

# **Processes And Issues For Improving Access To Medicines**

**Willingness And Ability To Utilise TRIPS  
Flexibilities In Non-Producing Countries**

**Professor Brook K. Baker**

**August 2004**

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To Utilise TRIPS Flexibilities  
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The DFID Health Systems Resource Centre (HSRC) provides technical assistance and information to the British Government's Department for International Development (DFID) and its partners in support of pro-poor health policies, financing and services. The HSRC is based at IHSD's London offices and managed by an international Consortium of seven organisations: Aga Khan Health Services Community Health Department, Kenya; CREDES-International, France; Curatio International Foundation, Georgia; IDS (Institute of Development Studies, University of Sussex, UK); IHSD Limited, UK); IHSG (International Health Systems Group, Harvard School of Public Health, USA); and the Institute of Policy Studies, Sri Lanka.

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Processes And Issues For Improving Access To Medicines: Willingness And Ability To Utilise TRIPS Flexibilities In Non-Producing Countries

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# 1 Executive Summary

## **KEY MESSAGES:**

- Globalised patent rights permit pharmaceutical companies to exclude lower-cost generic competitors and thus to set profit-maximising, monopoly prices.
- Expanded protection for drug registration data, e.g., data exclusivity, also delays generic entry thereby reducing price competition.
- The higher prices resulting from patents and data protection decrease access to medicines for poor consumers in developing countries.
- There is a looming crisis in accessing generic medicines in 2005 when leading generic producers, like India, must observe stricter patent protections for newer medicines.
- Accordingly, developing countries have an interest in using all lawful means to avoid patent and registration data barriers.
- Non-producing countries, countries with limited or inefficient capacity in their pharmaceutical sector for particular products, have a special interest in securing lawful sources of imports from foreign generic producers.
- Although a variety of options exists for accessing cheaper generic medicines of assured quality, e.g., parallel importation, compulsory licenses and the new WTO production-for-export system, there are many remaining barriers to access that must be addressed.

The burden of disease in developing countries is staggering, and that burden is exacerbated by inadequate access to skilled medical care and to medicines routinely used to treat and cure illness in richer countries. There are many explanations for this lack of access – widespread poverty, weak health systems and governmental neglect, both in developing and developed countries – but an additional, first-order explanation lies in the labyrinth structures of the international intellectual property regime including (1) the patenting and pricing of medicines<sup>1</sup> and (2) data exclusivity and marketing exclusivity rules that delay registration and sale of generic medicines.<sup>2</sup>

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## Chart 1 – Definition of Key Terms

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<b>Non-Producing Countries</b>	WTO members with insufficient or no manufacturing capacity in their pharmaceutical sectors for the product in question. According to a pro-access interpretation, the term includes countries with inefficient capacity, meaning an inability to produce and market the product competitively.
<b>Patent</b>	A territorial right to exclude others from making, using, offering for sale, selling or importing a product invention or from using an inventive process for 20 years; patents are ordinarily granted on a nation by nation basis only.
<b>Generic</b>	Equivalent version of an on- or off-patent medicine. Generic companies are drug companies that manufacture generic medicines.
<b>Drug Registration</b>	Marketing approval by a drug regulatory agency based on evidence establishing a medicine's safety, quality and efficacy.
<b>Bio-equivalent</b>	Measurement of blood or plasma concentrations of two drugs (or of a combined drug against the component drugs administered simultaneously) over time to characterise the rate and extent of drug absorption; if measured bio-availability of the two drugs is comparable, bio-equivalence demonstrates interchangeability in terms of expected safety and efficacy. <sup>3</sup>
<b>Data Exclusivity</b>	Prohibition against use of data submitted to secure regulatory approval and/or against relying on a prior regulatory approval to establish the safety and efficacy of a generic product can result in market exclusivity because it is frequently impractical for a generic manufacturer to duplicate clinical trials.

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In starkest terms, the current, expansive system of internationalised intellectual property rights (IPRs) means that research-based drug companies can obtain patents that grant them exclusive territorial rights to market innovative pharmaceutical processes and products almost everywhere in the world.<sup>4</sup> In turn, these globalised patent rights permit pharmaceutical companies to exclude low-cost generic competitors

and to set profit-maximising, monopoly prices. In addition to having expanded their patent rights internationally, research-based companies are gaining increased protection for data submitted to drug regulators for purposes of establishing the safety, efficacy and quality of their medicines. In particular, an expanded right of “data exclusivity” threatens to preclude registration of generic medicines even when patent rights are bypassed through lawful means. This is because the follow-on producer and drug regulators cannot use the earlier registrant’s data (or the fact of prior registration) to establish the safety and efficacy of the follow-on product even if it is proven bio-equivalent. Although this intertwined system of intellectual property protections for patents, data and their associated high prices is often defended as providing resources and incentives for research and development for the next generation of life-saving medicines, there is little doubt that higher prices affect access to existing (and future) medicines that are often unaffordable to developing countries and their impoverished residents.

Drug companies’ intellectual property rights affect all developing countries, but their impact is most pernicious in non-producing countries (NPCs) – countries that lack sufficient and efficient capacity to manufacture particular medicines locally and which must rely on foreign sources of supply even when they lawfully grant exceptions to patent rights on a specific medicine. This negative impact on the ability to import medicines reaches new heights in 2005, when all non-least-developed country WTO Member States will be obligated to grant patents on pharmaceutical products. Thus, important generic suppliers, like India, which have lawfully reverse-engineered and produced generic medicines of assured quality,<sup>5</sup> will no longer be able to produce and export post-1994/1995 patented medicines.<sup>6</sup> Accordingly, important sources of supply of low-cost, newer medicines for non-producing countries will be seriously constrained.

Despite the challenge arising in 2005, non-producing countries with inefficient or insufficient capacity in their pharmaceutical sectors have a variety of options for sourcing medicines from abroad. Some sourcing options, like those permitting export from and import to countries where a particular medicine is not patented, those permitting parallel-importation of patented medicines that have previously been sold in another country and those permitting varying quantities of medicines to be produced pursuant compulsory licenses and thereafter to be exported, were authorised in the original TRIPS Agreement and clarified further in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. However, since most compulsory licenses are subject to the requirement that drugs be supplied predominantly for the domestic market (except competition-based compulsory licenses granted according to Article 31(k)), compulsory licensing of newer medicines for export to non-producing countries will face a bottleneck condition in 2005. This bottleneck was addressed in the recent WTO Paragraph 6 Decision of 30 August 2003 (Paragraph 6 Decision), which produced a cumbersome, but potentially important mechanism for allowing trade in low-cost generic medicines.

This paper addresses varied ways by which a non-producing country may lawfully utilise TRIPS flexibilities, primarily by importing. However, it also briefly discusses means for promoting local production through pharmaceutical capacity building and through both compulsory and voluntary licensing. To aid decision-makers in understanding and evaluating the opportunities and constraints of each alternative, the paper briefly describes their respective advantages and disadvantages in terms of developing countries' sustainable access to more affordable medicines, highlighting differing legal interpretations, political realities and pragmatic administrative and economic constraints.<sup>7</sup> Attached, as an Appendix, is a series of flowcharts summarising the analytical decisions least-developed countries (LDCs) and other non-producing countries must make as they assess options for importing lower cost generic medicines of assured quality in light of TRIPS flexibilities, depending on the patent status of the medicines in both the importing and exporting country.

Non-producing countries' ability and willingness to use TRIPS-compliant flexibilities is negatively affected by a number of internal and external forces.

- The first major barrier is informational – confusion about the existing range of options for accessing cheaper generic medicines and uncertainty about patent status of particular medicines both in the importing non-producing country and in potential exporting countries.
- A second internal barrier is non-producing countries' limited technical capacity and willingness to amend their domestic laws to allow flexibility for procuring medicines and their constrained ability to amass and support the regulatory expertise necessary to administer those newly enacted flexibilities.
- The third barrier is external and concerns export capacity, namely the small number of no-patent and no-product-patent countries capable of exporting medicines of assured quality, the closing window for major generic producers like India as of 2005, and the uncertainty that producer countries will be willing and able to authorise and then process a large number of compulsory licenses for unlimited export under a competition-based compulsory license, non-predominant-quantity exports under an ordinary Article 31(b) compulsory license or quantity-specified exports under a Paragraph 6 Decision compulsory license.
- The fourth barrier is also external and overtly political – it consists of the continuing efforts of developed countries, acting at the behest of their research-based pharmaceutical industries, to interpret TRIPS flexibilities narrowly and to use trade and diplomatic pressure to deter non-producing countries from using the flexibilities that exist. This pressure is augmented by threats from industry about the impact of vigorous compulsory licensing schemes and eased drug registration for follow-on products on the future availability of patented medicines and on foreign investment both in the pharmaceutical sector and elsewhere.



Even more problematic than trade/diplomatic pressure and investment threats is developed countries' pursuit of bilateral and regional free trade agreements that bargain away developing countries' flexibilities to bypass patents and that raise new barriers to access to medicines particularly with respect to registration requirements.

Despite these barriers to utilising existing flexibilities for accessing medicines, in its more reform-based section, the paper analyses some in-country and regional intellectual property policy options for non-producing countries that might increase access to medicines, including:

- Eliminating the import/export patent-information thicket;
- Enacting TRIPS-compliant patent law reform in each country;
- Coordinating domestic compulsory licensing schemes, voluntary licensing regulations and competition policy;
- Easing issuance of competition-based compulsory licenses;
- Avoiding market segmentation between private and public sector health care and encouraging integration of drug procurement;
- Cooperating regionally to develop pro-health intellectual property and trade policy, to investigate joint compulsory licensing applications and to promote regional trade in generic medicines, especially within trading groups with 50% LDCs;
- Cooperating regionally to negotiate high-quality voluntary licenses that facilitate entry of multiple competitors, assure access to registration data, grant permission for cross-licensing of fixed-dose combination medicines and promote technology transfer;
- Cooperating regionally on drug registration to ensure marketing of drugs of assured quality, with preferential and expedited registration of medicines pre-qualified by the WHO and regional cooperation in post-marketing quality assurance;
- Creating regional mechanisms for pooled procurement;
- Investing in regional productive capacity and development of indigenous expertise with a special commitment to research and development for neglected diseases;



- Creating demand for access to medicines by supporting the Global Fund, the WHO 3-by-5 Plan and other global health initiatives, and by supporting the involvement of affected communities and NGO activists in IPR policy debates.

The paper concludes with options for policy-makers in the United Kingdom to adopt additional measures designed to aid non-producing countries' access to medicines, including:

- providing high-level technical assistance to non-producing countries and regions,
- promoting an Article 30 exception for production for export,
- encouraging the development of a competitive, high-quality generic industry,
- encouraging widespread licensing and technology transfer to developing countries for production of essential medicines, and
- considering life-saving medicines to be international public goods and requiring more research into neglected diseases and affordable access to medical innovations.



## 2 The International Intellectual Property Regime As It Affects Non-Producing Countries' Access To Medicines

### KEY INTERNATIONAL AGREEMENTS AFFECTING ACCESS TO MEDICINES

Four nestled texts – the original TRIPS Agreement, the subsequent Doha Declaration, the Paragraph 6 Decision and the Chairperson's Statement – collectively regulate international rights for the production and export of generic medicines and to import the same into non-producing countries.

1. The WTO Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS) created an integrated baseline of IPRs worldwide (1994).
2. The Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) clarified TRIPS flexibilities and asserted the primacy of public health and access to medicines for all (2001).
3. The Decision of 30 August 2003: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6 Decision) granted a TRIPS waiver for non-producing countries (NPCs) to import generic medicines pursuant to special compulsory licenses granting expanded rights of importation and exportation.
4. The Chairman's Statement clarified certain issues in the Paragraph 6 Decision, but its legal effect is much less certain.

Note: Negotiations are underway to amend the TRIPS Agreement in light of the Paragraph 6 Decision.

A new international system for securing intellectual property protections for pharmaceutical and other technologies was consolidated in 1994 when the World Trade Organization was founded and when its Member States adopted the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS).<sup>8</sup> Under key provisions relating to medicines, Member States must provide patent protection for a minimum of 20 years from the filing date of a patent application for any invention, including a



pharmaceutical product or process, which fulfils the criteria of novelty, inventive step and usefulness/industrial applicability. Although preceding patent-rule pluralism in both the developed and developing world had allowed policy-based discrimination between fields of invention, for example by excluding medicines, TRIPS expressly outlawed such discrimination, except for plant varieties, which require a *sui generis* system. Similarly, it became increasingly difficult to discriminate against imports in favour of locally produced products, thus allowing major pharmaceutical companies to control the *place* of production and even to disinvest in existing pharmaceutical capacity in developing countries.<sup>9</sup>

Via TRIPS, major pharmaceutical producers secured exclusive rights to exclude others from “making, using, offering for sale, selling or importing” patented pharmaceutical products or products made with a patented process. In addition, TRIPS protects undisclosed information (including clinical test data) submitted to governmental authorities for regulatory approval from “unfair commercial use”, a provision that is being interpreted by some developed countries to require data exclusivity for a fixed period of time (5–10 years). This interpretation of data exclusivity threatens to impede registration of generic drugs even where patent bars are lawfully overcome through compulsory licenses and government use orders.

## Chart 2 – Important IPR Dates Affecting Patents on Medicines

<b>Pre-1994/1995 Drugs</b> (“older drugs”)	TRIPS has no retroactivity, meaning that drugs for which patent applications had not be filled in the Member State until after Jan. 1, 1995, need not be patented. (Because of Paris Convention priority, the drug could have been invented and a patent filed as much as one year earlier.)
<b>Post-1994/1995</b> become “ <b>mailbox</b> ” drugs (“newer drugs”)	Developing countries, despite transition periods to TRIPS-compliant, were required to accept patent applications on post-1994/1995 (see above) inventions and keep them in a patent-queue “mailbox”. Most developing countries were required to start processing these mailbox patent applications in 2000 when they became TRIPS-compliant. Nevertheless, some countries, like India, did not provide product patents and had until 2005 to become TRIPS-compliant and thus need not process the applications until Jan. 1 2005.
<b>Transition periods:</b> <b>2000 and 2005</b>	As part of the IP trade-off, even during pendency in the mailbox, the patent applicant must be given 5-years of exclusive marketing rights (EMRs) once it registers the

“mailbox” medicine, assuming that the medicine had previously been patented and registered in another Member State.

(Note: India has granted EMRs on only two mailbox drugs thus far. Note: LDCs are not obligated to adopt EMRs until 2016.)

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**Post-2005 drugs**  
 (“newest drugs”)

Except for least developed countries, all WTO members, including India and other major generic suppliers, will have to grant patent protection for drug products as well as processes as of 2005.

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**Transition periods**  
**2006 – 2016**

Least developed countries must become TRIPS compliant by 2006 unless they obtain further extensions. Transition periods for patents on medicines, however, were automatically extended until 2016 pursuant to Para. 7 of the Doha Declaration, meaning that LDCs are not obligated as a matter of the TRIPS Agreement and sanction thereunder to enact patent protections or to enforce existing patent rights until Jan. 1, 2016. **Despite this new flexibility, national laws may still apply with respect to previously granted patents and thus even LDCs may need to issue compulsory licenses or government use orders with respect to previously granted patents.** Note: some LDCs may opt to continue to respect and grant pharmaceutical patents; all LDCs, however, retain the right under the Doha Declaration to seek further extensions before becoming TRIPS-compliant.

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**The date of passage of the TRIPS Agreement and transition periods within it create three classes of drugs that will have significant impact on import-sourcing options for particular medicines, depending largely on the date of innovation.<sup>10</sup>** As outlined in Chart 2 above, medicines can be classified depending on when they were invented, or more accurately when their patent applications were filed: (1) **older drugs** (pre-1994/1995), (2) **newer mailbox drugs** (1995–2005) and (3) **newest drugs** (post-2005). Because TRIPS had no retroactive effect, its passage did not change the patent status of any medicine in any particular country. Moreover, developing countries were given until 2000 to comply with TRIPS provisions, and LDCs were given six additional years until 2006, a deadline that was subsequently extended to 2016 with respect to medicines.<sup>11</sup> Finally, countries like India that had previously refused to grant patents for pharmaceutical “products” (while protecting “process” patents) were given until Jan. 1, 2005 to become TRIPS-compliant.



Although the extended transition period for LDCs to become TRIPS-compliant with respect to medicines removed the risk of TRIPS sanctions for delaying patents for medicines, for suspending existing patents, or for denying exclusive market rights for “mailbox” drugs, this extension did not extinguish existing patent holders’ vested rights under national law, meaning that LDCs with pre-existing patent regimes may still need to issue compulsory licenses or government use orders. Some commentators have suggested that an LDC could simply proclaim that it was suspending patent enforcement pursuant to Paragraph 7 of the Doha Declaration and **Malawi** for one appears to have followed this advice.<sup>12</sup> However, if an LDC has already granted a patent on a medicine, it faces a “takings” claim from the patent holder unless the LDC follows national law with respect to patent suspension or involuntary use. Despite this need to protect vested patent rights, LDCs can prospectively suspend further operation of their patent and market exclusivity schemes with respect to medicines only until 2016 (and they may seek further extensions thereafter).

### Chart 3 – Key Flexibilities under TRIPS

<b>Parallel Importation</b>	Comparison shopping for a patented medicine sold more cheaply in another country (based on international exhaustion rule); under a more liberal interpretation, it can also include importation of a product produced pursuant to a compulsory license or government use order.
<b>Compulsory License</b>	Permission from a government extinguishing patent exclusivity and permitting a licensee to use a patent without the patent holder’s consent; issuing government must follow certain procedures and licensee must pay a royalty to the patent holder.
<b>Government Use</b>	Permission for the government or its contractors to make use of the patented product or process for non-commercial purposes.
<b>Limited Exception</b>	Additional exceptions to patent-holders’ exclusive rights (best known example – Bolar exception permitting use of patented medicine to obtain marketing approval); under a liberal interpretation, might justify production-for-export.

In addition to these transition periods, there are substantive **flexibilities** in the TRIPS Agreement for sourcing more affordable medicines, as outlined in Chart 3 above, including:

- (1) autonomy under Article 6 to establish international exhaustion rules, which thereafter permit **parallel importation** of a patented medicine after its first sale or arguably after it has been marketed pursuant to a compulsory license or government

- use order (see subsection 3.2, *infra*),
- (2) authority consistent with Article 31 to issue **compulsory licenses** or **government use orders** for producing medicines (see subsection 3.3, *infra*), and
- (3) arguably permission under Article 30 to exercise **limited exceptions** to patent holders' rights to produce needed medicines (see subsection 3.4, *infra*).

