5. Has the TRIPS Waiver Helped the Least Developed Countries Progress Towards Innovation and Compliance?

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This chapter analyses the issue of waivers for the LDCs under the TRIPS Agreement in the context of how waivers help these countries graduate from the LDC category and progress towards TRIPS compliance. It also identifies the technical and infrastructural development and changes required as LDCs move towards TRIPS compliance, using the case study of Bangladesh.

5.1 Background: TRIPS Waivers for the LDCs and Designing a Plan of Action for Graduation and Progression Towards Innovation and Compliance

WTO members have agreed to extend the transition period for LDCs to implement the TRIPS Agreement until July 2021; it was previously due to end on 1 July 2013. Haiti submitted a request on 5 November 2012 and on behalf of the LDC group to extend the transition period further—specifically, until a given member graduates from being a LDC.¹ That proposal, among others, mentioned that “the situation of LDCs has not changed significantly since the last extension decision in 2005 ... [and

they] have not been able to develop their productive capacities and have not beneficially integrated with the world economy”. The Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Development Program (UNDP) and civil society organisations widely supported the proposal to give urgent consideration to the continued special needs and requirements of LDCs with respect to their social and economic development. UNAIDS pointed out that “an extension would allow the world’s poorest nations to ensure sustained access to medicines, build up viable technology bases and manufacture or import the medicines they need”.

There is thus a fair amount of consensus that LDCs should be allowed to suspend implementation of the TRIPS Agreement until graduation from the LDC category, or be given provision for voluntary compliance, considering economic, financial and administrative constraints and the need for these countries to enjoy flexibility in creating a “sound and viable technological base”. The finally-agreed extension allowed them a transitional period up until 1 July 2021. The LDCs also received separate extensions for pharmaceutical patent waivers until 1 January 2033. It is now important to evaluate when and how LDCs like Bangladesh might graduate from the LDC category and progress towards TRIPS compliance, which includes the introduction of pharmaceutical patents.

Without proper utilisation of the extended period and with continuation of inadequate institutional and infrastructural capacity, building programmes will simply result more time wasted with no progress towards a viable technological base in the LDCs. It is necessary to explore the extent to which the transition period has helped LDCs to become technologically advanced and transition from

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2 Ibid.
copycat to innovative nations. This chapter uses doctrinal research and a case study, deriving from surveys and interviews, on the pharmaceutical sector in Bangladesh. It explores challenges for public and health and the promotion of innovation in the pharmaceutical sector during progression towards TRIPS compliance. Bangladesh was chosen for the case study because it has greater technological capacity in the pharmaceutical sector and a stronger presence in international negotiations than other LDCs.

5.2 Extending the LDC Transition Period: Is it a Measure for Making a Viable Technological Base or Simply a Waste of Time?

While the initial deadline for transition to full compliance for LDCs was 1 January 2006, the TRIPS Agreement provides that the TRIPS Council7 “shall, upon duly motivated request by a LDC Member, accord extensions of this period”.8 Accordingly, there have been three subsequent extensions in favour of the LDCs. The first was particularly related to pharmaceutical patents and lasted until 1 January 2016. The second was approved by the TRIPS Council on 29 November 2005, and meant that LDCs would not have to apply TRIPS provisions (in general, not just as they apply to pharmaceuticals) other than Articles 3, 4 and 5 until 1 July 2013; this was again extended to 1 July 2021 by a TRIPS Council decision on 11 June 2013. The Doha waiver that specifically addressed pharmaceutical patents was further extended until January 2033 on the basis of a request from the LDC group. To this end, LDCs on several occasions requested an unconditional extension to the transitional period unless or until a particular member country graduates from LDC status. One important question arises as to whether the transition period is a measure for creating a viable technological base in the LDCs—including facilitating graduation from

7 Open to all members of the WTO, the Council for TRIPS is the body that is responsible for administering the TRIPS Agreement, and in particular monitoring the operation of the Agreement, http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm
8 Article 66(1), TRIPS Agreement.
the LDC category—or whether granting extension after extension is simply wasting more time.

Considering the danger of extension without any concrete steps, one study suggested that “the experience of the last decade strongly indicates that an extension alone would not lead to any IP-related improvements in LDCs. On the contrary, an unconditional extension would not resolve anything but would only further postpone the implementation of TRIPS by LDCs”.

The extensions granted to the LDCs based on Article 66.1 aim to provide them not merely with more time to comply, but are also meant to help LDCs develop their national policies and economies to ensure that the eventual implementation of the TRIPS Agreement will promote rather than undermine their social, economic and environmental wellbeing.

The 2005 TRIPS Council decision to extend the transitional period for the LDCs acknowledged the continuing needs of LDCs for technical and financial cooperation, “to enable them to realize the cultural, social, technological and other developmental objectives of intellectual property protection” as laid down in Articles 7 and 8 of the TRIPS Agreement.

