, WHO (World Bank, World Health Organization, 2015), and the Rockefeller Foundation for the Universal Health Coverage Coalition (<http://universalhealthcovereday.org/economists-declaration/#text>). There is little in these documents on the cost side of financing - how to ensure affordability for patients, broaden access to medicines, and the implications of policy choices embedded in trade and investment agreements on health policy. This is important for all countries, but particularly for least developed countries (LDCs) that have limited domestic resources, and little to gain from strong patent laws.

Why is this so? In part it is no doubt due to silo-thinking on the part of policy makers in both health and trade sectors (Horton & Lo, 2014). Despite the decades of work on the social determinants of health, health policy making continues to be dominated by the search for bio-medical solutions. Work on the social determinants of health have not always focused on global economic arrangements. It is also due to political resistance, especially on the part of trade negotiators and the interests that they defend who prefer to keep their turf clear of health concerns that compromise their interest driven priorities (Ottersen, et al., 2014). Attempts to introduce trade issues into health fora have long been resisted; for example, at the height of the campaigns for access to HIV/AIDS antiretroviral drugs, industrialized countries opposed discussion of the TRIPS agreement in the World Health Assembly of the WHO (t’Hoen, 2016).

In this context, the recent adoption of the sustainable development goals (SDGs) gives a potential boost to efforts to bring health priorities into trade negotiations. The SDGs not only contain targets to achieve UHC, access to medicines, promote research and development, protect policy space, and an equitable system of world trade, but these trade and health goals are intended to be ‘indivisible and interlinked’ (UN 2015, para 71). While each of the goals and targets is important, they are to be seen holistically, as an integrated agenda for sustainable development, and one of the key challenges is to promote policy coherence. UN debates on SDGs constantly emphasize the inter-relationship amongst targets as one of its defining features along with universality, yet what this actually means in practice is not always evident.<sup>1</sup> Nonetheless, the concept of an integrated framework has far reaching implications for the methodology of evaluating policies and implementation strategies;

<sup>1</sup> For example, it was one of the core themes debated in the plenary of the 2017 High Level Political Forum. And much of the debate involves efforts to give practical meaning to the idea of ‘inter-dependence’ amongst targets as much of the implementation efforts are organized sectorally, goal by goal or target by target.

implementation strategies for one target need to consider impacts on other targets. The Agenda 2030 and the SDGs achieved an important normative advance that helps recognize the inter-sectoral linkages such as trade and health, and an opportunity to advocate for health as a trade issue.

One of the deliberate strategies used by groups aiming to maintain strong IP protection has been ‘forum shifting’—strategically using multiple fora to win its negotiating position (Drahos, 2007) (Braithwaite & Drahos, 2000) (Sell, 2011). Having scored a substantial win with the TRIPS agreement, they faced increasing push back within the WTO from developing country coalitions, particularly to ensure implementation of the flexibilities. To counter these measures and to gain further provisions for stronger IP provisions beyond the TRIPS agreement, they shifted to bilateral and regional free trade agreements (FTAs) in the early 2000’s, starting with the US-Jordan FTA (Drahos, 2002) (Sell, 2011), and into the more recent plurilateral agreements such as the Trans Pacific Partnership (TPP). The SDGs can offer an alternative forum where coalitions promoting access to medicines and other public health priorities can counter TRIPS plus trade provisions.

This paper elaborates on the effects of the 21<sup>st</sup> century TIAs on restricting national policy space in achieving UHC, and more broadly the SDGs as an integrated agenda that incorporates targets for UHC, access to medicines and the promotion of research and development. We first document the common provisions of 21<sup>st</sup> century TIAs that impinge on national policy space for UHC. We illustrate this with the case of Bangladesh—an LDC that has used intellectual property (IP) and drugs policy to achieve significant improvements in access to health care and medicines. The second section elaborates on the concept of SDGs as an agenda for sustainable development and the inadequate targets for trade which ignore the post WTO agreements. In the final section, we reflect on challenges of political negotiations that governments face in pursuing the UHC agenda.

The paper aims to contribute to understanding the political origins of health inequity by reflecting on the gaps in the SDG agenda. It shows the contradictory trends taking place in international negotiations and standard setting: the trade agreements that sharpen corporate interests that compromise UHC goals; the international norm setting that give priority to UHC, access to medicines and national policy space and the need for an integrated agenda, but incorporates a weak trade agenda with respect to health as a trade issue. These inconsistencies reflect the continuing contestation over the management of intellectual property and health priorities by strategic use of fora by the contending states.

The paper is a part of a series of publications by the Independent Panel on Global Governance for Health, mandated to monitor the political origins of global governance for health. It builds on an earlier article by the Panel published in the *Journal of World Trade* (McNeil, et al., 2017) that gave an overview of the potential negative effects of the new models of trade and investment agreements.

## 2 Trade agreements and universal health coverage

While generating enough financial resources and ensuring equitable burden sharing, coverage, and benefits are clearly central issues in the design of an equitable UHC system, keeping costs affordable is also a key challenge. Governments in both industrialized and developing countries use a variety of policy approaches to do so. However, common provisions in the new era TIAs erode the ability of national governments to use policies for these purposes, particularly in areas of IP and government procurement of medicines.

### 2.1 New models of trade and investment agreements (21<sup>st</sup> century TIAs)

Increasing attention has been drawn to trade as a public health issue. The multilateral WTO agreements

in 1994 ushered in a new era that extended trade agreements beyond issues of tariffs and other barriers to trade in goods, into areas such as services, intellectual property, sanitary and phytosanitary standards, and the movement of persons. Agreements in these areas have meant the inclusion of provisions that affect national policy making in a wide variety of areas, including public health. Concerns have been raised with respect to the effect of trade in goods on accelerating dietary transitions, spread of tobacco and other harmful substances, and the effects of the agreement on services (GATS) on the privatisation of health care. The issue that has been arguably the most problematic has been the introduction of a global standard for intellectual property (IP) in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This standard considerably reduced the scope of national policy makers to protect medicines from patent monopolies that lead to high prices. Measures such as excluding pharmaceuticals from patenting, importing generic versions of drugs patented elsewhere, or domestic manufacture of generics by reverse engineering became no longer possible (t’Hoen, 2016).