Nevertheless, the overall effect of the TRIPS Agreement has been to consolidate the economic power and exclusive marketing privileges of the research-based drug industry. This consolidation will increase as of 2005 when major producers of generic medicines (most especially India) are required to adopt patent protections for medical products and when patent applications on post-1994/1995 "mailbox" patent applications must be processed by non-LDC Member States.

At the turn of the millennium, in response to trade pressure from developed countries and drug company lawsuits seeking narrow interpretations of TRIPS flexibilities, developing countries fought for greater recognition of public health priorities. This struggle reached its apex in Doha, Qatar, on November 14, 2001, when the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health [**the Doha Declaration**].<sup>13</sup> Although the Doha Declaration confirmed Member States' freedom to issue compulsory licenses, thereby permitting domestic production and/or importation of generic medicines, and to rely on parallel imports as an alternative source of lower-cost patented medicines, it left open issues concerning sources of medicines for **non-producing countries (NPCs)** that could not produce medicines through domestic manufacture because of insufficient or inefficient pharmaceutical capacity.

## Chart 4 – Production-for-Export Crisis

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**“Predominantly for domestic use” rule** in Art. 31(f) of the TRIPS Agreement limits the quantity of medicines that can be exported to NPCs.

Accordingly, **NPCs faced a production-for-export crisis** in accessing cheaper generic copies of newer and newest on-patent medicines beginning in 2005, as major producers, like India, would no longer be able to lawfully reverse-engineer generic medicines and export unlimited quantities to NPCs. Such countries also have to process “mailbox” patent claims that might render current lawful production of generics unlawful once a patent has been granted.

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For these non-producing countries, importation from exporters was problematic because of a requirement in TRIPS that countries issuing compulsory licenses must ordinarily produce **predominantly for their own domestic markets** rather than for export. This then was the essence of the **production-for-export dilemma** – desperate demand but no certain source of supply. Thus, Paragraph 6 of the Doha Declaration required a resolution to the production-for-export dilemma by the end of 2002.





Although countries regrettably failed to meet this deadline, WTO members did finally adopt a waiver via the Decision of 30 August 2003: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [**Paragraph 6 Decision**].<sup>14</sup> This Decision was supplemented by the General Council Chairperson's "clarifying" Statement.<sup>15</sup> Both the Paragraph 6 Decision and the Chairperson's Statement have been criticised for imposing numerous conditions and labyrinth procedural requirements.<sup>16</sup> Nonetheless, the Paragraph 6 system does partially address the sourcing needs of least developed and other non-producing countries, including those with and without a relevant patent on file.<sup>17</sup>

## Chart 5 – Non-Producing Countries Eligible to Use the Paragraph 6 Decision

**Least Developed Countries (LDCs)** are automatically eligible to utilise the Paragraph 6 Decision as an importer.

**Non-LDC NPCs** are eligible to import only if they determine that they have insufficient or inefficient capacity in the pharmaceutical sector and notify the WTO of their intent to use Paragraph 6 Decision import rights and the basis for determining that they lacked pharmaceutical capacity.

**No-patent countries** can import by notifying the WTO of their intent to import particular medicines pursuant to the Paragraph 6 Decision; they do not need to issue a compulsory license.

**On-patent countries** can import under the Paragraph 6 Decision only if they notify the WTO of their intent to do so and, if necessary, provide information on their determination that they lack manufacturing capacity for the relevant product; they must also issue a compulsory license or government use order permitting importation.

The Paragraph 6 Decision, while voluntarily excluding or limiting compulsory-license-based import rights of 45 countries, does permit LDCs and other non-producing countries to **import** medicines where no patent bar exists or to issue compulsory licenses and/or government use orders permitting them to exercise special import rights even where there are relevant patents on file. These sovereign decisions are not subject to pre-approval, but they do require notification to the WTO and are subject to a potentially troubling right of ad hoc review and consultation. Nonetheless, notifications and special compulsory-licenses-for-import issued pursuant to the Decision can be granted for all products produced in the pharmaceutical sector, including diagnostic kits, active pharmaceutical ingredients and vaccines.<sup>18</sup> However, except for licenses issued to permit governmental, non-commercial use, to address emergencies or matters of extreme urgency or to remedy anti-competitive practices; the prospective licensee must negotiate with the patent holder for a voluntary license on commercially reasonable terms for a reasonable period. This requirement clearly adds a period of procedural delay and uncertainty.



All WTO Members are eligible to be **exporters** under the Decision, but the system must be used “in good faith to protect public health and not be used as an instrument to pursue industrial or commercial policy objectives”, according to the Chairperson’s Statement. In order to export a patented medicine under the Decision, the exporting Member must issue a separate compulsory license for each medicine and for each country and must limit quantities to the amount necessary to meet the needs of the importing Member(s).<sup>19</sup> Royalty rates paid to the patent holder are set in the exporting country based on economic value in the importing country.<sup>20</sup> In addition to limiting the quantities produced, the exporter must also use special labelling or markings to differentiate products being exported pursuant to the Decision.<sup>21</sup> Even though product differentiation should reduce the risks of product diversion, the Decision requires further reasonable, administratively feasible measures within the importing country to reduce the risk of trade diversion and re-exportation. Finally, the Decision requires notification from the exporter concerning the identity and quantity of drugs being produced and exported and the distinguishing features of the products. (For further discussion of the Paragraph 6 system, see subsection 3.5, *infra*.)



### 3 Trips-Compliant Flexibilities for Export/Import and the Advantages/Disadvantages of Each

#### KEY MESSAGES:

In order to understand the upcoming analysis of TRIPS-compliant flexibilities for accessing cheaper generic medicines, it is important to remember the complex interaction between four factors:

- Flexibilities are affected by the medicine's patent status in both the importing and exporting country;
- Flexibilities for importing medicines differ for older pre-1994/1995 drugs, newer 1994/1995–2005 mailbox drugs and newest post-2005 drugs;
- International guidelines concerning key flexibilities are contained in the TRIPS Agreement, the Doha Declaration and the Paragraph 6 Decision as clarified by the Chairperson's Statement;
- Flexibilities are also limited and defined by domestic legislation in both the importing and exporting country.

Key TRIPS-compliant flexibilities for importing lower-cost generic medicines include:

- Unrestricted importation where there are no competing patents in either the importing or exporting country (technically, this is not a TRIPS flexibility because no patent bar exists);
- Parallel importation of previously sold patented medicines from another country if the importing country has adopted the international exhaustion rule; a more liberal interpretation permits importation of medicines produced pursuant to a compulsory license or government use order;
- Ordinary compulsory licenses and government use orders to import unlimited quantities of unpatented, older medicines and more limited quantities (less than predominant amounts of medicines produced pursuant to an ordinary compulsory license in the exporting country) of newer and newest medicines;
- Unlimited quantities of medicines produced pursuant to special competition-based compulsory licenses or government use orders issued in the exporting country;
- Unlimited quantities of medicines produced as a "limited exception" (because of strong opposition from the U.S., few, if any, exporters may risk this option);
- Specified quantities of medicines pursuant to notifications and compulsory licenses/government use orders issued pursuant to the Paragraph 6 Decision.

In addition to these importation options, NPCs may also choose a longer-term strategy of increasing domestic capacity to produce medicines pursuant to compulsory or voluntary licenses, depending on more robust technology transfer.

As demonstrated in Chart 6 below, non-producing countries retain a great deal of flexibility to use TRIPS-compliant mechanisms to access medicines from abroad, despite the inadequacies of the Paragraph 6 Decision.<sup>22</sup> It is important to note, however, that a particular country's options to import and/or export medicines might be circumscribed by national legislation and/or by TRIPS-plus provision in bilateral or regional trade agreements. These two challenges are discussed further in sections 4.2.1 and 3.7.4 *infra*.

## Chart 6 – Flexibilities for Export/Import

Exporting country's right to export, if:	Importing NPC's right to import, if:
<p><b>No patent(s) on file</b></p> <ol style="list-style-type: none"> <li>No quantity limits: <ul style="list-style-type: none"> <li>off-patent drug;</li> <li>no patent filed or patent found to be invalid;</li> <li>a pre-1995 medicine if the national patent regime did not grant product patents on pre-1995 drugs (best example, India).</li> </ul> </li> <li>Exportation of a drug previously sold by the patent holder or with its permission (this option can be restricted by contract or by limited sales in the exporting market).</li> </ol>	<p><b>No patent(s) on file</b></p> <ol style="list-style-type: none"> <li>Mainly in smaller and poorer countries: <ul style="list-style-type: none"> <li>no restrictions when importing from a no-patent country;</li> <li>may import non-predominant amounts from a country that issues an ordinary compulsory license, Art. 31(f);</li> <li>may import unlimited amounts from a country that issues a 31(k) license;</li> <li>may import needed quantities pursuant to August 30 Agreement.</li> </ul> </li> <li>May import a drug patented elsewhere after its first sale even in the absence of an int'l exhaustion rule.</li> </ol>
<p><b>Patent(s) on file</b></p> <ol style="list-style-type: none"> <li>Parallel "exportation" – exportation of a drug first sold by the patent holder or with its permission (this option can be restricted by contract or by limited sales in the exporting market); may also permit exportation of a medicine produced pursuant to a compulsory license.</li> <li>Compulsory licenses and government use:</li> </ol>	<p><b>Patent(s) on file</b></p> <ol style="list-style-type: none"> <li>Parallel importation if importing country has int'l exhaustion rule and if patent holder has voluntarily exhausted its rights by a first sale in another country, TRIPS Art. 6; may also permit importation of drug produced under compulsory license in exporting country (see section 3.2, <i>infra</i>);</li> <li>Regular compulsory license for</li> </ol>

- Issued predominantly for domestic use, Art. 31(f), (at least 49% can be exported, maybe more);
  - Issued for abuse of patent, Art. 31(k), (unlimited export).
3. Limited exception to permit export to a no-patent market or to effect a compulsory license in a non-producing importing country, Art. 30 (of questionable practicality/utility because of developed country antipathy to a broad construction of limited exceptions).
4. Paragraph 6 Decision compulsory license or government use order with all attendant notifications and limitations (will be required for post-1994/1995 mailbox drugs, post-2005 new drugs and even pre-1994/1995 drugs if patented in the exporting country; needed quantities only).
- import, Art. 31 (import allowed pursuant to Art. 27 because of its prohibition against discriminating against imports)
- Unlimited quantities from a no-patent exporter;
  - Limited, non-predominant quantities from an “ordinary” compulsory license exporter;
  - Unlimited quantities from a compulsory license exporter to redress anti-competitive practices; and
  - Unlimited quantities imported pursuant to an Art. 30 limited exception in the exporting country (questionable legal authority).
3. Paragraph 6 Decision compulsory license for import with all attendant notifications and limitations.

### 3.1 Options where there is no patent in the exporting country

#### KEY MESSAGE:

Options for sourcing newer and newest medicines from countries with no conflicting patents are largely illusory.

Many countries are theoretically permitted to sell generics medicines where medicines as a class, or particular pharmaceutical innovations, are not under patent protection in the exporting country. Unfortunately, many of these no-patent options are illusory because of the absence of qualified producers. Nonetheless, no-patent countries permitted to export, depending on their national legislation, include:

- (1) non-WTO members not bound by TRIPS if they have not patented particular medicines (few, if any, non-WTO members have meaningful productive capacity);
- (2) LDCs until 2016 (at present few LDCs have meaningful productive capacity to produce anything but finished products from imported ingredients; moreover, many LDCs have improvidently authorised product patents, though many research-based companies decline to file patents in such marginal markets);
- (3) countries that did not grant patents on medicines or grant protection for pharmaceutical “products” until compelled by national legislation or by TRIPS, can

routinely make generic versions of unpatented drugs (this is, and will remain, a very significant source of supply for older medicines, especially from India);<sup>23</sup>

(4) countries where a particular medicine is not patented because no patent was ever filed or because the patent has expired or been found invalid (there are few such countries because patent-holders tend to file for patent protection in countries with meaningful manufacturing capacity).

## Chart 7 – No Patent Options

### Advantages

The exporting manufacturer faces no procedural obstacles in its own country with respect to exporting a medicine.

An importing country with no patent bar can import the medicine at will.

Even an importing country with a conflicting patent will be permitted to issue a “routine” compulsory license to import unlimited quantities.

### Disadvantages

The no-patent sourcing option will decrease over time for several reasons including:

- More and more countries will become WTO members;
- Patent holders are likely to patent more widely in the future both to preserve their rights and to take advantage of planned harmonisation of patent registration through the WIPO or other regional entities;
- Transitional periods will expire even for LDCs.

Realistic sourcing options, e.g. India, will be limited to continuing supply of off-patent pre-1994/1995 medicines and of mailbox drugs for which no exclusive marketing rights or eventual patents have been granted.

## 3.2 Parallel imports

### KEY MESSAGE:

Parallel importation might provide some price relief for accessing patented medicines, but best price available on patented drugs rarely match those of the lowest priced generic, assuming generics are available. The more liberal parallel importation rule permitting importation of medicines produced pursuant to a compulsory license or government use order risks challenges from developed countries.

**Parallel importation** is comparison-shopping on an international scale. Where allowed by national law, parallel importation is most commonly understood to permit the importation, without the direct consent of the patent-holder, of a product voluntarily and legally marketed in another country by the patent-holder or its authorised licensee. The



rationale for permitting parallel importation is to promote pricing equity by allowing importation of a patented product marketed more cheaply in another country. This indirect self-competition is thought to increase the likelihood of fair pricing between countries. Article 6 of the TRIPS Agreement permits countries to adopt the principle of **international exhaustion**, which in turn allows the above-described parallel importation.<sup>24</sup> Any doubts on this score were eliminated by the Paragraph 5(d) of the Doha Declaration, which expressly recognised Members' right to elect their own exhaustion rule and thereafter to parallel import.

Under an even more liberal interpretation, a country that recognises "international exhaustion" might be permitted to import drugs produced under a compulsory license or government use order issued in another country, even if no compulsory license is issued in the importing state.<sup>25</sup> The uncertainty in using this approach is whether the product would have been "permissibly" placed in the stream of commerce if it were being commercialised via an "involuntary" license. Given U.S. opposition to ordinary parallel importation, it is possible that it would challenge this more liberal parallel importation rule were its usage to become widespread.

At present, only a minority of non-producing countries have adopted an international exhaustion rule in their national legislation, meaning that many, including **Malawi**,<sup>26</sup> do not yet permit parallel importation of patented medicines sold abroad.<sup>27</sup> However, one country, **Kenya**, has adopted a very robust parallel importation rule that not only permits parallel importation of patented medicines previously sold abroad, but also permits parallel importation of a generic medicine produced pursuant to a compulsory license.<sup>28</sup> Even more boldly, **Kenya** seems to permit parallel importation of any generic legitimately marketed abroad, including those produced where there is no conflicting patent. Unfortunately, this last option might be interpreted to conflict with the Kenyan patent bar and might be interpreted to violate Article 28.1 of the TRIPS Agreement as well.

The pharmaceutical industry is highly critical of parallel importation because it limits companies' ability to charge whatever a local market will bear and because it risks reducing profits in high-price countries. To allay this second risk, most developed countries have placed restrictions on parallel importation of medicines. For example, the U.S.'s modified rule on international exhaustion allows drug companies to place contractual limits on rights of export, whereas the E.C. permits regional importation only between members of the E.U. In addition, pharmaceutical companies have several private options to circumvent parallel importation rules. The most draconian would be to impose a uniform high price worldwide, thereby decreasing affordability in middle-income and low-income nations. Other solutions limit supply to an amount sufficient for internal consumption only,<sup>29</sup> or, as permitted by U.S. law, to impose contractual limits on unauthorised exportation of the product.<sup>30</sup> Alternatively, especially in a price-control jurisdiction, a company could charge two prices, one for domestic consumption and a second for re-exported products.<sup>31</sup>

These prohibitions against parallel importation back into a developed country market make the most sense when a patent holder has granted major price concessions to a particular developing country or region, as in the Accelerating Access Initiative. In this instance, it may be undesirable to permit a **developed** country to import a discounted medicine from a developing country if such importation would result in repeal of the price discount. However, this rationale should not bar parallel importation by **developing** countries that have not yet achieved discount pricing. A compromise is possible – there can be one parallel import rule for developing countries and another for developed countries. Although developing countries would be free to parallel import, developed countries would not be permitted to do so from nations receiving concessionary pricing. The E.U. has adopted a version of this rule favouring price-differentiation, but limiting importation back into the E.C. market.

## Chart 8 – Parallel Importation

### Advantages

Parallel imports of patented medicines are likely to be of assured quality and may already satisfy the registration requirements of the importing country.

Parallel imports can meet demand quickly, assuming adequate and sustainable sources of supplies in the exporting country.

Parallel importation permits patented drugs of assured quality to be purchased at their cheapest price through comparison shopping. Under the more liberal interpretation, parallel importation can permit importation of even cheaper generic medicines produced pursuant to a compulsory license or government use order.

### Disadvantages

To prevent profit loss in high profit markets, patent holders may raise prices in lower-price markets reducing availability of affordable medicines in developing countries.

Parallel importation can result in the sale of products without support or service for that product that are otherwise provided for direct sales.

The patent holder could easily impose contractual provisions prohibiting or limiting the export of the patented product to other markets reducing the importance of parallel imports as a sustainable source of supply.

Research-based pharmaceutical companies argue:

- that they might oppose adopting voluntary discount pricing schemes because of fear of grey market importation back to their high-profit, First World markets;
- that parallel importation might result in more counterfeit products, though there is little or no evidence in support of this concern; and
- that companies may lose profits important for research and development and/or reduce even further incentives for R&D on Third World diseases, though again there is little or no evidence in support of this argument given the relatively small proportion of global drug sales made in developing countries and given the relatively small amounts currently invested in neglected diseases.





In addition, some developed countries argue that parallel importation allows countries to “take advantage” of price control measures elsewhere even though they do not have comparable domestic legislation.

### 3.3 Compulsory Licenses (and Government Use Orders)<sup>32</sup>

#### 3.3.1 Article 31(b), (f) compulsory license – non-predominant quantities

##### KEY MESSAGE:

Ordinary compulsory licenses issued in an exporting country only allow exportation of non-predominant quantities, thereby reducing their impact as a primary source of supply for NPCs without patents and those granting their own licenses for importation. However, ordinary compulsory licenses can be granted on any grounds, including grounds that are health-related.

