nccr trade regulation
swiss national centre of competence in research

FNSNF
FONDS NATIONAL SUISSE
SCHWEIZERISCHER NATIONALFONDS
FONDO NAZIONALE SVIZZERO
SWISS NATIONAL SCIENCE FOUNDATION

Die Nationalen Forschungsschwerpunkte (NFS) sind ein Förderinstrument des Schweizerischen Nationalfonds.
Les Pôles de recherche nationaux (PRN) sont un instrument d'encouragement du Fonds national suisse.
The National Centres of Competence in Research (NCCR) are a research instrument of the Swiss National Science Fondation.

First Draft for Comment

TRIPS and Special & Differential Treatment – Revisiting the Case for Derogations in Applying Patent Protection for Pharmaceuticals in Developing Countries

Javier Lopez Gonzalez*

Maximiliano Mendez Parra*

Peter Holmes**

And

Anirudh Shingal***

May, 2011

Abstract

In this paper we apply an implicit threshold approach, malleable to the principle of graduation, to identify countries that should benefit from derogations from WTO TRIPS commitments for pharmaceutical patents under the tenets of Special and Differential Treatment. This is based on the identification of four broad constraints loosely classified as; economic constraints; access to pharmaceuticals; capacity constraints; and incidence of health outcomes. We identify these by means of analytical criteria and create a composite index that ranks countries according to the observed constraints which delimit the capabilities and desirability of implementing TRIPs disciplines. We discuss the use of negotiated weights and thresholds in determining participation and graduation into general provisions of the agreement. It follows that countries below the chosen threshold should be exempt from these hence receiving Special and Differential Treatment.

* University of Sussex and Iteas Consulting Ltd
** University of Sussex
*** World Trade Institute, Bern

1. Introduction

The introduction, during the Uruguay Round, of Trade Related Aspects of Intellectual Property Rights (TRIPs) to the remit of the WTO led to a broader debate on the desirability of having patent protection controls in developing countries. In this paper we focus on the possible costs and benefits of derogations from international patent protection provisions so as to identify countries that should benefit from a modulation of WTO commitments under the tenets of Special and Differential Treatment (SDT). We place particular emphasis on the desirability of such practices in the presence of both health and economic outcomes. In the process we aim to 'draw the line' (Deardorf, 1990) between countries that should and should not implement patent protection for pharmaceutical products in a way that maximises welfare but imposes the lowest negative externalities on the innovation process. To this end we employ an implicit threshold approach to arrive at a composite indicator that aggregates the main constraints that countries face in implementing WTO TRIPS provisions for patents in the pharmaceutical sector.

The problem is simple, the transposition of legislation and establishment of enforcement mechanisms for patent protection are costly and particularly so when the benefits of these largely accrue to firms in developed countries (Maskus 2000 and Lall & Albadejo, 2002). Furthermore the enforcement of these provisions affects both the price and accessibility of needed medicines. This results in an important asymmetry between the bearers of the costs and benefits of patent protection where the wedge between these tilts unfavourably for developing countries. A coherent international system should take these constraints into consideration in its application of differential treatment where modulation of commitments should be sought for a selection of developing countries. But in the process it must also provide a mechanism ensuring that pharmaceutical firms can reap the benefits of their innovative undertakings. One then needs to find an arbiter for the said modulation which takes into account the dynamics of country constraints in facing the aforementioned costs and benefits. This is not a new idea and one that has received strong support from the likes of Cottier (2006), Hoekman et al (2003), Keck and Low (2004), Micholoupoulos (2000) and Stevens (2002). This strand of literature proposes making participation into particular WTO agreements contingent on a set of observable and common analytical criteria. It is on the shoulders of this literature that we put forward a case study on the possible selection criteria that can be applied to the implementation of TRIPS provisions on patent protection for pharmaceuticals in developing countries. The aim of this paper is hence not to justify the case for SDT per se, but rather to identify and utilise a set of common constraints that countries share in an implicit threshold approach, malleable to the principle of graduation, to identify countries that should benefit from derogations from WTO provisions.

The main challenge is then to identify and apply analytical criteria that capture these constraints so that derogations from TRIPS provisions can be targeted to countries that justifiably need these the most and not to those that have arbitrarily self-selected into the 'development' group. We draw on the World Bank (2001) conclusions departing from the assumption that, for the case of pharmaceutical patent protection, the efficiency of applying these provisions "depends on economic and social circumstances". To the extent that the economic benefits from patent protection largely accrue to

countries with a high share of R&D expenditure in GDP (World Bank, 2001), developing countries could have little to gain from implementing such provisions into national legislation. But derogations from patent protection need be weighed against the long term goals of ensuring appropriate access to particular drugs that are much needed in response to health conditions that plague developing countries in greater abundance. The heterogeneity of social and health circumstances across developing countries presents an important case for the modulation of commitments under WTO legislation relating to TRIPs that go beyond the current delayed implementation provisions. Lall & Albaladejo (2002, p.9) go as far as arguing that, after considering the present value of the weighted long term benefits against the short term costs, a differentiated approach to TRIPs is "undisputable". This makes echo to a strong call for differential treatment for developing countries made by Oxfam (2001).

The primer under which this differentiation is to be carried out depends on the constraints that developing countries face in implementing such policies and in particular the associated costs that implementation generates. In light of these, any analytical criteria identified for the purposes of differentiation should not only be closely related to an identified 'constraint', but also be acquiescent to the principle of *graduation* (Cottier 2006). This principle seeks to provide an added flexibility to the international system by making implementation of WTO provisions contingent on overcoming a set of identified graduating constraints. Countries that fall below a chosen threshold would be entitled to derogations with respect to countries that fall above these. This method would be applied on a continuous basis so that the modulation of commitments would only kick-in when a set of observable constraints have been overcome. The first step towards the operationalisation of this proposition hence requires looking into the main implementation constraints faced by countries in transposing WTO TRIPs commitments. On a broad scale, and for the particular case of patent protection under the TRIPs agreement, we show that these constraints relate to the broader category of domestic regulatory reform. This in turn suggests that the costs of implementation will depend on issues such as institutional constraints related to both capacity and budgetary allocation; opportunity costs; as well as issues of national health systems and health security. Any form of progressive regulation need take into account the priorities of developing countries in this respect but must also consider the impact that non-participation will have on third countries.

We believe that there is certainly a case for protecting intellectual property rights and hold the recognition of this in the WTO as evidence of an implicit support to the notion of modulation of general principles in the presence of new issues that may require differential treatment such as TRIPs[1]. But we equally hold true that the benefits of patent protection are skewed towards developed country interests. These serve to promote, via a form of industrial policy, the development of a strong pharmaceutical industry in high income countries (Maskus 2000). Enforcing these provisions comes at the cost of beneficial technological transfers to the developing world and increases the dependence on pharmaceutical imports from developed countries. This sets in motion a vicious circle which may lead to capacity shortcomings in a way that is reminiscent of the food security argument. Maskus

[1] This alludes to the rather uncomfortable position of promoting protectionism where the WTO/GATT has generally been at the forefront of world liberalisation of trade.

(2000) alludes to this by arguing that the presence of onerous patenting provisions may impede the development of needed industrial capabilities in developing countries. These can be attained through the process of 'imitating' pharmaceutical production and can provide important benefits as the case of India exemplifies (see Lall & Albaladejo (2002) and Watal 2000). A mitigating factor to the loss of revenue that improper patent protection may incur on pharmaceutical firms is that this may be short lived because anecdotal evidence suggests that a lax patent enforcement mechanism sets in motion the needed incentives for the creation of coherent patent enforcement mechanisms. This is because as countries develop domestic capacity then firms will demand the presence of a fully functioning patenting mechanism so as to protect their innovative activities (Maskus 2000).

We also recognise that patent protection bears certain similarities to an old time argument for import substitution and hence liken the emergence of this to the push towards special and differential treatment[2]. One key but often forgotten point is the notion of national sovereignty over health outcomes[3]. This extends the principle of food security to health outcomes. The development of an appropriate system of industrial production in pharmaceuticals can have wide ranging implications for the supply of key pharmaceuticals needed to abate health concerns[4]. In this respect one can make a case for policies that encourage national production of generic pharmaceuticals. However, this need be weighed against the feasibility of attaining such goals using industrial policy. If countries require productive endowments and technological advances that are beyond their capabilities or reach, then importing such products remains the most viable option. The issue then becomes one of facilitating access for such products in markets where budgetary constraints exacerbate consumption given monopoly pricing.

One of the underlying assumptions of this paper is that there is an important argument for facilitating access of pharmaceutical products into countries that are most vulnerable. These countries tend to face a set of constraints that make purchase of such products costly not only in relative but also in real terms. In addition, these countries tend to be characterised by weaker health systems which entail a greater spread of illness and a lower capacity of reaction to national emergencies. On the basis of an identification of these constraints and taking into account the heterogeneity of incidence of these across the WTO defined 'development' group, we aim to provide a finer and more targeted differentiation schedule for the identification of countries which could benefit from SDT provisions. This in view of providing a more systematic approach to SDT in the context of the TRIPS agreement.

The remainder of this paper is organised as follows. In the next section we provide a discussion on the different inbuilt flexibilities of the TRIPs agreement and how these may not necessarily provide sufficient policy space for the particular concerns of developing countries. We then focus on the economic rationale of patent protection where we argue, on the basis of Deardorff (1992), that there might be a case for a geographical differentiation in patent protection provisions. This is then followed

[2] Albeit operating in the favour of developing countries

[3] The political climate in the Developing world during the 50's and 60's was of the opinion that self sufficiency in key sectors (known as base industries) was of uttermost importance, the pharmaceutical sector was viewed in this guise.

[4] The case of India and Brazil tend to be used in the literature as countries that have succeeded in creating the appropriate incentives to develop a strong pharmaceutical industry.

by an extensive review of the possible constraints that make developing countries particularly vulnerable to patent protection enforcement. The identification of these constraints then motivates a selection of indicators that capture these constraints. We then look at how these indicators can be combined to provide a list of countries that should be exempt from TRIPs provisions for patent protection in the pharmaceutical sector. Here we draw not only on indicators of economic performance, but also on measures of health risks and institutional constraints in an effort to capture the multifaceted nature of the constraints. The generalised example of the Pharmaceutical sector is chosen on the basis of Cottier (2006). He suggests that analytical criteria can serve to inform the desirability of implementation of the TRIPs agreement in patent protection for pharmaceuticals where differentiation and modulation of commitments take a progressive stance and apply differently contingent on countries levels of development or economic characteristics in the sector in question. Building on this example, we provide an economic rationale for the choice of these criteria and a procedural test for the graduating thresholds that could apply for this sector. The final section concludes with a discussion on how this methodology can be generalised to other WTO issues.

2. TRIPS agreement modalities

There is no specific agreement that establishes particular disciplines for pharmaceutical products in terms of intellectual property rights (IPR), however the TRIPS Agreement provides a framework with important procedural disciplines. In this section we discuss how these relate to developing countries so as to ascertain if there exist sufficient flexibilities in dealing with the particular needs of these countries. In the process, and on the basis of these flexibilities, we aim to see if there are implicit recognitions of possible constraints that countries may face in the implementation of the TRIPS agreement. The entrenched flexibilities in the agreement should reflect these constraints as voiced by countries concerns in the implementation of the agreement. We focus solely on the implications for the particular case of patent protection for pharmaceuticals and their impact on developing countries.

The TRIPS Agreement puts forward minimum standards of intellectual property rights common to all members[5]. Whilst additional commitments or disciplines may be introduced by members, protection of intellectual property rights remains under the tenets of both the National Treatment (Article II) and the most favoured Nation (Article IV) principles. However, and in contrast with other WTO agreements where countries can make different commitments (i.e. market access); the TRIPS agreement establishes disciplines that all members must comply with devoid of distinctions according to levels of development. For example, in terms of patents, all members are obliged to give the same level of protection to all patented products. The only form of differential treatment afforded to developing countries is an extended period for the implementation and modification of national legislation to accommodate the totality of the TRIPs agreement[6]. This is however a standard 'transitional' provision common across most WTO agreements which may be ill suited to the particular needs and constraints faced in certain developing countries. It implicitly recognises the

[5] Article II, par. 1, TRIPS

[6] References to Developing Countries and Least-Developed countries appear twice and six times respectively in the whole agreement, all of them in Part VI, Transitional Arrangements.

existence of diverging technical capabilities across countries in implementing agreements but presupposes that countries will be able to tackle these constraints in a fixed amount of time. The heterogeneity in capacity across the developing country grouping suggests that a common time lapse for implementation may be ill-suited and calls for SDT to be contingent on certain observable analytical criteria which delimit that these capacity constraints have been overcome[7]. This principle of graduation should be coherent with a set of analytical criteria that serve to identify the main constraints that countries face.

Section 5 of the TRIPS agreement outlines the disciplines on patents that are most relevant to pharmaceutical products and which have been subject to most contention. In general terms, TRIPs establishes that patents must be available to both products and processes without discriminating across the location of the invention or the field of technology, for a period not inferior to 20 years (Article 33). Article 28 then establishes the scope of protection where the patent must prevent other parties (without the patent owner consent) from making, using, selling or importing a patented product or process; as well as making, using, selling or importing a product obtained directly from a patented process.

In recognition of possible constraints in meeting the TRIPs agreement commitments, certain flexibilities were introduced to mitigate negative impacts on health outcomes. These were in the form of 'compulsory licenses' and 'exhaustion of rights' which aim at ensuring that the appropriate balance between the benefits of innovation and the costs of monopoly pricing is achieved. These flexibilities are however available to all signatories and hence do not constitute a form of SDT although they can be useful to developing countries in certain ways. Their main function is to control monopolist pricing strategies where compulsory licenses grant derogations from patent enforcement whilst exhaustion of rights seeks to reduce price discrimination. The implications of these for developing countries are discussed at greater lengths bellow where particular attention is given to the identification of constraints that these flexibilities aim to provide shelter from.

2.1 Compulsory Licenses

Compulsory Licenses serve the purpose of providing flexibility in the enforcement of patents under special mitigating circumstances. These are open to all WTO members and additive to the exceptions outlined in article 27, where members may exclude, from patent protection, inventions with the objective of protecting the "*ordre public* or morality"[8]. Article 31 allows some leeway in using patented inventions without the authorisation of the *right holder*. The article, rather than define an exception, imposes limitations on what is called a "compulsory license" where a license to manufacture the patented product is granted to a government or a third party, without authorisation or over the objection of the right holder. Article 31 (b) then establishes that a compulsory license is permissible if unsuccessful attempts to obtain authorization from the right holder on reasonable commercial terms

[7] Oxfam (2001) makes this point in its key demands to the WTO where they call for "longer transition periods for developing countries before they have to implement TRIPS, based on their attainment of development milestones rather than arbitrary dates"

[8] as well as the protection of human, animal and plant life in addition to the environment;

and conditions have anticipated its use. However, this limitation may be waived in the case of a "national emergency". Art. 31 (f) also establishes that a compulsory license shall be granted "predominantly for the supply of the domestic market" and also, that the right holder must be paid remuneration for such use taking into account the economic value of the authorization (Art. 31 (h)). These provisions raise a number of interpretational issues such as the length and depth of the attempted negotiations for licensing undertaken before making effective use of the patented product or the exact definition of a "national emergency"[9]. They equally implicitly recognise that there are special circumstances that demand special consideration and hence point to a set of possible existing constraints or negative impacts that arise in complying with WTO TRIPs provisions.