The TRIPS agreement includes a number of flexibilities to ensure that “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health...” (World Trade Organization, 1994) and spells out mechanisms that could be introduced by national governments to gain access to patented medicines through domestic manufacture (compulsory licensing) or imports (parallel imports) in cases of public need. These flexibilities were affirmed in the 2001 Doha Declaration. However, since then, very little use has been made of these flexibilities in part because they are difficult to implement, and in part due to obstructions (UN High Level Panel on Access to Medicines and Innovation, 2016) (UNAIDS, WHO, UNDP).

As we have argued in an earlier article (McNeil, et al., 2017), this trend has been taken to a whole new

level with an emerging new ‘model’ of trade agreements that have increasingly broadened their scope to increase provisions that regulate investments. Bilateral and regional agreements are proliferating and most—particularly those that involve the US and EU - include a common set of provisions that not only further strengthen IP provisions beyond the TRIPS agreement (‘TRIPS Plus’), but further extend into such areas as dispute settlement, public procurement, state owned enterprises, amongst others that intrude into national policy making for public health. The new model of ‘trade agreements’ are more appropriately ‘trade and investment agreements’ (TIAs). They contain provisions that are far ranging in a variety of areas that would be particularly intrusive and reduce policy space for public health priorities (McNeil, et al., 2017). This is of a wide range of concerns but is particularly important for achieving the target to achieve universal health coverage including access to medicines (3.8) because they impinge on a variety of areas critical to managing the national health system, including the management of prices of medicines and services to ensure affordability, the procurement of medicines, and the management of public services.

The most common elements of concern include: enhanced intellectual property standards; government procurement; and investor dispute settlement mechanisms. These provisions are found consistently in multiple bilateral, regional and plurilateral trade agreements that have been recently concluded or are under negotiations involving a wide range of countries through all regions of the world. Table 1 analyses a selection of important agreements including agreements in Asia (RCEP), Central America (CAFTA-DR), bilateral agreements with Korea (KORUS), India (EFTA), Jordan (US-Jordan FTA), Japan (JEFTA), as well as the agreement on services (TISA). We also include the Trans-Pacific Partnership (TPP) as agreed in 2016<sup>2</sup> and the Transatlantic Trade and Investment Partnership (TTIP) as they were most systematic and ambitious in including the

provisions we are concerned with. As some of the aforementioned TIAs are currently under negotiation, analysis has been made from leaked draft text, impact assessment, and government documents on negotiating priorities.

### *Intellectual Property*

Almost all of the new TIAs contain a section related to intellectual property which includes patents for medicines, with TRIPS Plus conditions - significantly strengthening patent monopolies and retarding the emergence of lower priced generics. These TIA provisions create conditions which supersede and replace domestic law, so that in many cases, national intellectual property policy would have to be revised to be compliant with the TIA. The increased protections which are required under the new era of TIAs may serve to replace the TRIPS standards for countries who are not even a party to the agreements in question. The WTO requires that countries use a most favoured nation policy when contracting with other member states—that they do not treat any contracting party with less favourable treatment than any third country with which it is partner in a TIA. If state A entered into a TRIPS plus agreement with state B, it could theoretically be argued that they would need to award the same increased intellectual property protections to any other state with which it engages (Liberti, 2010).

One of the most important measures is patent term extensions for new uses or methods (“evergreening”). Many new TIAs require granting of secondary patents on existing medicines, for any new formulations, dosages or uses even when there is no change to the epidemiological result of the medication—in other words, innovation. This effectively extends patents beyond the 20 years required by the TRIPS agreement. For example, the US-Jordan Free Trade Agreement in force since 2001 requires new uses extend the patent for 3 years. Studies have shown these provisions to be related to the higher prices of medicines in that country (Abbott, et al., 2012) (Oxfam International, 2007).

<sup>2</sup> While the US has withdrawn from the TPP, the other state parties are re-launching negotiations.

Table 1  
Selected Trade Agreements

Agreement	Status	Intellectual Property Ch	Data exclusivity	Patent term extensions for regulatory delays	Procurement Ch	SPS Ch	Transparency/Corruption Ch	Compulsory licences	Trade in health services (medical devices, insurance)	Dispute method
TTIP	In negotiations	Yes	Likely	Likely	Yes	Likely SPS +	Likely	Likely permitted	Unknown	ISDS, unknown method
TISA	In negotiations	Unknown	Unknown	Unknown	Unknown	Unknown	Likely	Unknown	Likely	ISDS, unknown method
CAFTA-DR	In force 2007	Yes	5 years	5 years	Yes	Yes	Yes	Permitted	No	ICSID or UNICTRAL
KORUS	In force 2012	Yes and evergreening	5 years	3-4 years	Yes +	Yes, but not subject to ISDS	Yes	Permitted	Medical devices	ICSID or UNICTRAL
JEFTA	In negotiations	Likely	Likely 5 years	Likely	Likely	Unknown	Unknown	Likely permitted	Unknown	Likely joint committee
CETA	Almost ratified	Yes	6 years	2 - 5 years	Yes	Yes, but EU would consider this SPS -	Yes	Permitted	No	Joint committee
RCEP	In negotiations	Yes, likely +	Yes	Proposed 5 years	Unknown	Unknown	Unknown	Proposal explicitly permits	Unknown	Unknown
US Jordan FTA	In force 2012	Yes and new uses protected 3 years	No	Yes, no time listed	Defers to WTO	No	No	Does not specifically say compulsory licences but allows flexibilities	Services trade defers to GATS	Joint committee
EFTA India FTA	In negotiations	Likely	In negotiations	In negotiations	Unknown	Likely SPS +	Unknown	Unknown	Unknown	Unknown

Another common feature is data exclusivity. The new TIAs extend monopoly protection not only to products and processes but also to the test data used in granting regulatory approval to the medicine. While the TRIPS agreement permits keeping clinical trial data private for an unspecified period after a patent expires, the new TIAs require that this data is protected from use in reviews of generics for a specified period of years. Regulatory agencies are then unable to review the efficacy of the generics in comparison with the patented versions. This delays the process of generics approval, slowing down the entry of lower priced equivalents into the market. In effect, this extends the patent monopoly for years after the 20-year patent has expired. This is not only important for patients access to medicines, but in cases where government is involved in procurement, impinging on its ability to contain the costs of the national health system and extend UHC.