If authorised by local law, Article 31 of the TRIPS Agreement permits a competent government authority to license the manufacture, sale and distribution of an invention to an authorised third-party or government agency without the consent of the patent-holder.<sup>33</sup> For example, pursuant to this authorisation, both **Kenya** and **Malawi** have adopted legislation authorising both compulsory licenses and government use orders.<sup>34</sup> **Because of the non-discrimination against importation rule in Article 27, an importing country can issue an ordinary Article 31(b) compulsory license or government use order to an exporter, but, as discussed further below, the quantities exported pursuant to a compulsory license or government use order issued in the exporting country may be limited to non-predominant quantities only if the medicine is patented in the exporting country.**

The permissible grounds for compulsory licenses<sup>35</sup> are not explicitly defined in the TRIPS Agreement, and thus developing nations have wide discretion in selecting health sensitive compulsory licensing policies. **Presumptively valid grounds for compulsory licensing include public health and the public interest broadly construed**, Article 8, national emergencies and matters of extreme urgency, Article 31(b), non-commercial governmental or “crown” use, *id.* and/or to remedy anti-competitive practices, Article 31(k).

Some of these grounds justify expedited governmental action. For example, under Article 31(b), when the government declares an emergency or a matter of extreme urgency, such as the AIDS pandemic, it can issue a compulsory license to begin commercial exploitation without first negotiating with the patent holder. Similarly, when the government is seeking a license for its own non-commercial use, the government is not required to seek prior approval. Finally, prior negotiations are not necessary when



redressing anti-competitive practices.

A particularly compelling ground for issuing compulsory licenses under TRIPS is to permit production of rational fixed-dose combination medicines, including triple-dose AIDS medicines. Proprietary companies have historically been unwilling to cross-license their products with competitors to permit co-formulation of FDCs, even though such medicines often have an important therapeutic advantages in terms of patient compliance with pill-dosage regimens. By facilitating the development and marketing of FDCs, compulsory cross-licensing can advance important public health goals in terms of disease treatment, eased procurement and distribution of medicine, and reduced drug resistance.

Although TRIPS is relatively silent about grounds for issuing a compulsory license, it is quite explicit about procedures that must be followed. Except in the special cases mentioned above, the potential licensee is required to seek a voluntary licensee on commercially reasonable grounds for a reasonable period. Article 31(b). In addition, the licensee is required to pay adequate compensation based on an individual determination. Article 31(h).<sup>36</sup>

Even if a compulsory license is granted, the patent-holder retains its underlying intellectual property rights. The license granted is non-exclusive, meaning the patent-holder and its other licensees can still compete; moreover, the license is non-assignable. Article 31(d). More significantly, the license is revocable if the circumstances that led to its granting have ceased to exist, though some consideration must be given to the interests of the licensee who may have invested heavily in order to manufacture the licensed product. Article 31(c) and (g).

As discussed previously, one of the most problematic features of Article 31 is that licenses must be issued “**predominantly for the supply of the domestic market**”, except in cases of anti-competitive patent abuse where this limit does not apply. Article 31(f), (k). The meaning of this “domestic supply” requirement is unclear as it might mean that “the predominant portion of products produced must be consumed domestically” or alternatively that “the license shall be predominantly for the benefit of domestic consumption”.<sup>37</sup> The latter interpretation would permit a country to export a majority of its production, if such export were necessary for production runs large enough to supply the domestic market efficiently. This is the preferable interpretation in terms of access to medicines because it could result in a regional manufacturer being able to supply several small markets in order to achieve economies-of-scale. Under any interpretation, however, an importing country could utilise a non-Paragraph 6 Decision compulsory license to import a non-predominant portion of an exporting country’s generic product produced pursuant to its own non-Paragraph 6 Decision compulsory license.



## Chart 9 – “Ordinary” Compulsory License/Government Use Order for Import and Export

### Advantages

Compulsory licenses to import generics can instantly meet demand depending on the producer(s)’s manufacturing capacity and on the registration status of the medicine.

With sufficient economies-of-scale based on demand from multiple nations, generic producers with export compulsory licenses should be able to produce medicines at greatly reduced prices (subject to countervailing possibility of abusive pricing). Large-scale manufacturers might also be able to establish more efficient product distribution systems.

Multiple compulsory licenses can be issued and each license can permit patented medicines to be combined to ensure development and registration of rational fixed-dose combination medicines that will ease patient compliance with complex treatment regimes.

### Disadvantages

The exporter will be permitted to export non-predominant amounts only. Unless it has a large internal domestic market for the medicine, quantities for export might prove to be inadequate.

Foreign manufacture does not increase local pharmaceutical capacity and economic self-reliance in the importing country.

There is some risk that major pharmaceuticals might simply buy out low-profit competing generic manufacturers eliminating established sources of supply.

Issuing compulsory licenses is procedurally burdensome. Because of these procedural burdens and because of pressure from certain developed countries, developing countries seem unwilling thus far to issue compulsory licenses. For example, neither **Kenya** nor **Malawi** has done so, and so far, only Mozambique, Zimbabwe and Malaysia have issued C.L.s or government use orders.

Widespread use of compulsory licenses for import might deter the development of a domestic pharmaceutical industry, but only if that industry is highly dependent on the domestic market.

### 3.3.2 Article 31(k) compulsory licenses – export/import of unlimited quantities

#### KEY MESSAGE:

Competition-based compulsory licenses are often administratively complex, but that complexity can be reduced by establishing streamlined procedures; a major advantage of such licenses is that they permit export of unlimited quantities of a medicine.

Fortunately, there is a predominantly-for-the-domestic-market exception in Article 31(k) where a patent-holder has acted anti-competitively. Although few, if any, developing countries have legislation authorising competition based compulsory licenses or have granted compulsory licenses on competition grounds,<sup>38</sup> there is flexibility under TRIPS<sup>39</sup> for developing countries to grant such licenses based on excessive pricing, refusals to license and denial of access to an essential facility (see, section 4.2.2, *infra* for a more detailed discussion of options for competition policy reform). A generic producer operating under a competition-based compulsory license could produce on a large scale for export, most relevantly even where an ordinary, non-Paragraph-6 compulsory license had been granted in the importing country. An additional advantage of such licenses is that they might provide for even broader remedies permitting access to confidential registration data and to manufacturing expertise.<sup>40</sup>

### Chart 10 – Import Based on an Art. 31(k) Compulsory License

#### Advantages

The exporting licensee can produce unlimited quantities and is not restricted in the amount it can export. Thus, importing countries can import unrestricted quantities of medicines if the product is not patented, if an ordinary compulsory license for import has been issued or even if the more liberal parallel importation rule is upheld.

Such importation can immediately meet demand, depending on the exporter's manufacturing capacity and on the registration status of the medicine.

The exporter is even more likely to reach efficient economies-of-scale and efficient distribution systems based on

#### Disadvantages

Obtaining a license for anti-competitive practices can be arduous, though innovative and efficient administrative procedures may ease this burden; nonetheless, such licenses might result in long delays if patent-holders exercise their rights of appeal.

Some of the competition theories advanced are relatively untested either administratively or judicially.

Few, if any, developed countries have developed a competition policy as robust as might be desired; legislative reform and administrative capacity building will be necessary.



aggregated demand from multiple nations.

Doctrinally, such licenses can be based explicitly on the desirability of rational fixed-dose combination medicines, utilising the essential facilities doctrine.

Such licenses justify lesser royalties and can require technology transfer of industrial expertise and full access to registration data despite data exclusivity rules.

Developed countries and pharmaceutical companies argue that granting a compulsory licensing based on anti-competitive practices may discourage foreign investment, retard transfer of technology and inhibit research and development into neglected diseases endemic in the exporting country. There is little to no evidence supporting this argument.

### 3.4 Article 30 limited exceptions – unlimited export/import

#### KEY MESSAGE:

An Article 30 limited exception for exporting medicines to non-producing countries is the most procedurally efficient mechanism, but its use has been curtailed by vociferous opposition from the U.S. and the research-based drug industry. However, such opposition should not preclude exploration and utilisation of a legally valid option.

The text of Article 30 of the TRIPS Agreement evidences sufficient textual plasticity to justify **limited exceptions** designed to address the public health needs of the developing world, including those arising for poor countries that are not able to make effective use of compulsory licenses because they lack meaningful capacity to manufacture medicines locally:<sup>41</sup>

Members may provide *limited* exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not *unreasonably* conflict with a normal exploitation of the patent and do not *unreasonably* prejudice the legitimate interests of the patent owner, *taking into account the legitimate interest of third parties*. (Emphases added.)

The language of Article 30 supports an interpretation that *some* impact on patent rights is permissible. For example, the first requirement of Article 30 is that the exception must be limited. Although “limited” might not permit total abrogation of patents, it must mean that some impact is permissible, such as the significant impact of the “Bolar” exception,<sup>42</sup> which can accelerate approval of generic competition by as much as three years, costing the patent holder millions, even billions, of dollars in lost sales in rich markets.

Similarly, the second and third clauses of Article 30 permit some conflict with the normal exploitation of a patent, though not an “unreasonable conflict” and some prejudice to the legitimate interests of the patent owner, though not “unreasonable prejudice”. In this regard, when producing for export under an Article 30 limited exception, there is no real curtailment of the patent holder’s rights in the producing country (domestic sales of the patented drug are not affected at all) nor even in the consuming country (either a royalty will be paid on an import compulsory license or there is no conflicting patent on file resulting in no rights to the patent holder). If the importing country had manufacturing capacity, it could produce medicines on its own pursuant to a domestic compulsory license. Thus, a limited exception in these circumstances simply gives non-producing countries a legal source of off-site manufacture, levelling the playing field vis-à-vis countries with productive capacity.

Finally, in addition to permitting some prejudice to the patent holder’s interests, the language of Article 30 requires that the exception be judged “taking account of the legitimate interests of third parties”, including presumably millions of poor people living with HIV/AIDS and other treatable diseases. Utilizing this liberal interpretation of Article 30, an exporting country could permit a manufacturer to produce medicines for export after notification of an public health need and of limited pharmaceutical capacity for the needed medicine in the importing country.

## **Chart 11 – Importation of Medicines Produced and Exported Pursuant to an Article 30 Limited Exception**

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### **Advantages**

Importation of medicines produced pursuant to a limit exception is the most efficient and expeditious method for accessing unlimited quantities of essential medicines.

Within the exporting country, utilising a limited exception could be based merely on notification from a country with insufficient manufacturing capacity that it has a public health need for a medicine; production would be for export only.

Within the importing country, the request for export would not be based on Paragraph 6 protocols, but could be based on the issuance of an import

### **Disadvantages**

Developed countries, particularly the U.S., and the patent drug industry have been adamantly opposed to the utilisation of limited exceptions in this context and thus might challenge them at the WTO or in court.

Recent negotiation history has shown decreased enthusiasm for an Article 30 production-for-export limited exception and that history, codified in the Paragraph 6 Decision, might be construed to preclude reliance on Article 30.

Even if a particular exporting country were willing to support the grant of limited exceptions, generic producers might be



compulsory license or on the absence of a patent.

loathe to take the commercial risk of investing in production and export under an untested method.

This option has been championed by the WHO, multiple NGOs, developing countries in post-Doha negotiations and even by several European countries.

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### 3.5 The Paragraph 6 Decision – export/import of needed quantities

#### **KEY MESSAGE:**

The Paragraph 6 system permits an exporter to supply specified quantities of medicine, but its conditions and labyrinth procedural requirements may severely limit its effectiveness.

In practical terms, the real difficulties of the Paragraph 6 Decision concern post-1994/1995 discoveries and expanded product-patenting rights arising in 2005 when countries like India will have to become fully TRIPS compliant and will have to provide patent protection both for post-1994/1995 pipeline/mailbox patent applications and for all post-2005 inventions. Of course, the Decision also applies to countries, like Brazil, where most medicines are on patent and where they seek to export predominant amounts under a non-competition-based compulsory license.

As previously outlined, there are multiple uncertainties and constraints arising from reliance on the Paragraph 6 Decision, mostly because it builds on the procedural complexity of double licensing under Article 31 of the TRIPS Agreement. Under the discipline of the two texts, in order to import medicines into a country where a drug is patented in both the importing and exporting country,<sup>43</sup> the following steps must be followed by both countries and the licensee:

- (1) The importing country's potential licensee(s) must ordinarily seek a voluntary license on commercially reasonable terms for a commercially reasonable period from the patent holder.<sup>44</sup> The importing country can ease this requirement by specifying a relatively short time for negotiations, e.g., 30–60 days, and by specifying presumptively reasonable and unreasonable terms (see discussion 4.2.2, *infra*).
- (2) Failing that, the potential licensee(s) must apply for a compulsory license from the importing country pursuant to procedures satisfying Article 31 of the TRIPS Agreement, including individual determinations, 31(a), limited scope and duration, 31(c) and (g),<sup>45</sup> non-exclusivity and non-assignability, 31(d) and (e),

- and rights of review, 31(i) and (j).
- (3) LDCs must notify the WTO of their intent to utilise the Paragraph 6 system for a particular medicine even though they are automatically eligible to import generics.<sup>46</sup> A non-LDC NPC, on the other hand, must assess its generic industry's capacity and/or willingness to produce the needed medicine locally, and, if capacity is insufficient, it must notify the WTO of its decision or intention to issue a compulsory license, specify the names and expected quantity of the product needed<sup>47</sup> and explain how the lack of capacity was established. This explanation is potentially subject to ad hoc challenge and review.<sup>48</sup>
  - (4) The importing country must license the potential exporter, presumably the one that has already engaged in voluntary license negotiations, Article 31(b); this license need not have quantity restrictions and could be issued for the remaining term of the patent so long as it was terminable when the public health need subsides or when domestic manufacturing capacity becomes sufficient.
  - (5) The exporter may once again need to seek a voluntary license on commercially reasonable terms for a commercially reasonable period in the exporting country, though this requirement is needlessly duplicative and irrational.<sup>49</sup>
  - (6) The exporter must seek and obtain a fully TRIPS-compulsory license from its own government on a single-country, single-product basis, Article 31(a), (c), (d), (e), (g), (i), (j); in addition, the export license must be for a specific quantity only.
  - (7) Royalty compensation must be individually determined based on economic value in the importing country; countries may be able to set presumptive rates of 2–6%.
  - (8) "The exporting Member shall notify the TRIPS Council of the grant of the license, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity (ies) for which it has been granted, the country (ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification shall also indicate the address of the website [upon which the licensee posts its required information]".<sup>50</sup>
  - (9) The exporter must investigate pill size, shape, colouring, labelling and packaging of the patent-holder's product in the importing country and differentiate its new product in material respects, unless it is demonstrably too costly or infeasible to do so.
  - (10) Likewise, the exporter must post information on a website before shipping detailing "the quantities being supplied to each destination and the distinguishing features of the product(s)".<sup>51</sup>
  - (11) The generic producer will need to seek product registration and prove bio-equivalence or similarity in the importing country despite the patent holder's likely effort to prevent what it calls "unfair commercial use" of registration data (but only if the country has adopted data exclusivity rules).
  - (12) This process must be repeated over and over again for every medicine and for every country to which or from the medicine will be exported. Moreover, despite permission to export a medicine multiple times under an existing license until





the specified quantity is reached, multiple, successive export licenses may ultimately be required for each medicine because of the precise-quantity requirements in the Decision. A more rational interpretation, however, may permit issuance of a single export license for a particular country and a particular product.

Obviously, this arduous mechanism is not the simple and efficient solution promised at Doha, and thus far, only Canada and Norway have passed legislation to authorise exports (though others are expected). No country, including neither **Malawi** nor **Kenya**, has yet passed Paragraph 6-compliant import legislation. Overall, the Paragraph 6 Decision constructs a complex, procedural labyrinth that stands between a willing, low-cost supplier and a country desperately needing imported generics. Although the Agreement has produced a modicum of certainty, it has done so at a high cost in terms of ease of use. Indeed, it may have erected such substantial procedural barriers that generic entrants will be deterred from ever venturing into the production-for-export market.

## Chart 12 – Importation Pursuant to the Paragraph 6 Decision

### Advantages

Covers all products in the pharmaceutical sector, including diagnostic test and active ingredients.

Not limited to emergencies or grave public health concerns like HIV/AIDS, TB and malaria and therefore it may be used to address many public health concerns.

Importation is available to all least developed countries and is further available to countries that determine that they have insufficient capacity in their pharmaceutical sector. Countries' determination of capacity is not subject to prior approval by the WTO. Liberal interpretation of the term insufficient capacity should permit countries to consider issues

### Disadvantages

Does not explicitly cover vaccines, but implicitly it does.

The U.S. may persist in trying to limit application of the Agreement to major infectious diseases.

Importing countries might be pressured concerning their intent to utilise the system and their evaluation of insufficient capacity in their pharmaceutical sector. Some developed countries might focus on theoretical rather than actual capacity. Capacity decisions and the grounds for determining insufficiency must be reported to the WTO. Other Members may question such determinations and WTO consultations might force countries to relinquish their import rights. Determinations of capacity



of cost-effectiveness and inefficient economies of scale. In addition, importation is available on a regional basis with rights of re-exportation within regional trade groups with more than 50% least developed country membership.

Any country may be a source of supply. Therefore, some developed countries with highly developed generic industries, like Canada, might be able to supply generics of assured quality.

Although all quantities must be exported, the exporting licensee will be able to aggregate demand from multiple countries and achieve economies of scale, but will need separate Paragraph 6 notifications and/or compulsory licenses from each country to do so.

Imported generics will be clearly labelled and easily identified.

Importers will not have to pay double royalties.

are subject to on-going review as capacity changes over time. Some developing countries might be tempted to invest in expansion of their pharmaceutical capacity even though that capacity will be non-competitive and unsustainable. That local capacity for a particular product might then be used against them in subsequent attempts to use the Paragraph 6 system.

The arduous procedural and notification requirements might deter some countries from opting to issue compulsory licenses for export. The sheer administrative/legal burden of the licensing procedures might overwhelm the bureaucratic capacity of many potential exporting nations.

Many of the most lucrative markets have been excluded from participation, thereby reducing assured purchasing power and reducing important and achievable economies-of-scale.

The requirement to differentiate medicines other than through labelling and packaging may add marginally to cost. Other anti-diversion measures may tax developing countries' capacity, whereas developed countries have the ability and self-interest to deter illegal trade in medicines.

Royalties must be set in the exporting country based on commercial value in the importing country, which is administratively burdensome and impractical. Moreover, even when the medicine is exported to a country without a patent, a royalty may need to be paid, though there is a counterargument that the value in the importing country is zero.



Procurement via import will be transparent.

Multiple notifications from both the importing and exporting countries and from the exporting licensee are duplicative, burdensome and might subject them to excessive oversight and manipulation, both by other Member States and by pharmaceutical patent holders.

