Country experiences in using TRIPS safeguards: Part II

The document provides a brief overview of country experiences with using the safeguard mechanisms available in the TRIPS Agreement to protect public health and access to medicines. It is written in response to requests to share such experiences. Part I of this note highlights examples of compulsory licensing and application of strict patentability criteria. Part II of this note highlights examples of the use of competition law and TRIPS safeguards specific to least developed countries (LDCs).

Competition law for access to medicines

Competition law is emerging as an important mechanism to enable access to medicines. Competition law maintains market competition by regulating anticompetitive behaviour by companies. It is known by different terms, e.g. it is known as anti-trust law in United States and anti-monopoly law in the People’s Republic of China. Competition laws and policies are important as they can compel industry to provide higher-quality goods and services at lower prices. According to UNCTAD: “In the pharmaceutical industry, competition can motivate brand companies to create new and improved medicines and encourage generic companies to offer less expensive alternatives.”

Competition policy works through enforcement (benefiting consumers by detecting, halting and correcting anticompetitive practices) and advocacy (thus participating more broadly in the formulation of a country’s economic policies.) UNDP’s 2014 Guidebook on Using Competition Law to Promote Access to Health Technologies provides useful information on competition law and access to medicines. The Guidebook notes that “the objectives of competition law vary: promoting consumer welfare, increasing access to important commodities or as an industrial policy objective to increase local participation in a sector. These objectives will often overlap. A core objective around the protection of consumer welfare operates by restricting or regulating unfair business practices and anti-competitive concentration of economic power. The objective of protecting consumer welfare is closely tied to the promotion and protection of human rights – in this particular context to the protection of the rights to life and health. For many LMICs (low- and middle-income countries), providing access to safe, effective and affordable health technologies is a major challenge that places a substantial burden on government and individual/family budgets.”

Anti-competitive practices and the TRIPS Agreement

The links between intellectual property rights (IPR) and anti-competitive practices finds reference in the TRIPS Agreement itself, which also recognises the discretion of Members of the World Trade Organization (WTO) in this area (See Box 1).

Article 8.2 of the TRIPS Agreement provides that WTO Members can take appropriate measures (so long as they are consistent with the TRIPS Agreement) to prevent the abuse of IPRs or the resort to practices that unreasonably restrain trade or adversely affect technology transfer. Article 40.1 notes an important recognition by WTO Members that some of these practices may be licensing conditions that restrain competition. Article 40.2 further recognizes the right of WTO...
Box 1: Anti-competitive behaviour and the TRIPS Agreement

**Article 8.2: Principles**

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

**Article 31 (k): Other use without authorization of the right holder**

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

**Article 40.1 and 40.2: Control of anti-competitive practices in contractual licences**

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include, for example, exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

Member governments to put laws in place to address such situations and also includes examples of such licensing practices, i.e. exclusive grant-back conditions, conditions preventing challenges to validity, and coercive package licensing.

Article 31 of the TRIPS Agreement that sets out the conditions for the grant of compulsory licenses is also relevant. Where a compulsory license is issued to remedy practices that are anti-competitive, some of these conditions are waived including requirements for efforts to be made to obtain voluntary licenses or that compulsory licenses must be predominantly for the supply of the domestic market. The amount of remuneration in such cases can also be set taking into account the need to correct anti-competitive practices.

**Interface between IP and competition law in the pharmaceutical sector**

On the one hand, IPRs provide exclusive rights while competition laws and policies seek to avoid market barriers and benefit consumers by ensuring effective competition between a multiplicity of suppliers. In some countries these two areas of law and policy operate separately. However, according to the Federal Trade Commission (FTC) of the United States (US), "certain types of conduct with respect to intellectual property may have anti-competitive effects against which the antitrust laws can and do protect. Intellectual property is thus neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them."3

