

## **LDC Members' Entitlement to and Need for a Further Extension of Their Pharmaceutical Transition Period**

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### **1. Introduction**

At the WTO TRIPS Council in October 2014, Bangladesh, on behalf of the LDC Group, delivered notice that the LDC Group would be applying for an extension of the pharmaceutical transition period currently set to expire on 1 January 2016.<sup>2</sup> The current pharmaceutical transition period is comprised of two WTO decisions, TRIPS Council Decision, IP/C/25,<sup>3</sup> addressing pharmaceutical product patent and data protections, and General Council Decision, WT/L/478,<sup>4</sup> addressing market exclusivity rights under Article 70.9. This 2002-2013 transition period was specifically without prejudice to the right of LDC Members to seek and obtain further extensions if requested. This special pharmaceutical transition period was first agreed upon in Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health based on the special public health needs of LDC Member States and their acknowledged right to take steps to ensure access to medicines for all.<sup>5</sup> Because these health needs persist, and in many ways are growing because of the continued threat of infectious, neglected, and non-communicable diseases, a further extension of the transition period is fully warranted. As evidenced by their continuing LDC status, LDC Member States still face unrelenting development and capacity challenges. To address their pressing public health needs, to secure their ability to progressively realize the right to health, and to ensure their continuing right of access to more affordable medicines of assured quality, LDC Members have an explicit right to seek and mandatorily obtain an extension of the pharmaceutical transition period.

The short answer to any concerns about the legal basis for a further pharmaceutical extension is that Article 66.1 of the TRIPS Agreement says that the TRIPS Council “**shall**, upon duly motivated request by a least-developed country Member, **accord** extensions of [the Article 66.1 LDC transition period]” – full stop, no if’s, and’s, or but’s. Not only are LDCs legally entitled to any requested extension, they need the specific pharmaceutical extension because it is clearer and more direct than the general TRIPS-compliance transition period adopted in 2013 that will expire in 2021. A pharmaceutical extension will give them total freedom of action to ignore pharmaceutical patents, data protections, marketing exclusivity rights, and hopefully mailbox obligations, so long as an LDC Member remains an LDC. Furthermore, the extension will allow them to meet pressing public health needs, to promote local pharmaceutical manufacturing capacity, to spend limited domestic and donor resources efficiently, and to fulfill their obligations with respect to the right to health.

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<sup>2</sup> KEI, WTO TRIPS Council (October 2014): Bangladesh states (on behalf of LDCs) – Extension of the 2016 transition period, available at <http://keionline.org/node/2158>.

<sup>3</sup> 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, [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).

<sup>4</sup> Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, [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).

<sup>5</sup> Doha Declaration on the TRIPS Agreement and Public Health, Paragraphs 7 and 4.

## 2. Legal Analysis – A Chronological History of Previous Extensions

Article 66.1 of the 1994 TRIPS Agreement reads as follows: “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 [emphases added].” This provision has been used to accord LDC Member States three extensions to date.

**Pharmaceutical Extension 2002-2016:** In 2001, following multiple actions by the US and others that had challenged low- and middle-income countries’ right to adopt and utilize flexibilities set forth in the TRIPS Agreement, the Africa Group demanded a clarification of those flexibilities from the TRIPS Council. The result was the Doha Declaration on TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) . In addition to confirming the right to address public health needs, to prioritize access to medicines for all, and to use parallel importation and to issue compulsory and government use licenses, Paragraph 7 of the Declaration directly addressed LDC Members need for an extended transition period with respect to pharmaceutical products:

We also agree that the 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. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Paragraph 7 constituted a “duly motivated request” to the TRIPS Council (see Preamble of IP/C/25).

Actualizing Paragraph 7’s command, the TRIPS Council Decision adopted on 27 June 2002 states: “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.” The Decision expressly provided for the right to seek further extensions: “This decision is made without prejudice to the right of least-developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.” The TRIPS Council discussed making recommendations to the General Council with respect to pharmaceutical obligations imposed during transition periods arising from Article 70.8 and 70.9 of the TRIPS Agreement, the so-called “mailbox” and “market exclusivity” provisions. In this regard, the TRIPS Council initially prepared a motivation to the General Council calling on it to grant a waiver on both Article 70.8 and 70.9 (JOB(02)57, 12 June 2002). After opposition from the US and certain European countries, the request with respect to the Article 70.8 mailbox provision was dropped (IP/C/W/359, 28 June 2002). In response to the TRIPS Council recommendation, the General Council granted a waiver on July 2002 (WT/L/478), by which the obligation under Article 70.9 to provide exclusive marketing rights for pharmaceutical products was also waived for LDCs until 1 January 2016.