The Decision creates some legal certainty by granting a waiver, but even greater certainty ultimately depends on amendments to the TRIPS Agreement.

Greater legal certainty comes at a great cost, particularly in terms of procedural complexity and delays built into a double-licensing system and the requirement that export licenses are for a specific quantity, necessitating iterative licensing for even one product.

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### 3.6 Two other sourcing options: local production via compulsory and voluntary licenses

#### KEY MESSAGE:

Although local production is facially appealing as a way to achieve technological development and to ensure a local, sustainable source of supply for needed medicines, the practicalities of jump-starting an economically competitive industry that produces medicines of assured quality is daunting. Nonetheless, local production can be catalysed in some countries by means of voluntary and compulsory licensing initiatives.

Resort to the five alternatives outlined above is dependent on import/export flexibilities within the existing TRIPS regime, but there are two other sourcing options (other than purchase through discount pricing), which are worth a mention: compulsory and voluntary licenses authorising local production. As part of their industrial or development policy, developing countries may want to develop indigenous capacity to manufacture pharmaceutical products by issuing **compulsory licenses or government use orders for local production**. To enable local production of cheaper generics, they can create incentives for entities ranging from purely domestic companies to subsidiaries of generic companies.<sup>50</sup> Similarly, they can encourage a wide range of productive activities varying from manufacture of both active pharmaceutical ingredients and final formulations to packaging of imported formulations. Developing countries can lawfully encourage this expansion of pharmaceutical capacity both by direct and indirect forms of support and by procurement preferences for locally produced pharmaceuticals, as long as they have not traded away these flexibilities in trade agreements.

However, the allure of local production may blind some developing countries to its true costs. To begin with, most developing countries will need to import active pharmaceutical ingredients which constitute the major cost component of medicines and thus the value added by local production will be far less than the medicine's final price. Additional risks arising from over-optimistic reliance on local production may include decreased flexibility to rely on Paragraph 6 Decision importation options in the future and higher prices for medicines that can be cheaper if sourced from overseas. In this regard, understanding economies-of-scale and the need for up-to-date technologies and a skilled workforce is vitally important. Because pharmaceutical products may be produced more efficiently in larger quantities<sup>53</sup> and then distributed through international trade, countries should hesitate to over-invest and over-rely on uneconomical and technologically obsolete local manufacturing facilities.

On the other hand, in terms of industrial development policy and ensuring multiple, sustainable sources of supply, it may be important to increase pharmaceutical capacity in developing countries, particularly for more technologically adept regional suppliers, like South Africa, which has used both voluntary licenses and the threat of compulsory licenses to re-energise its local generic industry. However, decisions to invest (and gamble) in increased local capacity should be ruthlessly conditioned on cost-effectiveness criteria, good manufacturing practices and sustainability.

### Chart 13 – Compulsory Licenses for Local Production

#### Advantages

Local production guarantees continuity of supply and permits easier testing of manufacturing processes and product safety.

Under certain conditions, local production builds local technological capacity, economic activity and employment, particularly of skilled labour.

Local production eases balance of payment problems for the value added by local production and typically keeps wealth and profits in the country where they might be invested to create even

#### Disadvantages

Developed countries and research-based drug companies argue that granting compulsory licensing for local production might discourage foreign investment, retard transfer of technology, including technology necessary for local production, and inhibit research and development, particularly R&D into the epidemic diseases of Africa, such as HIV/AIDS, malaria and TB. However, there is little or no empirical evidence for any of these commonly expressed concerns.

The quality of locally produced medicines might be problematic especially in countries that otherwise lack state of the art facilities and workforces and adequate resources and expertise for testing product quality and compiling post-approval reports of adverse effects.

Compulsory licensing for local production may not be possible in many countries that lack adequate pharmaceutical capacity and human capital. Moreover, these barriers to entry are certain to extend the time

more economic capacity.

within which drugs can be manufactured, thereby delaying effective responses to true public health emergencies.

Local markets may be too small to achieve economies-of-scale making local manufacture impracticable.

Issuing compulsory licenses for local production can be procedurally burdensome, though countries can choose to enact streamlined administrative procedures.

A second sourcing option is **voluntary licenses**. Although the attractiveness of voluntary licenses can be undermined when they produce too few competitors, when narrow geographical restrictions are imposed and when technological expertise is withheld, affirmative regulation of voluntary licenses, as discussed further in section 4.2.2. below, could result in meaningful access to locally produced generic products.

## Chart 14 – Voluntary Licenses Authorising Local Production

### Advantages

Voluntary licenses could be quickly negotiated without reliance on expensive and time-consuming administrative or judicial procedures.

They could support transfer of technology and local economic development/diversification, especially when the patent holder transfers production expertise.

They ordinarily permit access to registration data, despite data exclusivity rules.

They could (but need not) permit exportation to other developing countries.

### Disadvantages

The patent holder is under no compulsion to grant a voluntary license, though the background possibility of a compulsory license does exert some pressure.

The patent holder has superior bargaining power, leading to multiple potential defects, including market-segment (public sector only); geographical limitations; price control and excessive royalty rates. When left solely to the preferences of the patent-holder and the licensee(s), there is usually either a transfer of the monopoly or limited market sharing meaning that the local market is unlikely to become truly competitive and prices will remain high.

Most voluntary licenses do not yet permit cross-licensing with other companies to facilitate production of therapeutically appropriate fixed-dose combination medicines.

A broad pattern of voluntary licenses might retard the development of a dynamic, competitive and truly independent generic industry.

### 3.7 Four overarching concerns: an insufficient number of producers of particular products, insufficient demand to create a competitive, low-cost generic industry, drug registration requirements and TRIPS-plus provisions in bilateral and regional trade agreements

#### KEY MESSAGE:

Although this paper has attempted to outline major options that non-producing countries have for importing medicines, there are five political/pragmatic barriers to access that should be addressed:

- (1) the widespread need for legislative and regulatory reform in developing countries to make maximum use of TRIPS-compliant flexibilities for producing and accessing generic medicines;
- (2) the limited number of qualified producers for many important medicines;
- (3) insufficient current demand to reach efficient economies-of-scale and to simultaneously support competition;
- (4) difficulties in registering generic medicines; and
- (5) undesirable concessions in bilateral and regional trade agreements.

Because this paper addresses necessary legislative reform extensively in section 4.2.1, *infra*, the paper will only address the last four barriers at this time.

#### 3.7.1 Limited number of qualified generic producers for many newer medicines

The small number of high-quality generic producers that may be able to manufacture newer, widely patented medicines is a persistent problem for both importing and exporting countries. Very few countries, except notably India, have reverse engineered more recent, on-patent medicines, reformulated them, produced them according to Good Manufacturing Practices and established bio-equivalence according to international standards. As discussed further in section 3.7.3 below, generic companies are ordinarily precluded from marketing generics equivalents in developed countries until patent expiration, though in some countries they can register the medicine before patent expiration pursuant to the Bolar exception. Accordingly, they rarely begin to develop the drug and prepare a registration dossier until right before a patent ends. Thus, for many newer medicines, including important antiretrovirals (ARVs) like Efavirerz, there are few, if any, generic equivalents. **This profound lack of generic producers for newer medicines will not be overcome unless economic, procedural and technical barriers to entry are reduced – fundamentally, unless it becomes possible to estimate sufficient future demand to justify the costs of developing a particular generic equivalent for market.**

### 3.7.2 Insufficient demand, inefficient economies-of-scale and lack of competition

The benefits of utilising TRIPS flexibilities to secure generic sources of supply will be most significant when multiple producers can reach efficient economies-of-scale and when they thereafter compete to drive prices close to the marginal cost of production. WHO, UNICEF and other multilateral and national procurement agencies recognise the desirability of having several competing sources of supply, so that price competition can be maintained and so that the failure or stock-out of one company will not inadvertently stop the supply of essential medicines. Small developing countries with insufficient public or private resources for procuring medicines cannot individually create market incentives for even one generic producer, let alone incentives for a robust, competitive generic industry. In contrast, the Clinton Foundation brokered a historic breakthrough on ARV prices (less than \$140/year) primarily because it was based on aggregating large-scale demand from multiple importing countries. Moreover, instead of promoting entry by a single generic producer, the Clinton Foundation involved manufacturers of active pharmaceutical ingredients and at least three generic competitors. **Accordingly, if TRIPS flexibilities are to have any meaningful impact on access to medicines, it will be important to create and fund large-scale demand for medicines, not just by individual non-producing countries but also by as much of the non-producing region as possible.** The effect of this aggregated demand will be most significant in affecting the price of active pharmaceutical ingredients, but it might also be important with respect to formulated products as well.

### 3.7.3 Restrictions on drug registration

Because poor quality medicines can have such serious consequences for health, most countries have adopted exacting **quality, safety and efficacy** standards that require prior regulatory approval before a medicine can be distributed within domestic markets.<sup>54</sup> Although some countries cooperate in regional registration agreements and although others rely on prior registration by a stringent drug regulatory authority in another country, many countries require separate submission of safety/efficacy data as a pre-condition to domestic registration. To meet these requirements, research-based drug companies routinely amass voluminous documentation as part of their research and development of new drugs and they submit that information, on a confidential basis, to each national drug regulatory authority where they want to market the drug.

Generic companies are loath to undertake duplicative, costly and time-consuming clinical trials and thus ordinarily rely on regulatory agencies' ability to internally review and compare the follow-on product's data against the registration data submitted by the prior entrant (or to rely on a prior registration of the product domestically or elsewhere). Although the highest standard of comparison requires proof of the **bio-equivalence** of the generic follow-on, some developing countries accept a lesser standard of "similarity".<sup>55</sup>



Although Article 39.3 of TRIPS undoubtedly permits this practice,<sup>54</sup> despite mandating some protection against unfair commercial use of research-based drug registration data, there are several practical and legal barriers to the registration of generic medicines in developing countries. First, registration is time-consuming and costly, especially in relation to the anticipated volume of sales in small markets.<sup>57</sup> Second, some of the poorest developing countries have inadequately staffed and/or inefficient registration authorities, which mean that requests to register a generic can languish for years. Third, and perhaps worst, a stamp of approval from some of these authorities is unreliable.

Because of regulatory incapacity and/or weakness, some developed countries, e.g. the U.S., are urging developing countries to condition registration of both first entrants and follow-on drugs on prior registration by a “stringent” regulatory authority. Conveniently for patent holders, however, generic producers ordinarily have no incentive to register their products in countries that have stringent regulatory agencies, because those same countries refuse permission to sell the generic until patent expiration.<sup>58</sup>

Although it is generally undesirable in terms of access to medicines to require that the generic product be previously registered by a stringent authority, it may make sense to let a generic manufacturer rely “vicariously” on the registration of the originator product by a stringent regulatory agency and thereafter to establish similarity, or better yet, bio-equivalence, with that product. This solution is attractive since some research-based companies are neglecting to register their products in smaller developing countries – essentially abandoning the market. In this context, unless the generic entrant can rely on the fact of foreign registration and thereafter prove the equivalence of its product, it too may be barred from obtaining marketing approval because of the diseconomies of conducting clinical trials.

As an alternative strategy for raising the registration bar, the U.S. and major pharmaceutical companies are promoting harmonisation of registration standards at a “platinum” standard that produce no real gain in quality, safety or efficacy. Unfortunately, harmonising drug registration at an overly high standard that only research-based companies are prepared to meet will prevent dynamic competition from generic producers who otherwise produce drugs of assured quality.

The most troubling new barrier in access to medicines arises because major drug companies and their champions in the U.S. trade office are increasingly turning to **data exclusivity** and **patent/registration linkage** as tools for securing market domination. For example, in nearly all of its recent and pending bilateral and regional trade agreements, the U.S. is seeking data exclusivity for information that a company submits when registering a new drug entity for marketing approval, even when that entity is not itself separately patented. Once a country grants five years of data exclusivity on U.S. terms, generic producers are precluded from relying on pre-existing data to establish safety and efficacy even when the producer has evidence that the two drugs are bio-equivalent. Thus, in order to establish quality, safety and efficacy for purposes of drug

registration, the generic company would have to duplicate time-consuming, expensive and perhaps unethical clinical trials.<sup>59</sup> Since it would not make sense to do so for time reasons alone – clinical trials ordinarily take several years to complete – data exclusivity could be a death knell to an effective import/export compulsory license scheme, at least for the first five years that a new drug is on the market.

A five-year embargo on generics is bad enough, but in addition the U.S. is also trying to link drug registration to patent status and thus ensuring an even longer period of marketing exclusivity for patented medicines. For example, Chapter Fifteen Article 15.10.3 of the U.S./Central America Free Trade Agreement provides:

Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as, evidence of prior marketing approval in the Party or in another territory, that Party:

- (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and
- (b) if the Party permits a third person to request marketing approval of a product during the term of a patent identified as claiming the product or its approved use, it shall provide that the patent owner be informed of such request and the identity of any such other person.<sup>60</sup>

Although this provision permits registration applications during the term of a patent, it requires notification of such application to the patent holder, who can, thereafter, claim patent infringement or otherwise plan to defend or extend its patent. Even worse, the new clause precludes actual registration until patent expiration. Unless there is an implied limitation in this clause permitting registration of medicines produced under compulsory licenses, the U.S. may have succeeded, in bilateral and regional trade agreements with this term, in euthanising both the Doha Declaration and the Paragraph 6 Decision in one fell swoop. Sure, countries can theoretically bypass patents; but, if they give away registration rights in trade agreements with the U.S., they then confront an insurmountable regulatory barrier that precludes registration for the remaining term of a patent, or until the five-year data exclusivity term has concluded, whichever is later!<sup>61</sup> **Accordingly, unless clarified in binding terms, data exclusivity and exclusive marketing rights can derail or postpone access to lower cost, generic medicines even when patent rights are circumvented pursuant to TRIPS' flexibilities – this risk of further delays in accessing medicines must be avoided at all costs.**

One hopeful countermeasure to the data-exclusivity problem is the WHO Pre-Qualification Program that certifies safety, efficacy and quality of specific medicines



produced by specific manufacturers at specific facilities. WHO prequalification could justify expedited registration by developing countries and could permit them to bypass data exclusivity rules.<sup>62</sup> (The threat posed by patent/registration linkage, however, would remain.) Despite the appeal of regulatory reliance on WHO prequalification, developing countries should still insist that data exclusivity and registration/data linkage be excluded in new free trade agreements.

### 3.7.4 TRIPS-plus provisions in regional and bilateral trade agreements

Despite having agreed to patent flexibilities in the TRIPS Agreement, the Doha Declaration and the Paragraph 6 Decision, the U.S. and other developed countries continue to seek heightened intellectual property protections for pharmaceutical products in regional and bilateral trade agreements. To this end, in the past two years, the U.S. has concluded negotiations with Jordan, Chile, Singapore, Morocco and Australia and it is continuing to negotiate bilateral agreements with Thailand and other developing countries. In addition, it is pursuing regional negotiations in Central America, the Andes, Southern Africa and indeed the entire Western Hemisphere. In these negotiations, the U.S. is seeking to impose TRIPS-plus intellectual property protections that risk dramatically undermining both the Doha Declaration and the Paragraph 6 Decision by requiring countries to meet “standards of protection similar to that found in U.S. law”.<sup>63</sup> These standards:

- limit compulsory licenses to national emergencies, to governmental, non-commercial use and to anti-competitive practices remedies and preclude production for export;<sup>64</sup>
- bar parallel trade;<sup>65</sup>
- grant patent status for new uses and otherwise ease patent standards;
- extend patent monopolies for administrative delays;
- enhance protections for clinical trial data by providing at least five years of data exclusivity, thereby potentially delaying registration of medicines produced under compulsory licenses (discussed in 3.7.3. *supra*) and link drug registration rights to patent status, thereby granting absolute marketing exclusivity (discussed in 3.7.3. *supra*).

**To counteract the danger of ill-conceived trade concessions that narrow access to medicines, developing countries should adopt a collaborative position, resisting efforts to add TRIPS-plus measures in regional or bilateral trade agreements. TRIPS, the Doha Declaration and the Paragraph 6 Decision should be interpreted as creating a ceiling for intellectual property protections, not as a platform for further protections, particularly in the pharmaceutical sector. Only by uniting, can developing countries resist being picked off one-by-one and region-by-region by their most powerful trading partners.<sup>66</sup>**



# 4 Developing Countries' Pro-Active Options for Increasing Access to Medicines

## KEY MESSAGE:

Because existing flexibilities for accessing medicines are ultimately insufficient, developing countries must be proactive in reforming legislation and cooperating regionally to maximise access. They also have to encourage and engage activists and affected communities in their policy deliberations.

### 4.1 Eliminating the import/export patent-information thicket

A threshold problem in utilising sourcing options for medicines arises from the import/export patent-information thicket.<sup>67</sup> At present, it is difficult to discover whether a medicine is on patent or not and even more difficult to determine the number of patents that apply. This difficulty is intensified in developing countries with antiquated, paper-based patent systems and with systems that allow forfeiture or suspension of patents because of failure to pay annual patent fees. Not only must one investigate patent status in the importing country, there must be a full search in the exporting Member's patent office as well. Moreover, because of the territorial nature of patents, differing patent standards and differing filing decisions and filing dates, it is quite likely that a medicine's patent status in the importing country will differ significantly from that in the exporting country, complicating a generic company's efforts to use the TRIPS-compliant compulsory license.

Thus, a clear area of future reform is to make the compulsory license import/export system more rationale and user-friendly and to require patent-holders, WIPO and/or other multilateral agencies to create a central facility for listing pharmaceutical patents.<sup>68</sup> In addition to funding a central facility for such listings, developed countries could enact reforms requiring drug companies to list all patents they claim to hold in developing countries as a condition of granting marketing rights. Similarly, donor agencies could condition consideration of supply bids on drug companies' public disclosure of their patent claims in developing countries.

## 4.2 Promoting pro-health IP policies and practices within each developing country

### 4.2.1 Enacting TRIPS-compliant patent law reform

Optimal use of TRIPS flexibilities will ordinarily require extensive legislative and regulatory reform in developing countries,<sup>69</sup> both by importers and exporters.<sup>70</sup> The principal area of such reform is amendment of legislative and regulatory schemes to legalise resort to all flexibilities in the TRIPS Agreement and related texts. Although it is beyond the scope of this paper to describe those reforms in detail, Chart 15 highlights the minimal provisions that should be considered.<sup>71</sup> At a minimum, the legislative and regulatory language should clearly empower, and in some instances require, the appropriate regulatory agency to issue compulsory licenses or government use orders, particularly to redress an access gap.