In 2001 these interpretational issues were partially addressed in the "Declaration on the TRIPs Agreement and Public Health". According to the Declaration, Members have the right to determine what constitutes a 'national emergency' or other circumstances of equal extreme urgency. Where these are concerned, there is specific reference to AIDS, tuberculosis, malaria and other epidemics as cases that may trigger such conditions. But this leaves open the decision on what constitutes a case for granting a compulsory license to the discretion of each Member[10]. On the other hand, it was seen that, for most Developing Countries and almost all Least Developed Countries, the possibility of granting a compulsory licence could be an ineffective tool to deal with their concerns. This is because most of these countries have neither the productive nor the knowledge capabilities that the production of these types of drugs requires (Sykes, 2002). Particularly, most LDCs lack both the quality and quantity of human resources necessary to produce simple medicines. These domestic supply constraints result in countries' over reliance on imports to obtain medicines which raise concerns of access to drugs and security of supply. Article 31 (f) of the TRIPs Agreement would only allow for compulsory licences to supply domestic markets and, therefore, limit the possibility of importing cheaper generic pharmaceuticals from other countries by the least developed Members. In recognition of this shortcoming, which serves as an implicit identification of important supply side constraints, the interpretation of *Paragraph 6* of the 2001 Doha Declaration on TRIPs served to provide a partial waiver on Article 31 (f). It would allow some exporting countries to supply a limited quantity of a patented product and for a limited time to an eligible importing country. But the system would be limited to cases of national emergency or for public non-commercial use and available to those that notified the use of such measures to the Council for TRIPs[11]. In terms of payment to the right holder, the importer country would be waived from Article 31 (h) provisions of payment to the right holder as long as the exporter country had paid remuneration. These exceptions have now been included in Article 31 bis of the TRIPs agreement in the Hong Kong Ministerial of 2005. They wait for approval by two thirds of members for the amendments to be passed, till then the 2003 waiver applies.

[9] In addition to the definition of 'reasonable commercial terms'.

[10] In fact, the notion of "other epidemics" further leaves room for the justification of granting licenses to manufacture drugs in circumstances where any disease emerges where cases are above previous levels of incidence

[11] Paragraph 1. b of the Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health declares as eligible importing country to "...any least-developed country Member, and any other Member that has made a notification to the Council of TRIPS of its intention to use the system as an importer"

But the use of the provisions established in *Paragraph 6* remains low; to date, only two notifications to the Council on TRIPS have been made on one single operation of supply of medicines[12]. On October 2010 a meeting of the WTO intellectual property council made the first in depth analysis of these provisions[13]. It concluded that the notification procedures appeared to be too burdensome for some members. India was of this opinion arguing that the system of notifications could be too costly and cumbersome for importing countries. Developed countries on the other hand suggested that the low utilisation of this provision reflected other constraints such as health infrastructure, taxes and import duties which would need to be considered in granting rights to affordable access to medicines. The low utilisation of the provision hint at implementation problems as the procedure does not seem to be particularly onerous. It requires a simple and short notification containing information about the quantities and the type of medicine to be imported under compulsory licence. This suggests that there are perhaps other impediments to the use of such provisions. But these may be hard to capture given the lack of available information on the attempts to use these provisions. The unsuccessful intentions to use these may point to problems in the remuneration procedure. Paragraph 3 of the decision on the implementation of *Paragraph 6* established that the exporter and not the importer is to pay remuneration "taking into account the economic value to the importing Member". This could be a source of conflict with the right holder that may lead to the decision of not using the system if high payments are required. Unfortunately, there is little information about the occurrence of these instances.

The provisions for compulsory licences follow the general spirit of applicability of the agreement and are extended to all members irrespective of the level of development. However, Developed Countries conceded that they would not use such provisions as importers. This then establishes the provision as a *de facto* form of SDT in favour of Developing Countries and LDCs[14]. In the process of analysing the compulsory license provisions two important constraints that countries may face in implementing TRIPs emerge. The first relates to 'health emergencies' that supports the notion of derogations to general principles in the presence of constraining circumstances. The second is the problem of productive capacity constraints which are implicitly recognised in the interpretation of Paragraph 6.

2.2 Price discrimination and parallel imports

The exhaustion of intellectual property rights can play a role in helping developing country access important pharmaceutical products by acting on the price mechanism. However article 6 of the TRIPs Agreement suggests that exhaustion remains the competence of member countries where it states that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights". Exhaustion of IPRs is important because it deals with the question of resale of patented products to other markets. Full exhaustion implies that once a patented product has been sold, the Intellectual property associated with it is "exhausted" upon the first sale and hence the patent holders' rights are not enforceable in subsequent sales. The issue becomes relevant for the patent holder since,

[12]Canada reported its intention to export a particular drug to Rwanda for the treatment of HIV in 2007 IP/N/10/CAN/1

[13] Minutes of the meeting were not disclosed. A summary of the meeting can be found in http://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm

[14] Par. 1 b. Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health

if rights are exhausted after the first sale, it cannot enforce any price discrimination. This is important for Developing Countries since, besides transport costs or other trade barriers, it gives them the opportunity of importing a patented product from the country where a lower price is charged. The WTO jargon refers to this instance as "parallel imports"[15]. It provides countries that face productive capacity constraints some flexibility in their access to pharmaceuticals.

Cottier (1998) and Lahouel & Maskus (1999) offer a discussion on the legal debate in the interpretation of the exhaustion of property rights. In general terms these may be exhausted nationally or internationally[16]. In the first case rights end upon the first sale within a particular national territory but right holders may impede parallel trade with other countries. In the second case, rights are exhausted upon the first sale in any given market hence providing a means for parallel imports. Article 6 of TRIPS maintains national prerogatives as regulators of these provided national and MFN treatment are adhered to.[17][18] . It is generally recognised that international exhaustion is more favourable for developing countries because it facilitates parallel imports. However Sykes (2002) argues differently. If monopolists are unable to effectively price discriminate, theory suggests that they will charge the standard monopoly price uniformly across markets. This price is expected to be higher for developing countries than that which would be faced under a price discrimination scenario hence making consumers in developing country markets worse off. This then suggests that the effects of international exhaustion of IPRs on access to affordable pharmaceuticals in Developing country markets is ambiguous. On the one hand it is desirable because it enables parallel imports, but on the other it may apply upward pressure on the prices hence reducing the effective access to much needed medicaments.

One should not analyse the effects of the exhaustion of IPRs on price discrimination in isolation to the pricing strategies of large companies, particularly those that operate with distributors and licensees. This is because these private interactions will also determine the extent to which firms can price discriminate. Maskus and Chen (2004) suggest that local distributors may have incentives to make profits by cross-hauling products to other countries without the prior authorisation of the manufacturer (parallel imports). This would then imply the partial removal of price discrimination through arbitrage which would result in a convergence of retail prices. However, the feasibility of such practices will depend on the level of enforcement of the licenses and in particular the control that the producers have over the distributors. License holders may threaten distributors not to renew their rights if these are not respecting the areas assigned to them. If license holders operate through tighter controls then they can effectively control the cross-hauling process and hence implement price discrimination. Large pharmaceutical conglomerates tend to have physical presence in developing

[15] The concerns they raise are not dissimilar to those found in Free Trade Areas where countries avoid the entry of products via the lowest tariff through the use of Rules of Origin.

[16] Regional exhaustion is also possible

[17] This view is then reinforced in article 5 of the Declaration of the TRIPs Agreement and Public Health of 2001 by stating that "*The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge...*". Article 5, paragraph d. Declaration on the TRIPS Agreement and Public Health.

[18] The European Union, for example, has decided not to change its community-wide regime to international exhaustion.

countries either through local representatives or production facilities[19]. Even without production facilities, a local branch or representative is in charge of the commercialisation of the marketed products[20]. These branches do not operate in complete independence and their marketing strategies in each country as well as their import sources may be decided in the respective headquarters. These global supply strategies can effectively serve to price discriminate hence rendering any principle of exhaustion of property rights ineffective. Even with permissiveness for parallel imports, the choice of the origin of imports is curtailed by the conglomerates' global supply strategies and hence price discrimination remains possible. This then renders principles of exhaustion ineffective.

Overall, the varying provisions that aim at providing flexibility in the implementation of the TRIPs agreement provide unclear benefits to developing countries. Nonetheless, they help us identify the main constraints that countries may face in implementing patent protection. The presence of a 'compulsory licenses' provision within the agreement implicitly recognises that certain circumstances, such as national emergencies, demand special treatment. Indeed the Interpretation of paragraph 6 of the Doha declaration provided a strong basis for the precedent of public health over private property. Hence an identification of the occurrence of these special circumstances may serve the purpose of applying derogations to the general principles. This may be achieved through the use of analytical criteria that identify incidence of health emergencies over 'normal' values. Adding to this the issue of exhaustion also points to a broader problem in the pharmaceutical industry that is related to price dispersion. Countries which may be budget constrained may need to call in mechanisms that ensure appropriate supply of pharmaceuticals where compulsory licenses are useless due to supply capacity constraints in domestic markets. An identification of such constraints would also help inform possible derogations from general principles which ensure an appropriate access to needed pharmaceuticals. But before turning to the identification of these constraints by way of analytical criteria and the application of graduating thresholds, one need look into the economics of patent protection to determine the possible impact of these derogations on economic welfare.

3. The Economics of Patent Protection and the case of Developing Countries

The rationale for awarding patent protection to any industry derives from the recognition that some processes of innovation are costly and would not be undertaken unless protection is granted. Innovators are awarded patent protection through the conferral of monopolistic powers that aid to cover the R&D costs of the process of innovation. However, as in any monopolistic setting, inefficiencies arise via the sub-optimal consumption (supply) of the monopolistic product. Patent protection is hence to act as a balancing tool between the needed incentives for the innovative process and the inefficiencies generated through monopoly rents. Whilst these are generally mediated through an arbitrary time limited conferral of these monopoly powers, Deardorff (1992) makes an important case for the limitation of patenting protection geographically. He argues that "the case for universal

[19] F. Hoffmann-La Roche Ltd, Bayer, Glaxo Smith Kline and other big pharmaceutical conglomerates have physical presence with production, research and development, commercial or administrative facilities in a wide range of developing countries.
[20] When no local branch or representative is present, a branch or representative in another country is the one designated to commercialise their products in that country

patent protection is not a clear one [...] and that the concerns of some developing countries that they will be exploited by patent protection are not without foundation". Deardorff's (1992) theoretical model provides an important justification to the case of SDT in the application of TRIPs provisions for patenting pharmaceuticals based on distributional welfare effects. He demonstrates how these skew the benefits towards the producers of products with higher patent protection. The welfare implications are not innocuous given the explicit reference to "social and economic welfare" in the TRIPs Agreement objectives set out in article 7. However recognition is also awarded to the need to "balance rights and obligations" referring to the process of knowledge creation and transmission.

Where patent provision to the pharmaceutical industry in developing countries is concerned there is an overarching issue of health security where derogations need be tamed by the possible economic externalities these generate. A lax enforcement of patent systems can affect the innovation process through an inappropriate mix of incentives which may lead to negative and potentially long term consequences for developing countries at the expense of short term goals. An important facet to consider in the case of pharmaceutical products is that the technology needed for their development exhibits the properties of public goods. Once a drug is developed, the ingredients and the dosage in which these are to be mixed are easily replicable. The non-excludable and non-rivalrous nature of this type of technological progress can then lead to free riding which can affect the innovation process. The misappropriation of technological knowhow can result in an inappropriate distribution of the costs of innovation in turn resulting in lower (sub-optimal) undertakings of innovative endeavours which are beneficial to society. Patent protection can then be invoked to act as a balancing tool between the innovative process and the distribution of the proceeds of the technology by reducing the free-riding element and ensuring that the returns are awarded to the innovating firm[21].

The model discussed in Deardorff (1992) is particularly illuminating because it underlines the tensions between producers and consumers of products with strong R&D content. The model is one with two countries and a continuum of possible inventions. Gains are derived from an increased consumption or availability of new inventions but these need be weighed against the losses that transpire from the loss in consumer welfare as a result of monopoly pricing. Extending patent protection generates an unambiguous gain for the firms (countries) that develop inventions, however countries that do not produce these products end up transferring their consumer surplus to those that do. This very simple model clearly exposes the tensions in the debate held in international fore. The main proponents of patent protection are those who derive the associated monopoly profits, which are generally developed economies, but these clash with those that transfer their consumer surplus which tend to be the developing countries. Deardorff (1992) suggest that the balancing act between the benefits derived from the process of innovation and the costs of monopoly pricing is asymmetrical where the first of these sees important diminishing returns. This then suggests that extending patent protection to all countries is suboptimal as the negative impact of monopoly pricing becomes greater in the margin. He concludes that "as more and more of the world is already covered by patent

[21] But is it worthwhile noting that awarding patents is not the only compensating mechanism, and perhaps not even the most efficient one, for clearing these tensions between suppliers and consumers. Some may argue that subsidising R&D expenditure may provide an alternate control mechanism.

protection, the extra market that can be covered, and hence the extra invention that can be stimulated by extending patent protection still further, becomes smaller. Thus, at some point the costs due to extending monopoly pricing to existing inventions come to outweigh the benefits of generating new ones".

Whilst Deardorff's (1992) model exhibits certain shortcomings accruing to the linear and static nature of his theoretical model, some of the assumptions remain pertinent in the case of the pharmaceutical sector. One such assumption is the concentration of production in one country/region. Evidence (see Table 2) shows that there is indeed an important concentration of pharmaceutical economic activity in developed countries which then suggests that the benefits of patent protection largely accrue to these countries at the expense of the consumer surplus of developing countries. There is however a limiting assumption which can affect Deardorff's conclusions and is pertinent to our analysis, this is that the model does not provide an implicit treatment of the heterogenous demand for 'inventions'. In the case of pharmaceuticals in developing countries it is highly likely that the demand for these differ from that of developed countries[22]. Not extending patent protection to these markets could then result in a sub-optimal supply of specialised and much needed pharmaceutical products to developing countries. A simple example can illustrate the problem. If most HIV sufferers are located in developing countries and there exists no patent protection in these countries, then pharmaceutical companies may not engage in developing the necessary drugs for treatment given that there will be no guarantee that the investment needed for the development of such drugs would be recouped. If the innovative process is demand driven and only targets the concerns of developed countries it is likely that pharmaceutical production will be geared to developed country concerns which may not be the same as developing country needs. Troullier et al (2002) provide some support to this view by showing that drug development is closely associated to market demand forces. They show that only 1% of the new chemical products marketed between 1975 and 1999 were registered for diseases such as Tuberculosis, Malaria or other diseases which afflict developing countries in greater abundance. To the extent that this is true, then not having patent protection in place can have important negative long term consequences for developing countries through the created incentives in the innovation process leading to shortfalls in the supply of new innovative drugs to treat endemic developing country conditions. But it is equally possible that this low innovative output geared towards developing country needs is a result of the low purchasing power in such countries hence the introduction of patent protection may only exacerbate the real purchasing powers of medicaments. One need bear these longer term consequences in mind when suggesting the application of SDT in pharmaceutical products for selected developing countries.