Technical and financial cooperation have an important role to play in allowing LDCs to build a sound technological base. However, the extension decisions made to date do not seem to be linked or even relevant to supporting the development and dissemination of technologies in LDCs. For example, the 2005 decision refers to technical cooperation under Article 67, which has no other objective than to allow implementation of the TRIPS Agreement. Yet, it makes no reference to Article 66.2, which requires developed country members to “provide incentives to enterprises and institutions in their territories for the

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10 ‘Extension of the Transition Period for LDCs’.


12 Ibid.
purpose of promoting and encouraging technology transfer to [LDCs] in order to enable them to create a sound and viable technological base”.\(^\text{13}\)

It was also remarked that the language of Article 66.2 is vague and there is disagreement about the nature and quantity of the incentives that should be provided to the private sector to encourage such transfers.\(^\text{14}\) A study conducted by Surie Moon concluded it was unclear whether Article 66.2 had led to any increase in incentives for technology transfer to LDCs.\(^\text{15}\)

Article 67 requires developed country WTO members to provide “technical and financial assistance” in favour of developing country and LDC members “in order to facilitate the implementation” of the Agreement.\(^\text{16}\) However, the language used in Article 67 is also vague, and therefore the exact contours of the obligations it contains are unclear.\(^\text{17}\) Official WTO documents provide little guidance as to the exact meaning or interpretation of the terms in Article 67, and to date no dispute over the transitional arrangements in Part VI of TRIPS has been brought before the WTO’s dispute settlement body.\(^\text{18}\)

Therefore, both Articles 66.2 and 67 of the TRIPS Agreement have so far failed to deliver the expected positive outcomes for the LDCs.\(^\text{19}\) However, the TRIPS Council decision of 2005 established a process in which LDCs were requested to provide information on what they considered priorities for the technical and financial assistance that would enable them to successfully implement the TRIPS Agreement. Although all LDC members were originally requested to provide

\(^{13}\) Ibid.


\(^{15}\) For details, see Surie Moon, ‘Does Article 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999–2007)’, UNCTAD/ICTSD Project on IPRs, and Policy Brief Number 2 (2008).

\(^{16}\) Article 67 of the TRIPS Agreement shall include, but is not limited to, “assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel”.

\(^{17}\) ‘Transitioning to Intellectual Property’.

\(^{18}\) Ibid.

\(^{19}\) Ibid.
the TRIPS Council with this information by 1 January 2016, only 9 of
the 34 LDC members (including Bangladesh) have submitted their
assessments.\textsuperscript{20} Bangladesh submitted its priority needs assessment on
23 March 2010.\textsuperscript{21}

Some NGOs and other commentators criticised the priority needs
assessment as merely a delaying tactic used by developed country
members to further postpone honouring their promises for assistance.\textsuperscript{22}
These critics also claimed that the assessment would force LDCs to spend
already scarce resources on collecting data and information regarding
the status of their implementation of TRIPS.\textsuperscript{23} As there are no specific
guidelines for the appropriate scope, depth, breadth and criteria for the
priority needs assessment, those submitted so far differ significantly in
quality, scope, analytical reasoning and structure.\textsuperscript{24}

It is also apparent that some of the priority needs assessments
contained requests that go beyond achieving compliance with TRIPS
obligations and are designed to contribute to the establishment
of a national IP system beneficial to the country’s socioeconomic
development (e.g., Bangladesh’s priority needs assessment requested
US$14.5 million for community-based museums and for conducting
research on traditional knowledge).\textsuperscript{25} Some potential donor countries
believe that technical and financial assistance should be exclusively
targeted at bringing LDCs’ IP laws and institutions into compliance
with the obligations under TRIPS.\textsuperscript{26} However, the six LDCs that have so
far submitted assessments have received little response from developed
country members, and too little funding to make substantial technical
and infrastructural progress for possible graduation from the LDC
category and progression towards TRIPS compliance.

Therefore, the submission of priority needs assessments has not
triggered any substantive additional technical and financial assistance.\textsuperscript{27}

\begin{thebibliography}{9}
\bibitem{22} ‘Extension of the Transition Period for LDCs’.
\bibitem{23} Ibid.
\bibitem{24} ‘Transitioning to Intellectual Property’.
\bibitem{25} For details, see ‘Council for TRIPS, Priority Needs’.
\bibitem{26} ‘Transitioning to Intellectual Property’.
\bibitem{27} Ibid.
\end{thebibliography}
Considering the inadequate technical and financial cooperation from other WTO members, the lack of a positive attitude towards innovation and R&D by the national industries, and the lack of a proper plan of action by the LDCs at the national level during the transitional period, the question arises—have the LDCs such as Bangladesh gained from their LDC status and from the transitional period?