### Chart 15 – Pro-Access Legislative Reform

Legislative Reform in Importing Country	Legislative Reform in Exporting Country
<ol style="list-style-type: none"> <li>1. Authority to grant compulsory licenses on all permissible grounds:               <ol style="list-style-type: none"> <li>a. For emergencies and other matters of extreme urgency without prior notification (TRIPS Art. 31(b)); would be wise to designate HIV/AIDS, TB and malaria as public health matters of extreme urgency not subject to emergency declaration standards, constitutional or legislative (Doha Declaration para. 5(c));</li> <li>b. For governmental, non-commercial use without prior notification (TRIPS Art. 31(b));</li> <li>c. For non-emergency public health needs requiring access to more affordable pharmaceutical products (TRIPS Art. 31(b), Doha Declaration para. 5(b));</li> <li>d. To remedy anti-competitive practices and therefore to be able to export to other countries, no notification required (TRIPS Art. 31(k), Art. 40);</li> <li>e. Stipulation that all such licenses can be</li> </ol> </li> </ol>	<ol style="list-style-type: none"> <li>1. Authority to grant regular compulsory license on all permissible grounds (emergencies, governmental/non-commercial use, public health and to remedy anti-competitive practices) (TRIPS Art. 31(b), 31(k), Doha Declaration para. 5(b) and (c)).</li> <li>2. Authority to export non-predominant quantities pursuant to a regular compulsory license (TRIPS Art. 31(f)).</li> <li>3. Authority to export unlimited quantities in the event of practices found anti-competitive (TRIPS Art. 31(k), see section 4.2.2, <i>infra</i> re. grounds for issuing licenses for anti-competitive practices).</li> <li>4. Authority to grant compulsory licenses on the basis of notification of a Member to the TRIPS Council pursuant to the Paragraph 6 Decision.               <ol style="list-style-type: none"> <li>a. Should allow simplified procedures;</li> <li>b. Should allow joint consideration of concurrent licenses for multiple importers;</li> <li>c. Must require notification, procedures and limitations of the Paragraph 6</li> </ol> </li> </ol>



- satisfied by local production and/or import (TRIPS Art. 27.1);
- f. Special compulsory licenses for import when country determines it lacks sufficient local capacity to manufacture efficiently or in a timely manner (Paragraph 6 Decision);
- g. Ability to re-export regionally if part of a regional trade agreement (Paragraph 6 Decision para. 6(i));
- h. Ability to register generics produced under a compulsory license by comparison to prior registration data or by reference to prior registration (TRIPS Art. 39.3) and expedited registration based on WHO pre-qualification;
- i. Limits on patent-holders' rights of appeal and preclusion of injunctive relief; use administrative procedures;
- j. Royalty rates in a presumptive range (2–6%) see endnote 39, *supra*.
2. International exhaustion regime allowing parallel importation (TRIPS Art. 6, Doha Declaration para. 5(d)).
- Decision and perhaps the Chairperson's Statement);
- d. Should set compensation pursuant to a presumptive schedule (2–6%) based on value in the importing country;
- e. Should limit rights of appeal and preclude injunctive relief by patent holders;
- f. Should require least costly methods of differentiation to satisfy provisions concerning product diversion.
5. Authority to produce medicines for export based on a Paragraph 6 Decision request as a limited exception (TRIPS Art. 30 – untested).
6. Authority to produce medicines for export on humanitarian grounds as a limited exception (TRIPS Art. 30 – untested).
7. Authority for wholesalers and other buyers to export patented medicines already sold by patent holders to other developing countries to satisfy their parallel importation needs (TRIPS Art. 6).
8. Encourage technology transfer to developing countries without capacity to manufacture medicines.

#### 4.2.2 Coordinating compulsory license, voluntary license and competition policies

Although the principal focus of reform under the TRIPS and Paragraph 6 regime concerns authorisation for the issuance of compulsory licenses and government use orders, **policy makers in developing countries should also focus on reforming competition policy and regulating voluntary licenses in the pharmaceutical sector**. South Africa and **Kenya** have done a particularly good job of invigorating competition-based theories, and South Africa has litigated such claims at its Competition Commission. Unfortunately, **Kenya** thus far shows little evidence of enforcing its existing competition policy however good it is on paper.<sup>72</sup>

By their very nature, drug patents grant quasi-monopoly status and negatively effect competition in the short term because they enable the patent holder to exclude other manufacturers and vendors. Although “normal” exploitation of patent rights might not

constitute an anti-competitive practice because of countervailing public policies favouring innovation, **excessive prices** and **refusals to license** drugs might be held anti-competitive in particular settings, particularly where a pharmaceutical product dominates a therapeutic class, where product substitution is not feasible, and where a supra-competitive price prevails.

One of the most promising competition theories affecting access to medicines is one that addresses excessive pricing and refusals to deal where there is a resulting **access gap** for an essential product like medicines.<sup>73</sup> A particularly salient version of the anti-competitive, access-gap theory utilises the existing “**essential facilities doctrine**”<sup>74</sup> and focuses on the issue of downstream innovation, product improvements and/or drug combinations. In particular, establishing an essential facilities theory premised on the desirability of fixed-dose combinations is highly desirable in light of the recent recommendation of the WHO favouring fixed-dose ARV combinations as a first line therapy in resource poor settings.<sup>75</sup> Although patent holders have historically been reluctant to cross-license rational combinations to each other, generic companies face no such inhibition.<sup>76</sup>

As a remedy for the above-described anti-competitive practices, a country could issue an Article 31(k)-compliant license authorising unlimited export to other countries. An additional advantage of competition-based licenses is that they can provide remedies beyond circumvention of a patent.<sup>77</sup> As previously discussed, a competition-based license could require access to drug registration data or permit reliance on a prior registration, thereby greatly easing the ability of the generic licensee to establish bio-equivalence (or similarity), even where a country had improvidently granted data exclusivity rights. In addition, the patent holder might be forced to transfer secret manufacturing expertise.<sup>78</sup>

## Chart 16 – Competition Policy Reforms

### Advantages

Robust competition policy reform might lead to rules prohibiting:

1. Abusive or excessive pricing leading to a gap in access (S.A. Comp. Comm.);
2. Refusal to issue voluntary licenses (S.A. Comp. Comm.);
3. Lack of access to an essential technology or facility, especially important with respect to sourcing

### Disadvantages

1. It is difficult, but not impossible, to define legal principles for regulating excessive pricing and illegal refusals to license because patent protection is granted in substantial part as a reward for innovation and as a deterrent for copycat competition.
2. Administering a revised competition policy will tax existing administrative resources and expertise and litigating such cases is bound to provoke vigorous defences by patent holders.
3. Successful prosecution of cases involving multinational corporations relies on foreign information that might be hard to obtain, though



<p>fixed-dose combination medicines (S.A. Comp Comm.);</p> <p>4. Patent holder restrictions on right to “parallel export” to developing countries;</p> <p>5. Any and all other anti-competitive practices.</p> <p>Remedial reform could permit:</p> <ol style="list-style-type: none"> <li>1. Access to drug registration data;</li> <li>2. Access to manufacturing expertise.</li> </ol>	<p>there is an obligation of foreign Member cooperation under Art. 40.3 of TRIPS and agencies can presumably require drug company cooperation with information requests.</p> <p>4. Patent holders might withhold innovative pharmaceutical products from the markets where they lose exclusivity and they might attempt to thwart the issuance of compulsory licenses by granting voluntary licenses to favoured companies.</p> <p>5. Ministers of trade and industry might be worried about the impact of an over-robust competition policy on direct foreign investment, especially by IP industries.</p> <p>6. Developed country Members might consider an overly robust competition policy not to be TRIPS-compliant and resort to WTO dispute resolution even though Article 40.2 clearly authorises countries to enact legislation addressing abuse of patent rights.</p>
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An additional policy option that developing countries have for accessing generic medicines is to apply competition principles to the voluntary licensing of pharmaceutical products,<sup>79</sup> as **Kenya** has done.<sup>80</sup> Left to their own devices, patent holders and licensees often produce collusive licenses that merely transfer the patent-monopoly on terms highly favourable to the patent holder. For example, where voluntary licenses are relatively unregulated, pharmaceutical companies can increase the amount of compensation, limit permitted usages, prevent multi-sector distribution and limit geographical scope to prevent export.<sup>81</sup>

To counterbalance the risk of these anti-competitive outcomes in voluntary licensing negotiations, developing countries could choose to regulate the following features of voluntary licenses, particularly those negotiated pursuant to a compulsory licensing scheme: (a) ensuring a broad geographical scope and explicit options for export within a Paragraph 6 Decision authorised regional trade group; (b) prohibition of sector limitations (no public sector or NGO-only sector clauses); (c) non-exclusivity and a preference for licenses open to multiple entrants; (d) explicit permission to produce fixed-dose combination medicines where appropriate, e.g. HIV/AIDS; (d) requirements of some degree of technology transfer and/or manufacturing expertise; (e) authorisation to use or rely on registration data (or a prior registration) for purposes registering the licensed medicine; and (f) public disclosure of royalty rates negotiated within a range of reasonableness.<sup>82</sup>



As desirable as these reforms are, non-producing countries might hesitate to institute reforms that restrict investor's rights or that signal an "anti-business" environment. Moreover, many developing countries lack technical expertise in intellectual property and competition policy reform and existing technical assistance from WIPO and USAID contractors has historically not focused on maximising flexibilities. Thus, it will be important for developing countries to obtain highly qualified technical assistance from more pro-health sources such as the WHO, which is mandated to provide such assistance. An alternative approach would be to develop regional systems for developing and coordinating competition policy reforms, an option discussed further in section 4.3 below.

#### **4.2.3 Avoiding market segmentation between private and public sector health care and encourage integrated drug procurement**

**In an era when global health experts are seeking reinvigoration of public health sectors and national coordination for major pandemics like HIV/AIDS, developing countries should undertake measures that reduce internal market segmentation for pharmaceutical products so that the treatment of disease can increasingly be rationalised through an integrated health sector response.** In this regard, having a common sourcing and pricing scheme and a coordinated delivery system will reduce the risks of product diversion and arbitrage between the public and private sector. When trying to maintain a private sector/public sector market differentiation, it becomes virtually impossible to secure distribution channels to prevent theft, corruption and diversion to the more lucrative private market, undercutting the marketing advantage there anyway. Similarly, even within the private sector, most developing country consumers cannot afford higher priced medicines. Accordingly, if developing countries want to get the maximum treatment for the most people at the lowest cost, if they want to reduce product diversion, and if they want to avoid disruption of the public sector by private sector migration, they should resist market segmentation strategies and instead coordinate the purchase and distribution of low-cost essential medicines of assured quality.

### **4.3 Cooperating regionally and coordinating regional IP and access to medicine strategies**

The importance of regional cooperation, coordination and even harmonisation has been addressed in several consultations.<sup>83</sup> Some of the most pro-access suggestions are:

#### **4.3.1 Regional cooperation/coordination in developing pro-health intellectual property and trade policy**

Although harmonisation of intellectual property legislation and competition policy within regional trade groupings might be feasible, another alternative would be coordination, whereby countries consult with internal and external experts concerning flexibilities for





accessing medicines and thereafter consult regionally concerning policy options.<sup>84</sup> For example, countries could adopt model legislation, but rather than proposing a single text, they could develop alternatives adapted to the policy needs of particular countries. Likewise, developing evidence-based systems for evaluating and reporting best practices in intellectual property and competition policy reform and practice would be quite useful. In addition to coordinating regional intellectual-property/competition-policy reform, developing countries should coordinate IP-related trade policy for bilateral, regional and multilateral trade negotiations, especially since the U.S. and E.U. continue to seek TRIPS-plus measures in these forums.

#### **4.3.2 Cooperation in regional compulsory licensing schemes and regional trade, especially for trading groups with 50% LDCs**

If countries have coordinated their intellectual property schemes, they might also explore regional approaches to the timing and issuance of compulsory licenses. The actual issuance of regional compulsory licenses seems far-fetched except for entities like the African Intellectual Property Organization that grant patents on a regional basis. However, countries could coordinate their pursuit of compulsory licenses, for example, coordinating the timing of licenses to permit a prospective licensee to engage in a single coordinated negotiation with the relevant patent holder(s). Coordination could also help the presentation of a joint request for concurrent compulsory licenses for export under the Paragraph 6 Decision. An additional advantage of coordinating licenses regionally is that it might reduce purely domestic political pressure against such issuance, including those arising from drug company pressure and from local allegiance to drug company interests. Finally, and most importantly, such coordination could help ensure economies-of-scale and longer-term markets for potential generic entrants.<sup>85</sup> Since the overarching goal of assuring access to medicines is to provoke entry by multiple qualified generic producers, all of whom compete to lower prices, consolidating regional demand can lead to multiple, cheaper and more sustainable sources of supply.

#### **4.3.3 Regional cooperation for negotiating high-quality voluntary licenses facilitating entry of multiple competitors, access to registration data, permission for cross-licensing of FDC and technology transfer**

Although the creation of compulsory licensing options is a critical policy option, one of its greatest values is to create leverage for concessionary pricing and for issuance of quasi-voluntary licenses. The threat of compulsory licenses to induce price reductions has been best illustrated in Brazil. However, an even more recent example from South Africa demonstrates that using robust competition theories and the threat of compulsory licenses can induce voluntary licenses with favourable terms.<sup>86</sup> Using this precedent, which resulted in domestic production licenses to supply ARVs to the entire sub-Saharan region, there is no reason why countries cannot cooperate to negotiate regional voluntary licenses. To maximise the benefits of regional cooperation, it will be desirable to coordinate a pro-health and/or competition-policy framework that sets guidelines for

evaluating the terms of voluntary licenses. At a minimum, these licenses should allow for regional sales, be open to multiple generic producers, be long-term and involve small royalties, permit crossing licensing of rational fixed-dose combinations, allow access to confidential registration data and finally promote some degree of technology transfer.

#### **4.3.4 Regional pooled procurement mechanisms**

Multiple options for regional pooled procurement have been discussed at length elsewhere.<sup>87</sup> Although regional procurement will be difficult because of differing patent and registration issues in different countries,<sup>88</sup> such procurement, can lower prices, aid quality assurance, improve information concerning supplier performance and provide incentives for harmonisation of rational drug use and drug registration policies and practices. Models for regional cooperation range from informed buying, to coordinated buying, to group contracting and finally to central contracting and purchasing. According to investigators, the principle predictors of success in pooled procurement on a regional level are political will and organisation commitment, a permanent and autonomous procurement secretariat, harmonisation and standardisation, good pharmaceutical procurement practices, secure financing and prompt payment, quality assurance and side benefits.<sup>89</sup>

Options for pooled procurement will certainly be enhanced where there is regional cooperation in issuing compulsory licenses. However, even in the absence of such cooperation, there are already examples of multilateral organizations helping with regional procurement. For example, the WHO is leading coordination with respect to procurement of AIDS medicines with its new AIDS Medicines and Diagnostic Service. Similarly, PAHO has helped to organize pooled procurement at discounted prices for several Latin American countries.

#### **4.3.5 Shared investment in regional productive capacity and development of indigenous expertise with a special commitment to R & D for neglected diseases**

In subsection 3.6, this paper addressed the possibility of relying on TRIPS-compliant local production of generic medicines. As noted, most developing countries lack sufficient market size and/or technological capacity to support a highly competitive pharmaceutical industry focused solely on a domestic market. Even though domestic production might not be feasible, regional production may be, at least in the long run, though there are many complications in planning and implementing a regional approach, not the least of which is competition between regional partners about where to site pharmaceutical facilities.

Even though many regional economic communities have a mandate for developing regional scientific and technological capacity, only ASEAN seems to have undertaken detailed planning for industrial plants designed to meet regional needs of essential



commodities. In addition to requiring local incorporation, local operation and partial local ownership, the ASEAN regional agreement requires participation by at least two companies located in different countries and its further requires resource sharing and industrial cooperation. This agreement has not yet been used for pharmaceuticals, but it could be.

Another variant of regional cooperation is technology transfer from more technologically advanced developing countries like India and Brazil, each of which is involved in current projects for developing pharmaceutical capacity in select African countries. In the end, whatever form of cooperation there might be to develop regional pharmaceutical capacity, it should involve a commitment to funding research and development for endemic, neglected diseases.<sup>90</sup>

Paradoxically, there is a potential problem concerning the development of regional export capacity contained in the “industrial/commercial policy” prohibition of the Chairperson’s Statement. However, since the Paragraph 6 Decision favours reaching economies-of-scale in technology transfer involving LDCs, it would be incoherent not to tolerate planning and coordination of regional pharmaceutical capacity even though that expanded capacity is pursued pursuant to “development” as well as access goals.

#### **4.3.6 Regional cooperation in drug registration to ensure marketing of medicines of assured quality, with preferential and expedited registration of medicines pre-qualified by the WHO, and regional cooperation in post-marketing quality assurance**

One of the most crucial and obvious areas of regional cooperation, well underway already, is drug registration. Despite considerable complexity in coordinating registration of medicines given differing national policies concerning essential medicines, rational drug use and a host of other issues, regions in Latin America and the Caribbean, in Africa and in South East Asia have begun to harmonise and/or share drug registration responsibilities.

In this regard, it will be important for developing countries to make use of the WHO Pre-Qualification Project, which is currently pre-qualifying specific AIDS medicines produced by certain manufacturers in particular plants, to inform their own drug registration decisions. Thus, one important form of regional cooperation, especially in regions where there is a weak regulatory infrastructure, would be to rely on WHO pre-qualification to justify temporary waivers from registration requirements and/or to permit expedited approvals.

Whatever regional approaches are selected for regional registration, it will be critical to establish independent, highly qualified and transparent authorities that can monitor WHO Good Manufacturing Practices and who can further conduct post-marketing surveillance via well-equipped, well-maintained and well-staffed quality control

laboratories. This is a particularly promising form of regional cooperation where a small number of regional facilities can handle highly technical needs of an entire region.

#### **4.4 Creating demand for access to medicines and for medicines procurement**

Intellectual property reform does not spring solely from the mind of technocrats, aid agencies and experts. To date it has been catalysed first by imagining that people living with treatable diseases like HIV/AIDS are entitled to life-prolonging or life-saving treatment and by an active social movement that identified and then fought against an intellectual property system that was deeply problematic for developing countries in terms of access to medicines. Under a dynamic theory of political change, in order to energise continuing intellectual property reform and to expand access to medicines, it will be necessary to create even more social demand and to support the engaged participation of activists and of people living with HIV and other endemic diseases of the Global South.