Many recent TIAs include data exclusivity requirements such as the US-South Korea TIA, KORUS, agreed in 2012, which requires data exclusivity for 3 to 5 years after patent expiry for new chemical entities (USTR, 2012). CAFTA-DR, an agreement between the United States, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the Dominican Republic which has been in force since 2007, requires 5 years of data exclusivity (USTR, 2007). These provisions are also not unique to the United States. The EU-Canada Comprehensive Economic and Trade Agreement, CETA, requires 6 years of data exclusivity (Canadian Government and the European Union, 2017). The Regional Comprehensive Economic Partnership, RCEP, which is being negotiated by China, India, many members of the TPP, and numerous other countries in the Pacific, also includes provisions on data exclusivity and patent term extensions in leaked draft versions of its intellectual property chapter (RCEP, 2016).

Special data exclusivity arrangements are made for new innovations, particularly biologic drugs. The “generic” version of these drugs are known as biosimilars, and the protection period for biosimilars

differs from that of traditional generics in recent TIAs. The TPP required 8 years of data exclusivity after expiry of the monopoly of a biologic, which was one of the most hotly contested negotiating issues. This is unsurprising as biologics are expensive and generate high profits (Erwin A. Blackstone & Joseph P. Fuhr, 2013) while comparison with the original data is particularly crucial in the review of biosimilar candidates for approval. Constraining the ability of regulatory agencies to speed the entry of biosimilars thus makes cost containment strategies even more difficult.

In addition to ever-greening and data exclusivity, there are other common provisions, such as restrictions on the government to revoke patents, and requiring patentability of living organisms such as plants, which has implications for food security, health, and livelihoods (Lindstrom, 2010). Thus, the increased intellectual property protections seen in many of the post TRIPS trade and investment agreements may hinder the ability of local governments to use their intellectual property regime in order to promote and protect public health. As the agreements often do not contain any language on TRIPS flexibilities, restrict the ability to revoke patents, and require that more matter is deemed patentable, whether a process, product, animal or plant, the spread of TRIPS plus regimes across the world strengthens monopolies. The overall effect of these provisions is to render the flexibilities built into the TRIPS agreement, and reaffirmed in the Doha Declaration, redundant.

These provisions also have a broader effect on the generics market for pharmaceuticals. Because they create multiple barriers to entry for generic companies, they not only make it difficult for generic companies to operate domestically but to export (Drahos, 2007). This has wide ranging implications for the survival of generics companies and the competitiveness of the generics market itself.

### **Government procurement**

A common TIA provision with significant and direct consequences in shrinking policy space for UHC is government procurement. In most countries, governments are involved in the procurement of medicines and devices, either through direct procurement, setting or regulating prices, and negotiating with companies. The ability of the government to negotiate and set prices or otherwise manage prices has an essential role in the national health system, ensuring that medicines are affordable for citizens, and that UHC can be extended. Provisions that require governments procure medicines in public health plans through certain mechanisms with specific requirements have been introduced into TIAs, and have become particularly contentious. These provisions jeopardise a government's ability to negotiate prices and threaten the bargaining power upon which national health care systems rely.

For example, KORUS contains an entire chapter (chapter five), on the procurement of medical devices and pharmaceutical products (USTR, 2012). It requires a reimbursement rate for pharmaceutical goods and medical supplies to be based on a competitively derived market price. Moreover, manufacturers may apply for even higher rates that could cover other uses or indicators for the same product.

Procurement issues cover areas beyond the purchasing of pharmaceutical products and medical devices, as even services supplied in the context of a government administered health plan may be on the table. An analysis on the effects of provisions found in leaked texts of the TTIP on the United Kingdom's National Health Service found that if NHS and the health sector are not excluded from procurement commitments, a possibility in light of recent laws liberalizing health service provision, foreign providers could potentially challenge contracts in that country which are against their interests (Koivusalo & Tritter, 2014).

Procurement was a particularly contentious issue in the TPP negotiations. The agreed text includes a lengthy section in the Transparency chapter spelling

out a requirement for party governments to disclose the methods and experts utilised to reach an agreement on whether a drug will be covered and for how much. Initially, leaked versions of the agreement required provisions similar to that in KORUS - that countries reimburse pharmaceutical companies based on competitive market derived prices in each party's territory (Lopert & Gleeson, 2013). This terminology meant that the price of a medicine could not be negotiated and regulated by the government. Rather, a market price would be set which would be reflective of the prices of competitors' drugs. Of course, as this clause was coupled with stringent IP requirements that create a monopoly for the patent holder, the market price would certainly not reflect any competition. This clause would have completely eroded the power of agencies to negotiate reimbursement of drug costs to pharmaceutical companies. This clause was rejected and removed from the final text, but the section that remained still endangered the ability of public health care agencies to effectively negotiate with pharmaceutical companies.

It is important to note that there is no comparable requirement of transparency for pharmaceutical companies. There is no requirement, for example, for a firm to disclose the actual cost of research and development, clinical trials, percentage of R&D spent on advertising, or the actual cost of production of a medicine, which could certainly be important in a fully transparent negotiation on reimbursement. This onerous requirement of full disclosure for government agencies and not for the pharmaceutical companies with whom they are negotiating presents a risk for information asymmetries and power imbalances within negotiations.

Government regulatory reimbursement regimes, or agencies responsible for price negotiations and the procurement of medicines, are found in countries around the world whose governments engage in acquiring medicines or medical devices. New Zealand has an agency called PHARMAC, whose responsibility it is to negotiate medication pricing with pharmaceutical companies and determine which drugs will be publicly funded by the national

health care system. Since 2000, PHARMAC has saved the New Zealand government over US\$ 5 billion through negotiations with pharmaceutical companies and careful decisions about which drugs to fund (Gleeson, 2013). In France, whose health system is highly rated by the WHO, COMEDIMS (Comité des Médicaments et des Dispositifs Médicaux Stériles / Committee on Medicinal Products and Sterile Medical Devices) determines which products will be included in the health insurance plan and at what price. In the United Kingdom, the UK National Centre for Health Clinical Excellence (NICE) makes decisions on which drugs to include on the NHS formulary and at what cost to the government. Japan has arguably one of the most effective price control mechanisms which has resulted in low expenditures as proportion of GDP, while achieving high health outcomes (Hashimoto, et al., 2011). The government sets a nationally uniform fee schedule for services and medicines. The process of fee revisions that takes place every two years involves consultations and negotiations involving ministries of health, finance, as well as lobby groups of service providers and pharmaceutical companies (Campbell & Ikegami, 1998).