5.3 The Case of Bangladesh: Has the Country Gained from its LDC Status and the Transition Period?

Bangladesh has been an LDC for almost four decades, even after the three-decade long *Programs of Action* adopted by the UN in the 1980s to support the development and eventual graduation of the LDCs. LDCs have enjoyed a transitional period granted by the WTO in which they do not need to comply with the TRIPS Agreement, and a waiver for pharmaceutical patents lasting more than 15 years. The question arises: what has Bangladesh gained from its LDC status and waiver from TRIPS obligations, including the pharmaceutical patent waiver? Bangladeshi economist Wahiduddin Mahmud considers that most LDCs have failed to gain from their status for two reasons: First, international plans and commitments have not only proved inadequate to addressing the structural handicaps that affect the LDCs, but their implementation has also fallen short of targets relating to aid, trade and WTO provisions. Second, the capacity to take advantage of international support measures is often severely constrained by weak institutional and governance structures—particularly in politically fragile and conflict-torn LDCs.

However, without these support measures, the LDCs might have fared even worse, and the measures have provided at least some limited benefits. For example, Bangladesh has been able to benefit from LDC-specific support measures, particularly with respect to trade preferences. A large part of Bangladesh’s garment export, for example, has gained from the duty-free access of LDC exports to the markets of the EU and the U.S. In the last 15 years, Bangladesh’s share of apparel exports to

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28 Wahiduddin Mahmud, ‘Has Bangladesh Gained from its LDC status?’, *The Daily Star* (28 May 2010).
the EU and the U.S. has more than doubled, and it is now third among exporters to the EU and fourth among exporters to the U.S.\textsuperscript{30}

Further, utilising the TRIPS waiver for pharmaceutical patents, Bangladesh gained from pharmaceutical exports earning US$46.0 billion in 2011, an increase of 16.1\% over the US$39.6 billion of sales in 2010.\textsuperscript{31} Bangladesh also gained self-sufficiency in the pharmaceutical sector and now supplies almost 97\% of medicines for the local market.\textsuperscript{32}

However, Bangladesh devoted too much of its developmental efforts and economic diplomacy to exploiting the benefits of its LDC status and TRIPS waiver, including for pharmaceutical patents. The textile and pharmaceutical sectors in Bangladesh devoted too much effort to gaining quick cash by way of increasing exports rather than engaging in basic development. The textile sector in Bangladesh engaged in producing cheaper garments, defying international labour standards and social compliance, and even creating building and infrastructural security issues, which resulted in the collapse of a building that killed more than two thousand garment workers.\textsuperscript{33}

Leading pharmaceutical companies in Bangladesh are concentrating mainly on producing generic medicines and gaining quick cash by exporting to non-WTO members, LDCs and other developing countries where these medicines are off-patent. Although the NDP tried to encourage the twin goals of ensuring access to medicines and investing in basic research, most local pharmaceutical companies in Bangladesh are not interested in basic research.\textsuperscript{34}

There is even criticism that leading pharmaceutical companies in Bangladesh are more interested in exports than in supplying the local

\textsuperscript{30} Ibid.
\textsuperscript{31} An Overview of the Pharmaceutical Sector in Bangladesh'.
\textsuperscript{32} Ibid.
\textsuperscript{34} During surveys, few pharmaceutical companies in Bangladesh disclosed their ratio of investment to basic research. However, by analysing the annual reports of leading pharmaceutical companies in Bangladesh, the author found that all the leading pharmaceutical companies invested less than 1\% in research and development (R&D).
market. The field studies undertaken in Bangladesh for the current study revealed that some important medicines for treating diabetes and cardiovascular disease are either not available or are in short supply in retail pharmacies; thus, a patient needs to go from one pharmacy to another in search of a particular medicine, and may need to pay more than the retail price.

In the absence of strong regulatory bodies and a proper plan of action, the gains made by Bangladesh in the pharmaceutical sector during the initial pharmaceutical patent waiver period could not provide the country with any further benefit that might help it graduate from the LDC category and transition from a copycat to an innovative nation. A leading pharmaceutical businessman in Bangladesh remarked that by putting restrictions on the MNCs in 1982 (after which all of the leading global pharmaceutical companies either closed or suspended their manufacturing operations in Bangladesh) and encouraging only imitation in the pharmaceutical sector, Bangladesh missed the opportunity to build an innovative pharmaceutical sector.

Bangladesh has already reached a stage of development where it should pay more attention to improving production efficiency, skills and entrepreneurial capabilities rather than merely seeking preferential LDC treatment. In the pharmaceutical sector, it should pay more attention to basic research, production efficiency and collaboration with global research institutions and other global pharmaceutical companies for joint research and technology transfer, rather than simply relying on off-patent imitated medicines and requesting further extensions of the pharmaceutical patent waiver. In the long run, without acquiring advanced technological skills and investing in basic research, Bangladesh cannot serve the growing local market for patented medicines.

Of course Bangladesh should take advantage of its LDC status and TRIPS waiver as much as possible, but it should also begin to plan for how and when it might graduate from LDC status and achieve innovation and TRIPS compliance.

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35 This concern was raised and supported by a number of the interviewees in Bangladesh.