Developing countries' utilisation of TRIPS flexibilities will ultimately depend on increased demand for access to treatment and to medicines and on sustained, meaningful investment in health sector capacity to increase the efficiency and rationality of procurement, distribution, prescription and use of medicines. For many developing countries, these investments will come primarily from international donors through debt relief and foreign aid, though countries must also be encouraged to increase their own investment in health care capacity and health sector reform.

To ensure adequate funding for these crucial health care investments, the international community and developing countries in particular will need to support major multilateral initiatives like the Global Fund and the WHO 3-by-5 initiative. In particular, activists in the developed world will need to launch sustained campaigns targeting donor governments and asking that they pay their proportionate share of global need on a sustainable basis.<sup>91</sup> Likewise, within developing countries, activists will need to fight their governments for an enduring fiscal and programmatic commitment to reverse the tide of death.

Since the moving force for treatment demand and for investment in the health sector has been and will continue to be a vibrant movement within civil society, policy makers should recognise the value added by involving people living with diseases and their advocates in the intellectual property reform process. Instead of marginalising participation by infected and affected communities and NGO activists, policy makers should support their right to access information concerning intellectual property proposals and to participate in policy deliberations.



#### 4.4.1 Support the Global Fund, WHO 3-by-5 Plan and other global health initiatives

The Global Fund is a major source of purchasing power for procuring medicines for AIDS, TB and malaria. It has a two-year head start on the U.S. Global AIDS Initiative and it has already authorised nearly \$3.1 billion dollars in expenditures over the first two years for 250 projects in 130 different countries (five-year commitments total \$5.4 billion through 2008). By the end of its current four-round commitments, the Global Fund will have succeeded in placing nearly 1.6 million people on antiretroviral treatment. Given this track record and despite glitches in disbursements and irregularities within country coordinating mechanisms, developing countries should support the Global Fund on an individual and regional basis both by demanding full funding for the Global Fund and by drafting high-quality proposals for dramatically scaling up the response to the HIV/AIDS, TB and malaria pandemics.

To date, developing countries' treatment proposals to the Global Fund have been relatively limited in scope and vision, perhaps out of concern about sustainability. Nonetheless, developing countries should seek technical assistance for preparing Global Fund applications that propose immediate utilisation of existing programmatic capacity and investment in new infrastructure and human capital for scaling-up universal-access treatment, care and prevention programs. To finance these bold proposals, developing countries should demand a regular replenishment process by which rich donor countries pay their equitable share of Global Fund funding requirements.

In addition to supporting the Global Fund, developing countries should commit to and advocate for the WHO 3-by-5 program and other global health initiatives. The symbolism of 3-by-5 cannot be over-estimated. It represents a commitment to speeding complicated medicines and sophisticated long-term health care to millions of people living with HIV in developing countries. It represents a dramatic statement that people need not die prematurely and that access to life-sustaining medicines is a basic human right.

To energise their own pro-health initiatives, developing countries must resist efforts by the World Bank and particularly the International Monetary Fund to block foreign donations or to limit public expenditures in the health sector. Fiscal limits imposed by those agencies, historically part of their infamous structural adjustment policies, risk strangling a more heroic response to compelling public health needs just as efforts that are more proportionate are getting off the ground.<sup>92</sup> Developing countries need many more health workers, better working conditions and higher pay in order to reverse the brain drain that leaves them bereft of the human resources necessary to future health care delivery.<sup>93</sup> They cannot tackle their escalating health crises unless they are permitted to spend more health care dollars.

Both the World Bank and IMF claim that they are easing their guidance on spending limits and that they are becoming more flexible especially where external donor aid is offered on a sustainable basis.<sup>94</sup> However, concerns remain that short-term macroeconomic policies and overwrought vigilance on inflation might directly or indirectly slow developing countries' ability and commitment to scaling up their efforts to rehabilitate health sector capacity, to recruit a new cadre of health workers,, and to provide comprehensive treatment, care and prevention services to the millions who need them.

#### **4.4.2 Involvement and coordination of affected communities and NGO activists**

Much of the important advocacy work on access to medicines, particularly in the context of HIV/AIDS, has been based on the activism and commitment of people living with HIV/AIDS and their allies in NGO and activist communities both in developing and developed countries. Although these constituencies already have a significant degree of expertise on IPR issues, that expertise is uneven and needs to be more widely spread. Increased access to this expertise is particularly important where entrenched bureaucracies and developing country legislators are inhibited from enacting reforms by threats and inducements from major pharmaceutical companies and rich country representatives. Absent pressure from disease-affected communities and their allies, local decision-makers might otherwise lack the political will to instigate many of the intellectual property reforms discussed previously.

To ensure accountability, to adapt to local conditions, to achieve community ownership and buy-in, and to benefit from the creative and knowledgeable input of affected communities and activists, developing countries should be encouraged to assist the formation of access coalitions and partnerships. In particular, these constituencies should have greater access to country-coordinating mechanisms that are drafting proposals and overseeing programmatic implementation of Global Fund programs. They should also have access to decision-makers responsible for intellectual property and competition policy reform and for implementation of access-to-medicines initiatives.





## 5 Conclusion and Policy Recommendations for DFID

This paper catalogues the flexibilities that non-producing countries have under the existing intellectual property rules to procure cheaper medicines from abroad through lawful means. Although parallel importation, compulsory licenses and government use orders, limited exceptions and the new Paragraph 6 system all have a role to play; the sad truth is that most NPDs are still ill-prepared and ill-resourced to make maximum use of these flexibilities. Moreover, many of these flexibilities, especially the Paragraph 6 system, impose burdensome conditions and procedural requirements that threaten, at the very least, to complicate and delay access to more affordable medicines.

DFID and policy makers in the U.K. must carefully assess the limitations that developing countries have to access more affordable generic medicines essential to their ability to address the public health crises that are decimating their economies, communities and families. Policy makers need to broadly construe pro-access norms and the existing flexibilities and they need to investigate whether current means for accessing medicines are sufficient. If access is insufficient, as the author believes they are, decision-makers must counterbalance demands of the research-based pharmaceutical industry designed to preserve its rights to make future profits off a thin layer of elites in developing countries against an indefensible loss of access to life-saving medicines for millions of poor people.

This paper has presented some in-country and regional intellectual property policy options for non-producing countries that might increase access to medicines. Clearly, the U.K. could and should support these options:

- Eliminating the import/export patent-information thicket;
- Enacting TRIPS-compliant patent law reform in each country;
- Coordinating domestic compulsory licensing schemes, voluntary licensing regulations and competition policy;
- Avoiding market segmentation between private and public sector health care and encouraging integration of drug procurement;
- Avoiding trade concession in bilateral and regional free trade agreements that create TRIPS-plus standards, this vigilance is particularly important with respect to data exclusivity and patent/registration linkage;
- Cooperating regionally to develop pro-health intellectual property and trade policy,



- to investigate joint compulsory licensing applications and to promote regional trade in generic medicines, especially within trading groups with 50% LDCs;
- Cooperating regionally to negotiate high-quality voluntary licenses that facilitate entry of multiple competitors, assure access to registration data, grant permission for cross-licensing of fixed-dose combination medicines and promote technology transfer;
- Cooperating regionally on drug registration to ensure marketing of drugs of assured quality, with preferential and expedited registration of medicines pre-qualified by the WHO and regional cooperation in post-marketing quality assurance;
- Creating of regional mechanisms for pooled procurement;
- Investing in regional productive capacity and development of indigenous expertise with a special commitment to research and development for neglected diseases;
- Creating demand for access to medicines by supporting the Global Fund, the WHO 3-by-5 Plan and other global health initiatives and by supporting the involvement of affected communities and NGO activists in IPR policy debates.

In addition to this fairly limited set of initiatives, DFID and U.K. decision-makers could consider and then champion a more visionary set of policy options, e.g.:

- Providing pro-health technical assistance to non-producing countries and regions, and providing financial support for such assistance by the WHO, pursuant to its mandate, to enact flexibilities under TRIPS, to amass administrative expertise and to generate scaled-up proposals for treatment to the Global Fund, the World Bank and other multilateral and bilateral funding agencies.
- Resuscitating the Article 30 limited exception option for producing generic medicines for export. Removing restrictions on access to registration data in order to facilitate the registration of bio-equivalent generic products and assisting low-cost generic producers to get their products pre-qualified by the WHO and registered for use in developing countries.
- Ensuring that generic producers have access to up-to-date industrial know-how, by invigorating technology transfer and otherwise, and that developing countries increase their collective ability to produce and trade generic medicines of assured quality within a competitive generic market that achieves meaningful economies of scale.
- Supporting public policy and incentives designed to encourage segmentation between developed country markets and developing country markets with a high disease burden; one particularly attractive alternative is that patent holders grant licenses to qualified generic producers to supply developing countries with essential medicines and that they transfer technology and know-how in the process. (Note: the Lilly MDR-TB Partnership is an important example of this kind of initiative.)
- Joining a growing public health and human rights consensus that medical



technologies are too important to relegate solely to private interests codified in the current intellectual property system and that the right to health requires that life-saving medicines be considered international public goods.<sup>95</sup> Accordingly, measures must be taken to ensure innovation with respect to neglected diseases, i.e. significantly higher and targeted public funding for research and development, and additional measures must be taken to ensure access to resulting medical products. Measures for increasing access include guaranteeing licenses to generic companies that supply developing countries with medical inventions subsidised with public funds; eased access to licenses for product improvement like fixed-dose combination AIDS medicines; and even “open source” drug discovery rules for tropical diseases.<sup>96</sup>

This paper has not been commissioned to address these broader policy options in detail. Instead, it has focused on doing everything possible to make sure that maximum use is made of the existing flexibilities developing countries have for accessing medicines, as arthritic as they sometimes are. Nonetheless, broader measures must also be explored lest the world apply band-aids to a fatal haemorrhage. A trickle of medicines procured through costly, time-delayed and burdensome procedures, will not alleviate the crisis of access that confront developing countries. As noted by many others, a one-size-fits all intellectual property regime ill serves the interests of poor consumers in poor countries. Since progressive realisation to health and access to medicines are fundamental human rights, policy makers must use imagination and political courage to catalyse their realisation.



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# Appendix I

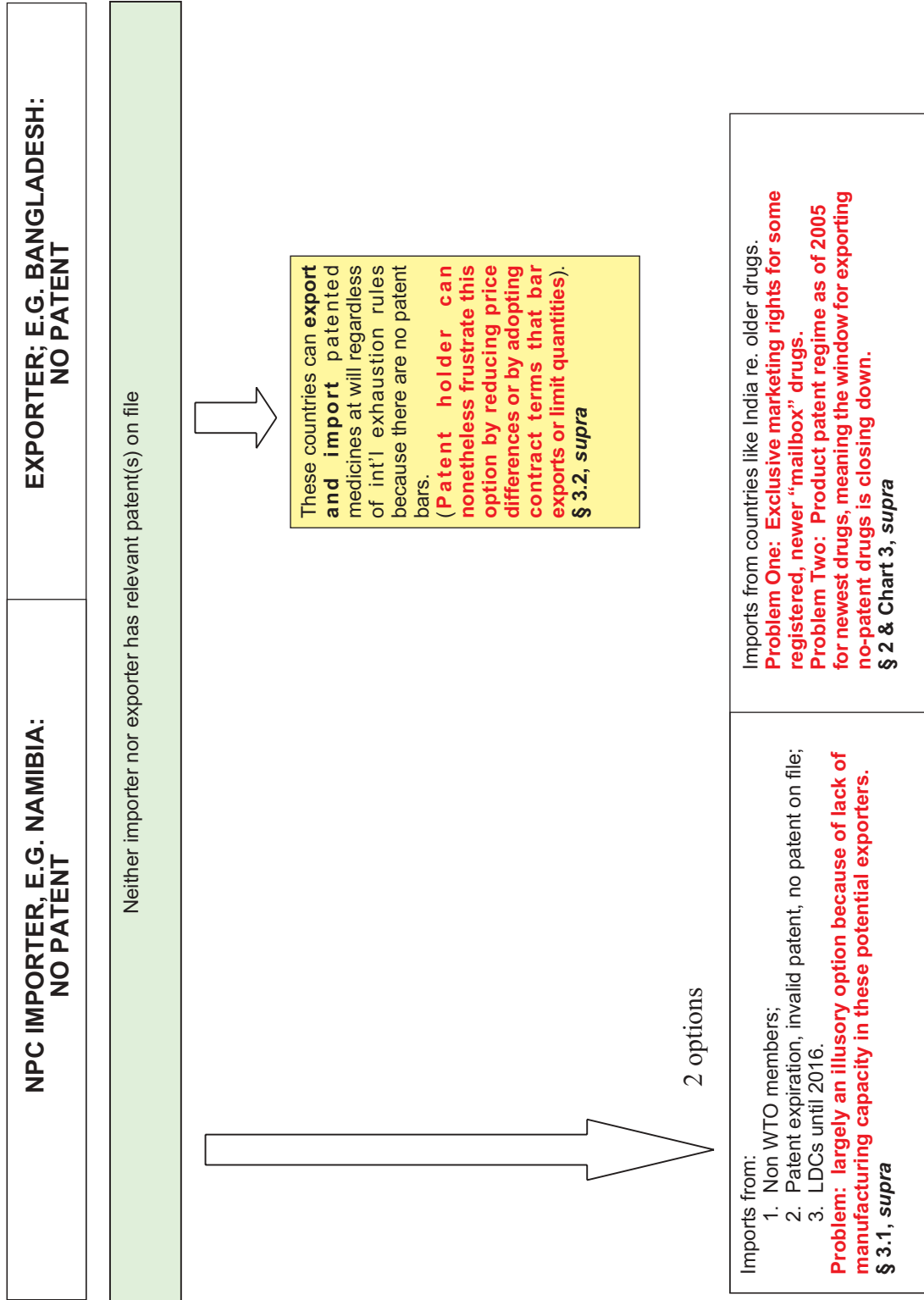
Non-producing countries' options for accessing medicines depend substantially on the patent status of the particular medicine in both the importing and exporting country. There are four permutations with respect to an export medicine's patent status, each of which will be analysed in a separate flowchart. Where medicines are on-patent in both importing and exporting countries, there is a separate flowchart for least developed and non-least developed countries. To aid the reader in using the Flowcharts below, they are referenced to relevant portions of the text.

The reference to country examples below and in the Flowcharts has not been based on a thorough examination of their existing legislative schemes but rather on their status as countries with few or no patents (Namibia, Bangladesh, Ethiopia and India [with respect to older medicines]), their status as countries with patents on important ARVs (China, South Africa, Uganda, Columbia, Canada and Brazil), their status as LDCs (Bangladesh and Uganda) or not, and their relevant capacity to produce pharmaceuticals for export (Bangladesh [perhaps], China, India, Canada and Brazil).

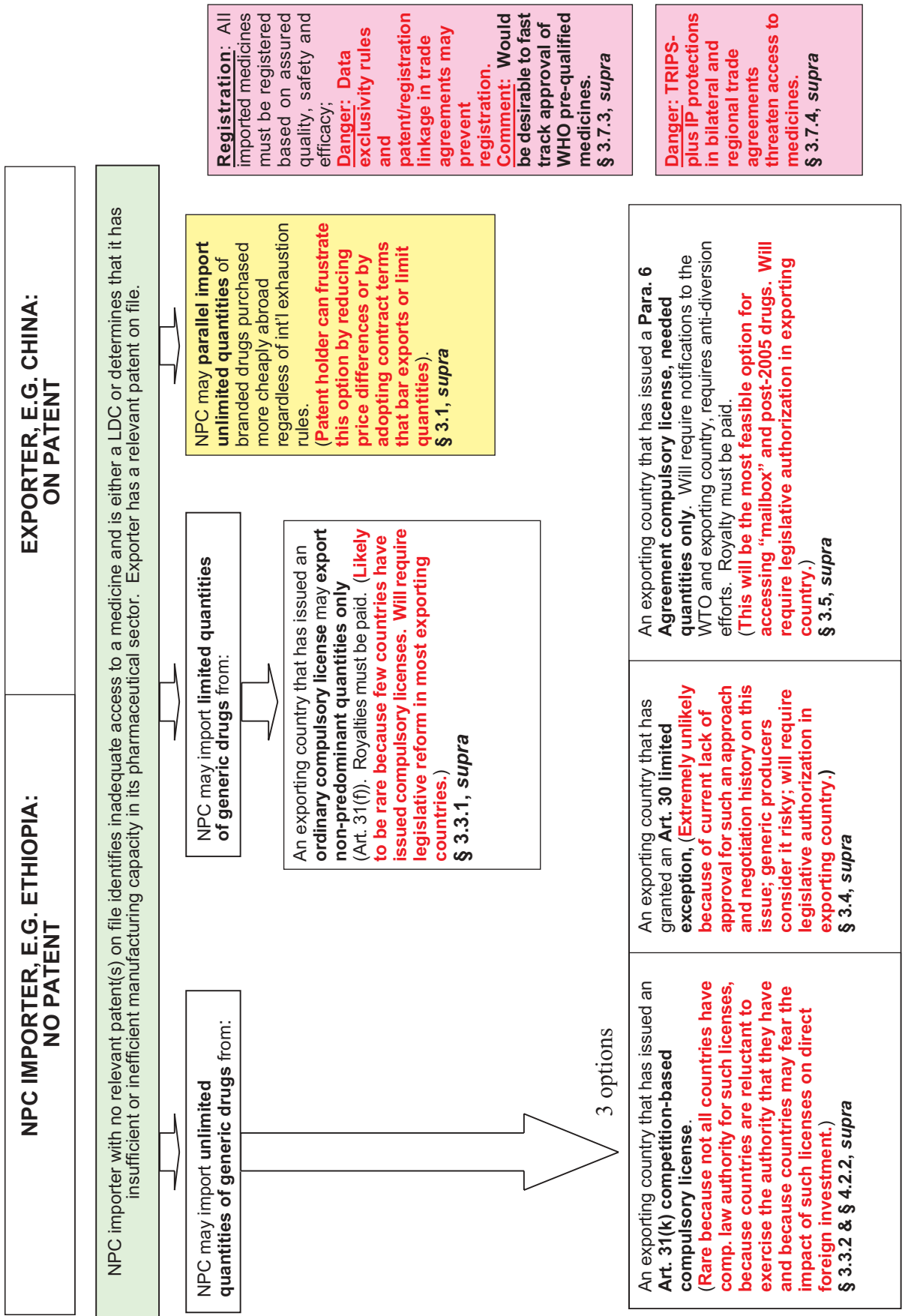
## **PATENT STATUS PERMUTATIONS – GUIDE TO FLOWCHARTS**

<b>Flowchart One</b>	No patent in either the importing country, e.g. Namibia, or exporting country, e.g. Bangladesh.
<b>Flowchart Two</b>	No patent in the importing country, e.g. Ethiopia, but a relevant patent in the exporting country, e.g. China.
<b>Flowchart Three</b>	A relevant patent in the importing country, e.g. South Africa, but no patent in the exporting country, e.g. India.
<b>Flowchart Four (LDCs); Flowchart Five (non-LDCs)</b>	Relevant patents in both the importing country, e.g. Uganda or Columbia, and exporting country, e.g. Canada or Brazil.