Surely, much of the price savings to governments were the result of the selection of generic drugs over name brand, but one cannot discount the savings that came from the negotiating power of the organisations. As an example of one medicine, a 2015 analysis of the price of sofosbuvir and ledipasvir/sofosbuvir treatment in 26 OECD countries found a great deal of variation in price for the brand-name version of the medicines across the spectrum of OECD countries. This study, which assumed a 23 per cent discount on the brand name drug, reported prices for a course of treatment of sofosbuvir ranging from USD PPP \$64,680 in the United States, \$28,092 in Norway, \$41,938 in New Zealand, \$33,284 in the United Kingdom, \$38,163 in France, and \$70,331 in Turkey (Iyengar, et al., 2016).

These countries use varying forms of price control when procuring medicines for public health systems or when drugs enter the market, and the negotiation of how the medicines may be priced is often

confidential. The key difference, however, is that the variation in these prices is not reflective of an intellectual property policy, but of the power of government negotiations in securing and procuring drugs at specific prices. These pricing negotiations are essential to the effective operation of national health care agencies everywhere. While the prices discussed above for branded sofosbuvir are arguably still too high for any national health system, it is the variation in price which is of interest.

### *Investor state dispute settlement*

In order to guarantee that these provisions in the new era of trade and investment agreements are applied and upheld, countries which are party to the agreement agree to settle any disputes not through domestic courts, but through private arbitration referred to as “investor state dispute settlement” (ISDS) within the International Centre for the Settlement of Investment Disputes (ICSID) or other arbitration bodies. The decisions made are binding and have important impacts on domestic laws and policy.

In many TIAs, intellectual property is defined as “investment”, and IP holders are emboldened to take entire countries to court over any threats to that investment. The concept of investment itself is also defined quite broadly, encompassing tangible and intangible property, a company or interests in the assets of a company located in the host state, any claim to money or claim to performance having an economic value which is associated with an investment, and any licenses and permits permitted under a contract (Guzman, 1997). Thus, including ISDS in a TIA opens countries to suits over even lost potential profits, as if investment itself guaranteed profitability.

The rulings of an arbitration panel will not only influence the case at hand, but will have implications for future regulations within the host state. Government regulations in the period after an ISDS panel, when the decision is awarded in favour of the private firm, have been observed to react to the

regulatory standard in the previous period. While the arbitration does not set legal precedent, the incentive for tightening regulations after the dispute will be lower as governments react to an adverse ISDS ruling (Kohler & Stähler, 2016).

Powerful actors use the tool of ISDS to influence decisions, and thus domestic policy, in their own favour to maximise their profits. Developing countries are subject to a disproportionate number of claims in ICSID and UNCTAD, which may owe to the fact that as the relatively capital scarce party in a TIA, they generally receive more investment, but relative to their GDP, developing countries pay more in damages than developed nations (Gallagher & Shrestha, 2011). Many TIAs, including CAFTA, KORUS, and draft text from TTIP, contain a “choice of forum” clause awarding the complaining party the right to determine the forum in which the complaint is heard. This clause disproportionately benefits the wealthier country which is more likely to bring a claim (Lindstrom, 2010).

It is true that developing countries often do win their cases, but this fact misses the broader implication of ISDS. The threat of arbitration is costly, averaging US\$ 8 million for each party (European Commission, 2015), and can lead to negative trading negotiations or relationships with other countries who perceive a case as a signal of broader institutional weakness of investor property right protections. Even the threat of a suit may prevent developing countries from enforcing a regulation or decision necessary to promote health and well-being or protect the population (Gallagher & Shrestha, 2011). Not only are ISDS cases arbitrated in private with no democratic participation or input from individuals within the country, but their decisions may have a real impact on policies affecting citizens.

ISDS cases have been brought to arbitration which affect a range of government policies to protect and promote health. There have been numerous examples of sanitation services companies bringing suits against governments who cancel permits for environmentally unsafe facilities. Eli Lilly, a US based

pharmaceutical corporation, brought a suit against Canada over a dispute about Canada’s patent regime and interpretation of patentability criteria. When investment is defined so broadly, any regulation by the agencies responsible for controlling domestic health care costs and outcomes may be determined to be in violation of an investor’s property rights. This environment results in regulatory chill, as policy makers act with an abundance of caution and avoid implementing or enforcing policies to protect or promote well-being among their population when aware of the threat of a suit from a foreign investor (Tienhaara, 2011).

While settling disputes through ICSID is common, some TIAs develop their own methods for arbitration. A leaked impact assessment performed by the EU during ongoing negotiations for their FTA with Japan (JEFTA) discusses a more modern system than ICSID, and references the controversy which surrounded ISDS in the TPP and TTIP negotiations (European Commission, 2016). CETA uses “mediation” rather than arbitration, and the agreement creates its own tribunal if mediation fails (Canadian Government and the European Union, 2017).

In a highly-publicised case emblematic of how ISDS impinges on the policy space for protecting public health, Philip Morris sued the government of Uruguay for its requirement that tobacco products be sold in plain packaging, with no advertising or branding marks. After advertising of tobacco products was limited and the size of health warnings on individual product packaging was increased, Philip Morris claimed that its intellectual property rights were violated, and demanded damages for lost profits. While Philip Morris ultimately lost the suit, the case of a large corporation threatening legal action against a state attempting to protect and promote public health is not uncommon (Crosbie, Sosa, & Glantz, 2017).

Australia implemented a similar law in 2012 in an attempt to curb tobacco use. Claiming that intellectual property rights had been violated, transnational tobacco companies based in Cuba,

the Dominican Republic, Ukraine, Honduras and Indonesia initiated proceedings against Australia in the WTO, while Phillip Morris Asia initiated proceedings against Australia under the bilateral investment treaty between Australia and Hong Kong (Gruszczynsk, 2014). In this instance, the ongoing claims against Australia caused a chilling effect in other governments wishing to pursue similar plain packaging laws. For example, New Zealand passed a similar law, though the enactment was made dependent upon the outcome of the cases against Australia (Gruszczynsk, 2014).