The Canadian Competition Bureau has issued guidelines on circumstances where they would consider intervention, "given that competition law may result in limitations on the terms and conditions under which the owners of IP rights may transfer or license the use of such rights to others, and on the identity of those to whom the IP is transferred or licensed."4 The South African Competition Commission explains that, "firms are not automatically exempted from the rules of the Competition Act as a result of the rights granted in terms of laws like the intellectual property laws ... firms cannot be automatically allowed to continue with a particular prohibited practice as outlined in
the Competition Act because that practice is allowed by another Act.\textsuperscript{5}

In the pharmaceutical sector and in the context of IP, competition laws and policies will aim to strike a balance between the rights of inventors and consumers.\textsuperscript{6} Although there is considerable variation in national competition laws, competition authorities typically investigate and remedy the following practices (examples related to IP are given though the scope of conduct covered in these categories is far broader):

- **Anti-competitive arrangements:** Competition laws usually examine two kinds of anti-competitive arrangements, i.e. horizontal and vertical. While the anti-competitive conduct in these arrangements may differ, the objective is often the same, i.e. obtain prices or sales above those that would result from a competitive market.
  - Horizontal anti-competitive arrangements: usually involve two or more independent enterprises that are competitors acting in concert. “Pay for delay” or “reverse payments” where patent holders pay generic competitors to withdraw patent challenges or delay market entry fall in this category (see US below).
  - Vertical anti-competitive arrangements: usually involve the supply and distribution chain of a single producer. Licenses from patent holders to generic companies featuring restrictive conditions including those enumerated in Article 40 of TRIPS fall in this category (see South Africa below).

- **Abuse of dominant position (or unilateral conduct):** Competition law examines “monopoly” or “dominant position” separately as enterprises that control markets may not need agreements to dictate pricing or supply. In the context of pharmaceuticals, patents on medicines may result in a dominant position and excessive pricing, refusal to deal or license patents (see Italy below) or abuses of IP rights including through patenting strategies and sham litigation (see Italy below) fall into this category.

- **Review and control of mergers:** where two pharmaceutical companies combine or there is an acquisition, two suppliers may be replaced by one for some medicines or therapeutic segments; competition authorities often require that IP in such products is licensed or sold to third parties before they approve the merger to ensure continued competition (see South Africa and US below).

Many countries have used competition law successfully to promote access to medicines. Some country experiences are below.

### South Africa

In September 2002, several people living with HIV/AIDS, health-care professionals, trade unions and the Treatment Action Campaign (TAC), a nongovernmental organization, filed a complaint with the Competition Commission of South Africa against GlaxoSmithKline (GSK) and Boehringer Ingelheim. According to one of the complainants, the complaint was filed after a campaign that lasted nearly four years, requesting pharmaceutical companies to issue unconditional voluntary licenses against a fair royalty rate of 4%–5%. As companies failed to respond, “now we are asking the Competition Commission to investigate the complaint and to refer it to the Competition Tribunal”.\textsuperscript{7}

In October 2003, the Competition Commission announced that it was referring the case to the Competition Tribunal for determination as the two companies had been found to have abused their dominant position through excessive pricing, refusing access to essential facilities and exclusionary acts whose anticompetitive effect outweighed technological, efficiency or other pro-competitive gains. The Commission stated that it would request the Tribunal to authorize compulsory licenses and a penalty of 10% of the annual turnover from the companies’ antiretroviral (ARV) business in South Africa. According to the Commissioner, “the very goals of our Competition Act – promoting development, providing consumers with competitive prices and product choices, advancing social and economic welfare and correcting structural imbalances – have been made difficult in this context by the refusal of the respondents to license patents.”\textsuperscript{8}

Before the Tribunal could hear the matter, the case was settled on 9 December 2003. Boehringer Ingelheim agreed to offer licences for nevirapine to Aspen Pharmacare Holdings Ltd and to two other appropriate “entities”. According to the settlement, these licences would allow supply to both the public and private sectors, permit export to other sub-
In 2017, the Competition Commission of South Africa announced an inquiry into the pricing of cancer medicines including two that are patented. Against Roche, an abuse of dominant position investigation has been initiated related to the provision of trastuzumab, a treatment for breast cancer on the ground that “Roche and its USA-based biotechnology company, Genentech Inc. (Genentech) have and continue to engage in excessive pricing, price discrimination and/or exclusionary conduct in the provision of breast cancer medicine in South Africa.” Against Pfizer, an excessive pricing investigation has been initiated in the case of lung cancer medication known as xalkori crizotinib.