FLOWCHART ONE



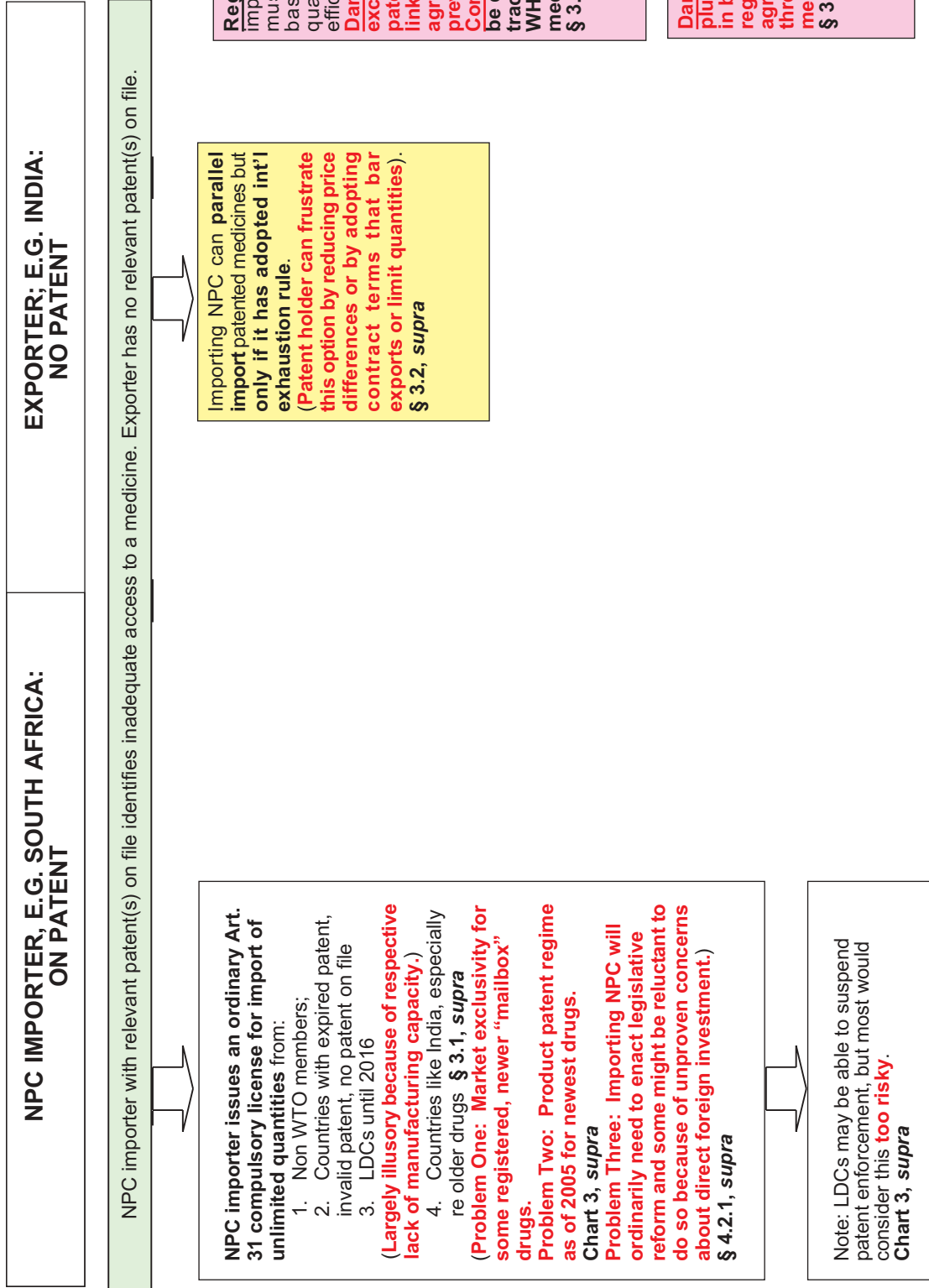
FLOWCHART TWO



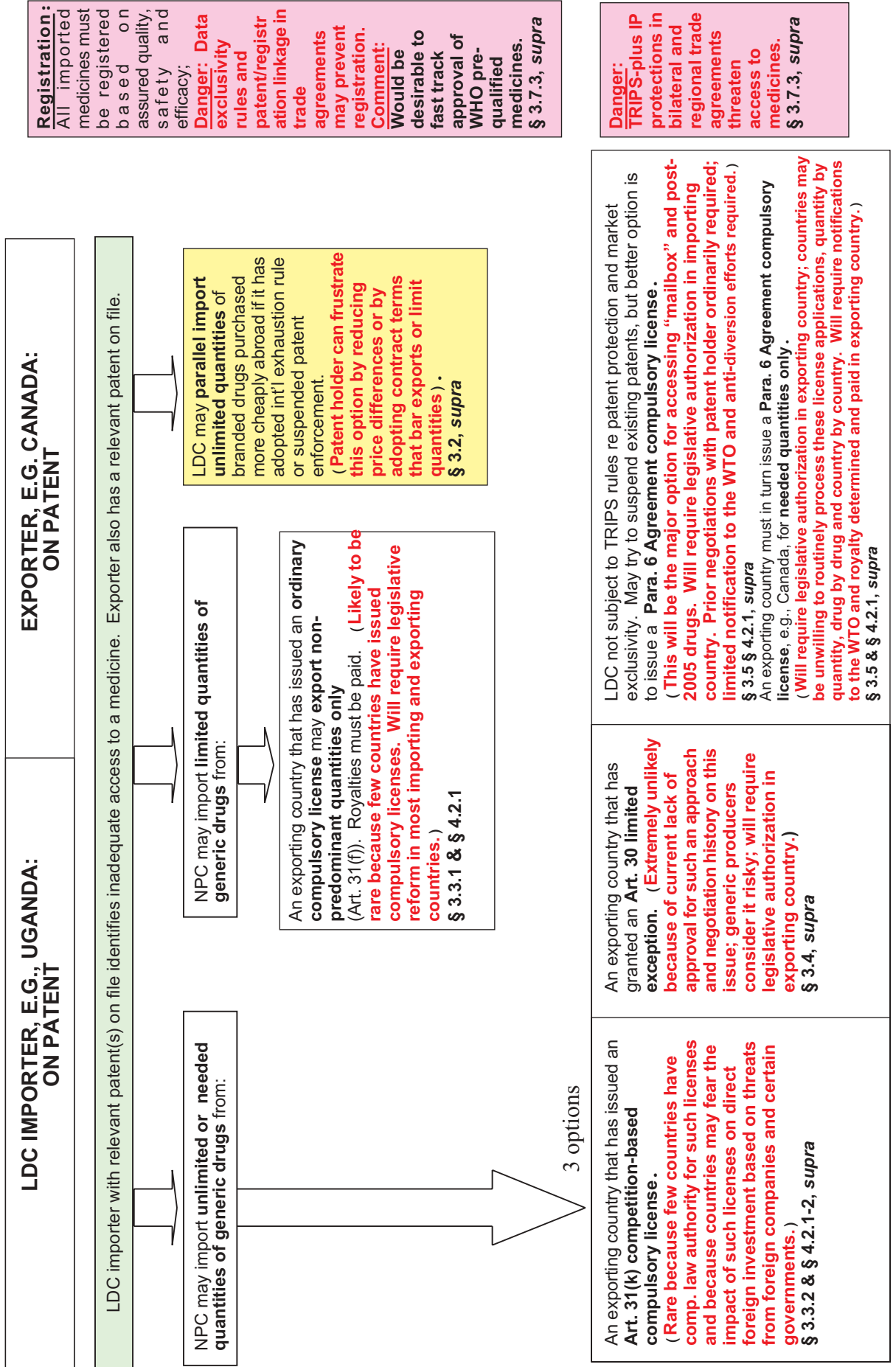
**Registration:** All imported medicines must be registered based on assured quality, safety and efficacy;  
**Danger:** Data exclusivity rules and patent/registration linkage in trade agreements may prevent registration.  
**Comment:** Would be desirable to fast track approval of WHO pre-qualified medicines.  
§ 3.7.3, *supra*

**Danger:** TRIPS-plus IP protections in bilateral and regional trade agreements threaten access to medicines.  
§ 3.7.4, *supra*

FLOWCHART THREE



FLOWCHART FOUR

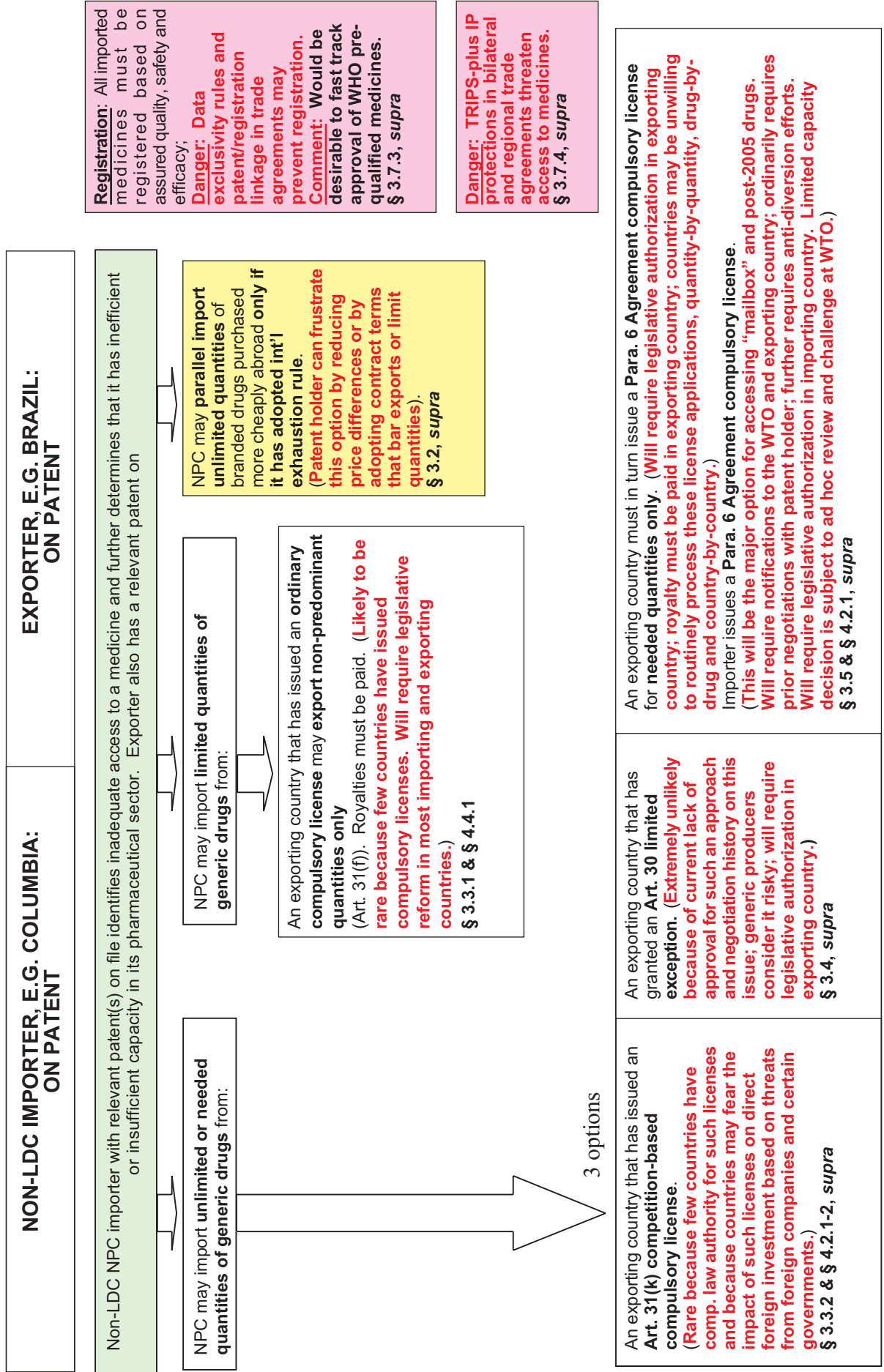


**Registration:** All imported medicines must be registered based on assured quality, safety and efficacy;  
**Danger: Data exclusivity rules and patent/registration linkage in trade agreements may prevent registration.**  
**Comment:** Would be desirable to fast track approval of WHO pre-qualified medicines.  
 § 3.7.3, *supra*

**Danger:** **TRIPS-plus IP protections in bilateral and regional trade agreements threaten access to medicines.**  
 § 3.7.3, *supra*



FLOWCHART FIVE



3 options

## Notes

1 Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, 34–38 (London 2002).

2 Data exclusivity rules in bilateral and regional trade agreements increasingly forestall marketing approval for generics during the term of a patent and sometimes even in the absence of a patent. Although this paper primarily addresses patent flexibilities for non-producing countries, it briefly highlights registration barriers as well. Another DFID paper, Hill & Johnson “*Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries*” (DFID 2004) addresses registration of medicines more comprehensively.

3 For a more detailed discussion of bio-equivalence, see U.S. Food and Drug Administration, Draft Guidance for Industry: Average, Population and Individual Approaches to Establishing Bio-equivalence (1999) available at <http://www.fda.gov/cder/guidance/1716dft.pdf>.

4 Patents are territorial, meaning that a patent holder must file a separate patent application in each country where it requires protection; if it doesn't file in Country A and if the application is not subsequently granted, it has no rights of exclusion in that country. However, the WTO-based system of intellectual property rights guarantees innovators access to patent protections in many countries that did not previously provide patent protection for pharmaceutical products.

5 Although the quality, safety and efficacy of some generic products is assured through screening by the WHO Prequalification Project or through registration by a stringent regulatory agency, there are pharmaceutical products being produced that are substandard or even counterfeit.

6 Because the WTO TRIPS Agreement was adopted, effective January 1, 1995, it needed to make provisions for the intellectual property status of medicines invented after that date, especially in countries that did not already provide patent protection for pharmaceutical products. Under the “mailbox” rule in Article 70 of the TRIPS Agreement, transitional countries are supposed to hold post-1994/1995 patent applications in a “mailbox” pending their TRIPS compliance in 2000, 2005 or 2016 (for LDCs). At that time, the patent application would be given priority according to the date of filing and the patent, if granted, would extend for the remainder of its 20-year term. In some instances, the new post-mailbox patent might preclude further production of generics already being marketed. Moreover, even while the patent application is in the “mailbox”, the patent holder is given five years of exclusive marketing rights (EMRs) if the product has been registered for distribution by the country's drug registration agency and if the product has been patented and approved for marketing by another WTO Member State.

7 When discussing “disadvantages”, the paper references arguments frequently advanced by the research-based pharmaceutical industry and developed countries that often act as a deterrent to utilisation of a particular flexibility. It does not do so to suggest that NPDs should be motivated by these arguments, many of which lack an empirical foundation.

8 Art. 8(1), Marrakesh Agreement Establishing the World Trade Organization, Annex

1C, 33 I.L.M. 81 (1994) available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

9 There is evidence of such disinvestment in local capacity in Chile, Peru and South Africa. The extent to which Article 27.1 prohibits local working (local manufacturing) requirements is disputed.

10 The dates and drug classes described do not have as much significance for countries that do not have to rely on importation to fulfill a compulsory license nor do they have much significance for countries, other than India, that might become major exporters. Many of these countries, like Brazil, had already adopted patent regimes and had granted patents on most important medicines even before TRIPS.

11 Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/25 (July 1, 2002) available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm); Least-Developed Country Members – Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, WT/L/478 (12 July 2002) available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art70\\_9\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm).

12 See, Robert Lettington & Chikosa Banda, Malawi: Case Study (DFID 2004).

13 WT/MIN (01)/DEC/2 (Nov. 20, 2001).

14 WT/L/540 (Sept. 2, 2003).

15 JOB(03)/177 (Aug. 28, 2003) available at [http://www.wto.org/english/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm). The legal significance of the Chairperson's Statement is quite debatable – at best, it might be used for interpretive guidance.

16 Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines: A "Gift" Bound in Red Tape (Sept. 10, 2003) available at <http://www.cptech.org/ip/wto/p6/ngos092003.html>.

17 Capacity issues exist for countries with relevant patents on file and those with no such patents; the Paragraph 6 Decision acknowledges this reality and permits countries with and without relevant patents to import medicines from an exporting country that has its own relevant patents.

18 Although not directly mentioned in the text, vaccines are produced in the pharmaceutical sector and they should be deemed to be covered by the Decision. Paul Vandoren and Charles Van Eekhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making It Work*, 6 J. World Intellectual Prop. 779, 784 (2003).

19 The requirement of specific quantities for export licenses may require consecutive export licenses even for a single product. This is a highly undesirable interpretation; it would be far more logical and consistent with the overarching policy of the Doha Declaration to allow export pursuant to a Paragraph 6 Decision compulsory license for as long as the need persists.

20 A second royalty in the importing country is not required.

21 Although special labelling and packaging are probably required, further efforts to differentiate the colouring/shaping of the product need only be done where it is

feasible and does not have an unexpectedly significant impact on price.

22 According to para. 9 of the Paragraph 6 Decision, the Agreement does not limit pre-existing flexibilities for accessing imported generics:

This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

23 India can continue to make lawful copies of pre-1995 medicines for export without restriction and will continue to be able to do so indefinitely. The story for post-1994/1995 medicines is more complicated because of a “mailbox rule” in Article 70 of the TRIPS Agreement (*see* fn. 6, *supra*). Drugs in the patent “mailbox” will be processed in India as of 2005 (and in the meantime, a limited number have received exclusive marketing rights). Even newer post-2005 drugs will be routinely patented in India because its transition period to exclude product patents expires on 1 January 2005.

24 In TRIPS terminology, a patent-holder’s right to limit further distribution of a product after its first sale has been “exhausted” once the product has been marketed by the patent-holder. Most countries, including many non-producing countries, have adopted a principle of national exhaustion, which only permits resale within a country after its first sale. Other countries, including **Kenya**, have adopted an international exhaustion rule, meaning that products can be lawfully imported from any foreign source once the patent holder or its licensee had been remunerated for its invention (exhausted its rights) via an original sale. Europe has adopted a third alternative, namely regional exhaustion, which permits the free flow of IP-protected goods from one EU member to another. Article 6 of TRIPS states that exhaustion disputes are not subject to WTO dispute settlement processes.