It is however difficult to reconcile pharmaceutical companies insistence on widespread patent enforcement with the amount of patent applications made by right holders in developing countries. Attaran (2004) found that pharmaceutical companies were not deeply involved in applying and maintaining patents for essential medicines, as defined by the WHO, in developing countries. Where these companies had the option of maintaining these, because a patenting law existed, they only

[22] Owing to, for example, the heterogenous spread of Malaria which is skewed towards developing countries affecting the demand for drugs treating this condition.

undertook such actions in 31% of cases. The remarkably low application of patents in developing countries may support the notion that the marginal revenue from obtaining a patent, given the level of income in some very poor countries, may not be worth the effort. The current trends suggest that market size plays a key role where patenting activity tends to be more frequent in countries with larger populations and higher income per capita (Attaran 2004 and Watal 2000). This indicates that pharmaceutical companies tend to target patent protection towards the upper deciles of the distribution of developing countries. But a counterargument to the above may explain the low application for patents in developing countries as a result of lax enforcement of IPR in these countries. This chicken and egg argument is hard to disentangle. Is patenting of pharmaceuticals in developing countries low because of revenue consideration or is it due to the lack of enforcement mechanisms?

However, the market size argument highlights the possible importance of patenting in not only the largest developing countries (China, India, and Brazil) but also those with relatively high income per capita such as Argentina[23]. In fact, the importance and indeed the future demand potential from these big developing countries need be considered in the context of modulation of commitments. Nogues (1993) points out that in terms of present value, a dollar generated from patent protection today in developing countries, particularly in Argentina, Brazil, India, Mexico, Korea and Taiwan; is worth much more than one dollar obtained by extending the patent life in developed countries. This then suggests that the size of the possible consumer base and pharmaceutical markets in these countries may play a key role in the demands for TRIPS enforcement.

The economic distribution of gains and losses from the enforcement of patenting provisions need be considered when formulating policy, but these are overshadowed by the concerns for health outcomes in developing countries. Deardorff's (1992) model looks at innovative activity, IPR and the distribution of rents but not at the impact that monopoly pricing has on access to needed pharmaceuticals. In the next section we deal with this issue where we look at the constraints that countries encounter in accessing medicines and in setting up health systems. Here we pay particular attention to the resources that need be devoted for the implementation of patenting provisions and the impact of these on health outcomes.

4. Constraints faced by Developing Countries in Implementing Patent Protection for Pharmaceuticals.

The endemic health concerns in developing countries are only exacerbated by the lack of access to affordable medicines which puts important pressures on health care strategies in these countries. The impact of patent protection on the price of pharmaceuticals is a likely contributor to the lack of access to affordable medicines but one need note that its elimination will not come as a golden pill. Nor will it solve these countries major health issues (Watal 2000). Even in countries where patent laws have been permissive, or levels of enforcement are low, access to medicines remains sub-optimal (Attaran,

[23] During the 1990's Argentina was subject to an important pressure from the US to modify its centennial patent laws. In 1997 the US removed Argentina as beneficiary of preferences in some products in its Generalised System of Preference as a retaliation measure. For further details see Vicente (1998)

2004). This is because as long as income levels remain low, so too will access to medicines and provisions of general health care.

To operationalise the modulation of WTO TRIPS commitments one needs to identify the main constraints that countries face in implementing these commitments. Having already identified some of the economic constraints in the previous section we now turn to the more prescient health aspects and provide a discussion on how analytical criteria can serve the purpose of capturing these constraints. Our main objective is to typify the type of health concerns that exist in developing countries so that we may gauge the extent to which countries are constrained in the implementation of TRIPS. In the process, and in the spirit of Stevens (2002), we seek to indentify common constraints serving the purpose of classifying countries according to shared similarities amongst themselves but also shared dissimilarities with respect to other general and more developed groupings. We identify three broad categories; the first is access to needed pharmaceuticals; the second relates to capacity in meeting health priorities in developing countries; whilst the third occupies the incidence of disease in these countries.

4.1 Access to Pharmaceutical Products

One of the main contributing factors to the low access to pharmaceuticals in developing countries can be seen to be the high prices that these products command. Hoen (2002) makes this important point and also underlines that the prevalence of infectious diseases such as HIV/AIDS, Malaria, respiratory diseases and tuberculosis kills around 10 million people every year where 90% of these are located in developing countries. This is significantly higher than the share of the population that they occupy. Day (2006) further notes that over 0.5 million children die yearly from AIDS where 95% of these are located solely in the African continent[24]. The high incidence of diseases, coupled with the low spending powers of developing countries begs the question of the impact that greater access to pharmaceuticals can have on developing country health outcomes. One can ascertain the importance of this by comparing the death rates from HIV/AIDS across developed and developing countries under the presumption that spending power differences explain some of the variation in outcomes of diseases. Xiao (2009), citing figures from the WHO report, suggests that the incidence of death from HIV/AIDS is 6,235 times greater in Botswana than it is in the UK. This figure gives us a back of the envelope yardstick of the severity of the problem of accessing pharmaceuticals. Whilst this marked discrepancy cannot be solely attributed to problems of access to pharmaceuticals, patents, and in particular their impact on pricing mechanisms, are likely to play a key role (Hoen 2002). Watal (2000) suggests, using evidence for India, that the overall weighted price of pharmaceuticals increased by 26% after the introduction of patenting provisions in India. This then suggests that access to pharmaceuticals and pricing mechanisms cannot be considered in isolation.

The first constraint that developing countries face in accessing needed pharmaceuticals is the lack of purchasing power due to reduced incomes and high prices. If one is to consider a modular approach to SDT in TRIPS one need take into account GDP per capita as a proxy for the shortfall in purchasing

[24] The UNAIDS Report on the Global AIDS Epidemic 2010 suggests that two thirds of world AIDS victims; 76% of Women and 92% of Children Afflicted with AIDS are located in Sub-Saharan Africa.

power across countries. If patent protection further increases prices then the application of TRIPS provisions will only exacerbate the already delicate situation of developing countries. Oxfam (2001) provides some anecdotal evidence on the impact of patent protection on access to drugs for the case of Brazil and treatment of HIV/AIDS. They suggest that under a government funded programme, the cost of providing anti-retroviral (ARV) drugs in Brazil amounted to $3,000 per patient per year. This because 10 of the 12 key drugs needed for treatment were produced as generics. In contrast the cost in the USA was seen to be of $10,000 per patient per year. The large discrepancy between these highlights the problem of prohibitive prices on developing countries. It also points to another constraint that countries face in accessing needed drugs and this has to do with budgetary shortfalls in implementing health programmes aimed at citizens. These can be captured rehashing the Brazil example. In Oxfam's (2001) example the government backed AVR drugs campaign targeted 95,000 patients who benefited from treatment. If we apply the US prices to this programme as a counterfactual of what Brazil would have had to pay in the presence of patents and assume the same budget allocation, one would see the amount of possible treated patients fall to 28,500 (Just 30% of the treated patients with generics). Hence one can see how countries that are more severely budget constrained than Brazil and have just as great an incidence of disease can face important challenges in meeting health outcomes with more expensive drugs due to patents. MSF (2005) also provide compelling evidence on the link between patents and the cost of pharmaceuticals for the case of India. They suggest that the creation of a competitive generics market in India reduced the cost of AVR treatment by 83% leading them to suggest that *"generic competition has shown to be the most effective means of lowering medicines price"*.

It is however worthwhile noting that the above examples serve illustrative purposes only and are generally applicable to countries that have the productive capacity to engage in the manufacture of generics. This is relevant to middle income countries but does not hold for those countries in the lower spectrum of the income scale. Whilst Maskus (2000) advocates that 'imitation' can lead to the development of local capacity, the removal of patent provisions is possibly a necessary but not sufficient condition for a reduction of prices from the use of domestic generic products. The human capital needed for such production tends to demand the use of high quality practitioners, factors that are in short supply in least developed countries. Access to pharmaceuticals then needs to be ensured by the international trading system for those countries that most need it. The removal of patent provisions coupled with an explicit system that deals with the supply of generics across countries would serve this purpose. This then suggests that domestic productive capacity should also play a role in determining the desirability of implementing TRIPS provisions failing such a system.

4.2 Capacity constraints

One key factoid that is often cited in the literature refers to the large share of costs that pharmaceuticals occupy in total health expenditure (66% according to Watal 2000). Countries that are already constrained in their budgets will become more so should patent protection increase the price of pharmaceuticals as Hoen (2002) suggests. Inappropriate or insufficient tax collection mechanism, the over-reliance of budget revenue on import duties where these are being reduced due to reciprocal bilateral trade deals (i.e. the EPAs) only exacerbates an already precarious budgetary condition. One

then need consider several indicators as measures of budgetary constraints. One key indicator to serve this purpose can be the per capita share of government revenue. This will identify possible general budgetary constraints, but it need be complemented with an indicator on expenditure on health systems. Here one may look at per capita government spending on health and per capita total spending on health. These combined indicators may give us a metric of the cross-sectional short fall in meeting demand for health outcomes.

Adding to the constraints that countries may face as a result of more expensive pharmaceuticals are the expenses that are incurred as a result of transposing TRIPS commitments into national legislation. Lybbert (2002) refers to these costs as the direct costs of implementation where these capture the costs of creating the appropriate legal infrastructure; administrative capacity; and enforcement mechanisms. These direct costs are to be added to the indirect costs which occur when more patents are called for as a result of stronger enforcement mechanisms. Given that the innovation process is largely located in developing countries, the World Bank (2001) estimates that the indirect costs alone could cost poor countries above $20 billion in transfers to developed countries. But there is a third type of cost that is hardly mentioned in the literature and which relates to the opportunity cost that is implicit from the direct cost. Devoting resources to TRIPs implementation clearly requires, in the presence of limited resources, not devoting funds to other activities which could provide far reaching benefits to developing countries (i.e. infrastructure projects, hospitals or further investment in education). Whilst these opportunity costs are hard to gauge they are likely to be important, particularly when it has been established that the benefits from patent protection largely accrue to developed country firms. Government spending on TRIPS implementation can then be seen as a cash transfer from developing to developed countries as the World Bank (2001) suggests.

4.3 Incidence of Disease

The aforementioned access and capacity constraints need be weighed against the degree of incidence of disease in developing countries. There is little added value in enumerating the severity of health problems in developing countries. But whilst most studies focus their attention on the incidence of targeted diseases such as HIV, Malaria and Tuberculosis, it is worthwhile noting that these are not the only diseases that plague Developing Countries. Many other common diseases have an equally high incidence and devastating impact. These can generally be easily treated with available pharmaceuticals. The problem of access to pharmaceuticals and capacity to deal with health emergencies are direct functions of the incidence of disease by country. One should thus introduce indicators of incidence of disease as factors that determine the modulation of WTO commitments under the primer that countries that suffer most should receive more consideration. These indicators can be easily ranked on a per-capita basis for cross-country comparisons which may help us gauge the relative severity of health outcomes.

5. Capturing the Constraints using Analytical Criteria

To operationalise the threshold approach to derogations from TRIPs commitments for the pharmaceutical sectors one need use a set of analytical criteria that serve to identify the constraints

that countries face as a result of or in the process of implementation. Some important and overarching limitations need be noted. Firstly, there will invariably be a mismatch between the analytical criteria used and the actual constraint identified owing to the fact that the analytical criteria will at best be a proxy for a given constraint. This then requires finding an appropriate methodology that combines a set of indicators, the choice of which will need take on board a set of assumptions and/or a weighting structure. Taking an econometric approach or even one relying on a weighting structure will come with its methodological shortcomings providing the second limitation. Stevens (2002) used very simple rankings for the purpose of differentiation but was limited by a coherent method that combined his identified indicators. Another important challenge will come when choosing the implicit threshold. Placing the graduating threshold will need be carefully considered. Objectivity would be preferred to facilitate the process however one cannot rule out the possibility of negotiating the thresholds. The last, and perhaps the most prescient problem relates to data availability. This is particularly important for the implementation of a targeted differentiation strategy and more so when this is for a very specific sector of the economy such as pharmaceuticals. Gaps in data will affect the unified approach to ranking countries according to constraints based on analytical criteria and may in turn severely jeopardise the approach. This is because lack of data for a given country will result in its elimination from the sample and hence the SDT approach will not be implementable for that country. One need then find appropriate treatment for the countries where data is unavailable.

Bearing these in mind, we concern ourselves presently with an exposition of the identification, by means of analytical criteria, of the countries that may be constrained in their implementation of TRIPS provisions according to the four main identified constraints. We begin with a summary table of these and a suggestion of the indicators that can be used. The table follows from the discussion in the previous section but proposes a further disaggregation of the issues that the indicators try to capture. Hence taking the first 'Economic' constraints we see that the main issues identified in the literature relate to looking at the benefits; the size and competitiveness of the pharmaceutical market; and the possible negative impact on third parties that derogations from WTO provisions may generate. We look at what these indicators tell us with regards to preliminary groupings that may be exempt from provisions to later develop an approach that combines these in a way that will aid us with the selection procedure. We will rely on readily available databases such as the World Development Indicators; trade figures from COMTRADE; and the DALY.