36 Stated by Shamson H. Chowdhury, CEO of Square Pharmaceuticals in Bangladesh (Speech during Pharma Expo, Dhaka, 2009).
5.4 Progress Towards Graduation and Compliance

Bangladesh successfully used its LDC status to gain economic benefits for its textile sector, but that gain has not been realised in regulatory development, improvement of quality of life, investment in education and public health, maintenance of international labour standards, or social and security compliance. Simply by making a quick profit in one sector, a country cannot graduate from LDC status – not without a proper plan of action for development, integrating all relevant criteria for graduation.

Bangladesh has become self-sufficient in the pharmaceutical sector and its pharmaceutical companies export generic medicines to more than 107 countries. However, due to the lack of any plan of action for encouraging investment in basic research, and the absence of institutional and infrastructural capacity building, the country remains in a similar situation to 1995, when the transitional period was introduced for LDCs under the TRIPS Agreement, in terms of IPR administration and basic research in the pharmaceutical sector. Even after a decade and a half of transitional periods under the TRIPS Agreement, LDCs like Bangladesh are still facing institutional, infrastructural, social, technological and public health constraints, despite some progress in the pharmaceutical sector. Without a proper plan of action, Bangladesh will neither gain from LDC status nor achieve long-term benefits from waiver periods for general obligations or pharmaceutical patents under the TRIPS Agreement.

5.4.1 When and How Might LDCs Graduate from this Category?

Although originally including 25 countries, the current LDC list comprises 49 countries: 33 are in Africa, 13 in Asia Pacific and one in Latin America. Three eligible countries declined to become LDCs: Ghana, Papua New Guinea and Zimbabwe. Since its inception, only four countries have graduated from the LDC list: Botswana on 19 December 1994, Cape Verde on 20 December 2007, Maldives on 1 January 2011 and Samoa on 1 January 2014. Bangladesh joined the LDC category in 1975 and remains on the list, although it has shown more economic development than other low-income LDCs.
A country may be designated as an LDC if it meets the following three criteria:

- “low income”, based on Gross National Income (GNI) per capita (a three-year average), with thresholds of US$905 for cases of addition to the list.
- “human assets weakness”, based on a composite index (the Human Assets Index, HAI) that consists of indicators on nutrition, health, school enrolment and literacy.
- “economic vulnerability”, based on a composite index (the Economic Vulnerability Index, EVI) that includes indicators on natural shocks, trade shocks, exposure to shocks, economic smallness and economic remoteness.

Low-income countries with populations greater than 75 million are not eligible for inclusion.

Although initially there was no criteria for graduation from LDC status, in 1991 it was suggested that a country would be recommended for immediate graduation if it met at least two of the three criteria in relation to income, human assets and economics, in two consecutive triennial reviews. In 2006, the criteria for recommendation for graduation were revised to include exceptional cases in which the GNI per capita of a country is at least twice the graduation threshold levels.

Compared to the typical small LDC, Bangladesh is considered more resilient to shocks and has the ability to diversify its economy by taking advantage of the economies of scale supported by a relatively large domestic market. This is why Bangladesh is considered one of the least economically vulnerable LDCs as measured by a composite index reflecting various structural features of the economy, such as the share of primary production, exposure to shocks and export instability. In terms of its EVI, which is one of the three criteria for LDC classification, Bangladesh easily qualifies for graduation. In terms of the LDC criterion relating to HAI, which reflects the health and educational status of a
population, Bangladesh has been making good progress and is ahead of some non-LDC countries like Pakistan, although its score is still somewhat below the threshold level for graduation.

The other criterion is GNI per capita, for which Bangladesh is mid-ranking among LDCs. Therefore, it would be difficult to fulfil this criterion for graduation in the short term unless there is rapid progress in industrial development, commercialisation of research or development of strong creative industries (which are knowledge-based, rather than requiring a huge investment base, which is the case for information technology and IP-based industries).

Considering the above criteria for graduation from LDC status, it is interesting to consider how the competitiveness of local industry and a proper plan for human development may qualify Bangladesh for graduation and support its progression towards innovation and TRIPS compliance.

5.4.2 Competitiveness of the Local (Pharmaceutical) Industry and a Plan for Graduation from the LDC Category and Progress towards TRIPS Compliance: The Context of Bangladesh

Bangladesh has already met the EVI threshold and therefore needs to meet only one of the remaining two criteria to graduate from LDC status:

- Under a business-as-usual scenario, Bangladesh will meet the graduation threshold for lower-middle-income country by 2047 (based on an average growth rate of 5.9%).
- Under a recent performance-based scenario (2007–10), Bangladesh will meet the graduation threshold for a lower-middle-income country by 2039 (based on an average growth rate of 6.3%).

The large population size in Bangladesh is limiting per capita income. Therefore, if it is possible to increase investment in health, education, skill development, and the supply of efficient and skilled people in industry,

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40 Ibid.
to create employment and advance industrialisation, Bangladesh could meet the graduation threshold in the next 15–20 years.