There is a common phrase which appears in bilateral and multilateral agreements, both within TIAs and in agreements within the WTO. The wording may change slightly, but it appears as a disclaimer, that the parties maintain the right to set policies to protect public health, and that nothing in the agreement should prohibit them from doing so. In practice, this disclaimer has little hope of enforcement. By allowing investors to bring claims to a special arbitration mechanism, in which the arbitrators are likely not public health experts, the decision on whether a policy is necessary is made within a system designed for trade and investment analysis (Ganguly, 1999). The topic of public health requires a public domain, but the ISDS process requires that the topic is litigated in the domain of private investors and private interests.

## 2.2 21<sup>st</sup> century trade and investment agreements and achieving universal health coverage

The new model of TIAs have both direct and indirect implications for government policy space to achieve UHC. They are particularly significant for the impact on government ability to contain prices through regulation or negotiations, and through the use of generics. TRIPS plus provisions put an upward pressure on branded drugs, particularly for drugs with large and growing demand, such as cancer. But more generally, provisions for government procurement and ISDS will erode important policy tools to manage the prices they pay.

Cost containment is one of the critical elements which national governments have and continue to use in ensuring their citizens have access to affordable health care, in countries as diverse as Japan, New Zealand and Bangladesh. Yet it is hardly discussed in the proliferating debates about policy options that focus on how to generate funds to finance health care whatever the costs might be. The argument against price controls in pharmaceutical markets is that by controlling prices, and therefore reducing profits to pharmaceutical corporations, there is less money to be invested into research and development, leading to less development of new chemical entities (see: (Vernon, 2005), (Acemoglu & Linn, 2004). This argument is not immune to criticism, as countries around the world regulate prices while pharmaceutical corporations enjoy record profits and unprecedented levels of innovation. As information is not freely available on actual research and development spending, the defence of deregulation of pricing markets for pharmaceutical goods represents the type of informational asymmetry which stipulations on procurement policies in trade agreements intensify.

Prices are controlled by public health institutions through a variety of mechanisms, including profit controls, by imposing a maximum limit on the profits that can be made by pharmaceutical firms; external reference pricing, in which a maximum reimbursement level is set based on the prices of similar drugs in other countries; therapeutic reference pricing, which may set a reference price for a patented drug based on the price of a similar generic; or through other methods, often combined with policies encouraging the use of generic drugs when available and economic evaluations (Sood, De Vries, Gutierrez, Lakdawalla, & Goldman, 2009). A study of a broad range of direct and indirect price control strategies in European Union countries' public health plans found that using reference based pricing helped to encourage the prescribing and use of less expensive drugs with the same efficacy, helping to control prices to the patient and health system (Ioannides-Demos, Ibrahim, & McNeil, 2002). A review of the effectiveness of these methods in nineteen OECD

countries found consistent reductions in pharmaceutical revenues, with direct price controls reducing revenues by 16.8 per cent (Sood, De Vries, Gutierrez, Lakdawalla, & Goldman, 2009).

In virtually all public health care systems—whatever the model used for procurement—the government is intimately involved in the process of acquiring medicines, setting prices, and negotiating reimbursement rates with industry. When states are the purchasers for a medication for their entire population, they become directly involved in the negotiations for the purchase with the seller, in this case pharmaceutical corporations. Most states have an agency which directly negotiates with the pharmaceutical corporation on the price which they will pay for the medicine.

Corporations are motivated to negotiate as an entire population represents a large market share, and if governments determine that the medicine is too costly even after attempting to negotiate the price, they may turn to generic versions of the medicine, as governments maintain the right to issue compulsory licenses if negotiations fail. Regulators do not only negotiate prices, but undertake their own assessments to determine what the price of a medicine should be. Clinical trial financial data is not made public, and without this information, it is difficult for regulatory agencies to determine the actual funds spent on development of a medicine, and thus the price necessary for the manufacturer to recoup their expenses. The EU's regulatory agency, for example, the European Medicines Agency, hosts advisory sessions between health technology experts, drug developers and regulatory agencies which influence the design of clinical trials to help ensure greater transparency on development cost and efficacy (Hans-Georg Eichler, Hugo Hurts, Karl Broich, & Guido Rasi, 2016).

### 3 Case of Bangladesh

The provisions found in this new era of TIAs will have different impacts on countries as they interact with existing laws, policies and institutions. But tracing the effects in one country offers an illustrative lesson of the causal chain linking TIAs and policy space for UHC.

As a least developed country, Bangladesh has been exempt from many of the required agreements of the WTO, including TRIPS, the Agreement on Government Procurement, and the Agreement on Subsidies and Countervailing Measures. Bangladesh has used the space afforded to it as an LDC to implement several national drug policies which have allowed it to promote public health, control the prices of medical goods and devices, and expand its own pharmaceutical manufacturing sector. The policies which have been pursued by the Bangladesh government have been essential to creating a dynamic pharmaceutical sector, which is now the largest white-collar employment sector in the country, and exports to over 100 countries, including the United States (Sultana, 2016), and Bangladesh is the only LDC with such a robust pharmaceutical industry (Azam & Richardson, 2010). While access to care is stratified among socioeconomic lines, the government has succeeded, as of 2011, in supplying 97 per cent of drugs in the health care market through domestic production (Kathuria & Mezghenni Malouche, 2016).

Bangladesh has achieved these goals and grown its infant pharmaceutical industry through the strategic implementation of several government policies, all of which would be at risk if Bangladesh signed onto any of the “new era” TIAs. While simply becoming TRIPS compliant would require fundamental changes to Bangladesh's drug policies, intellectual property regime, and the way in which it promotes its infant pharmaceutical industry, becoming competitive in the global market and signing onto TIAs would require even more.

### 3.1 Current Bangladesh drug policy under World Trade Organization regime and least developed country waiver

At present, Bangladesh uses three main drug policies in order to regulate the use and development of pharmaceuticals in the country, as well as an intellectual property regime which governs patent terms and patentability criteria. As it is exempt from TRIPS regulations on patents, in 2008 the Department of Patents, Designs and Trademarks suspended the patenting of pharmaceuticals in Bangladesh until 2016, as at that time it was thought that Bangladesh would have to become TRIPS-compliant (Azam & Richardson, 2010) (the waiver for LDCs has since been extended to 2033). It offers patent terms for 16 years, does not contain any patent protection for plant and animal varieties, and allows foreign patents to be cancelled after four years if the product is not also manufactured in Bangladesh. The law allows for the issuance of compulsory licenses, and the license is not limited to government use. Patents must be approved within 18 months in Bangladesh, otherwise they are refused (The Patents and Design Act, 1911, Act no. II of 1911).