Table 1: Summary of Constraints and Possible Indicators

Constraint	Issue	Possible Indicators
Economic	Benefits	- R&D / GDP capturing the gains derived from IPR protection (World Bank 2001) - Concentration of Production and/or trade
	Competitiveness	Revealed Comparative Advantage or trade balance to capture Cottier's (2006) propositions
	size of Pharmaceutical market	Share of pharmaceuticals in total trade
	Impact of non-compliance of third countries	Share of world GDP capturing market size

Access to Pharmaceuticals	Purchasing Power Productive capacity	GDP per capita (X-M)/(X+M) gauges the trade balance and hence possibly the dependence on imported pharmaceuticals
Capacity Constraints	Costs	Per capita budget revenue to capture government budget shortfalls in meeting Health outcomes National expenditure on Health (Both private and public) Population (Watal 2000)
Incidence of Disease	comparative spread of illness	Incidence of diseases (DALY database) Created indicator RDI (Revealed Death Incidence, like RCA but on death figures)

5.1 Economic Constraints and distribution of pharmaceutical production

As the World Bank (2001) and Deardorff (1992) suggest, the economic benefits of patent protection will be reaped by the countries that produce products with a high content of IPR. Enforcement of patents can then translate into a cash transfer from countries that do not produce these products to those that do. This means that the enforcement of patent protection has important distributional consequences. The extent to which these occur can be broadly gauged through the underlying trade flows. Table 2 shows the flow of pharmaceutical products between and within developed and developing countries[25].The concentration is evident where almost 88% of pharmaceuticals exports originate from developed countries, leaving the remaining 12% to developing countries. Where imports are concerned, the distribution is a little less concentrated with more than 68% of these flowing towards developed countries. The table further shows that around 70% of developed country exports are destined towards other developed countries. Here we might be witnessing a high degree of intra-industry or intra-firm trade in the form of non-retailed pharmaceutical products exported from one country to be used in the production of retail pharmaceuticals in another country. This phenomenon is also seen in the origin of Developed country imports, where almost 86% of imports originate from other developed countries. But these instances may be equally revealing of differences in demand structure between developed and developing countries. Where exports are concerned, developing countries tend to have a more balanced geographical distribution in terms of destination; the table shows that almost 50% of exports are destined to other developing countries. One marked result is that of a large share of developing country imports originating from developed countries. Whilst this is unsurprising it does reveal an important distinction between developed and developing countries placing the latter as important consumers of pharmaceutical products from the former. This then suggests that we are not far off the theoretical model that Deardorff (1992) exposes which again lends support to his conclusion pointing to a possible case for a geographical limitation of patenting provisions.

Table 2. 2008 Pharmaceuticals trade (in millions of USD)

	Exports	Imports

[25] As defined by code 54 on SITC rev. 3 it includes pharmaceuticals and non retail chemicals and pharmaceuticals.

	Developed Countries	Developing Countries	Total	Developed Countries	Developing Countries	Total
Developed Countries	149,888.98	62,274.89	212,163.87	146,998.61	24,380.58	171,379.19
Developing Countries	14,245.09	15,316.46	29,561.55	61,565.22	17,141.56	78,706.78
Percentages						
Developed Countries	70.65	29.35	87.77	85.77	14.23	68.53
Developing Countries	48.19	51.81	12.23	78.22	21.78	31.47

Source: UN Comtrade

Note: Total imports and Total exports do not match due to missing data.

Looking at more geographically disaggregated data in a selection of countries shows that, even within Developed Countries, there is concentration taking place. Excluding Intra-EU trade, the European Union accounts around 53% of Developed Country exports and 46% of total World pharmaceutical exports. This makes the EU, by a large margin, the largest exporter of pharmaceuticals. However, the role of Switzerland in total pharmaceutical exports is also noteworthy and stands at nearly 18% of total world pharmaceutical exports. Table 3, which is ranked according to the size of total exports, highlights the international presence of some important developing countries. China accounts for 3.35% of total pharmaceuticals exports. Together with India, they are the largest net exporters of pharmaceuticals among Developing Countries. But other countries also emerge such as Israel, Mexico, Brazil, Korea, and Argentina. To the extent that these countries may have reached international competitiveness in the pharmaceutical industry one could consider, on the basis of Cottier's (2006) argument, that TRIPs provisions would need apply. When looking at imports, Table 3 reveals that these Developing countries also attract large quantities of pharmaceutical imports. With the exception of China and India, almost all Developing countries are net importers of pharmaceuticals which may suggest that for these countries international competitiveness has not yet been attained[26]. The Table then suggests that one need carefully look at both China and India to determine the extent of their competitiveness in international markets. These countries will also be important because they have growing incomes per capita and have a huge population hence derogations from TRIPs commitments may incur important impacts on third country producers of pharmaceuticals. These negative third country impacts can be grasped by either looking at the size of a given country's GDP with respect to world GDP or alternatively the share of total world population they occupy. The larger this number is, the higher the impact of derogations for producers of pharmaceuticals the rest of the world.

Table 3. 2008 Pharmaceutical trade by country (In millions of USD)

	Exports				Imports			
	Developed Countries	Developing Countries	Total	% of total	Developed Countries	Developing Countries	Total	% of total
European Union	67,940.71	44,051.49	111,992.21	46.33	48,040.83	11,888.65	59,929.48	23.96
Switzerland	34,518.58	9,626.77	44,145.34	18.26	17,575.17	202.51	17,777.67	7.11
United States	32,435.60	4,782.20	37,217.80	15.40	49,955.44	9,912.74	59,868.18	23.94
China	4,666.64	3,424.26	8,090.90	3.35	5,007.76	519.10	5,526.86	2.21
Canada	5,582.21	328.81	5,911.02	2.45	10,393.96	785.84	11,179.80	4.47
India	2,307.66	3,515.09	5,822.75	2.41	1,058.28	811.29	1,869.56	0.75

[26] The Rest of the World, composed entirely of Developing Countries, account for around 11% of total pharmaceutical imports.

	Exports				Imports			
	Developed Countries	Developing Countries	Total	% of total	Developed Countries	Developing Countries	Total	% of total
Singapore	4,044.13	926.62	4,970.75	2.06	1,576.06	331.24	1,907.30	0.76
Israel	4,651.72	190.29	4,842.01	2.00	1,309.58	60.20	1,369.78	0.55
Japan	2,899.17	763.49	3,662.66	1.52	10,227.32	771.19	10,998.52	4.40
Australia	1,641.79	1,706.87	3,348.66	1.39	6,667.49	393.71	7,061.20	2.82
Mexico	395.02	1,080.28	1,475.30	0.61	4,050.25	554.99	4,605.25	1.84
Brazil	332.62	718.16	1,050.78	0.43	4,163.55	807.60	4,971.15	1.99
Korea Rep.	385.43	630.15	1,015.58	0.42	2,988.83	451.18	3,440.00	1.38
Norway	658.90	48.25	707.15	0.29	1,796.12	29.82	1,825.93	0.73
Argentina	146.06	539.80	685.85	0.28	1,052.85	259.50	1,312.35	0.52
Jordan	19.04	478.47	497.51	0.21	372.43	79.31	451.75	0.18
Turkey	257.12	212.11	469.24	0.19	4,425.96	312.49	4,738.45	1.89
Bulgaria	54.54	330.17	384.71	0.16	727.61	87.44	815.05	0.33
Colombia	15.56	356.89	372.45	0.15	837.49	374.70	1,212.20	0.48
Costa Rica	122.04	204.65	326.69	0.14	321.40	210.31	531.71	0.21
Russian Federation	35.10	287.67	322.77	0.13	7,429.18	1,767.62	9,196.81	3.68
Croatia	153.91	167.53	321.44	0.13	682.51	126.28	808.80	0.32
Thailand	78.73	212.52	291.25	0.12	1,170.41	271.46	1,441.88	0.58
Hong Kong	11.15	251.04	262.19	0.11	1,434.69	326.97	1,761.66	0.70
Romania	74.64	161.21	235.84	0.10	2,354.04	295.35	2,649.39	1.06
Indonesia	75.86	154.21	230.07	0.10	372.81	181.19	554.00	0.22
Serbia	18.52	190.95	209.47	0.09	564.05	143.69	707.74	0.28
New Zealand	167.90	40.39	208.28	0.09	766.21	64.89	831.10	0.33
South Africa	46.24	149.97	196.21	0.08	1,387.30	277.34	1,664.65	0.67
Syria	1.36	193.20	194.56	0.08	75.72	74.95	150.67	0.06
Rest of World	396.13	1,867.85	2,263.98	0.94	19,778.49	9,148.58	28,927.08	11.57
Total	164,134.07	77,591.34	241,725.42	100.00	208,563.83	41,522.15	250,085.98	100.00

Source: UN Comtrade

5.2 Access to pharmaceuticals

Country access to key pharmaceuticals is likely to depend on the purchasing power and on the capacity to source these either domestically or from sources abroad. The key variable, in addition to purchasing power is thus the price of said pharmaceuticals, however these prices are not readily available hence other means need be used to gauge the access problems that countries face[27]. Here we consider the extent of domestic production capabilities and in the process the distribution of domestic consumption across national or international sources. This allows us to determine not only the exposure of countries to pharmaceutical imports and the domestic capacity of producing these, but also the domestic competitive climate[28]. Looking at this for a selection of countries due to data availability constraints, Table 4 highlights some interesting observations. The first is that the larger the country (in terms of its GDP), the smaller is the share of imports in the supply of demand. For example, the US and the European Union supply their respective domestic demands with around 30% of imports. Developed countries tend to show comparable shares. As a corollary, developing countries

[27] Extensive country surveys can serve the purpose of gauging prices but these are inpractical in the context of our investigation.

[28] Unfortunately, the availability of production data is limited which impedes a more comprehensive treatment on production and domestic consumption of pharmaceuticals

have a larger dependence on international sources for pharmaceutical product consumption. However the case of China and India stand at odds with the general observations. They exhibit strong domestic production and little reliance on imported pharmaceuticals to satisfy implicit domestic consumption; shares of 10% and 16% respectively lend support to this point. The case of Mexico is somewhat similar but to a lesser extent[29].. In light of these figures one could argue that where there is strong domestic pharmaceutical production there might be a case for the enforcement of patenting rights. Cottier (2006) is of this view where he suggests that one need consider not only international competitiveness, but also the domestic competitive environment and the interplay between domestic and foreign sources for pharmaceuticals.

Table 4. 2005 Pharmaceuticals balance by country (In millions of USD)

	Production	Exports	Imports	Calculated Consumption	% Imports /consumption
Australia	4,376,789	2,463,125	7,061,204	8,974,868	78.7
Bulgaria	304,295	124,063	815,051	995,283	81.9
Chile	746,249	66,968	720,360	1,399,641	51.5
China	51,870,686	3,777,728	5,526,864	53,619,822	10.3
Colombia	1,263,427	263,801	1,212,195	2,211,821	54.8
Ecuador	170,758	32,350	688,919	827,326	83.3
Ethiopia	19,613	203	222,551	241,960	92.0
European Union 25	208,249,937	72,349,786	59,929,485	195,829,635	30.6
Georgia	7,920	4,233	213,875	217,562	98.3
India	12,489,478	2,761,837	1,869,563	11,597,204	16.1
Indonesia	2,074,988	112,364	553,996	2,516,619	22.0
Japan	70,016,114	3,327,426	10,998,516	77,687,204	14.2
Jordan	362,494	274,763	451,745	539,476	83.7
Malaysia	320,827	134,827	929,207	1,115,207	83.3
Mexico	11,516,814	1,403,237	4,605,249	14,718,826	31.3
Morocco	544,613	33,371	460,485	971,726	47.4
Norway	1,155,607	533,152	1,825,934	2,448,390	74.6
Panama	31,547	15,193	270,976	287,330	94.3
Peru	413,729	17,091	458,165	854,802	53.6
Romania	470,544	41,956	2,649,394	3,077,982	86.1
Russian Federation	2,275,424	201,089	9,196,808	11,271,143	81.6
Turkey	4,370,850	316,712	4,738,448	8,792,586	53.9
United States of America	165,969,000	25,159,579	59,868,182	200,677,603	29.8

Source: United Nations UNIDO

Note: Mexico and Japan data from OECD Stan database.

Cottier (2006) suggests that the nature of the WTO can be subsumed into a regulation of the competitive environment between domestic and imported products and hence forms of SDT or graduating constraints should be contingent on competitive shortfalls where commitments kick in after international competitiveness is attained[30]. This proposition hinges on identifying international competitiveness where the obvious candidate for such measure is the revealed comparative advantage

29 The lack of data for Brazil and Korea, as well as other countries, is limiting

[30] This principle is similar to that applied to graduation in the GSP of the EU where competitiveness is related to market shares and preferences are removed when a market share threshold is breached.

of a country in pharmaceutical products. However disentangling the domestic and foreign component of pharmaceutical demand is hard due to the lack of appropriate domestic production data. One can however use certain trade metrics to gauge the possible domestic competitive environment. We propose the use of an indicator motivated by the intra-industry trade literature where we capture the share of the trade balance in pharmaceuticals as a proportion of the total trade of these.

$$\text{Normalised Trade Balance} = \frac{(X_i^k - M_i^k)}{(X_i^k + M_i^k)}$$

Where X and M identify exports and imports respectively, k is the sector under analysis (the pharmaceutical sector) and i is the country under investigation. The indicator serves identify the reliance on either imported or exported pharmaceuticals as a measure of competitiveness. If a country only imports these products then the expression will tend to minus one. On the other hand if the country in question only exports these products, then the expression tends to plus one. The presumption here is that competitiveness should be captured by way of a positive balance of trade in pharmaceuticals[31]. To the extent that some richer developing countries have developed a strong domestic pharmaceutical industry, as Watan (2000) and Nogues (1993) show for India and Argentina respectively, Cottier's (2006) proposition gains prominence. Domestic competitiveness in these countries has lead to increasing competitiveness in international markets and hence international commitments should kick-in accordingly.

5.3 Government Capacity Constraints

Budgetary constraints in developing countries pose a serious threat to dealing with important health outcomes. Table 5 presents the average total per capita expenditure and the public per capita expenditure on health in different regions of the world. The disparity in the health expenditure, both public and total, is clear.. On average, Developed Countries spend 19 times more on health care than the Sub-Saharan Africa grouping. If we consider public expenditure, the difference becomes more marked; Developed country governments spend 25 times more than their developing counterparts. These figures hide a big dispersion. In Ethiopia, for example, the total per capita health expenditure is of around $30 while in the United States this figure is in the order of $7500; 250 times more. It is clear that some of the differences in per capita expenditure in health can be explained by levels of income in addition to the heterogeneity of the groupings, but it points to one of the main constraints that Developing and LDCs have in dealing with health issues. Either private or public expenditure on health are extremely low and this explains part of the high incidence of diseases that can be easily treated with medicines (as seen in Table 6)[32].

[31] One would also want to include a measure of market concentration to gauge the competitive environment in the country in question as Cottier (2006) suggest. Fair competition amongst foreign firms operating in the domestic economy can be jeopardised through patent infringement of these and hence need be tamed. One can capture the degree of competition in a given market by way of a herfindahl indicator that is commonly used in the competition law literature. However its computation requires data on the presence of domestic and foreign firms in these markets which is not readily available.

[32] One need bear in mind that other factors such as education, or lack of sanitation which serve preventative roles also affect the high incidence of disease.

Expenditure on medicines constitutes the largest share of total health spending in developing countries. Watal (2000) points out that it could represent almost 2/3 of total health expenditure where much of this is out-of-pocket given the weakness of public health services hence being a contributor to impoverishment. But the regional figures we present do not reveal such large out of pocket expenditures as Watal suggests. Whilst in Developed Countries 75% of the health care is financed by the Government, this figure falls to 57% in Sub-Saharan Africa. However, when we look at country data, we find evidence of a wide ranging distribution with the likes of Nigerian government expenditure taking 24% of the total health bill. Nevertheless, the situation is not better when the Government finances a large share of health expenditure since medicines take a large part of this expenditure. Collins-Chase (2008) cite evidence where the yearly wholesale price for an antiretroviral treatment in South Africa ranges from $750 for public procurement to $2000 when sold to private person. It is clear, from the figures presented in table 5, that medicines are unaffordable at current levels of health care expenditure. Moreover, not only can medicines represent a large share of the total health expenditure, it could also be a heavy burden for the economy as a whole. Collins-Chase, for example, highlights that the cost of AIDS treatments has taken 3.8% of GDP in Lesotho.