A study by Debapriya Bhattacharya and Lisa Borgatti showed that Bangladesh could graduate in the next 15–20 years if it emphasised substantial improvement in its human capital, particularly reducing two worsening indicators: child mortality rate and secondary school enrolment ratio.\(^4\) Bangladesh could meet the graduation threshold by 2027 and graduate by 2033 if it improved its HAI and continued its progress in the EVI.\(^4\)

While planning for graduation from LDC status, it is important for Bangladesh to take into account issues relating to the TRIPS Agreement in general and pharmaceutical patents in particular. If Bangladesh qualifies for graduation before the expiration of the transitional period for LDCs, it may need to implement the TRIPS Agreement despite having regulatory bodies such as the Patent Office (DPDT). Local industries like the pharmaceutical industry may not be ready to cope with pharmaceutical patent issues. Thus, it may be important to make an integrated plan for graduating from LDC status and graduating from the TRIPS waiver together.

In the context of the WTO, the principle of graduation as illustrated by Cottier seeks to provide an added flexibility to the international system, making implementation of WTO provisions contingent on overcoming a set of identified graduating constraints. Taking into account social and economic development, it could also be commensurate with the level of competitiveness of the industries and sectors concerned.\(^5\) Countries that fall below a chosen threshold would be entitled to derogations.\(^6\) The threshold could be used to define the application of a particular agreement or a particular rule to a particular industry in a country.\(^7\) Here, an attempt is made to define the threshold for pharmaceutical patents under the TRIPS Agreement in the context of the pharmaceutical sector in Bangladesh.

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\(^4\) Ibid.

\(^5\) Ibid.

\(^6\) ‘From Progressive Liberalization to Progressive Regulation’.

\(^7\) Ibid.
There is little or no research on whether the introduction of an IP regime in general and pharmaceutical patents in particular might help a country meet the criteria for graduation from LDC status. In the case of two countries that to date have graduated from LDC status, there is no genuine link between graduation and the introduction of an IP regime. Rather, Maskus argued that the presence of onerous patenting provisions may impede the growth of the necessary industrial capabilities of developing countries.\textsuperscript{46} Developing countries might attain industrial and technical capabilities by “imitating” pharmaceutical production, which could provide important benefits with respect to further development of R&D, as was the case in the Indian pharmaceutical sector.\textsuperscript{47} Through this process, countries could develop their domestic capacity so that firms would demand the presence of a fully functioning patenting mechanism to protect their innovative activities.\textsuperscript{48}

Cottier suggested that countries need to consider not only international competitiveness, but also the domestic competitive environment and the interplay between domestic and foreign sources for pharmaceuticals.\textsuperscript{49} The nature of the WTO obligations can be subsumed into regulation of the competitive environment between domestic and imported products; hence, graduation should be contingent on competitive shortfalls, where commitments kick in after international competitiveness is attained.\textsuperscript{50}

Cottier further added that countries, regardless of their qualification, would be obliged to introduce patent protection for a particular sector once their domestic industry had achieved a level of competitiveness defined on the basis of economic factors and data.\textsuperscript{51} However, below this threshold, industries would be allowed to develop in accordance with domestic needs and engage in producing generics irrespective of


\textsuperscript{50} Ibid.

\textsuperscript{51} Ibid.
patent protection abroad.\textsuperscript{52} Many countries in the past (e.g., India and Italy) have followed that path and built their industrial base.\textsuperscript{53} Thus, it would be a viable solution for the LDCs to engage in technological and institutional development, and introduce pharmaceutical patents once they have attained a certain level of competitiveness.

However, further research is needed on how to measure defined levels of competitiveness and the threshold for graduation. Using country-specific data, economists could create a composite index specific to a particular sector to determine competitiveness and therefore obligations to introduce patent protection for that sector. Cottier and colleagues,\textsuperscript{54} in a study based on earlier work,\textsuperscript{55} developed a checklist that included large market size, local demand, highly skilled labour forces and abundant natural resources.

Further, Lopez Gonzalez et al. created a composite index for graduating thresholds that could apply in the pharmaceutical sector.\textsuperscript{56} The authors identified three broad categories for a procedural test: access to required pharmaceuticals, capacity to meet health priorities in developing countries and the incidence of disease in these countries.\textsuperscript{57} Based on these criteria, the study developed a list of countries including Bangladesh that should be exempted from TRIPs provisions for patent protection in the pharmaceutical sector.\textsuperscript{58}

As the LDCs are in a transitional period for TRIPS general obligations and enjoy a pharmaceutical patents waiver based on their institutional, administrative and financial constraints, the author of this study

\textsuperscript{52} Ibid.
\textsuperscript{53} Ibid.
\textsuperscript{54} Thomas Cottier, Shaheeza Lalani and M. Temmerman, ‘Use it or Lose it? Assessing the Compatibility of the Paris Convention and TRIPS with Respect to Local Working Requirements’, Working Paper (18 February 2013), World Trade Institute, University of Bern, Switzerland.
\textsuperscript{57} Ibid.
\textsuperscript{58} Ibid.
considers that the following issues need special attention. Moreover, further research is required to determine competitiveness and readiness to introduce for patent protection for the pharmaceutical sector:

- The ability of local pharmaceutical production facilities and pharmaceutical imports to meet local needs, and the ratio of pharmaceutical exports, if any, by the domestic pharmaceutical industry.