The 1940 Drugs Act first prohibited the import of a drug unless its complete formula is displayed on the packaging (The Drugs Act of 1940, Act no. XXIII of 1940). The law also requires that Bangladesh maintains the right to regulate the mode of labelling drugs imported for sale (The Drugs Act of 1940, Act no. XXIII of 1940). This may lead to disputes with manufacturers over marketing rights. The Drugs Control Ordinance of 1982 further outlined the government's drug policy, and was important for the development of Bangladesh's pharmaceutical industry. Notably, the government is permitted to fix the prices of drugs at certain levels, which controls costs for the public health sector. Bangladesh also restricts the imports of any medicines if the drug or a substitute is produced in Bangladesh (Government of Bangladesh, 1982). The National Drug Policy of 2005 reiterated many of the policies of the 1982 law, and served to further bolster the domestic pharmaceutical sector. This

policy also stated that the government would provide basic services and facilities to local drug manufacturing industries (Government of Bangladesh. Ministry of Health and Family Welfare).

### 3.2 Potential consequences of transition to TRIPS regime

As a least developed country, Bangladesh enjoys exceptions from WTO regulations on procurement, subsidies and intellectual property. In the event that the country transitioned out of least developed status and had to implement WTO regulations, the impact on patients and the domestic pharmaceutical industry would be tremendous.

First, Bangladesh would have to update its patent law in order to harmonise with other WTO member states, adopting the TRIPS agreement. Bangladesh would have to increase patent terms to twenty years, extend patents to pharmaceutical products and processes, and allow patent protections on animal and plant varieties. Patents could no longer be cancelled simply because they are registered by foreign entities, and compulsory licenses could only be issued by governments. Article 44 of the TRIPS agreement requires that countries have mechanisms for a party to file for an injunction in the event of infringement of a patent, and that authorities would be able to seize imported goods which infringed on a patent (World Trade Organization, 1994). Bangladesh would have to add in the injunction and enforcement mechanisms, beyond their existing language on patent infringement. It would likely be difficult for Bangladesh to continue to require that complete formulaic information on any imported drug is displayed on its packaging, as the information could be considered a trade secret (World Trade Organization, 1994).

The import substitution led strategy which Bangladesh has employed to bolster its infant industry would likely be in jeopardy as well. If products, even those no longer under patent, were not allowed to be imported, it is likely that Bangladesh would face complaints of uncompetitive practices. The

2017 Trade Policy Agenda and 2016 Annual Report from the United States Trade Representative specifically mentioned concern for the pharmaceutical import licensing practices of Bangladesh (Office of the United States Trade Representative, 2017), and minutes from three meetings of the Committee on Import Licensing of the World Trade Organization documented concerns from the United States and European Union about Bangladesh's import licensing practices (Committee on Import Licensing, 2016) (Committee on Import Licensing, 2016) (Committee on Import Licensing, 2017). In these documents, officials from the United States and EU raise concerns that a registration with the Drug Regulatory Authority was necessary prior to the import of a drug, and that the registration was not given if a similar product existed already in the Bangladesh market. TRIPS is not the only WTO agreement which Bangladesh may adhere to when they graduate from LDC status. The Agreement on Government Procurement (GPA) provides exemptions to LDC countries, but in full effect could have significant impact on the procurement of medicines for the domestic population in the context of a national health policy. In the unlikely event that Bangladesh signed up to the GPA, it would not be able to give preferential treatment to the medicines created by domestic manufacturers, as the GPA requires that all member states agree to treat foreign suppliers no less favourably than domestic sources (World Trade Organization, 2014). In addition to the agreement on procurement, the services and facilities given to local drug manufacturers under the National Drug Policy of 2005 could be considered a violation of the Agreement on Subsidies and Countervailing Measures, which defines subsidies as any financial transfer, tax credits, government purchases of goods, or any income or price support (World Trade Organization, 1994). A transition to full compliance with the WTO would require that these infant pharmaceutical corporations fully compete with other established firms in the global market with little financial support from the government.

### 3.3 Potential consequences of joining a trade and investment agreement

Using its LDC status strategically, Bangladesh has avoided joining on to TIAs. Recent statements from officials in Bangladesh have indicated that they are unlikely to join any free trade agreement until they graduate to the status of a lower middle income country, before or around 2025 (The Financial Express Bangladesh, 2016). Once this transition occurs, however, it is likely that Bangladesh would join a free trade agreement in order to keep its domestic pharmaceutical industry competitive in the global market. Bangladesh's drug policies reflect the importance of the growth of its pharmaceutical industry, and generic drugs created in the country are exported to 80 countries worldwide (Hoq, Ahsan, & Tabassum, 2013).

The agreements referenced above reflect only the minimum changes which Bangladesh would need to make to become fully WTO compliant, and the new era of TIAs consistently demand ever higher requirements and restrictions on domestic policy space. Bangladesh's achievements are based upon public policies, and a restriction of the policy space would not only be of concern to its pharmaceutical industry, but to patients as well. Under the terms of Bangladesh's constitution, the government is obligated to provide medical care to its citizens, and improving public health is a stated responsibility of the State, though in practice individuals often must turn to the private sector in order to obtain care (Ahmed, et al., 2015). The portion of total health expenditure which was publicly financed has been slightly declining in recent years, hovering between 28 and 34 per cent. At the same time, out-of-pocket expenditure has been climbing, reaching 67 per cent in 2014 (World Bank, 2017).

Although domestically produced medicines are available, the market through which patients receive them suffers from poor management and regulation (Ahmed, et al., 2015). As individuals are responsible for fulfilling their own health needs, they would

bear the effects of an unregulated market. Signing onto a TIA like the ones discussed throughout this paper would align the policies of Bangladesh with the interests of powerful countries, but would prohibit state actors from implementing the policies necessary to expand domestic coverage for patients through a public system.