In certain cases of mergers, the US Federal Trade Commission has effectively ordered compulsory licensing or sale of patents to ensure continued competition.

In 2007, the Commission received a complaint from TAC alleging that Merck and MSD (its South African subsidiary) had abused their dominant position in the case of efavirenz (used in first-line ARV treatment) on which MSD’s patent would expire in 2013. TAC’s complaint was based on Merck’s refusal to issue reasonable and non-discriminatory licenses to generic manufacturers. Before the conclusion of the investigation, the matter was resolved with MSD and Merck issuing multiple licenses.

In 2009, TAC, along with other organizations, also filed submissions in the Commission’s review of the proposed merger of GSK and Aspen highlighting concerns regarding generic competition for the ARV abacavir after the merger. The Commission finally approved the merger with the condition that GSK issue non-exclusive licenses for abacavir to several competitors.

In 1997, the FTC found that the merger of Ciba-Geigy and Sandoz would have an anticompetitive impact on the innovation of gene therapies. The FTC also found that they were in direct competition in the case of certain medicines. According to the FTC,

**United States of America**

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the gene therapy market, “was highly concentrated and that Ciba and Sandoz were the two leading commercial developers of the gene therapy product. Moreover, entry into the gene therapy markets was difficult and time-consuming because any entrant would need patent rights, significant human and capital resources, and FDA approvals.”

The FTC ordered that the new company formed from the merger – Novartis – would be required to grant any request for a non-exclusive license to certain patented technologies for gene therapy products for an upfront payment of US$ 10,000 and royalties of 1%-3%. Novartis was also required to grant non-exclusive licenses of patent rights related to cancer, graft versus host disease (GVHD, and haemophilia and was barred from acquiring exclusive rights in certain IPs related to chemo-resistant gene therapy.

In 2002, as part of the consent order for the merger of Amgen Inc. and Immunex Corporation, the US FTC required the grant of several licences including for tumour necrosis factor (TNF) inhibitors which treat inflammation in patients with autoimmune diseases. Immunex was one of two companies marketing TNF inhibitors and Amgen was one of three companies with TNF inhibitors in clinical development. The FTC required Amgen to licence patents to Serino (a Swiss company developing a TNF inhibitor for use in Europe), that blocked Serino’s ability to market in the U.S.

In 2006, the FTC required the licensing of certain IPs on drug-eluting stents to a competitor as a condition for Guidant’s acquisition by Boston Scientific.

The US FTC has also been actively investigating the so-called “pay for delay” or “reverse payment” settlements between patent holders and generic companies. These agreements are characterized by (monetary or non-monetary) payments from patent holders to competitors to settle patent litigation and for the competitor to delay or abandon market entry. Since 2001, the FTC has filed a number of lawsuits to stop such agreements which a 2010 FTC study estimated cost consumers US$ 3.5 billion annually.

In 2013, the US Supreme Court affirmed a ruling in Merck & Co. Inc. “to assess the abusive nature of unjustified refusals to grant licences that were indispensable for the production of active ingredients in quantities sufficient to allow wide distribution of generic drugs, to the benefit of competition and consequently of consumers.”