- Strong local market and export opportunities for economies of scale to recover investment costs and make profits for reinvestment in R&D.

- The nature, quality, safety and efficacy of domestic pharmaceutical production measured in light of a number of WHO pre-qualified pharmaceutical plants based on GMP, U.S. FDA-approved manufacturers and certification for exports by highly regulated markets like the EU, Australia and Canada.

- Health infrastructure and healthcare facilities in particular LDCs, and out-of-pocket expenditure for health. Despite having local pharmaceutical production and cheaper medicines, citizens in the LDCs may have access problems, considering 100% out-of-pocket expenditure for medical treatment and the absence of health insurance. Therefore, the additional cost for patented medicines may make these inaccessible to them. To evaluate this, healthcare and public health data from the WHO could be utilised.

- Prevalent diseases and the ratio of off-patent and patented medicines used for treatment in the particular country. This needs to be evaluated with respect to the extent to which local production facilities could supply medicines (both generic and patented) for those diseases in the country concerned.

- The level of local innovation and progression of R&D as evidenced by increasing the number of patents by local industries and research institutions in the pharmaceutical sector. National patent office data from individual LDCs and global patent applications from a particular country, under the PCT system of the WIPO, could be used to classify levels of innovation. However, all 24 LDCs that are party to the PCT are from Africa. None of the Asia Pacific, Latin American or Caribbean LDCs are members of the PCT. In the absence of PCT data, patent applications by citizens of a particular

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59 ‘Summary Table of Membership of the World Intellectual Property Organization (WIPO) and the Treaties Administered by WIPO, plus UPOV, WTO and UN’, http://www.wipo.int/treaties/en/summary.jsp
country to the patent offices of the EU, Japan and U.S. could be used.

- Competition between domestic and foreign companies in the local market, which could be determined based on the ratio of shares in the pharmaceutical sales and on comparison of selected product prices.

- Technical capacity and facilities for basic research at national research institutions and local companies as evidenced by their research results, successful applications for product and process patents, research articles in internationally reputable journals, use of technologies, and cooperation and joint research with global research institutions and pharmaceutical companies.

- Financial strength and the ratio of investment for R&D as reflected in the annual reports of the leading local pharmaceutical companies. The financial constraints of a particular LDC must also be examined based on economic data.

- An adequate supply of technically skilled and efficient human resources for the pharmaceutical industry, drawn from science and technology graduates of national higher education institutes.

- Strong and efficient regulatory bodies. National patent offices need to be equipped with modern technologies and should have efficient patent examiners; a patent information system for the status and description of existing, expired and pending patent applications; an online patent database; and an efficient adjudication system to deal with pharmaceutical patent applications and analyse substantive and procedural requirements. The DGDA needs continuous supervision to maintain the quality of medicines produced and imported for the local market. The DGDA should have adequate expertise to identify counterfeit medicines.

- Infrastructural facilities such as cost-effective and adequate energy supplies, efficient local transport, port facilities for export and import, and international transportation. As infrastructural facilities could reduce cost of production, and facilitate the efficient import of raw materials and export of medicines, this needs to be taken into consideration for determining the competitiveness of the local industry.

- Working conditions (job security, standard wages for employees and other labour costs, safety standards, unemployment benefits, health and accident insurance, etc.) need to be considered for the long-term sustainability of local industry.
• Although low wages and the low cost of employment conditions may provide short-term profits for the local industry, in the long run this will not help it become a sustainable business competitor and attract technical and skilled people. Thus, LDCs need to have in place employment and labour laws ensuring safe, comfortable and fair working conditions for the long-term sustainability and competitiveness of the local industry.60

If the above conditions are evaluated—along with existing indexes such as the HDI,61 World Bank data on basic infrastructure, the High Technology Infrastructure Index and the Residents Patent Index—to create an innovation capability and competitiveness index, this would be useful in determining the status of the pharmaceutical sector, a possible plan of action and support measures, and the time required to attain competitiveness and hence achieve compliance.62

Based on the above criteria, LDCs such as Bangladesh may be encouraged to submit reports on their pharmaceutical sectors (and in turn on other sectors of vital importance) to the TRIPS Council along with their general technology needs assessment and a sector-specific

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60 For example, although Bangladesh is the second largest apparel exporter in the world after China, poor working conditions and a lack of adequate safety measures led to the collapse of a garment factory in April 2013, killing over one thousand workers. This sparked a huge debate and a good number of importers of apparel from Bangladesh suspended their orders. This will have serious negative impacts for the stability of the industry.