**First TRIPS-compliance Extension 2005-2013:** The 10-year exemption from implementing TRIPS obligations granted to LDCs in Article 66.1 of the TRIPS Agreement was scheduled to expire on 1 January 2006. Following a duly motivated request submitted by LDCs as a group in October 2005, the TRIPS Council adopted a decision (IP/C/40) which gave LDCs an extension of

7.5 years that exempted LDCs from having to apply any TRIPS provisions, other than Articles 3, 4 and 5 until 1 July 2013 (2005 LDC Extension). Regrettably and without legal justification under the language of Article 66.1, that extension contained a stay-put or no-roll-back provision that prohibited LDCs from overturning existing levels of TRIPS-compliant IP protection.<sup>6</sup> On the plus side, the extension directly acknowledged LDC Members' right to seek a further extension of the pharmaceutical extension and of the general compliance extension.<sup>7</sup>

**Second TRIPS-compliance Extension 2013-2021:** Pursuant to express allowance for countries to seek a further extension of 2005 LDC Extension, on June 11, 2013, the TRIPS Council further extended the general TRIPS-compliance transition period until 2021.<sup>8</sup> In Paragraph 2 of this decision, Members recognized the progress LDCs had already made towards implementing TRIPS and LDCs expressed their "determination" to preserve and continue this progress. As a partial improvement over the 2005-2013 LDC Extension, which contained a no-roll-back clause, the 2013 decision did not affect LDCs' right to fully use flexibilities in the TRIPS Agreement and to seek further extensions of the transition period.

2. Recognizing the progress that least developed country Members have already made towards implementing the TRIPS Agreement, including in accordance with paragraph 5 of IP/C/40, least developed country Members express their determination to preserve and continue the progress towards implementation of the TRIPS Agreement. Nothing in this decision shall prevent least developed country Members from making full use of the flexibilities provided by the Agreement to address their needs, including to create a sound and viable technological base and to overcome their capacity constraints supported by, among other steps, implementation of Article 66.2 by developed country Members.

Like the previous 2005 Extension, this extension was also without prejudice to the pharmaceutical extension or further extensions of the general TRIPS-compliance transition period.<sup>9</sup>

### **3. Why a Further Pharmaceutical Extension is Required**

Some sources are questioning why a pharmaceutical extension is needed. They apparently believe that the Second TRIPS-compliance Extension 2013-2021 is strong enough to protect all of the interests of LDC Members with respect to access to medicines. It can also be anticipated

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<sup>6</sup> Extension of the Transition Period Under Article 66.1 for Least Developed Country Members (IP/C/40, 30 November 2005), Paragraph 5: "Least-developed country Members will ensure that any changes in their laws, regulations and practice made during the additional transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement."

[http://www.wto.org/english/tratop\\_e/trips\\_e/ta\\_docs\\_e/7\\_1\\_ipc40\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc40_e.pdf).

<sup>7</sup> Ibid. Paragraph 6: "This Decision is without prejudice to the Decision of the Council for TRIPS of 27 June 2002 on "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), and to the right of least-developed country Members to seek further extensions of the period provided for in paragraph 1 of Article 66 of the Agreement."

<sup>8</sup> Extension of the Transition Period Under Article 66.1 for Least Developed Country Members (IP/C/64, June 12, 2013), Paragraph 1.

[http://www.ipi.gov.mz/IMG/pdf/Decisao\\_do\\_Conselho\\_do\\_TRIPS\\_da\\_OMC\\_sobre\\_a\\_extensao\\_do\\_prazo\\_de\\_transicao\\_para\\_os\\_PMA.pdf](http://www.ipi.gov.mz/IMG/pdf/Decisao_do_Conselho_do_TRIPS_da_OMC_sobre_a_extensao_do_prazo_de_transicao_para_os_PMA.pdf).

<sup>9</sup> Ibid. Paragraph 3: "This Decision is without prejudice to the Decision of the Council for TRIPS of 27 June 2002 on "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), and to the right of least developed country Members to seek further extensions of the period provided for in paragraph 1 of Article 66 of the Agreement."

that the U.S. and E.U. might press this argument and that they might continue to press the view, as they did in 2013, that preserving and extending IP protection is more important than preserving policy space to attend to persistent development challenges. Contrary to such claims, there are at least six reasons why a pharmaceutical extension is required:

**LDC Members are legally entitled to any further extension of the pharmaceutical transition period that they request:** By its own terms, Article 66.1 of the TRIPS Agreement states that further extensions shall be granted upon properly motivated requests – this language is obligatory. Similarly, Paragraph 7 of the Doha Declaration and all three existing Article 66.1 extension discussed above explicitly reference the right of LDC Members to seek further extensions of the Pharmaceutical Extension. This right was specifically included in the Second TRIPS-compliance Extension 2013.