Table 5. Average expenditure per capita on health 2008. (USD PPP)

	Per capita Government	Per capita total
Developed Countries	2,339	3,118
Western Asia	669	1,101
Caribbean	503	830
South-eastern Europe	472	769
Latin America	351	608
Eastern Asia	320	570
South-eastern Asia	217	423
Oceania	323	374
CIS	203	371
Northern Africa	209	358
Southern Asia	123	233
Sub-Saharan Africa	93	163

Source: Own elaboration based on WHO

Adding to the heavy burden on public health care systems, an epidemic, such as AIDS or Malaria, can have wide ranging implications for developing countries. Indeed, the instance of these attenuating circumstances is clearly made reference to in the use of compulsory licenses within the TRIPs agreement. Increases in mortality and morbidity affect households, the private sector and the Government. The economic impacts of AIDS, for example, translates into a reduction of the household saving rate as these use more income on medical assistance (Collin-Chase). This then has important implications on future growth rates. Freire (2004) finds a fall of 18% in the savings rate as a consequence of the epidemic. In addition, and where saving capacity is low such as in Sub-Saharan Africa, households may need to reduce expenditure on other vital products. Arndt and Lewis (2001) show that AIDS increases the health expenditure to 10-15% of total expenditure, at the expense of other non-food expenditures.

5.4 Capturing Incidence of Disease across countries

The incidence of death can serve identify the severity of health outcomes across countries. Table 6 presents figures across regional groupings in share format using the Death and disability adjusted life year (DALY) database by region. The DALY is a measure of the burden of a disease measured as years lost due to illness, disability or early death and it is calculated by the World Health Organisation. Taking the aggregate shares; infectious and parasitic diseases (IPDs) is the highest cause of death with a 19.8% incidence; followed by Neuropsychiatric disorders (13.1 %); and Cardiovascular diseases (9.9%). This table is useful in that it captures more than deaths from diseases by including injuries ranging from traffic accidents, suicides and wars. Moreover, it delimits deaths related with nutritional and other living conditions. The Table also reports a revealed incidence indicator (RII) which is motivated by Balassa's (1966) revealed comparative advantage (RCA) indicator. It compares the share of outcomes from a given condition in a region to that of the world. Values above 1 (marked with gray shading) then indicate regional outcomes from a given condition that are above world averages. Looking at this regional distribution some marked differences between regions emerge. For example, the incidence of IPDs is Developed countries is very low (RDI of 0.1) whereas in Sub-Saharan Africa and Oceania is relatively high (RDI of 2.14 and 1.23 respectively). These differences reflect more than discrepancies in levels of development as they are also the result of geographical location where the incidence of tropical diseases such as Malaria is higher. Certain similarities are also worthwhile noting too, Neuropsychiatric disorders have similar incidences across most regional groupings such as; Developed countries; Latin America; Eastern Asia; and Northern Africa[33]. This leads to an important point originally remarked by Lanjouw (2001). He suggests that diseases can be categorised into those that predominantly affect developing countries, those that affect the developed world and those that affect both. The implications of this are important for the identification of groups of countries who should benefit from a modulation of WTO commitments as it gives us a first step in identifying countries by shared similarities but dissimilarities with other groupings (Stevens 2002). In the case of incidence of disease it makes sense to classify countries according to similar incidences of disease.

It is clear that infectious and parasitic diseases are the main cause of death and disability in the developing World. However, the Table also reveals the importance of other treatable diseases or conditions where medicines play a key, albeit not unique role, in their treatment. For example, in Southern Asia, 11.7% and 9.2% of the DALYs are due to Neuropsychiatric Disorders and Cardiovascular Diseases. These match the incidence of infectious diseases in this region. The incidence of these two causes combined is greater than infectious diseases in South-east Asia. The treatment of these diseases requires medicines that may also be hard to afford for impoverished households. But medicines are not the sole treatment to these conditions and the quality and quantity of medical services are also likely to play a determinant position.. But to the extent that they play a central role in the treatment of some of these diseases the reduced access to these due to high prices may play a key role in the high numbers above reported. This then suggests that just taking IPDs as sole indicator of health concerns as is regularly done in the literature may provide misleading results.

[33] Some of these conditions, it is important to remark, are more related to the person lifestyle such as alcoholism.

Table. 6. 2004 DALY and Revealed Incidence Indicator (RII) by cause and region

	Developed	South-eastern Europe	CIS	Northern Africa	Sub-Saharan Africa	Caribbean	Latin America	Eastern Asia	Southern Asia	South-eastern Asia	Western Asia	Oceania	Total
Infectous and parasitic diseases	**2%**	**2.1%**	**6%**	**8.6%**	**42.3%**	**16.7%**	**7.9%**	**6.2%**	**19.1%**	**16.5%**	**8%**	**24.37%**	**19.8%**
	0.10	0.11	0.30	0.43	2.14	0.84	0.40	0.31	0.96	0.83	0.40	1.23	
Respiratory infections	**1.1%**	**1.5%**	**2.6%**	**4.2%**	**11.4%**	**5.1%**	**3.4%**	**1.9%**	**7.7%**	**4.7%**	**5.5%**	**5.6%**	**6.4%**
	0.17	0.23	0.41	0.66	1.78	0.80	0.53	0.30	1.20	0.73	0.86	0.88	
Maternal conditions	**0.5%**	**0.4%**	**0.7%**	**2.9%**	**3.9%**	**2.5%**	**1.9%**	**0.9%**	**3.1%**	**2.9%**	**2%**	**3.6%**	**2.6%**
	0.19	0.15	0.27	1.12	1.50	0.96	0.73	0.35	1.19	1.12	0.77	1.38	
Perinatal conditions	**1.2%**	**1.9%**	**3.1%**	**9.1%**	**10%**	**6.4%**	**5.7%**	**5.4%**	**12%**	**6.2%**	**10.8%**	**10.3%**	**8.3%**
	0.14	0.23	0.37	1.10	1.20	0.77	0.69	0.65	1.45	0.75	1.30	1.24	
Nutritional Deficiencis	**0.6%**	**1.3%**	**1.4%**	**2.7%**	**3.1%**	**3%**	**2.1%**	**1.6%**	**3.2%**	**2.7%**	**3.6%**	**6.4%**	**2.5%**
	0.24	0.52	0.56	1.08	1.24	1.20	0.84	0.64	1.28	1.08	1.44	2.56	
Malignant Neoplasms	**15.3%**	**12.4%**	**7.3%**	**4.1%**	**1.6%**	**5.1%**	**6%**	**9.6%**	**2.8%**	**4.7%**	**4.4%**	**3%**	**5.1%**
	3.00	2.43	1.43	0.80	0.31	1.00	1.18	1.88	0.55	0.92	0.86	0.59	
Other neoplasms	**0.3%**	**0.2%**	**0.1%**	**0.5%**	**0.1%**	**0.2%**	**0.2%**	**0.1%**	**0.1%**	**0.1%**	**0.3%**	**0.1%**	**0.1%**
	3.00	2.00	1.00	5.00	1.00	2.00	2.00	1.00	1.00	1.00	3.00	1.00	
Diabetes mellitus	**2.8%**	**2%**	**1%**	**1.5%**	**0.6%**	**2.7%**	**2.7%**	**1.6%**	**0.9%**	**1.9%**	**1.4%**	**1.4%**	**1.3%**
	2.15	1.54	0.77	1.15	0.46	2.08	2.08	1.23	0.69	1.46	1.08	1.08	
Nutritional/endocrine disorders	**1.5%**	**0.6%**	**0.6%**	**1.2%**	**0.8%**	**1.7%**	**1.7%**	**0.6%**	**0.1%**	**0.6%**	**0.8%**	**0.8%**	**0.7%**
	2.14	0.86	0.86	1.71	1.14	2.43	2.43	0.86	0.14	0.86	1.14	1.14	
Neuropsychiatric disorders	**25.7%**	**18.4%**	**14.5%**	**16.7%**	**5.1%**	**16.5%**	**21.8%**	**18.5%**	**11.7%**	**13.3%**	**12.8%**	**10.1%**	**13.1%**
	1.96	1.40	1.11	1.27	0.39	1.26	1.66	1.41	0.89	1.02	0.98	0.77	
Sense organ disorders	**7.1%**	**5.8%**	**4%**	**8.8%**	**2.4%**	**4.5%**	**4.9%**	**10.3%**	**6%**	**7.2%**	**4.4%**	**3.1%**	**5.7%**
	1.25	1.02	0.70	1.54	0.42	0.79	0.86	1.81	1.05	1.26	0.77	0.54	
Cardiovascular diseases	**15.8%**	**30. 3%**	**27.1%**	**14%**	**3.8%**	**9.9%**	**9.1%**	**12.2%**	**9.2%**	**9.9%**	**12.3%**	**9.2%**	**9.9%**
	1.60	3.06	2.74	1.41	0.38	1.00	0.92	1.23	0.93	1.00	1.24	0.93	
Respiratory diseases	**5.9%**	**2.5%**	**2.4%**	**3.7%**	**1.9%**	**3.6%**	**5%**	**7.4%**	**3.4%**	**4%**	**3.5%**	**2.7%**	**3.9%**
	1.51	0.64	0.62	0.95	0.49	0.92	1.28	1.90	0.87	1.03	0.90	0.69	
Digestive diseases	**4%**	**4.4%**	**4.8%**	**4%**	**1.5%**	**2.9%**	**3.8%**	**3.2%**	**2.8%**	**3%**	**2.3%**	**3.1%**	**2.8%**
	1.43	1.57	1.71	1.43	0.54	1.04	1.36	1.14	1.00	1.07	0.82	1.11	
Diseases of the genitourinary system	**1%**	**0.9%**	**0.8%**	**1.9%**	**0.6%**	**0.9%**	**1.3%**	**1.3%**	**0.9%**	**1.3%**	**1.5%**	**1.2%**	**1%**
	1.00	0.90	0.80	1.90	0.60	0.90	1.30	1.30	0.90	1.30	1.50	1.20	
Skin diseases	**0.2%**	**0.2%**	**0.3%**	**0.4%**	**0.2%**	**0.4%**	**0.4%**	**0.2%**	**0.2%**	**0.4%**	**0.2%**	**0.5%**	**0.3%**
	0.67	0.67	1.00	1.33	0.67	1.33	1.33	0.67	0.67	1.33	0.67	1.67	
Musculoskeletal diseases	**4.4%**	**4.4%**	**2.7%**	**2.2%**	**0.6%**	**2.3%**	**2.6%**	**3.6%**	**1.5%**	**2.4%**	**2%**	**2.7%**	**2%**
	2.20	2.20	1.35	1.10	0.30	1.15	1.30	1.80	0.75	1.20	1.00	1.35	
Congenital abnormalities	**1.2%**	**1.1%**	**1.4%**	**2.5%**	**1.5%**	**1.6%**	**2.4%**	**1.2%**	**2%**	**1.3%**	**2.5%**	**2.4%**	**1.7%**
	0.71	0.65	0.82	1.47	0.88	0.94	1.41	0.71	1.18	0.76	1.47	1.41	
Oral diseases	**0.7%**	**0.7%**	**0.5%**	**1%**	**0.2%**	**1.1%**	**1.3%**	**0.5%**	**0.5%**	**0.7%**	**0.7%**	**0.4%**	**0.5%**
	1.40	1.40	1.00	2.00	0.40	2.20	2.60	1.00	1.00	1.40	1.40	0.80	
Unintentional injuries	**6%**	**6.8%**	**13.5%**	**8.5%**	**5.5%**	**9.1%**	**8%**	**11%**	**10.3%**	**13.2%**	**13.8%**	**6.7%**	**9.1%**
	0.66	0.75	1.48	0.93	0.60	1.00	0.88	1.21	1.13	1.45	1.52	0.74	
Intentional injuries	**2.9%**	**2.3%**	**5.2%**	**1.4%**	**2.9%**	**4%**	**7.8%**	**2.6%**	**2.4%**	**2.8%**	**7.3%**	**2.4%**	**3.2%**
	0.91	0.72	1.63	0.44	0.91	1.25	2.44	0.81	0.75	0.88	2.28	0.75	
Total DALY (in 000)	121 268	8 503	70 778	25 946	391 416	8 708	90 380	212 323	428 842	119 885	42 980	2 221	1 523 248

Source: Own elaboration based on WHO

In Table 7 we present DALY rates by regional groups for a more disaggregated selection of the infectious and parasitic diseases (IPDs). This gives us a more comprehensive picture of the causes of death and disability that affect the poorest countries in the World. To give a sense of the real magnitude and quantity of years of life lost to these diseases we report absolute figures. From the table we see that the highest incidence of death occurs in the Sub-Saharan African region followed by Southern Asia and then South-eastern Asia. Among the IPDs, Diarrhoeal is the cause with the largest death incidence followed by HIV, Tuberculosis and Malaria. But to the extent that the treatment of

Diarrhoeal diseases relies less on access to drugs and more on sanitation or rehydration therapy[34] one can infer that the impact of patents on this sector may be much reduced. Nevertheless, other infectious diseases such as HIV, Tuberculosis, Malaria and other Tropical diseases do require specific drugs that may be subject to patents.

The HIV/AIDS epidemic in Sub-Saharan Africa is noteworthy. Around two thirds of the incidence of this disease is in countries located in this region[35]. The case of Malaria is even more marked in this region but this may be driven by the specific geographical and climatic conditions which also need be taken into account. Where Tuberculosis is concerned, incidence is more widespread, again skewed towards Sub-Saharan Africa but also Southern Asia. This disease is one of particular interest as it is easily preventable with access to an appropriate vaccine (this in contrast with Malaria and HIV which have no such cures). This implies that a more effective way of preventing this disease should be possible by way of granting affordable access to this vaccine. But one must also consider broader issues of access beyond patenting which relate to distribution. This point then highlights the importance of access to adequate health care which may be beyond the realm of the provision of affordable medicines. To the extent that the TRIPs agreement recognises cases of national emergencies for compulsory licence provisions, the use of the DALY to capture these instances can be supported.