61 The Human Development Index (HDI) is a composite statistic of life expectancy, education, and income indices used to rank countries into four tiers of human development, a concept of well-being based on a capability approach. It was created by the Mahbub ul Haq in 1990. In his capacity as Special Advisor to the UNDP Administrator, Haq initiated the concept of Human Development and the Human Development Report as its Project Director. He engaged other renowned experts, such as Paul Streeten, Inge Kaul, Frances Stewart, Amartya Sen and Richard Jolly, to prepare annual Human Development Reports. See Mahbub ul Haq, Reflections on Human Development (Oxford University Press, 1996).

62 However, using World Bank data Rajah Rasiah analysed capability building in the developing countries in the context of the TRIPS Agreement. He based his analysis on the Basic Infrastructure Index, the High Technology Index and the Resident Patent Data Index. He concluded that LDCs are seriously disadvantaged as they lack the high technology infrastructure to participate actively in the innovation process; yet achieving even adequate basic infrastructure and fulfilling the TRIPS Agreement may hinder technological capability building and competitiveness for the LDCs (he classified them as less industrialized developing economies, or LIDE). See for details, Rajah Rasiah, ‘TRIPS and Capability Building in Developing Economies: Critical Issues’, Journal of Contemporary Asia 33.3: 338–62.
needs assessment, such as for technology in the pharmaceutical sector. Based on such reports, technological and financial assistance could be requested from the developed countries, utilising Articles 66.2 and 67 of the TRIPS Agreement, and also from the WIPO, WHO, UNIDO and other relevant international organisations. The TRIPS Council and the developed countries could also provide access to their reports on when and how the pharmaceutical sector in a particular LDC would be ready for graduation, and the nature of financial and technical cooperation needed to make such progress towards TRIPS compliance. Technical and financial cooperation will, therefore, be a key element in ensuring that LDC members of the WTO are prepared to apply TRIPS in a manner appropriate to their socioeconomic condition and to the stage of technological development and competitiveness of a particular sector. This could be replicated to some extent in other sectors that have patent-intensive industries.

Although patent protection on the price of pharmaceuticals has likely contributed to a lack of access to affordable medicines, its elimination would not be a silver bullet, nor would it solve these countries’ major health issues. Even in countries where patent laws have been permissive or levels of enforcement are low, access to medicines remains suboptimal.

Therefore, determining the competitiveness of its local pharmaceutical industry and identifying thresholds for graduation based on the above criteria should help determine the ideal time for the introduction of pharmaceutical patents, as well as the capability of a particular LDC

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63 Article 67 of the TRIPS Agreement places an obligation on developed country WTO members to provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed WTO members.

64 The WTO–WIPO Cooperation Agreement of 22 December 1995 stipulates that legal and technical assistance and technical cooperation relating to TRIPS be provided to developing countries by the WIPO. See the text of the Agreement at http://www.wto.org/english/tratop_e/trips_e/intel3_e.htm


to deal with administrative, institutional and financial constraints in
general and public health problems in particular.

In the course of transitioning from the patent waiver period to the
introduction of patent protection, developed country members are
expected to “provide incentives to enterprises and institutions in their
territories” for the purpose of promoting and encouraging technology
transfer to the LDCs, thus ensuring the achievements of the objectives
and principles of the TRIPS Agreement as set out in Articles 7 and 8.
It is also important that LDCs themselves initiate capacity-building
programmes targeting their domestic institutional and infrastructural
constraints.

5.5 Progress towards Graduation and Compliance:
Institutional and Infrastructural Issues in Bangladesh

Developing appropriate plans of action and introducing adequate
capacity-building initiatives within a range of institutions for
progression towards innovation and TRIPS compliance, and at the same
time meeting local societal and developmental goals such as incentives
for the local pharmaceutical industry and ensuring that access to
medicines is long term, are very challenging tasks for LDCs. However,
they are essential for implementing the objectives, principles, rights and
obligations of the TRIPS Agreement in a manner conducive to the social
and economic development goals of LDCs. The alternative is a narrow
approach focused only on compliance with the TRIPS provisions.68 On
the other hand, the IPR and pharmaceutical sector-related institutional
and infrastructural solutions that are often used in developed countries
may differ from those best suited to the needs of the LDCs. Bangladesh
may need additional institutional and infrastructural capacity-building
initiatives, considering its low level of technological development,
bureaucratic hurdles, lack of access to information and culture of

Implementing the TRIPS Agreement in LDCs’, ICTSD Programme on Intellectual
Property Rights and Sustainable Development, International Centre for Trade and
non-cooperation between bureaucrats, policymakers, academic institutions and local industries.\textsuperscript{69}

The necessity of technical and infrastructural development was supported by a number of interviewees in this study. One remarked that:

apart from policy options for patent law reform, the Government of Bangladesh may need to take technical and infrastructural steps for the effective outcome and promote pharmaceutical research and ensure access to medicines in the country. Ultimately technical capacity building in the pharmaceutical sector and greater public-private partnership for R&D can make a balance. Simply making patent law either weak or TRIPS compliant can make no difference.\textsuperscript{70}

Another expert commented that:

The DDA and patent office should have adequate expertise to deny any patent registration and registration of pharmaceuticals respectively if it considers little improvement and may become a threat to public health in the country. There should be greater public access to the patent office to gain information about patent applications, expired patents and granted patents in the field of pharmaceuticals.\textsuperscript{71}