In June 2005, an interim measure was issued in relation to a pharmaceutical product (Tienam) based on the active ingredient Imipenem Cilastatina which is an antibiotic used to treat serious infections often contracted in hospitals. While Merck had a patent in Italy, it no longer had any patent rights over the product in other European countries. Still it refused to grant a license for the production of the drug in Italy for export to counties not covered by patents. ACGM obliged Merck to grant a license so that, “chemicals companies having plants in Italy to be already in a position, at the completion of the proceedings, to export the product in question to European countries where Merck has already lost all patent rights, in advance of the arrival of those markets of generic drugs which will compete with Merck’s Tienam product.”

The proceedings against Merck finally concluded in March 2007, when Merck also committed to provide free licenses for the manufacture and sale in Italy of the active ingredient finasteride (used in the treatment of prostate hypertrophy) and related generic drugs. According to ACGM, “this ruling needs to be seen in the wider context of the Authority’s efforts to encourage businesses to adopt commitments aimed at improving market conditions, competition and consumer choice. In
the pharmaceuticals sector in particular the Antitrust Authority’s initiative is aimed at encouraging more widespread use of generic products.”

In February 2006, ACGM found that Glaxo’s refusal to grant a license to an Italian company, Fabbrica Sintetici Italiana (FIS), for the production of Sumatriptan Succinate (an active pharmaceutical ingredient to manufacture triptans that treat migraines) for use in European countries where Glaxo no longer held patent rights was an abuse of dominant position. ACGM found that Glaxo had a quasi-monopoly globally and occupied a dominant position in the Spanish (58% market share) and Italian markets (96% market share) and that Glaxo’s refusal to license had no objective justification. No fine was imposed, however, as Glaxo issued the requested licenses to FIS in the course of the proceedings.

In 2012, ACGM found that Pfizer had abused its dominant position in applying a complex strategy to delay generic entry for glaucoma medicines based on the active ingredient latanoprost and ordered the stopping of the unlawful practices as well as a fine of 10.6 million euro. ACGM calculated losses of 14 million Euros of lost savings to the National Health Service. Pfizer held 60% of the market share for latanoprost (which it sold as Xalatan). ACGM’s investigation revealed that that the main purpose of Pfizer’s strategy was to delay generic entry from September 2009 (when its patent in Italy was expiring) to January 2012 in line with the expiry of its patents in other countries. “The result of this strategy was that the first market entry was not possible until May 2010, with the last operators entering the market more than a half years after patent expiration ... the delayed entry of the manufacturers of generics gained the company a seven-month extension of its monopolistic profits, which amounted to approximately 17 million euros (based on the market share gained by generic manufacturers during the first seven months of market entry).”

The complex strategy employed by Pfizer in this case included:

1. In 2002, thirteen years after the filing of the main patent, Pfizer filed a divisional application before the European Patent Office whose claims also covered latanoprost;
2. Once the European divisional patent was obtained in January 2009, Pfizer validated this patent only in Italy and then applied for the Supplementary Protection Certificate (“SPC”), in order to extend its new patent protection in Italy until July 2011, like in other Member States;
3. Pfizer started patent-related litigation before civil and administrative courts, to restrain generic companies from entering the market;
4. Pfizer also commenced actions aimed at preventing Italy’s national drug regulatory body from granting generic companies marketing authorizations;
5. Pfizer further applied for an extension of protection by means of a paediatric experimentation with no real intention of developing the paediatric version (if granted, this would have extended the length of protection for six more months, until January 2012).

In 2014, ACGM’s ruling in the Pfizer case was upheld by the Council of State, the highest administrative court on competition in Italy. The Council of State found that although Pfizer’s actions individually were legal, they amounted to an “abuse of rights” i.e. where a right is exercised for a purpose other than for which it was granted. In order to invoke this category of “abuse of rights,” there must be, “(i) the existence of a right; (ii) the possibility to effectively use such right in different manners; (iii) the exercise of the right in a reprehensible manner, although formally legitimate; (iv) the resulting unjustifiable disproportion between the benefit of the right’s owner and the harm caused to the counterparty. In other words, the abuse of rights does not suppose a formal infringement of laws, but the distorted exercise of the granted rights, for purposes different from those meant by the legislator.”