25 Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, Section X.2 (2000).

26 **Malawi** has no express provision recognising international exhaustion, though certain officials claim there is implicit support in national law for parallel importation. See, Robert Lettington & Chikosa Banda, *Malawi: Case Study* (DFID 2004).

27 If the importing country does not have a conflicting patent on file, it does not need to have adopted the international exhaustion rule in order to import a patented product sold cheaper elsewhere.

28 The patent-holder assent is assumed since it has been compensated with a royalty payment by the compulsory licensee. See Peter Munyi & Robert Lettington, *Kenya: Country Study* (DFID 2004).

29 This strategy is already being pursued in Canada where U.S. consumers are beginning to engage in a larger volume of internet sales with Canadian distributors.

30 Margret Barrett, *Symposium: The United States’ Doctrine of Exhaustion: Parallel Imports of Patented Goods*, 27 N. Ky. L. Rev. 911 (2000).

31 See, e.g., Michael Bailey, Ruth Mayne & Dr. Mohga Smith, *Fatal Side Effects:*

*Medicine Patents under the Microscope*, 24 (Feb. 2001) available at <http://www.oxfam.org.uk/cutthecost/downloads/policy3.rtf>.

32 When the government licenses another entity to produce or procure generic versions of the patented product for non-governmental use, this grant is ordinarily called a compulsory license. The term government use refers to the circumstances where a government or its contractor bypasses a patent in order to satisfy non-commercial, governmental purposes. It is important to note that such a purpose can include providing a pharmaceutical product on a not-for-profit basis to the NGO and/or private sector.

33 The majority of developing countries appear to have some compulsory licensing provisions in their patent legislation, but few have truly comprehensive compulsory licensing clauses that expressly allow utilisation all existing C.L. flexibilities.

34 For a description of **Kenya's** very broad compulsory license and government use legislation, see Peter Munyi & Robert Lettington, *Kenya: Country Study* (DFID 2004) (describing C.L. rights where markets are not being supplied on reasonable terms and where a patented invention is dependent on an earlier patent and government use rights when issued in the public interest or where the patent exploitation is not competitive). For a description of **Malawi's** somewhat narrower legislation, see Robert Lettington & Chikosa Banda, *Malawi: Case Study* (DFID 2004).

35 When referring to compulsory licenses, this paper should be understood to be addressing both classic compulsory licenses and government use orders unless otherwise indicated.

36 Despite a requirement of case-specific determinations, however, it might be appropriate to set presumptive rates between 2–6%. James Love, *Access to Medicine and Compliance with the WTO TRIPS Accord: Compulsory Licensing: Models for State Practice in Developing Countries*, paras. 35–42 (2001) available at <http://www.cptech.org/ip/health/cl/recommendedstatepractice.html>. UNDP royalty guidelines recommend normal rates of 2 to 6 percent; Japan's 1998 Royalty Guidelines for government-owned patents range from 0–6%.

37 Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. Pa. J. Int'l Econ. L. 1069, 1075–1094 (1996).

38 **Kenya** and South Africa are important exceptions with respect to authorising competition-based licenses. For example, **Kenya** authorises government use orders to remedy anti-competitive practices. It also permits its regulators to review the terms of voluntary licenses, though this right of review is rarely exercised. See Peter Munyi & Robert Lettington, *Kenya: Country Study* (DFID 2004). In South Africa, a recent Competition Commission case and the threat of compulsory licenses resulted in the negotiation of voluntary licenses on antiretrovirals with GlaxoSmithKline and Boehringer-Ingelheim.

39 Since TRIPS provides no definition of anti-competitive practices, since Article 1 permits Members to implement TRIPS “within their own legal system and practice” and Article 8.2 grants Members authority “to prevent abuse of intellectual property rights...



or the resort to practices that unreasonably restrain trade”, and finally, since Article 40 empowers Members to address anti-competitive practices in licensing agreements, Members are permitted to develop definitions of anti-competitive behavior so long as they are not transparently TRIPS-nullifying.

40 Article 31, on its face, only permits exceptions to patent exclusivity, and does not directly grant authority to permit exceptions for trade secret protections including industrial expertise and confidential registration data submitted to regulatory agencies. Competition law, however, often includes this authority.

41 Although there is no direct sanction for an Article 30 approach in the Paragraph 6 Decision, pursuant to para. 9, “Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 3.” Article 30 is still one of those flexibilities.

42 The Bolar exception was first recognised in the U.S. and permits a generic company to formulate a generic medicine and to prepare its drug registration dossier even before the competing patent expires. Although the generic company cannot obtain final marketing approval in the U.S. until the patent expires, it does gain valuable time to bring the generic drug to market. The WTO has since concluded that Bolar is a permitted limited exception under Article 30. *Canada—Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, March 17, 2000. The WTO panel found that manufacture before patent expiration to register a medicine, the so-called Bolar exception, was lawful, but that a six-month stock-piling rule was unlawful. Concerning the point under discussion, *Generic Medicines* found that any exception that resulted in a “substantial curtailment of [any exclusionary right] cannot be considered a limited exception”. *Id.* at paragraph 7.44. **Kenya** has adopted the Bolar exception in its patent legislation, but **Malawi** has not. See Peter Munyi & Robert Lettington, *Kenya: Country Study* (DFID 2004) and Robert Lettington & Chikosa Banda, *Malawi: Case Study* (DFID 2004).

43 The requirements are eased in the no-patent context. No compulsory license will be necessary in the importing country, but the importing country will still need to notify the WTO of its intended use of the Paragraph 6 system if it intends to import from a country that has to overcome its primarily-for-domestic-use export limitation. The exporting country will still need to follow all of the outlined procedures.

44 Prior negotiation is not required under Article 31 (b) and (k) where the license is being sought with respect to: (1) an emergency or other matter of extreme urgency (HIV/AIDS, TB, and malaria are such emergencies, Doha Declaration, para. 5(c)); (2) governmental, non-commercial use; and (3) remedies for anti-competitive practices.

45 Article 31(c) limits a license to the purpose for which it was authorised; Article 31(g) mandates termination when those circumstances cease to exist and are unlikely to reoccur. In the event of ordinary public health licenses, the duration would be at least as long as the public health problem prevails. However, the Annex to the Paragraph 6 Decision further limits the license to the period that local capacity is insufficient. Thus, increased capacity in the domestic pharmaceutical sector can result in termination of the license.

46 Paragraph 2(a) Paragraph 6 Decision.

47 Paragraph 2(a), Annex.

48 The Chairperson's Statement requires notification to the WTO to include information on how the Member had established that it had insufficient or no manufacturing capacity for a particular product. It further clarifies that such notification shall be brought to the attention of the TRIPS Council at its next meeting and that any Member may bring any matter related to the interpretation or implementation of the decision to the TRIPS Council for expedited review. Finally, the Statement clarifies that a Member's "concerns" that the terms of the Decision have not been followed will permit utilisation of the "good offices" of the Director General or the Chair of the TRIPS Council to find a mutually agreeable solution. The author is worried that this system of ad hoc review might encourage some Members to second-guess and exert backroom pressure concerning determinations of incapacity in the domestic pharmaceutical sector.

49 Although this result seems unnecessarily duplicative, especially since the licensee involved probably first sought a voluntary license in the importing country, the current text of Article 31(b) and the failure of the Paragraph 6 Decision to address this second negotiation would seem to require this ridiculous result. (Note: prior negotiation is not required for emergencies, non-commercial government use or to remedy anti-competitive practices.)

50 Paragraph 2(c).

51 Paragraph 2(b)(iii).

52 Some developing countries might also want to attract subsidiaries of patent-holding companies and/or want to build up their own indigenous research and development capacity. In such instances, developing countries might reach a different decision about how routinely they issue compulsory licenses. Even if they do grant licenses liberally, it is not clear that they can issue C.L.s in a way that systematically discriminates against imported patented medicines compared to locally produced, patented medicines.

53 The importance of economies-of-scale, particularly in drug formulation, is debated and should be the subject of further investigations. For an argument that they are important, see Warren Kaplan, *A Local Production: Industrial Policy and Access to Medicines: An Overview of Key Concepts, Issues, and Opportunities for Future Research*, World Bank Meeting on the Role of Generics and Local Industry in Attaining the Millennium Development Goals in Pharmaceuticals and Vaccines, available at [http://www.worldbank.org/hnp/hsd/documents/pharma\\_production.pdf](http://www.worldbank.org/hnp/hsd/documents/pharma_production.pdf).

54 If medicines do not contain the correct active ingredients in correct quantities, if quality and efficacy deteriorate because of improper handling or expiration or if medicines contain harmful substances, patients will be exposed to substandard or even dangerous therapies that can lead to treatment failure, drug resistance and even death. Accordingly, drug regulatory agencies have been established to set standards and to review registration applications by judging the medicine's quality (specifications for active ingredients, impurity profiles and manufacturing standards) and its safety and therapeutic efficacy.

55 It is important to note that medicines purchased by the Global Fund to Fight AIDS,



TB and Malaria, the World Bank and the U.S. PEPFAR program will at a minimum require proof of bio-equivalence – mere similarity will not suffice.

56 See Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (South Centre, Geneva, 2002).

57 The burden can be less where the drug registration authority is permitted to rely on a prior registration.

58 They do so pursuant to a linkage between registration status and patent status such that the drug regulatory agency ordinarily cannot register a generic product if the originator product is still on patent.

59 The trials might be unethical because not only they do not advance medical knowledge, but also because therapeutic advances may render the original trial protocol, e.g., placebo control, unethical.

60 <http://www.ustr.gov/new/fta/Cafta/text/index.htm>.

61 The U.S.T.R. has claimed in a recent letter to Congress that “side letters” to the Morocco and Central American Free Trade Agreements clarify that new intellectual property rules in FTAs, including data exclusivity, will not limit “effective utilisation” of post-Doha flexibilities or prevent those countries from taking “necessary measures to protect public health”. More specifically, the U.S.T.R. argued that compulsory licenses grant implied exceptions to data exclusivity and patent/registration linkage rules. However, it remains unclear how stringently the U.S. will interpret the phrase “necessary to protect public health”. In international trade disputes, “necessary” is recognised as a stringent term. For example, a measure may be deemed “necessary” to promote public health only if there is no other way to achieve the public health objective, even if the alternatives are not politically or economically viable.

Accordingly, until more explicit pro-health clarifications are formalised and codified in the text of FTAs, it is likely that developing countries and compulsory licensees will be deterred from utilising the full range of TRIPS flexibilities, especially where FTAs also include “investment clause” that would enable drug companies to sue developing countries for infringement of their data rights.

62 WHO has already pre-qualified several generic producers of ARVs and a short list of fixed-dose combination generics, which are not currently available from research-based companies. However, because of after-discovered irregularities at certain contract research organisations that conducted bio-equivalence studies, several ARVs from Cipla and Rambaxy have been temporarily withdrawn from the WHO prequalification list. WHO, Three AIDS Medicines will be removed from prequalification list this week (Aug. 4, 2004) available at <http://www.who.int/mediacentre/releases/2004/pr53/en/>.

63 This is a commonly stated goal in all U.S. trade negotiations and is an explicit policy objective in U.S. trade promotion legislation.

64 It appears that the U.S. is not aggressively pursuing limitations on compulsory licenses with poor and middle-income developing countries, though such provisions remain in proposed FTAA text and were included in the U.S.-Singapore FTA.

65 Again, it appears that the U.S. may not be aggressively pursuing limits on parallel

importation for developing countries, though such limits were included in the U.S.-Singapore and U.S.-Australia FTAs.

66 In tri-party negotiations this past year, India, Brazil and South Africa have committed themselves to publicly resisting trade agreements that heighten intellectual property protections. India-Brazil-South Africa (IBSA) Dialogue Forum: Plan of Action, para. 45, available at <http://www.dfa.gov.za/docs/2004/ibsa0305a.htm>.

67 See, Medecins San Frontieres, *Drug Patents under the Spotlight: Sharing Practical Knowledge about Pharmaceutical Patents* (2003).

68 Fortunately, the World Health Organization has committed itself to creating a **patent-status** database for AIDS medicines within its new AIDS Medicines and Diagnostics Service, but this service only applies to a narrow range of medicines. See WHO, *Investing in a Comprehensive Health Sector Response to HIV/AIDS* (Draft May 11, 2004). There is a similar need for more comprehensive information concerning the **registration status** of all essential medicines. At present, such a resource exists only for AIDS medicines. See UNICEF *et al.*, *Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS, Annex 2A* (June 2004).

69 For example, both **Malawi** and **Kenya** have failed to adopt legislation permitting them to maximise their access to medicines.

70 Extensions of transitional periods for LDCs might permit them to state a general intention not to enforce previously granted patents, though this approach risks litigation by patent holders with vested rights. See discussion in Section II, *supra*.

71 A manual addressing post-Doha, but pre-Paragraph 6 Decision legislative reform has been produced by the Third World Network, *Manual on Good Practices in Public Health-Sensitive Policy Measures and Patent Laws* (2003). This and other guides to model legislation should be useful to countries needing to reform existing legislation, though it may also be necessary to have expert, in-country consultations.

72 Peter Munyi & Robert Lettington, *Kenya: Country Study* (DFID 2004).

73 Adrian Hollis & Sean Flynn, *An Economic Analysis of Compulsory Licenses for Needed Medicines* (Draft Dec. 15, 2003).

74 See Robert Pitofsky *et al.*, *The Essential Facilities Doctrine Under U.S. Antitrust Law*, 70 Antitrust L.J. 443 (2002); Valentine Korah, *The Interface Between Intellectual Property And Antitrust: The European Experience*, 69 Antitrust L.J. 801 (2002); Sergio Baches Opi, *The Application of the Essential Facilities Doctrine to Intellectual Property Licensing in the European Union and the United States: Are Intellectual Property Rights Still Sacrosanct?*, 11 Fordham Intell. Prop. Media & Ent. L.J. 409 (2001).

75 Fixed-dose combination ARVs (3-in-1 pills) have been endorsed by the WHO as a crucial component of its ambitious plan to help the world treat 3 million people living with AIDS by the end of 2005. WHO *Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach*, 9–13 (Dec. 2003); WHO & UNAIDS, *Treating 3 Million by 2005: Making it happen – the WHO Strategy* (Dec. 2003).

76 Research-based companies have recently indicated a greater willingness to create FDCs in light of fast-track registration processes for fixed-dose combination medicines announced by the U.S. Food and Drug Administration.

77 Competition remedies are often designed to ensure full competition from the newly authorised competitor. (Note: there clearly arguments that regular compulsory licenses grant implied access to registration data, especially since such access is permissible under Article 39.3 of TRIPS and since the state practice of many countries permits such access. When a compulsory license is issued, it is clearly in the public interest to simultaneously grant access to registration data to establish bio-equivalence.)

78 Both of these expanded intellectual property remedies have been granted in U.S. anti-trust cases involving pharmaceutical companies.

79 The regulation of anti-competitive features of voluntary licenses is directly authorised by Article 40 of the TRIPS Agreement.

80 Peter Munyi & Robert Lettington, *Kenya: Country Study* (DFID 2004).

81 There are some recent high-profile exceptions, particularly licenses granted by Eli Lilly on its tuberculosis medicines. See <http://www.lillymdr-tb.com/facts.html>.

82 One danger of over-reliance on voluntary licenses is that they can retard the development of a generic industry that is sustainable and can reliably respond to public health needs in non-producing countries. For this reason, some advocates prefer reliance on compulsory licenses as a way to invigorate generic entry and reject an analysis that issuing such licenses to a dynamic generic industry primarily advances commercial/industrial development purposes condemned in the Chairperson's Statement.

83 See, e.g., Sisule F. Masungu, Susan Villanueva & Roxana Blasetti, *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks* (South Centre, Geneva, April 2004).

84 ASEAN is currently engaged in one such project and is coordinating meetings between internal and external experts and key policy personnel throughout the region.

85 The Clinton Foundation secured huge price discounts for ARVs – down to less than \$140/person/year – largely by ensuring large-scale sales.

86 South Africa Competition Commission Media Release No. 33 OF 2003 (10 December 2003) available at <http://lists.essential.org/pipermail/ip-health/2003-December/005716.html>.

87 Management Sciences of Health, *Regional Pooled Procurement of Drugs in Sub-Saharan Africa* (2003); Management Sciences of Health, *Regional Pooled Procurement of Drugs: Evaluation of Programs* (2002).

88 Even if you harmonise patent and registration rules regionally, there might still be important differences in patent and registration status in different countries.

89 Management Sciences of Health, *Regional Pooled Procurement of Drugs in Sub-Saharan Africa* (2003); Management Sciences of Health, *Regional Pooled Procurement of Drugs: Evaluation of Programs* (2002).

90 Several developing countries announced a South-South agreement for regional cooperation concerning HIV/AIDS research at the XV International AIDS Conference in Bangkok.

91 Global need just for AIDS, tuberculosis and malaria are currently estimated at \$15 billion in 2005 and rising to \$24 billion in 2007. See UNAIDS, *2004 Report on the*

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*Global AIDS Epidemic* (2004) and previous estimates concerning cost of comprehensive interventions addressing tuberculosis and malaria.

92 See UNAIDS, *2004 Report*, 145–146.

93 See Physicians for Human Rights, *An Action Plan to Prevent Brain Drain: Building Equitable Health Systems in Africa*, 79–89 (June 2004).

94 See *Sizable boost in HIV/AIDS assistance will challenge low-income countries*, 33 IMF Survey 202 (July 12, 2004) available at <http://www.imf.org/imfsurvey>; *An Interview with Peter Heller on financing for HIV/AIDS prevention and treatment*, IMF Civil Society Newsletter (August 2004) available at <http://www.imf.org/External/NP/EXR/cs/eng/2004/081304.htm#p2a>; Adam Wagstaff & Mariam Claeson, *The Millennium Development Goals for Health: Rising to the Challenges*, chs. 4 and 9 (World Bank 2004).

95 Peter Drahos & John Braithwaite, *Proceedings of the 2002 Conference Access to Medicines in the Developing World: International Facilitation or Hindrance?: Panel # 1: The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in Context: Economics, Politics, Law and Health: Intellectual Property, Corporate Strategy, Globalisation: TRIPS in Context*, 20 Wis. Int'l L.J. 451 (2002)

96 Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?* available at <http://www.public-domain.org/node/view/44>.