Table. 7. 2004 DALY (in millions) in Infectious and parasitic diseases by region

	Tuberculosis	Malaria	HIV/AIDS	Diarrhoeal diseases	Childhood-cluster diseases	Tropical cluster diseases	Meningitis	Other Infectuos and parasitic diseases	TOTAL
Developed	122	2	600	283	50	1	62	416	1,536
South-eastern Europe	65	0	15	22	3	0	2	27	135
CIS	1,525	3	951	976	19	6	79	306	3,865
Northern Africa	140	45	70	845	129	27	76	484	1,815
Sub-Saharan Africa	11,465	32,202	47,358	33,272	13,546	6,415	380	6,373	151,012
Caribbean	134	16	436	303	102	13	30	144	1,178
Latin America	751	74	1,350	2,174	133	519	59	850	5,910
Eastern Asia	3,859	27	679	3,921	557	9	393	1,891	11,337
Southern Asia	10,977	928	4,044	25,398	13,773	4,598	692	7,102	67,512
South-eastern Asia	4,864	528	2,952	3,629	1,597	471	207	2,351	16,599
Western Asia	251	45	29	1,833	271	37	82	345	2,893

Source: WHO

[34] UNICEF/WHO 2009 « Diarrhoea: Why children are still dying and what can be done"

[35] . We present in the annex, for further reference, the information in this table disaggregated by country

Notes: Other infectious and parasitic diseases includes Hepatitis, STDs excluding HIV, dengue, leprosy and intestinal nematode infections.

6. Combining the Analytical Criteria into a Composite Indicator

The indicators exposed in the previous section served the purpose of underlining the heterogeneity in the constraints that countries face in their application of patenting provisions for pharmaceuticals under the TRIPS agreement. Operationalising the application of SDT according to these constraints requires combining these indicators into a composite measure. We employ a composite indicator approach which aggregates ranked criteria according to a weighted structure and discuss both the methodological implications and the possible role of negotiations in shaping the selection of both the weights and the thresholds. We choose composite indicators because they serve as a good tool for summarising and combining data that come in different units. Additionally, using an aggregating technique that relies on rankings is useful because it is in the relative standing of countries in the constraints they face that we are ultimately interested in for the creation of an exclusion list. Alternative approaches involve the use of econometrics and one such study that uses econometric techniques to identify vulnerable countries is by the Commonwealth Secretariat (1999). They use a two-step estimation where output volatility is regressed against a series of independent variables. The estimated coefficients are then used as the weights for the calculation of a vulnerability index. The problem with such an approach is two-fold. First there may be issues with the estimation procedure itself, owing to either unobserved heterogeneity or the selection of countries that will affect the estimated coefficients, but ultimately the main problem is that it is a non-transparent methodology that will be hard to defend in the international arena. Going down the composite indicator route, despite its shortcomings, has the important advantage of being transparent and easily predictable.

In the creation of a composite index, we follow the recommendations of Lopez Gonzalez et al. (2011) where we use readily available international datasets to identify the different sets of constraints above outlined.

6.1 Method

Once the constraints that countries face in their implementation of TRIPs provisions have been outlined one need identify and combine the indicators that capture these constraints. We approach this using an aggregation technique that relies on rankings. Hence for each indicator we rank countries against each other, we then use the common ranking unit and apply sets of weights to create a composite indicator. Setting these weights can be somewhat arbitrary and hence it is suggested that these be the result of a negotiated procedure. This suggestion stands on the precedent of negotiated coefficients for the Swiss formula for developing country liberalisation. The particular structure of weights that we employ in this paper serve as an illustration; in particular, we set uniform weights across each constraint and then simulate changes to these to determine the sensitivity of the lists according to the weights chosen.

We first relate each constraint to its corresponding indicator. Taking the economic constraints first, which gauges the distributional implications and the competitiveness of the pharmaceutical sector we use the following indicators:

- Revealed Comparative Advantage (RCA) on pharmaceutical products using 2008 exports. Source UN Comtrade.
- Share of pharmaceutical products in total imports using 2008 imports. Source: UN Comtrade
- Share in World Purchasing Power Parity (PPP) GDP year 2008. Source: World Bank's World Development Indicators

To assess the degree of access to pharmaceutical products across countries (or the access constraints) we look at purchasing power and domestic supply capacity by way of the following indicators:

- GDP per capita (PPP) year 2008. Source: World Bank's World Development Indicators
- Grubel-Lloyd (X-M)/(X+M) for the year 2008. Source: UN Comtrade

Looking then at capacity constraints where implementation costs are being captured uses:

- Per capita total expenditure on health for the year 2008 (PPP). Source: WHO
- Population year 2008. Source: World Bank's World Development Indicators

Finally, the incidence of disease constraint is addressed by taking the simple average between the ranks obtained from the following indicators:

- DALYs per 100,000 people on Infectious and parasitic diseases (2004). Source: WHO
- DALYs per 100,000 people on rest of diseases and conditions (2004). Source: WHO

The DALY on the 'rest of diseases and conditions' is obtained by subtracting the number of DALYs due to infectious and parasitic diseases from the total number of DALYs. Therefore, the DALYs on the rest of diseases also contains the incidence of other conditions not directly related with the use of pharmaceutical and medicines such as injuries and deaths due to accidents or conflicts. It is possible to construct a more refined indicator that circumscribes to agents and diseases that can be prevented and treated by medicines. However, the incidence on the ranking is expected to be minimal.

For each constraint we use an average ranking score hence deriving a preliminary composite score across each constraint. Whilst it is already possible to introduce weights at this stage, we choose not to as we are interested in identifying not only the overall rankings in terms of all conditions, but also the countries that are most constrained by each of the conditions. Effectively, this method is analogous to placing an equal weighting to each of the indicators within a given constraint. One of the benefits of such an approach is that it allows us to subsume the weights to be chosen by a negotiated approach into a more compact form where these can be chosen according to a constraint rather than the more abstract indicator. Implicitly, we recommend that negotiations be made on the weights of the constraints rather than those of the indicators themselves.

We then need determine the geographical applicability of such a procedure. We suggest that this be applied predominantly across the self-selecting 'developing country' grouping. Developed countries are already well defined as are the LDCs. The problem in the application of differential treatment mainly arises through the heterogeneity of the developing grouping where richer countries like Korea are placed on an equal footing with poorer countries such as Kenya. The desirability of such an approach and a discussion of this heterogeneity is provided in Lopez Gonzalez et al (2011). Applying

this procedure to developing countries only is likely to be contentious, but it is justified on the basis that some countries are better equipped to implement new WTO legislations than others and that the analytical criteria chosen should be able to differentiate across these. But the method that we propose is equally applicable to all countries within the WTO as the calculation of rankings is independent of the amount of countries that are considered. Despite our recommendation that this procedure be applied to the developing country grouping alone, we present results where we include the LDCs too. This is to ensure a certain degree of coherence across the analysis and to show that even when the criteria are applied across all non-developed countries the lists that are created generate results coherent with the exclusion of LDCs from general WTO principles.

The choice of weights will then be pivotal in the creation of a final list of countries. The heterogeneity present in the developing country group will manifest itself through the rankings according to each constraint, hence giving more weighting to one over the other is likely to produce somewhat different lists. Clearly, under a negotiated procedure, countries most afflicted by a given constraint are likely to lobby stronger for it to receive a higher weighting in the final decision. Some countries will have important pharmaceutical production and trade, but will be afflicted by higher degrees of disease incidence. These will negotiate for stronger weights on the latter rather than the former. Our method circumvents the multidimensionality of the issue by using information on all constraints, but the weighting will remain subject to negotiations and hence, to a certain extent to a degree or arbitrariness. Despite the possibility of reducing this arbitrariness of selection of weights through econometric techniques such as in Commonwealth (1999), this comes at the cost of increasing complexity and reducing the transparency of the process. In addition, the use of such techniques is unlikely to be accepted as previous attempts have demonstrated[36].

6.2 Results

Using the above methodology, we present some preliminary results on what the lists could look like given certain assumptions on the weighting structure. We conduct a sensitivity analysis to illustrate how the variation in the weights chosen affects the final outcome. Before we turn to this we look at the correlation across the different indicators. If these are found to be collinear, then the weighting structure is likely to matter very little. A high degree of correlation suggests the use of one indicator rather than a selection of indicators thus reducing frictions arising through negotiated processes and on the basis that it would provide sufficient information on country standings. Table 8 shows that indicators across the different constraints do not have high degrees of correlation and hence variance across these can be exploited for the selection procedure. Variance within constraints is equally interesting. For the case of economic constraints we see that the RCA and the share of exports are collinear which suggests that we can drop one of these indicators without loss of generality[37]. Other than the health indicators, the within group correlation seems to be low suggesting that we are

[36] The weights assigned to the unit values obtained from the databases COMTRADE and WTO IDB to transform non-ad valorem tariff into ad-valorem equivalents for both applied and bound tariffs in the Agriculture negotiations in the Doha round were subject of negotiations and not the result of any econometric analysis on the characteristics of the two databases used.

[37] WE drop the share of export in the creation of the lists

capturing different aspects of each of the identified constraints. The between constraint correlations also provide important information. If we take the RCA measure and the Normalised Trade Balance measure we see a strong correlation. This is expected as competitive countries should be those that are better off in their trade balance. Another notable correlation is that of per capita expenditure on health and GDP per capita and suggests that some of the capacity constraints and the access ones may be determined simultaneously. The negative correlation between the health outcomes and the other constraints suggests that access, capacity and economic constraints can affect health outcomes. What is interesting is that there is a positive relation between health outcomes and the share of pharmaceutical imports in total trade. This then points to access to pharmaceuticals via imports as a contributing factor to improved health outcomes. Although these correlations do not imply causation and the relation might be spurious it remains insightful to look at these and derive some prima facie observations on the co-movement of the identified variables. In particular on how these may affect the health outcomes variables.

Table 8: Correlation Coefficients across selected indicators

		Economic				**Access**		**Capacity**		**Health**	
		RCA	*Share in total exports*	*Share in imports*	*Share of world GDP*	*GDP per capita*	*X-M/(X+M)*	*expenditure on health (p.cap)*	*Population*	*DALY - IPD*	*DALY - Rest*
Economic	*RCA*	1.00									
	Share in total exports	1.00	1.00								
	Share in imports	-0.00	-0.00	1.00							
	Share of world GDP	0.08	0.08	-0.18	1.00						
Access	*GDP per capita*	0.08	0.08	-0.27	0.04	1.00					
	X-M/(X+M)	0.72	0.72	-0.20	0.40	0.05	1.00				
Capacity	*expenditure on health (p.cap)*	0.31	0.32	-0.24	0.06	0.83	0.27	1.00			
	Population	0.12	0.12	- 0.18	0.92	-0.07	0.44	-0.09	1.00		
Health	*DALY – IPD*	-0.26	-0.26	0.40	-0.17	-0.37	-0.31	- 0.47	-0.09	1.00	
	DALY – Rest	-0.26	-0.25	0.40	-0.14	-0.47	-0.28	- 0.55	-0.04	0.79	1.00

6.2.1 Arbitrary or negotiated weighting structure

As a first exercise, we provide a list of 25 countries, in Table 9, where we apply different sets of weights across the different constraints (we hold constant a uniform weighting structure within these). These lists serve to identify the countries that may be considered for graduation from SDT provisions in the pharmaceutical sector. In the first column we use a uniformly weighted structure. In the remaining columns, a higher weight (0.7) is assigned to the lead constraint in the title and 0.1 to the others. Hence for the 'Higher Economic' column, the economic constraints receive a weight of 70% and the remaining constraints one of 10% in the composite indicator. For expositional purposes we present only the top 25 countries, but the entire list can be found in the appendix (Table A1).

Table 9 Composite Index under different weights on constraints

Equal Weights	Higher Economic	Higher Access to pharmaceuticals	Higher Capacity constraints	Incidence of diseases

Rep. Korea	11.7	China	13.5	Israel	7.7	Rep. Korea	10.4	Israel	7.7
Israel	15.4	Rep. Korea	15.9	Rep. Korea	12.2	Mexico	14.0	Rep. Korea	8.3
Mexico	15.5	India	16.0	Argentina	13.0	Argentina	14.5	Chile	12.0
Argentina	17.5	Mexico	19.2	Mexico	13.7	Brazil	17.3	UAE	12.5
Chile	19.4	Israel	22.8	Croatia	17.2	Turkey	19.3	Mexico	15.2
China	20.8	Malaysia	23.6	Chile	18.3	Chile	21.6	Costa Rica	15.5
Turkey	22.7	Argentina	24.2	Uruguay	19.3	Israel	23.6	Qatar	17.0
Croatia	24.2	Indonesia	25.3	Costa Rica	20.6	China	24.5	Oman	17.1
Malaysia	24.4	Chile	25.8	Turkey	22.3	Malaysia	25.7	Croatia	18.1
UAE	26.0	Thailand	27.3	Macedonia	23.0	South Africa	25.7	Argentina	18.4
Costa Rica	26.8	Turkey	28.7	Malaysia	23.0	Saudi Arabia	26.3	Bahrain	19.0
Brazil	27.5	Morocco	29.5	Brazil	24.2	Colombia	27.9	China	20.3
Uruguay	28.0	Uruguay	29.8	China	24.8	Venezuela	28.7	Turkey	20.5
Colombia	30.8	Pakistan	30.0	Colombia	24.9	Egypt	30.7	Jordan	22.2
Oman	31.6	Croatia	30.5	UAE	26.6	Croatia	31.0	Malaysia	25.4
Macedonia	32.6	Egypt	30.7	Oman	28.2	Thailand	31.6	Macedonia	25.7
Jordan	32.9	UAE	30.8	Jordan	28.8	Ukraine	32.4	Saudi Arabia	25.7
Egypt	33.1	Brazil	31.0	Mauritius	30.5	UAE	34.1	Uruguay	27.7
Thailand	33.2	Colombia	33.9	Thailand	31.3	Costa Rica	34.4	Tunisia	28.2
Saudi Arabia	33.5	South Africa	34.3	South Africa	32.9	Peru	34.8	Saint Lucia	28.3
Qatar	34.3	Paraguay	35.1	Peru	33.0	Uruguay	35.2	Venezuela	29.3
Morocco	34.3	Oman	36.2	Venezuela	33.8	India	36.4	Panama	29.4
Venezuela	35.1	Bangladesh	36.4	India	34.6	Viet Nam	36.8	Georgia	29.5
India	35.5	Philippines	36.4	Indonesia	34.9	Morocco	37.1	Albania	30.6
Peru	35.9	Costa Rica	36.5	Egypt	34.9	Indonesia	39.4	Morocco	32.3

Despite the weights and cut-off points being set subjectively, the results obtained already point to some important issues in the implementation of such an approach. First to be noted is that there appears to be a certain degree of homogeneity across the lists where 12 countries appear in the top 25 irrespective of the weights used. Table 10 identifies these countries where the column with the heading '5' identifies the countries that are in the top 25 in the 5 instances of Table 8. Taking the example of Korea and Israel, we see that not only are these countries in all lists, but they are in fact in the top places in these classifications. This category of country, which would also include the likes of Mexico, Argentina, Chile and Turkey are those where, on the basis of our methodology, a re-classification and hence re-incorporation into the general provisions of the agreement can be supported. These should not receive differential treatment in TRIPs provisions. But whilst, and under the assumption that this methodology is ratified, there will be little dispute about this selection of countries, it is in the consideration of the countries that appear near the bottom of the table, hence near the threshold, or in some lists but not others, that complications will arise in the selection procedure. Taking the example of Brazil which appears in all but the incidence of disease column, one need carefully consider how such a country is to be treated with respect to TRIPs commitments. Would there be enough support to leaving Brazil out of SDT provisions on the basis of the other constraints, or should weights be geared to disease outcomes rather than economic considerations? These are important issues for negotiation, but a discussion of these is beyond the scope of this paper.