Broad scope of competition law

Although the country experiences discussed above are IP related, the scope and breadth of the use of competition law and policy in the pharmaceutical sector is far broader. WHO, WIPO and WTO have noted that “competition policy is relevant to all stages in the process of supplying medical technology to patients, from their development to their sale and delivery.” Competition authorities
in several countries have not only investigated and taken steps in cases involving patent settlements, licensing practices and pricing policies but they have also acted to prevent collusion among suppliers of medical technology participating in procurement processes.

The table below from UNDP highlights some key examples.25

Table 1: Examples of competition law actions in the pharmaceutical sector

<table>
<thead>
<tr>
<th>Country and date of action</th>
<th>Description of action</th>
<th>Pharmaceutical product</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>France 2013</td>
<td>Following complaint by Teva, French Competition Authority found that Sanofi-Aventis abused dominant position with strategy to denigrate generic versions of its branded drug, Plavix</td>
<td>clopidogrel</td>
<td>Fine of €40.600 million imposed on Sanofi-Aventis</td>
</tr>
<tr>
<td>European Union 2012</td>
<td>European Court of Justice affirmed Commission finding of abuse of dominant position by AstraZeneca by providing misleading information to patent office and deregistering product to inhibit generic entry</td>
<td>Losec</td>
<td>Fine of €52.5 million imposed on AstraZeneca</td>
</tr>
<tr>
<td>Colombia 2009</td>
<td>Finding less than three homogenous products on the market, the National Medicines Pricing Commission regulated price of medicine sold by Abbott Laboratories</td>
<td>Lopinavir and Ritonavir</td>
<td>Average reduction of price between 54% and 68% per person per year</td>
</tr>
<tr>
<td>Italy 2007</td>
<td>Competition authority initiated investigation into abuse of dominant position by Merck</td>
<td>API Finastertide</td>
<td>Efendant agreed to grant free licences to allow manufacture and sale of API prior to expiration of patent term</td>
</tr>
<tr>
<td>South Africa 2003</td>
<td>Finding by Competition Commission of excessive pricing and denying a competitor an essential facility against pharmaceutical companies following complaint from activist groups</td>
<td>AZT, lamivudine and nevirapine and fixed close combinations containing these ARVs</td>
<td>Led to voluntary settlement agreements with GlaxoSmithKline and Boehringer Ingelheim providing for licensing of patents to a total of seven generic companies based on 5% royalty</td>
</tr>
<tr>
<td>United States 2000</td>
<td>Federal Trade Commission charged generic producers with restraint of trade and conspiracy to monopolize markets for two generic drugs; settlement agreed</td>
<td>Lorazepam and Chlorazepate</td>
<td>Lead defendant (Mylan) placed $100 million into escrow account for distribution to purchasers of relevant drugs during time period covered by settlement</td>
</tr>
</tbody>
</table>

25Competition law is considered to be an under-used measure to deal with the abuse of IP rights and, as noted above, can play a useful role in such cases. However, as UNDP notes, “the increased use of competition law and policy is not without its challenges. These include the relative novelty of these measures in many developing countries; the lack of a substantial body of precedent; underdeveloped competition law frameworks; and capacity constraints concerning enforcement structures in developing countries.”

Developing and least developed countries therefore need to establish legal and policy frameworks and institutions on competition law that are adapted to their circumstances. South Africa’s Competition Act includes in its purpose, the advancement of “social and economic
welfare of South Africans” and “to increase the ownership stakes of historically disadvantaged persons.”77 Several developing countries are putting competition legislation and authorities in place and could consider including the protection of public health and ensuring access to affordable medicines as a key objective of their competition policy.