The exact requirements which Bangladesh would be facing when joining a TIA are unknown, and the recent agreements may be used as a predictive model of what may be proposed. While Bangladesh currently uses price controls for medicines, at a worst-case scenario, they could join an agreement requiring pricing review boards for any procurement, like KORUS. Data exclusivity, at a minimum of 5 years, would be highly likely, and is appearing in negotiations of TIAs with India, another major pharmaceutical exporter. Patent term extensions for regulatory delays are also highly probable. Beyond the pharmaceutical industry, patents on varieties of plants are likely, impacting Bangladesh's agricultural sector. Whether through ICSID or another avenue, Bangladesh would certainly face a dispute resolution method in private arbitration, opening the country to suits from powerful and wealthy private corporations. These conditions would not only impact manufacturers, patients, and consumers within Bangladesh, but also individuals in other countries who could benefit from imports of medicines from Bangladesh through compulsory licensing.

Bangladesh has made great progress in the development of a domestic industry which can both drive economic growth and increase health outcomes. For this growth to be sustainable, however, the policies which serve as the foundations of these institutions must be sustainable. As others have observed, social and political sustainability are fundamental to a health system (Borgonovi & Compagni, 2013). Limiting the political ability to set policies that can adapt and change to social needs stunts the sustainable development of the health care system.

## 4 Universal health coverage, access to medicines and trade as inter-related issues in the sustainable development goals

### 4.1 The integrated agenda

As stated in the Preamble of Agenda 2030, one of the challenges in implementing the SDGs is to ensure coherence among strategies pursuing different goals and targets: “The interlinkages and integrated nature of the Sustainable Development Goals are of crucial importance in ensuring that the purpose of the new Agenda is realized” (United Nations, 2015). The idea of SDGs as an integrated agenda in which the goals and targets are ‘interdependent’ and ‘indivisible’ arises from the concept of sustainable development itself. From its origins, this concept was addressing the apparent tensions between multiple objectives of ‘development’: production and consumption to meet human needs as against natural resource depletion and pollution. The inter-relationship between these and other processes are central to ensuring that improvements in human well-being do not lead to environmental destruction, poverty and inequality. Sustainable development is thus a multi-dimensional process, better understood as a system comprised of multiple elements which interact with one another rather than a linear process.

This approach is in fact a radical epistemic departure from the conventional thinking of development centred around economic growth. It departs from the assumption that development is a linear process. And even if multiple dimensions of development can be recognised, conventional assumption is that they can be neatly separated out as if they were all exogenous elements in a broader process.

From its origins in the 1970s, the concept of sustainable development was premised on these interlinkages: that environmental challenges could not be understood nor resolved out of the context of

social and economic development<sup>3</sup>. The concept was a response by developing countries to the agenda - mostly advocated by European countries - that pursued environmental sustainability out of context of developmental challenges. At the core was the argument that environment was a development issue, poverty was an environment issue, and so on; the problems of environmental destruction cannot be solved without addressing poverty and inequality. The 17 SDGs incorporate a wide range of priorities, but each has been discussed for decades; what is new is the fact that they are all combined in a single agenda and understood to be inter-related.

The structure of the SDGs reflects this systems approach to development and contrasts with the MDGs which are conceptualised in a more conventional development economics logic. Where the goals and targets were outcomes in the MDGs, the SDGs contain both outcomes and 'means of implementation' in their targets. Whereas in the MDGs, it was argued that it while the global community could agree on common outcomes, these outcomes could be achieved by different means, the SDGs explicitly recognise targets and goals are not only ends with intrinsic value, but have instrumental effects on the achievement of other goals and targets. This raises the question of coherence and consistency; trade targets for example are important for achieving health goals and these different targets may not always be consistent.

3 For a brief overview of the history of sustainable development as a concept, see:

J.C. Dernbach, (1998). Sustainable development as a framework for national governance. *Case Western Reserve Law Review*, Volume 49, Issue 1, Fall 1998.

D. Mebratua (1998). Sustainability and sustainable development: historical and conceptual review, *Environmental Impact Assessment Review*, Volume 18, Issue 6, November 1998.

S. Parkin, F. Sommer and S. Uren (2003), Sustainable development: understanding the concept and practical challenge. *Proceedings of the Institution of Civil Engineers, Engineering Sustainability* 156, Issue ES1, March 2003.

## 4.2 Trade as a health agenda in the sustainable development goals

The SDGs contain important elements of trade as a health issue, particularly the tensions among the strong IP requirements of the TRIPS agreement that lead to high prices that restrict access to medicines, and to underfunding of innovation for health priorities that result from market based IP incentives. Target 3.8 to achieve UHC also specifically includes access to medicines, the contentious issue related to IP and the TRIPS agreement; "to achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all" (United Nations, 2015). There is a target to promote research and innovation (3.b) that specifically mentions the objectives of access to medicines and the use of TRIPS flexibilities; 'support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and in particular, provide access to medicines for all'. (United Nations, 2015). Beyond these targets, the SDG framework is very weak. The indicators are either non-existent or do not capture the problems of access to medicines and innovation gaps. Indicators for access to medicines are: immunization rates (3.b.a) and the availability and affordability of essential medicines (3.b.c) (United Nations, 2017). Thus, access to medicines (including vaccines) focuses on the medicines that are non-controversial from the IP perspective—the medicines for which generics are widely available—at least assuming that 'essential medicines' refers to the WHO essential medicines list. It does not include the problem of access to high priced branded drugs around the world. For innovation, the indicator is

official development aid for medical research and basic health sectors which does not capture the issue of research and development of new drugs, which is funded through national public programs (not development aid) or the private sector and rarely by development aid. The issue is not the ability of developing countries to become cutting edge manufacturers of innovative drugs but to access latest global technology.

Moreover, the new issues raised by the new TIAs are not mentioned. As widely acknowledged, and also diagnosed (Sengupta, 2016), the trade agenda in the SDGs is limited to the WTO issues addressed in the Doha Round priorities, and does not address issues raised by trade agreements outside of the WTO.

One positive element in the SDG agenda is the target to respect national policy space. However, here again, the target is then weakened by its indicator which is limited to aid-donor relationships; the use of ‘country owned results frameworks and planning tools’ by donors (17.15.1) (UN, 2017).