Table 10: Count of appearances in Table 9

Times in top 25 lists with different weights				
5	4	3	2	1
Argentina Chile	Brazil Colombia	Saudi Arabia South Africa	El Salvador Indonesia	Albania Bahrain

China	Egypt	Tunisia	Oman	Georgia
Costa Rica	India	UAE	Pakistan	Peru
Croatia	Jordan	Venezuela	Paraguay	Qatar
Israel	Macedonia			St Lucia
Korea	Panama			Ukraine
Malaysia	Thailand			Vietnam
Mexico				
Morrocco				
Turkey				
Uruguay				

The case of India presents similar challenges to those of Brazil. Having a strong pharmaceutical industry, higher weights on economic constraint (where it ranks third after China and Korea) imply graduation into general provisions, however its very low position in the other constraints suggest that India could be exempted from the general provisions of the TRIPS agreement. India's sensitivity to the chosen threshold is important too. If we had chosen this to be the top 20 countries rather than the top 25, India would have only appeared in the list of excluded countries on economic grounds. Its low GDP per capita and expenditure on health coupled with a high incidence of disease would suggest that India would not be graduated on the basis of a threshold set at 20 countries. The case of India serves to illustrate the broader issues that arise from the selection of both weights and thresholds.

Similar to the determination of the weights, there are different procedures that can be invoked to determine the thresholds in addition to the arbitrary top 20-25 country procedure discussed above. One can use statistical methods, once the weights have been agreed, and exclude countries in the top deciles of the composite score. The outcomes of this procedure will then depend not only on a country's performance but also on the performance of the rest of the countries or the relative position in the distribution. But this threshold continues being arbitrary and not related to any observable criteria. One can also have a threshold that is determined through other observable criteria. A first alternative in this line is to use a score threshold. If a country is below a given score then it can be considered for graduation into the general agreement provisions. However, given the composite nature of the indicators, the setting of this threshold number would also be devoid of objectivity. In addition, rankings, being ordinal in nature would be valid in relative terms but lack interpretational value hence will be hard to justify to a country that is near the threshold and asked to graduate because they score under say 30.

It is possible then to choose the threshold in terms of other criteria. One possibility is selecting countries that would be exempted from general provisions on the basis of a cumulative participation in world trade or in pharmaceutical trade. In Table 11 we present such a procedure where the selection is made on the basis of a threshold of a cumulative share in either total or pharmaceutical trade (or indeed on both). Here the negotiated threshold would be one where countries agree on an acceptable amount of trade that can be excluded from general provisions. Let us then consider that accord is reached on a threshold that exempts countries which, ranked according to the list, occupy only 5% of trade in Pharmaceuticals. Table 11 shows that under such threshold criteria and for an equal weights approach (first column), the cut-off point would stand after Venezuela. This would leave India as a country which holds its rights to receive differential treatment in TRIPs provisions.

What is interesting with such an approach is that it is not subject to a choice of countries that can benefit from derogations, but rather based on an acceptable part of the market that can be excluded from general provisions.

Despite this approach being interesting, one can easily argue that there is a certain level of endogeneity in the sense that countries with lax implementation of TRIPs provisions are likely to be engaged in the production of generic pharmaceuticals rather than engaging in trade. One can then take a similar threshold but base it on the cumulative share of world trade. The negotiated 'exclusion zone' would be something akin to a total market share of a certain value. For illustrative purposes we take this market share to be 20% of world import demand which can be excluded from the TRIPs agreement. Under such a threshold 20% of the world trade market receives SDT in TRIPs provisions. Here the cut-off point in the first column will stand between Croatia and Malaysia.

This analytical criteria based approach to the selection of graduating countries is not without its problems either. Trade based measures can be volatile particularly in their compilation in more recent years. This means that countries near the threshold would graduate in and out of the provisions regularly. To avoid such instances, one can propose setting the trade based thresholds on averages across a selection of years. Determining graduation into and out of the commitments in TRIPs provisions would then be subject to breaching the established ceiling during a pre established period of time. This is similar to the technique that the EU uses in determining graduation into and out of preferential status in the GSP. Additionally, and as can be seen from Table 11, the cut-off points may occur in between a given country's trade, hence a decision need be made if countries where these instances occur are to be graduated in or out of the provisions. Let us consider that the negotiated approach yields a cut off point of 10% of pharmaceutical trade and an equally weighted structure across the indicators (column 1). The case of Turkey becomes ambiguous as the greater share of its trade is within the negotiated limit of exclusion but there is a significant part that lies outside this limit. One need then think very carefully on how to treat such instances.

Table 11. Ranked countries and cumulative share of trade in pharmaceuticals and in total trade

Equal Weights			Higher Economic			Higher Access to pharma			Higher Capacity constraints			Incidence of diseases		
	ph	tot		ph	tot		ph	tot		ph	tot		ph	tot
Rep. Korea	83.6	63.0	China	85.4	70.0	Israel	83.9	59.8	Rep. Korea	83.6	63.0	Israel	83.9	59.8
Israel	84.8	63.5	Rep. Korea	86.3	73.8	Rep. Korea	84.8	63.5	Mexico	84.8	65.6	Rep. Korea	84.8	63.5
Mexico	86.1	66.1	India	87.9	75.9	Argentina	85.2	64.1	Argentina	85.2	66.1	Chile	85.0	64.1
Argentina	86.5	66.7	Mexico	89.1	78.6	Mexico	86.5	66.7	Brazil	86.4	67.8	UAE	85.2	65.6
Chile	86.6	67.2	Israel	90.4	79.1	Croatia	86.7	66.9	Turkey	87.5	69.2	Mexico	86.5	68.2
China	89.4	78.0	Malaysia	90.6	80.7	Chile	86.9	67.4	Chile	87.7	69.8	Costa Rica	86.6	68.3
Turkey	90.5	79.5	Argentina	91.0	81.2	Uruguay	86.9	67.5	Israel	88.9	70.3	Qatar	86.7	68.7
Croatia	90.7	79.7	Indonesia	91.2	82.4	Costa Rica	87.1	67.6	China	91.7	81.1	Oman	86.7	68.9
Malaysia	90.9	81.3	Chile	91.4	82.9	Turkey	88.2	69.1	Malaysia	91.9	82.7	Croatia	86.9	69.1
UAE	91.2	82.7	Thailand	91.7	84.5	Macedonia	88.2	69.1	South Africa	92.3	83.4	Argentina	87.4	69.7
Costa Rica	91.3	82.9	Turkey	92.8	85.9	Malaysia	88.4	70.7	Saudi Arabia	92.7	85.2	Bahrain	87.4	69.8
Brazil	92.6	84.5	Morocco	92.9	86.2	Brazil	89.6	72.3	Colombia	93.0	85.6	China	90.1	80.6
Uruguay	92.6	84.5	Uruguay	92.9	86.3	China	92.4	83.1	Venezuela	93.4	86.1	Turkey	91.2	82.0
Colombia	92.9	84.9	Pakistan	93.1	86.5	Colombia	92.7	83.4	Egypt	93.6	86.5	Jordan	91.4	82.1
Oman	93.0	85.1	Croatia	93.3	86.7	UAE	93.0	84.9	Croatia	93.9	86.7	Malaysia	91.6	83.7
Macedoni	93.0	85.2	Egypt	93.6	87.1	Oman	93.0	85.2	Thailand	94.2	88.2	Macedon	91.6	83.7

Equal Weights			Higher Economic			Higher Access to pharma			Higher Capacity constraints			Incidence of diseases		
	ph	tot		ph	tot		ph	tot		ph	tot		ph	tot
a												ia		
Jordan	93.2	85.3	UAE	93.8	88.6	Jordan	93.2	85.3	Ukraine	94.8	88.9	Saudi Arabia	92.0	85.5
Egypt	93.5	85.6	Brazil	95.0	90.2	Mauritius	93.2	85.3	UAE	95.0	90.4	Uruguay	92.1	85.6
Thailand	93.8	87.1	Colombia	95.3	90.5	Thailand	93.6	86.8	Costa Rica	95.2	90.5	Tunisia	92.2	85.8
Saudi Arabia	94.2	89.0	South Africa	95.7	91.2	South Africa	93.9	87.5	Peru	95.3	90.8	Saint Lucia	92.2	85.8
Qatar	94.2	89.3	Paraguay	95.8	91.3	Peru	94.0	87.8	Uruguay	95.3	90.8	Venezuela	92.5	86.4
Morocco	94.3	89.6	Oman	95.8	91.5	Venezuela	94.4	88.4	India	96.9	93.0	Panama	92.6	86.4
Venezuela	94.7	90.2	Bangladesh	95.8	91.7	India	96.0	90.5	Viet Nam	97.1	93.6	Georgia	92.7	86.5
India	96.3	92.4	Philippines	96.0	92.2	Indonesia	96.1	91.7	Morocco	97.2	93.9	Albania	92.7	86.5
Peru	96.4	92.6	Costa Rica	96.2	92.3	Egypt	96.4	92.1	Indonesia	97.4	95.1	Morocco	92.8	86.8

Source: Own

Notes: the share of developed countries in pharmaceutical trade, with the help of table (put reference to table presented before), is around 78%. On the other hand, the share of developed countries in total trade is around 49%

We do not preclude the use of other indicators in setting the thresholds. In fact, some of the same indicators used in calculating the rankings could serve the purpose of setting the thresholds. This is because in calculating these rankings we use the ordinal nature and not the cardinal properties which could serve to inform the thresholds. One could also use the share of world GDP to determine the size of the acceptable excluded market.

7. Conclusions

In this paper we have shown how one could go about creating a system where SDT is made contingent on a set of analytical criteria which are grounded on the identification of constraints in meeting the demands of the international system. Our results indicate that the use of composite indicators and subsequent rankings can serve to evaluate the desirability of implementing WTO TRIPs commitments. In the process we discuss the role of negotiations in setting the weights of each constraint and the thresholds that delimit the applicability of SDT for the TRIPs agreement. Our results suggest that there are countries classified within the 'developing country' grouping that may have surpassed the general constraints that make enforcement undesirable. This implicitly recognises that there are other sets of countries within this grouping that face mitigating circumstances which make the implementation of TRIPs commitments objectionable. Instead of fixed time-delayed enforcement of WTO TRIPs provisions, we propose the use of graduating thresholds to determine countries that should be streamlined into the general provisions of the TRIPs agreement and those that should not.

However the principle of graduation needs careful consideration. Primarily, negotiations on the applied thresholds (as well as the weighting structure) are likely to be contentious given what is at stake. Additionally, one need consider that even for countries at the top end of the classification, constraints in implementing TRIPS commitments will remain as the case of Brazil shows. Countries that are close to the negotiated thresholds will also need to receive special considerations too. The assessment of the outlined constraints must be carried out periodically and graduation should be based on a breach of the thresholds during an established period of time. This will ensure that

countries near the threshold do not graduate or de-graduate at each assessment. These countries should also begin to receive assistance in view of upgrading their capacity to deal with the new provisions that graduation bring into force. Similarly, special attention need also be given to the existence of volatile economic cycles and catastrophic health pandemics. To the extent that these can be captured through similar sets of indicators, they also need to feed into the provision of differential treatment.

The contribution of this paper is not limited to the case of SDT in WTO TRIPs commitments as the method can be generalised to other WTO provisions. The methodological foundations, following the recommendations of Lopez Gonzalez et al. (2011), suggest that any award of SDT need be primarily based on the identification of the constraints and the distributional implications that enforcement of WTO provisions imply. These then need be associated to a set of observable criteria which need be combined to capture the prevalence of the constraints across countries. Using weights and thresholds to create a composite indicator, we suggest that such a method is desirable in providing a more targeted and needs-based approach to SDT. The transparency and predictability of this simple approach makes for a more realistic implementation that an approach based on econometric estimation.

But this approach is not without its shortcomings. It requires that countries accept sets of common indicators to be used to capture other identified and agreed upon constraints. It also adds more negotiating issues to an already over-burdened negotiating table and pre-supposes that accord will be reached. However, in light of the current deadlock in the negotiating process, such an approach to SDT may offer desirable flexibilities and hence help shape a new system that is more development friendly.

Bibliography

Arndt, C., & Lewis, J. D. (2001). The HIV/AIDS pandemic in South Africa: sectoral impacs and unemployment. *Journal of International Development , 13* (4), 427-449.

Attaran, A. (2004). How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries. *Health Affairs , 23* (3), 155-166.

Collins-Chase, C. T. (2008). The Case Against TRIPS-plus Protection in Developing Countries facing AIDS Epidemics. *University of Pennsylvania Journal of International Law* .

Cottier, T. (2006). From progressive liberalisation to progressive regulation in WTO law. *Journal of International Economic Law* , 1-43.

Cottier, T. (1998). The protection of generic resources and traditional knowledge: towards more specific rights and obligations in world trade law. *Journal of International Economic Law , 1* (4), 555-584.

Day, M. (2006). Half a Million Children a yer die of AIDS through lack of drugs. *BMJ* .

Deardorff, A. V. (1990). Should Patent Protection Be Extended to All Developing Countries. *The World Economy , 13* (4), 497-508.

Deardorff, A. (1992). Welfare effects of global patent protection. *Economica , 59*, 35-51.

Freire, S. (2004). Impact of HIV/AIDS on Saving Behaviour in South Africa. *Forum Paper.* Somerset West: African Development and Poverty Reduction: The Macro-Micro Linkage.

Grabowsky, H. G. (2002). Patents, innovation and access to new pharmaceuticals. *Journal of International Economic Law , 5* (4), 849-860.

Hoeckman, B., Michalopoulos, C., & Winters, L. A. (2003). Special and differential treatment in the WTO after Cancun. *The World Economy , 27* (4), 481-506.

Hoen, E. (2002). TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha. *Chicago Journal of International Law , 3* (1), 27-46.

Kleck, A., & Low, P. (2004). *Special and differential treatment in the WTO: Why, when and how?* Geneva: Economic Research and Statistics Division, WTO.

Lahouel, M., & Maskus, K. E. (1999). Competition Policy and Intellectual Property Rights in Developing Countries: Interests in Unilateral Initiatives and a WTO Agreement. *The WTO/World Bank Conference on Developing Countries' in a Millenium Round.* Geneva: WTO Secretariat, Centre William Rappard.

Lall, S., & Albaladejo, M. (2002). *Indicators of the Relative Importance of IPRs in Developing Countries.* QEH .

Lanjouw, J. O. (2001). A Patent Policy Proposal for Global Diseases. *Annual World Bank Conferences on Development Economics.* Washington, DC: World Bank and Oxford University Press.

Lybbert, T. J. (2002). On assessing the cost of TRIPS implementation. *World Trade Review , 1* (3), 309-321.