Least developed countries

Least developed countries (LDCs) are the only World Trade Organization (WTO) Members who now enjoy transition periods. Article 66 (Box 2) of the TRIPS Agreement provided LDCs with a ten-year transition period to comply with the agreement.78 Article 66 also recognizes the right of LDCs to get further extensions of the transition period on a “duly motivated request”. LDCs taking advantage of the transition period that did not make available product patents for pharmaceuticals when the TRIPS Agreement came into force on 1 January 1995 were also required to set up a “mailbox” to receive patent applications and grant exclusive marketing rights on those applications under certain circumstances.

At present, two separate transition periods are available to LDCs. The first is to comply with the TRIPS Agreement by 2021. The original ten-year transition period for LDCs to comply with the TRIPS Agreement recognized in Article 66 was due to expire in 2005. In 2005 this transition period was extended by 7.5 years to June 2013 when it was further extended till 2021.79

The second transition period is to grant or enforce patents on pharmaceutical products by 2033. This transition period specific to pharmaceuticals was first recognized in the Doha Declaration. LDCs received an extension for the grant or enforcement of patents and test data protection on pharmaceuticals as well as a waiver of their obligations to provide exclusive marketing rights during the transition period, till 2016.80 On 6 November 2015, on a request from the LDC Group in the WTO, the TRIPS Council extended the transition period relating to pharmaceutical products to 2033.81 On 30 November 2015 a further decision was taken to waive the mailbox and exclusive marketing rights requirements.82 The waiver of the mailbox requirement is a new and important addition to the previous extension decision.

Both transition periods are subject to further extensions on a duly motivated request from the LDCs.

Box 2. Provisions in the TRIPS Agreement specific to least developed countries

Article 66: Least developed country Members

(1) In view of the special needs and requirements of least developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least developed country Member, accord extensions of this period.

(2) Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base.

Some LDCs have incorporated the transition periods into their laws. Cambodia was the first LDC to incorporate one of the transition periods in its law; over time, other LDCs like Uganda have included more expansive provisions on transition periods. Both laws described below reference the 2016 pharmaceutical transition period as they were enacted before the recent extension of the period to 2033.

Cambodia

Cambodia enacted a TRIPS-compliant patent law in 2003, and joined the WTO in October 2004. Under the Doha Declaration on the TRIPS Agreement and Public Health, Cambodia and other least developed WTO Member States have the right to postpone the implementation of patents for pharmaceuticals until 2016. Cambodia has made use of this right by explicitly incorporating it in its patent law (see Box 3).

Uganda

In 2014, Uganda enacted an Industrial Property Act in which it included a specific provision excluding pharmaceutical products and test data from patent protection while also providing for a conditional exemption from the enforcement of process
patents. The exemption is also reflected in the 2017 regulations adopted under the Act.

**Box 3. Article 136 of Cambodia’s Law on Patents, Utility Models and Industrial Designs, 2003**

“The pharmaceutical products mentioned in the Article 4 of this Law shall be excluded from patent protection until January 1, 2016, according to the Declaration on Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health of the Ministerial Conference of World Trade Organization dated November 14, 2001 in Doha of Qatar.”

The use of the LDC transition periods is important from a public health perspective as they minimize patent barriers to the import or even local production of generic medicines. As UNAIDS and UNDP note “…without the requirement of providing intellectual property protections, LDCs are free to follow the historic path of copying and adaptation to develop their technological capacities, at the same time strengthening their human, administrative, financial and other capacities…”

33 In 2011 UNCTAD released a series of case studies of local production including in three LDCs (Bangladesh, Uganda and Ethiopia) and concluded that local production is feasible in LDCs which may promote access to medicines. Several LDCs are exploring the feasibility of local production and make use of the transition periods to this end. The African Union’s Pharmaceutical Manufacturing Plan for Africa Business Plan (PMPABP) 2012, for instance, identifies the use of TRIPS flexibilities and particularly the use of the LDC transition periods as central to the success of local pharmaceutical production. Local production in LDCs can also provide an alternative source of generic supply for developing countries; the example of local production of medicines for hepatitis C treatment in Bangladesh noted below is a case in point.