**The Second TRIPS-compliance Extension 2013-2021 does not provide the same level of open-ended freedom from recognizing and enforcing pharmaceutical patent, data-protection, and market-exclusivity rights as would a further extension of the existing Pharmaceutical Extension:** On its face, paragraph 2 of the Second TRIPS-compliance Extension 2013-2021 contains expressions of LDCs' intention to make progress towards implementation of the TRIPS Agreement. In the wake of this Extension, the European Union went so far as to argue that this language was legally binding and equivalent to a no-roll-back or stay-put requirement.<sup>10</sup> This author strongly disagrees with that interpretation, but even if this language is not fully enforceable, it expresses an intention that simply does not and should not exist with respect to pharmaceutical IPRs.

The urgency of access to more affordable generic pharmaceuticals makes it imperative that LDC members have no IP recognition or enforcement obligations with respect to those products. The clarity on this point in Paragraph 7 of the Doha Declaration and in the Pharmaceutical Extension 2002 allowed at least 25 LDCs to declare existing pharmaceutical product patents unenforceable in their countries thereby facilitating importation or procurement of HIV-related generics medicines.<sup>11</sup> LDC Members are entitled to the same degree of clarity and freedom to act post-2016.

**LDC Members face crushing public health needs and compelling right to health obligations and therefore need access to the most affordable generic medicines of assured quality:** Without going into great detail, LDC Members face growing burdens of neglected, infectious, and chronic non-infectious disease. Because of market failure in the patent-based innovation system, diseases that mainly affect poor people in lower income countries – so-called neglected diseases, including Ebola – still do not have many treatment options. Although HIV, TB, and malaria are all being addressed, there are still growing costs relating to treatment and prevention. Finally, people living in LDCs face growing burdens of diabetes, heart disease, cancer, and other non-communicable diseases. These public health burdens must be addressed through the most cost-effective and equitable means possible. LDC Members, like other countries, have an obligation to their nationals to progressively promote, protect, and realize the right to health,

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<sup>10</sup> An EU release on 11 June 2013 stated: “Where least-developed countries voluntarily provide some kinds of intellectual property protection even though they are not required to do so under the TRIPS Agreement, they have committed themselves not to reduce or withdraw the current protection that they give.”

<sup>11</sup> UNAIDS, *Implementation of TRIPS and Access to Medicines for HIV after January 2016 : Strategies and Options for least Developed Countries*, UNAIDS Technical Brief, 4 (2011), [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258\\_techbrief/TRIPS-access-medicines-LDC\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief/TRIPS-access-medicines-LDC_en.pdf)

including the right of access to medicines for all. The fiscal challenges of responding to their health needs is growing as global health aid stagnates, as seen in the dwindling resources of both the Global Fund and the U.S. PEPFAR program.

**LDCs still have the same or worse “economic, financial and administrative constraints” that they had in 1994 and in 2002:** Article 66.1 directly references the key capacity constraints that LDC Members faced at the time of passage. Those capacity constraints are long-lasting and remain largely unaddressed to the present. In some ways, capacity constraints are even more pressing, especially in the health sector, as the burden of infectious and non-communicable disease grows. Addressing those constraints takes both political will and resources. The more LDCs might spend on pharmaceutical IPR recognition and enforcement and the more they spend on higher-price, IP-protected innovator drugs, the less they will have to invest in human resources for health, health infrastructure, health system strengthening, and the myriad other dire development shortcomings they face.

**LDCs have the same “need for flexibility to create a viable technological base,” including in pharmaceuticals:** Article 66.1 also directly references LDC Members need to expand their technological capacities. This recognition is certainly broad enough to cover pharmaceutical capacity. In the absence of exclusive rights, LDC Members and their nascent pharmaceutical industries will be free to invest in strengthening pharmaceutical manufacturing capacity and building out the network of suppliers and distributors that will strengthen their technological base and potentially produce cost savings as well, particularly if they are free to export to regional or even global markets. Indeed, LDC Members could have a unique advantage to have patent-free access to produce newer pharmaceuticals that are widely patented in key producer countries like India. In essence, select LDC Members that invest in pharmaceutical sector strengthening can pursue a path of generic production, market expansion, and manufacturing efficiency and quality that helped propel India’s industry to where it is today. However, LDCs and local companies will only make the needed investments if LDC Members have a sufficiently long extension on pharmaceutical products to make those investments profitable. Unduly short extensions, even if extended time and time again, will, in contrast, be essentially meaningless in terms of incentivizing and capacitating local generic production.