Lopez Gonzalez, J., Mendez Parra, M., and Holmes, P. (2011), Towards a New Age in Special and Differential Treatment, (mimeo)

Maskus, K. E. (2000). *Intellectual Property Rights in the Global Economy.* Washington, DC: Institute for International Economics.

Maskus, K. E., & Chen, Y. (2004). Vertical Price Control and Parallel Imports: Theory and Evidence. *Review of International Economics , 12* (4), 551-570.

Medecins Sans Frontieres. (2005). *Untangling the web of price reductions: a princing guide for the purchase of ARVs for developing countries.*

Michalopoulos, C. (2000). *Trade and development in the GATT and WTO: The role of special and differential treatment for developing countries.* World Bank.

Nogues, J. J. (1993). Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries. *The Developing Economies , XXXI* (1), 24-53.

Oxfam. (2001). *WTO Patent Rules and Access to Medicines: The pressure Mounts.* Oxfam Briefing Papers 01.

Stevens, C. (2002). *The future of SDT for developing countries in the WTO.* Sussex: Institute for Development Studies.

Sykes, A. O. (2002). TRIPS, Pharmaceuticals, Developing Countries and the Doha "Solution". *John M. Olin Law & Economics Working Paper No. 140* .

Troullier, P., Olliaro, P., Torreele, E., Orbinski, J., Laing, R., & Ford, N. (2002). Drug development for neglected diseases: a deficient market and a public-health policy failure. *The Lancet , 359*, 2188-2194.

Vicente, W. S. (1998). A Questionable Victory for Coerced Argentine Pharmaceutical Patent Legislation. *University of Pennsylvania Journal of International Economics* .

Watal, J. (2000). Access to Essential Medicines in Developing Countries: Does WTO TRIPS Agreement Hinder it? *Technology and Innovation Discussion Paper* .

Watal, J. (2000). Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement. *The World Economy , 23* (5), 733-752.

World Bank. (2001). *Intellectual property: balancing incentives with competitive access.* Washington, DC.: Global Economic Prospects.

Annex

Table A1. Composite Ranking under different weights

Equal Weights		Higher Economic		Higher Access to pharma		Higher Capacity constraints		Incidence of diseases	
Republic of Korea	11.7	China	13.5	Israel	7.7	Republic of Korea	10.4	Israel	7.7
Israel	15.4	Korea	15.9	Korea	12.2	Mexico	14.0	Korea	8.3
Mexico	15.5	India	16.0	Argentina	13.0	Argentina	14.5	Chile	12.0
Argentina	17.5	Mexico	19.2	Mexico	13.7	Brazil	17.3	UAE	12.5
Chile	19.4	Israel	22.8	Croatia	17.2	Turkey	19.3	Mexico	15.2
China	20.8	Malaysia	23.6	Chile	18.3	Chile	21.6	Costa Rica	15.5
Turkey	22.7	Argentina	24.2	Uruguay	19.3	Israel	23.6	Qatar	17.0
Croatia	24.2	Indonesia	25.3	Costa Rica	20.6	China	24.5	Oman	17.1
Malaysia	24.4	Chile	25.8	Turkey	22.3	Malaysia	25.7	Croatia	18.1
UAE	26.0	Thailand	27.3	Macedonia	23.0	South Africa	25.7	Argentina	18.4
Costa Rica	26.8	Turkey	28.7	Malaysia	23.0	Saudi Arabia	26.3	Bahrain	19.0
Brazil	27.5	Morocco	29.5	Brazil	24.2	Colombia	27.9	China	20.3
Uruguay	28.0	Uruguay	29.8	China	24.8	Venezuela	28.7	Turkey	20.5
Colombia	30.8	Pakistan	30.0	Colombia	24.9	Egypt	30.7	Jordan	22.2
Oman	31.6	Croatia	30.5	UAE	26.6	Croatia	31.0	Malaysia	25.4
Macedonia	32.6	Egypt	30.7	Oman	28.2	Thailand	31.6	Macedonia	25.7
Jordan	32.9	UAE	30.8	Jordan	28.8	Ukraine	32.4	Saudi Arabia	25.7
Egypt	33.1	Brazil	31.0	Mauritius	30.5	UAE	34.1	Uruguay	27.7
Thailand	33.2	Colombia	33.9	Thailand	31.3	Costa Rica	34.4	Tunisia	28.2
Saudi Arabia	33.5	South Africa	34.3	South Africa	32.9	Peru	34.8	Saint Lucia	28.3
Qatar	34.3	Paraguay	35.1	Peru	33.0	Uruguay	35.2	Venezuela	29.3
Morocco	34.3	Oman	36.2	Venezuela	33.8	India	36.4	Panama	29.4
Venezuela	35.1	Bangladesh	36.4	India	34.6	Viet Nam	36.8	Georgia	29.5
India	35.5	Philippines	36.4	Indonesia	34.9	Morocco	37.1	Albania	30.6
Peru	35.9	Costa Rica	36.5	Egypt	34.9	Indonesia	39.4	Morocco	32.3
Tunisia	36.0	Peru	37.2	El Salvador	35.0	Tunisia	39.6	Mauritius	34.7
Panama	37.4	Jordan	37.2	Panama	37.2	Philippines	40.4	Viet Nam	34.7
Indonesia	37.6	Saudi Arabia	37.6	Tunisia	37.5	Qatar	40.7	Paraguay	35.8
Bahrain	37.8	Macedonia	37.7	Paraguay	37.6	Ecuador	40.9	Colombia	36.3
South Africa	38.7	Viet Nam	38.0	Guatemala	38.2	Lebanon	41.4	Antigua and Barbuda	36.3
Paraguay	39.2	Tunisia	38.8	Morocco	38.3	Panama	41.7	Egypt	36.4
Viet Nam	39.4	Qatar	39.9	Qatar	39.5	Pakistan	43.4	Lebanon	37.2
Mauritius	40.1	Dominican Republic	40.9	Dominican Republic	39.7	Jordan	43.5	Brazil	37.4
Ukraine	42.0	Panama	41.4	Fiji	40.5	Dominican Republic	43.6	Dominica	38.0
El Salvador	42.4	Guatemala	41.5	Bahrain	40.6	Guatemala	43.6	Peru	38.7
Pakistan	42.4	El Salvador	42.2	Pakistan	41.3	Macedonia	44.3	Jamaica	40.6
Philippines	42.5	Mauritius	42.5	Botswana	41.6	Oman	44.7	Armenia	41.4
Dominican Republic	43.6	Ukraine	43.0	Ecuador	42.4	Bahrain	45.7	Ecuador	41.5
Guatemala	43.6	Bahrain	45.9	Ukraine	43.2	Nigeria	46.2	Thailand	42.7
Georgia	43.8	Kenya	46.0	Saudi Arabia	44.3	Trinidad and Tobago	47.8	Fiji	42.9
Ecuador	43.8	Nigeria	46.3	Georgia	45.7	El Salvador	47.9	Saint Kitts and Nevis	43.5
Lebanon	44.1	Sri Lanka	46.5	Bangladesh	46.2	Sri Lanka	48.2	Moldova	43.6
Saint Lucia	44.5	Saint Lucia	47.6	Philippines	47.0	Paraguay	48.4	El Salvador	44.6
Bangladesh	47.9	Fiji	48.2	Trinidad and Tobago	47.2	Georgia	50.5	Philippines	46.1

Equal Weights		Higher Economic		Higher Access to pharma		Higher Capacity constraints		Incidence of diseases	
Trinidad and Tobago	48.1	Venezuela	48.4	Saint Lucia	47.2	Bangladesh	50.7	Nicaragua	46.9
Albania	48.7	Botswana	49.0	Bolivia	47.6	Albania	51.9	Grenada	47.0
Fiji	49.6	Trinidad and Tobago	49.3	Lebanon	48.0	Botswana	52.4	Cape Verde	47.2
Sri Lanka	50.7	Georgia	49.3	Viet Nam	48.2	Mauritius	53.0	Trinidad and Tobago	48.4
Armenia	52.5	Lebanon	50.1	Swaziland	53.0	Ghana	53.1	Namibia	49.4
Botswana	53.0	Ecuador	50.3	Kenya	53.7	Kenya	53.7	Ukraine	49.5
Republic of Moldova	53.5	Ghana	50.5	Namibia	53.9	Bolivia	54.5	Dominican Republic	50.5
Bolivia	53.8	Angola	51.5	Armenia	54.0	Saint Lucia	55.0	Indonesia	51.1
Antigua and Barbuda	54.0	Senegal	52.4	Saint Kitts and Nevis	55.2	Angola	55.1	Sri Lanka	51.2
Jamaica	54.3	Tanzania	52.6	Antigua and Barbuda	55.2	Antigua and Barbuda	55.8	Guatemala	51.4
Kenya	55.4	Bolivia	52.7	Ghana	56.1	Honduras	56.7	Saint Vincent and the Grenadines	52.3
Saint Kitts and Nevis	55.5	Albania	53.3	Moldova	56.2	Uganda	56.9	Honduras	53.1
Ghana	56.2	Armenia	53.8	Papua New Guinea	56.8	Saint Kitts and Nevis	57.3	Belize	53.9
Namibia	56.8	Jamaica	55.1	Sri Lanka	56.9	Moldova	57.4	India	55.0
Honduras	57.6	Honduras	56.7	Angola	57.8	Cambodia	58.7	Pakistan	55.1
Nigeria	57.7	Moldova	56.8	Nigeria	58.5	Jamaica	58.9	Mongolia	55.2
Grenada	58.1	Papua New Guinea	58.3	Grenada	59.0	Nicaragua	59.2	Maldives	55.2
Dominica	59.7	Nepal	59.1	Albania	59.1	Namibia	59.6	Suriname	57.5
Nicaragua	61.0	Cambodia	61.6	Saint Vincent and the Grenadines	59.5	Tanzania	59.7	Bangladesh	58.5
Suriname	61.3	Suriname	62.7	Gabon	59.8	Cameroon	60.4	Kyrgyzstan	60.1
Papua New Guinea	61.6	Djibouti	63.4	Dominica	61.4	Gabon	60.4	Bolivia	60.2
Senegal	62.4	Mongolia	63.9	Congo	61.8	Armenia	60.9	South Africa	62.0
Angola	62.6	Uganda	64.2	Cape Verde	62.2	Senegal	61.0	Papua New Guinea	63.7
Maldives	63.1	Namibia	64.3	Suriname	62.3	Nepal	61.8	Ghana	65.1
Mongolia	63.8	Grenada	64.7	Jamaica	62.5	Grenada	62.0	Gabon	65.5
Saint Vincent and the Grenadines	63.9	Haiti	65.5	Senegal	63.7	Maldives	62.4	Guyana	68.3
Cape Verde	64.0	Nicaragua	65.8	Honduras	64.2	Suriname	62.6	Kenya	68.4
Gabon	64.8	Saint Kitts and Nevis	66.0	Djibouti	66.0	Dominica	64.1	Nepal	68.7
Belize	65.0	Côte d'Ivoire	66.1	Mongolia	66.0	Kyrgyzstan	65.5	Botswana	68.9
Nepal	65.1	Swaziland	66.4	Belize	66.2	Côte d'Ivoire	65.7	Lesotho	69.3
Tanzania	65.9	DR Congo	67.0	Chad	66.2	DR Congo	66.1	Congo	69.6
Swaziland	66.5	Madagascar	67.4	Maldives	67.2	Fiji	66.6	Djibouti	72.6
Cambodia	66.5	Maldives	67.4	Guyana	67.7	Saint Vincent and the Grenadines	67.3	Senegal	72.7
Kyrgyzstan	67.7	Mozambique	67.5	Rwanda	68.8	Rwanda	67.6	Cambodia	73.7
Uganda	68.0	Mauritania	67.7	Uganda	70.4	Madagascar	67.7	Madagascar	74.0
Djibouti	68.9	Guyana	67.8	Nepal	71.1	Papua New	67.9	Mauritania	74.9

Equal Weights		Higher Economic		Higher Access to pharma		Higher Capacity constraints		Incidence of diseases	
Guyana	69.4	Kyrgyzstan	68.1	Mali	71.6	Guinea Zambia	68.5	Haiti	74.9
Congo	69.8	Cameroon	68.3	Cambodia	71.9	Burkina Faso	68.5	Swaziland	77.3
Madagascar	70.9	Belize	68.8	Nicaragua	72.1	Chad	68.6	Tanzania	77.4
Haiti	71.7	Antigua and Barbuda	68.8	Tanzania	74.1	Mozambique	68.7	Gambia	78.1
Cameroon	72.3	Guinea-Bissau	70.9	Madagascar	74.6	Swaziland	69.2	Cameroon	78.1
Mozambique	74.1	Cape Verde	72.2	Mauritania	75.2	Mongolia	69.9	Nigeria	79.8
Côte d'Ivoire	74.3	Congo	72.5	Haiti	75.8	Haiti	70.7	Benin	80.4
Mauritania	74.6	Guinea	73.5	Burkina Faso	76.0	Belize	71.0	Uganda	80.6
Rwanda	75.2	Gabon	73.5	Burundi	76.2	Benin	71.1	Mozambique	80.7
Chad	75.6	Dominica	75.3	Kyrgyzstan	77.2	Mali	71.9	Togo	81.8
DR Congo	75.9	Benin	75.3	Côte d'Ivoire	78.3	Malawi	73.3	Guinea	82.7
Benin	77.3	Saint Vincent and the Grenadines	76.6	Mozambique	79.8	Djibouti	73.8	Burkina Faso	85.0
Burkina Faso	77.5	Zambia	76.6	Zambia	80.2	Guyana	74.0	Rwanda	86.2
Mali	77.6	Sierra Leone	77.2	Lesotho	80.4	Guinea	74.3	Angola	86.3
Lesotho	77.9	Rwanda	78.3	DR Congo	80.8	Cape Verde	74.5	Côte d'Ivoire	87.0
Zambia	79.0	Mali	78.5	Gambia	81.7	Congo	75.3	Chad	88.4
Guinea	80.7	Chad	79.0	Benin	82.2	Togo	76.7	Mali	88.7
Burundi	81.6	Burkina Faso	80.6	Cameroon	82.3	Burundi	78.0	Burundi	88.8
Gambia	82.0	Malawi	83.1	Malawi	83.5	Niger	78.0	DR Congo	89.8
Malawi	82.8	Lesotho	83.4	Sierra Leone	86.0	Lesotho	78.6	Guinea-Bissau	90.6
Togo	84.6	Burundi	83.7	Guinea-Bissau	87.0	Mauritania	80.9	Zambia	90.7
Guinea-Bissau	84.8	Gambia	86.0	Togo	91.7	Gambia	82.3	Malawi	91.3
Sierra Leone	86.0	Niger	86.6	Guinea	92.3	Sierra Leone	84.5	Central African Republic	93.1
Niger	90.1	Togo	88.0	Niger	97.5	Central African Republic	88.0	Sierra Leone	96.2
Central African Republic	92.6	Central African Republic	91.2	Central African Republic	97.9	Guinea-Bissau	90.6	Niger	98.1