### Bangladesh

Bangladesh does not enforce pharmaceutical patents. Bangladesh’s National Drug Policy restricts local manufacture by multinational companies except for the purposes of export. The policy also launched government pharmaceutical companies to cater to local needs for essential medicines while also encouraging the private sector. Imports of medicines already produced in the country are not allowed. This means that the local market is largely supplied by the over hundred operational pharmaceutical companies in Bangladesh; a significant change from 1982 when multinational companies controlled over 70% of the market. In 2015, the global significance of local production in Bangladesh became evident when Incepta, a Bangladeshi pharmaceutical company, launched the first generic version of sofosbuvir, a directly acting antiviral (DAA) critical in the treatment of hepatitis C. Subsequently Bangladeshi companies also launched generic versions of other DAAs and their combinations.

### Lessons

Some preliminary conclusions and lessons can be drawn from these experiences. These include:

- competition law is an under-used measure to deal with the abuse of IP rights and can play a useful role particularly in the pharmaceutical sector to ensure competition and lower prices;
- competition laws and policies can and have been used to protect public health in developed and developing countries;
- the use of competition law, the launch of competition investigations or filing of strong competition complaints can be instrumental in securing generic production and supply of patented medicines;
- civil society groups such as people living with HIV or health groups can play an effective, important role in filing competition complaints or interventions in competition investigations;
- while the use of competition law in developing countries is limited, it can be adapted to their circumstances and resources;
- LDCs should make full use of the 2021 and 2033 transition periods and consider incorporating these in their patent laws;
- LDC transition periods can be used effectively to import generic medicines or to establish local production.
**Box 4. Sections 8(3)(f) and 101(15) of Uganda's Industrial Property Act, 2014 and Section 3 of the Industrial Property Regulations, 2017**

8(3) The following shall not be regarded as inventions and shall be excluded from patent protection— (f) pharmaceutical products and test data until 1 January 2016 or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on Trade-Related Aspects of intellectual Property Rights under the World Trade Organization;

101. Special provisions on enforcement of patent rights

(15) The rights accruing from patents for pharmaceutical processes shall not be enforceable until 1 January 2016, or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on Trade-Related Aspects of Intellectual Property Rights under the World Trade Organization if alternative processes for making pharmaceutical products that are not subject to exclusive rights are not available and those patents, if enforced, indirectly give rise to market exclusivity of the pharmaceutical products in question.

Section 3 of the Industrial Property Regulations, 2017

3. Non-application to pharmaceutical products

(1) These Regulations shall not apply to pharmaceutical products.

(2) For the avoidance of doubt, the registrar shall not accept an application to register a patent, utility model, industrial design or technovation relating to pharmaceutical products, microbiological products and processes for producing pharmaceutical products, until 1 January 2016, or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on Trade-Related Aspects of Intellectual Property Rights under the World Trade Organization.

**Further reading**


5. WHO, WIPO and WTO. Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade: Trilateral Study. 2013. Available at http://apps.who.int/iris/bitstream/10665/78069/1/9789241504874_eng.pdf?ua=1&ua=1


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12. Ibid.


22. Claudia D’Amore. The Administrative Supreme Court confirms the ICA’s decision to condemn Pfizer for abuse of dominant position aimed at delaying the market entry of generic pharmaceutical companies. DOI: 10.12870/iar-9935. Available at http://iar.agcm.it/article/download/9935/9268

23. Ibid.


26. Ibid at p.8


28. During the transition period, LDCs are, however, required to comply with Articles 3 (national treatment), 4 (most-favoured nation treatment) and 5 (which specifies that national treatment and most-favoured nation treatment are not required in the case of WIPO’s multilateral agreements on the acquisition or maintenance of IP) of the TRIPS Agreement.

29. See WTO Document IP/C/64
30. “Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement,” WTO. Declaration on TRIPS and Public Health. Doha: 2001 (Doha Declaration).

31. See WTO Document IP/C/73

32. See WTO Document WT/L/971