**For LDCs, IP in general is a problem, not a solution – all the more so for medicines:** Rich countries and many multilateral institutions push intellectual property rights as a tool for innovation, technology transfer, foreign direct investment, and development more generally. The U.S. and the E.U. pushed this argument repeatedly during the negotiation of the Second TRIPS-compliance Extension 2013-2021. However, the evidence with respect to IPRs in these regards is highly contested and both the empirical and theoretical literature suggestions that low-income countries are better off without strong IPRs than with them.<sup>12</sup> Avoiding IPRs with respect to pharmaceutical products will not have negative impacts on LDCs’ development potential as is claimed by rich countries seeking to protect their IP-based industries – avoidance will be essential to avoiding pharmaceutical hegemony and monopoly pricing.

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<sup>12</sup> Brook K. Baker, *Debunking IP-for-Development: Africa Needs IP Space Not IP Shackles in INTERNATIONAL ECONOMIC LAW AND AFRICAN DEVELOPMENT* (Laurence Boule, Emmanuel Laryea & Franziska Sucker eds. 2014). The Global Commission on HIV and the Law has called for a review of IP protections on medicines and for a suspension of enforcement of IPRs on medicines in low- and middle-income countries; it has also called for the LDC pharmaceutical extension discussed herein. HIV AND THE LAW: RISKS, RIGHTS & HEALTH, 86-87 (2012).

#### **4. LDCs Need an Unlimited Extension without Conditions and Waivers from Articles 70.8 and 70.9 for as Long as a Member Remains an LDC**

The important elements of a further extension of the Pharmaceutical Extension are quite clear:

**No conditions:** LDCs first Pharmaceutical Extension was without conditions and the upcoming extension should be without conditions as well. There should be no questions on this point.

**Duration:** Each LDC Members should have the benefit of an extended pharmaceutical transition period as long as it is an LDC. By the very definition of remaining an LDC, the collective global judgment is that such countries face severe capacity and technological constraints. Even relatively long extensions like the 13½ year extension granted in 2002 are not long enough for many LDCs given the long and arduous path to graduation/transition to non-LDC status. An open-ended extension is especially necessary for nascent domestic pharmaceutical firms that need a protracted window within which to develop their technological and manufacturing capacity. Private firms are risk averse, and might simply avoid needed investments if the rug can be pulled out from under them because of actions taken at the WTO. Some countries might pressure LDCs to accept an extension that is co-terminus with the Second TRIPS-compliance Extension 2013. Agreeing to this would be a mistake, first because it would not be long enough and second because it could complicate negotiations for further extensions in 2021.

**Waive market exclusivity:** To allow exclusive marketing rights for non-recognized patents under Article 70.9 would fly in the face of reason. There is ample precedent from the original Pharmaceutical Extension decision to justify a direct recommendation from the TRIPS Council to the General Council that an extension of the Article 70.9 waiver be granted.

**Waive mailbox requirements:** Regrettably, the request for a waiver with respect to a mailbox for pharmaceutical product patent applications required under Article 70.8 was dropped in 2002. The TRIPS Council meeting notes at that time show that there was opposition to the waiver from certain rich country members (Switzerland, European Communities, and United States).<sup>13</sup> Those countries seemed to be operating on the assumption that LDC Members must have operational patent offices that could collect patent applications. However, Article 66.1 and the Second TRIPS-compliance Extension both allow LDCs not to have any IPR rights or IP offices whatsoever. LDC Members should not have to spend any of their scarce resources collecting illusory pharmaceutical patent applications that probably shouldn't be filed in LDCs in the first place.

#### **5. Conclusion**

The WTO should be lining up support for an unconditional extension of the pharmaceutical production transition period and for a General Council waiver with respect to obligations under TRIPS Article 70.8 and 70.9 until such time as an LDC Member is no longer an LDC. Rich countries should expend their efforts in really promoting technology transfer and aiding the development of LDC Members instead of engaging in an irrational lobbying effort to give LDCs less than they need and less than they are legally entitled to. LDC Members must intensify their joint advocacy and hold firm on their key demands – they need give up nothing in exchange for the assertion of their clear rights under Article 66.1, Paragraph 7 of the Doha Declaration, and the previous three LDC transition period extensions. Developing country Members should rally to support their LDC sister countries to show South-South solidarity on the right to health. Finally,

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<sup>13</sup> Minutes of Meeting of Council for TRIPS held on 25-27 June (IP/C/M36), 18<sup>th</sup> July 2002.

health activists and advocates, Northern and Southern, should also engage in the kind of strategic advocacy that helped win the Second TRIPS-compliance Extension in 2013.