In essence, the trade agenda in the SDGs is to pursue and conclude the Doha Round of WTO negotiations, despite the reality that the Doha Round is unlikely to progress, and that rules of global trade are being written outside the WTO through bilateral and regional TIAs. The three Goal 17 targets are the same as those included in the Millennium Development Goals (MDGs) with some minor revisions and rearrangements of targets and indicators.

## **5 Concluding reflections: Political origins of universal health coverage and access to medicines as a trade agenda in the sustainable development goals**

The SDG framework has strong targets for UHC, access to medicines, innovation and links to IP issues in trade agreements. It is intended to be a transformative and integrated agenda that acknowledges that

global efforts for sustainable development must be underpinned by economic models and policy frameworks consistent with these aims. The inconsistency of trade and investment agreements with UHC and access to health is one of the important contradictions that needs to be addressed. Yet the agenda is very weak in doing so in the structure of trade targets and indicators for UHC, access to medicines, innovation, and in its outdated strategy of focusing on the Doha Round negotiations.

Why is this text so incomplete? They reflect the politics in contestation over ideas driven by interests to shape the international development agenda. But ironically, the weaknesses do not arise from a process or agenda dominated by corporate interests and the rich industrialized countries. The SDGs are a major departure from the MDGs in the politics of formulation that was unprecedented. The process of inter-governmental negotiations avoided the North-South and regional divides that drive most UN General Assembly Negotiations. The process was open, led by states rather than by technocrats, and more open to consultations with civil society actors who mobilised massively. This more open and democratic process is no doubt one reason behind the shift in agenda from the MDGs to the SDGs. The SDG agenda was an explicit rejection of the MDGs - as a North-South aid agenda to end poverty in developing countries—in favour of a broader conception of development. The agenda is a major advance for developing countries, and stakeholders that pursued views on development strategies that went beyond the MDGs and agendas that were advocated; governance and human rights, security by Western donors; inequality within and between countries by developing countries; environmental sustainability by environmentalists; industrialization and growth through industrial policy by African countries and other developing countries; and global economic governance by developing countries. It is a more ambitious agenda that seeks a ‘transformative change’ and aims to address some of the root causes of inequality, environmental destruction and social exclusion, and the commitment to ‘leave no one

behind' which has become something of a signature rallying call for the SDGs. The core themes of the agenda as a whole reflect important gains for developing countries: universality, integration, means of implementation and the principle of common but differentiated responsibilities.

Why did this process leave such a weak trade agenda? The trade targets are elements of norms related to global economic governance, including issues of governments' commitments that go beyond national borders, to putting in place global economic governance that facilitates sustainable development. They are a part of the stand-alone goal (17) for "strengthening the means of implementation and revitalising the global partnership for sustainable development". These issues were some of the most contested issues in the negotiations over the SDGs. The process of SDG negotiations was unprecedented for the duration, intensity and scope of engagement of states, civil society and other stakeholders, and the controversies over global governance reflected a historical division between developing and developed countries over inequities in global trade rules, concessional financing, access to technology, asymmetries in voice in international rule making, and more recently governance of international investment and finance, and taxation. These elements were either lacking or weakly reflected in the MDGs, under the 'partnership' goal (goal 8) and even those were not achieved. From the beginning of discussions about agenda 2030 and the SDGs<sup>4</sup>, it was acknowledged by all parties that the new goals needed to include stronger commitments to global economic issues. In addition to the 'partnership' agenda, developing countries also pressed for 'means of implementation' in both the free-standing goal and under each of the other 16 goals. The concept of 'means of implementation' overlaps with the concept of 'partnerships' but derives from the UNCED process and focuses more explicitly on policy reforms, and access to

technology necessary for mitigation and adaptation to environmental destruction.

The 2030 agenda (United Nations, 2015) also includes a special section on the subject and states that the MOIs "are key to realizing our Agenda and are of equal importance with the other Goals and targets. We shall accord them equal priority in our implementation efforts and in the global indicator framework for monitoring our progress." Indeed, the High Level Political Forum (HLPF) that reviews progress for SDGs focuses on several selected goals each year, but Goal 17 is included each year. In the latter period of negotiations, developing countries also pressed for the principle of Common but Differentiated Responsibilities (CBDR). This was ultimately included in the agenda document as an important principle.

These strong commitments of principle in the Agenda 2030 and Goal 17, however, begin to unravel in the specific targets for trade, and in the definition of indicators. On the one hand, the WTO-centric agenda can be explained by the strengths in the asymmetry of power and interests. The trade agenda was being negotiated within the Financing for Development, and the realistic likelihood of a more pro-developing country agenda was thin. One negotiator also remarked that they were fearful that even the MDG language would be dropped. The unravelling in the targets and indicators are perhaps more likely to be explained by greater ease of agreeing to principles but stronger opposition to mechanisms of implementation, as well as greater ability of better resourced groups to influence technocratically demanding negotiations. The selection of indicators in the statistical fora were less open, and civil society groups had less opportunity to give inputs.

Ultimately these contradictory elements of the Agenda 2030 reflect the successful use of 'forum shifting' by the coalition defending strong IP. Forum shifting has been a core strategy since at least the 1994 TRIPS agreement if not longer, and must be studied longitudinally as the protagonists shift fora to reclaim lost ground (Drahos, 2007).

<sup>4</sup> At the time this was referred to as the Post-2015 agenda, an agenda to follow the expiry of the MDGs in 2015. The discussions started in July 2012.

Draho points out 'Intellectual property is an area where structural power meets and usually trumps the negotiating conditions and tactics of the weak.... Negotiations over them will not end any time soon.' (Draho, 2007, p. 39) Draho recommends therefore that the best strategy for developing countries would be to counter the forum shifting by IP interests and suggests that traditional coalitions amongst governments would be unlikely to work because of pressures for defection. Therefore, the most promising avenue would be to 'escalate their networking across time and place in order to protect precious negotiating gains made in one time and place' (Draho, 2007,

p. 39). The current political commitment to UHC and the SDG targets 3.8 and 3.b offer an important opportunity to counter the forum shifting strategy into TIAs.

The Lancet-University of Oslo Commission on Global Health called for greater attention to the political origins of health inequalities that lie in the ineffective functioning of global institutions. Notwithstanding these gaps, the SDGs are an important normative advance and provide a significant potential to leverage advocacy for health as a trade agenda.

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