Also showing dissatisfaction with the existing facilities and lack of proper action on the part of the Government of Bangladesh, one industry expert commented on the “inordinate delay for the establishment of the Active Pharmaceutical Ingredients (API) Park and no proper initiative for the establishment of a bio-equivalency lab at the DDA with all modern facilities is a sign of sheer negligence on the part of the government … we want action in practice not in words”.\textsuperscript{72}

It is clear that Bangladesh needs to seriously consider technical and infrastructural capacity-building issues to better serve its pharmaceutical industry, promote innovation and ensure access to medicines, while

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{70} Email interview with an IP law academic, in Brazil, 12 March 2012.
\item \textsuperscript{71} Interview with a policy analyst from a leading public health NGO, in Dhaka, Bangladesh, 7 March 2012.
\item \textsuperscript{72} Interview with the CEO of medium-sized local pharmaceutical company in Bangladesh, in Dhaka, Bangladesh, 25 January 2012.
\end{itemize}
\end{footnotesize}
making the transition towards a TRIPS-compliant patent regime. Some important technical and infrastructural policy issues will now be discussed.

5.5.1 Capacity Building in the Department of Patents, Designs and Trademarks, and Intellectual Property-related Institutional and Infrastructural Issues

The functions of the Patent Office (under the DPDT in Bangladesh) will increase rapidly after the implementation of a TRIPS-compliant patent regime. The DPDT needs adequate expertise to ensure that an invention is absolutely new and not similar to any previously granted patents. To perform this function, the DPDT must be equipped with adequate technical resources and professional staff with experience in the relevant fields. Its present workforce does not meet these requirements: its current total number of 112 staff consists of 1 registrar, 4 deputy registrars, 9 assistant registrars, 25 examiners and 73 support staff. Of the 112 officials, less than 50% work in the field of patents. Arguably, the present number of 25 examiners is not sufficient to ensure timely assessment of patent applications; one interviewee suggested that the existing examiners also lack the proper training and technical facilities to deal with complex applications in the field of pharmaceuticals.

It is relevant that neither the present patent law nor the Draft PDA 2010 and Draft Patent Law, 2012 deal with the human-resource issues of the DPDT. Fortunately, the need to modernise the DPDT has been recognised: in 2009, Bangladesh initiated two relevant projects with the technical and financial assistance of WIPO. Unfortunately, however, neither project delivered any meaningful suggestions for the development of the DPDT due to a lack of coordination between local experts and technical staff at the DPDT, the traditional and procrastinating bureaucratic process in Bangladesh, a lack of integrated

73 Email interview with a deputy director of the Patent Office of Bangladesh (anonymous), in Dhaka, Bangladesh, 27 September 2010.
74 Email interview with a patent examiner (anonymous), in Dhaka, Bangladesh, 27 September 2010.
75 The projects are the Modernization and Strengthening of Patents and Designs Systems in Bangladesh and the Nationally Focused Action Plan for the Government of Bangladesh for Modernization of the Patent Office.
approaches and a lack of interest from the WIPO in engaging local experts.

The joint EU–WIPO Programme on IP (2008–11) tried to support modernisation of the national IP legislative system, and to raise awareness about the importance of IP protection in the public and private sectors.\(^76\) However, due to slow bureaucratic processes, lack of inter-ministry coordination in Bangladesh, and lack of understanding on the donors’ part about local priorities and bureaucratic processes, a Swiss–Bangladeshi project on IP capacity-building remained dysfunctional.\(^77\) Without an understanding of local priorities, the needs of local people, the necessity of local inventors, institutions, industry and the engagement of experts with an understanding of IP law and institutions in Bangladesh, no bilateral capacity-building project can deliver meaningful results for IP in Bangladesh. Based on the field studies and perceptions of stakeholders in Bangladesh, a number of IP-related institutional and infrastructural issues have been identified in this study that seem to be very important for Bangladesh during the post-TRIPS patent regime. They are discussed below.

**Patent Information System.** A database is required of patents, non-working patents and expired patents. In Bangladesh there is currently no patent information system at the DPDT, and public access to the patent database is mostly restricted and subject to slow bureaucratic processes. Further, as the DPDT to date has used a paper-based patent application system, it is difficult to extract patent information about any particular invention without personally visiting the DPDT and going through the long bureaucratic process to gain access to the required information. From the perspective of the local generic producers in Bangladesh, it is vital to highlight the increased importance of making use of inventions that have entered the public domain. To ascertain

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\(^77\) The Swiss report to the WTO stated that “The Bangladeshi-Swiss Intellectual Property Project (BSIP) was approved by Switzerland in 2011. Approval from Bangladesh, however, was left pending until 30 June 2015, at which time the dedicated project funds were forfeited and the project was cancelled accordingly”. See, WTO (document no. IP/C/W/610/Add.3), Communication from Switzerland (23 September 2015) p.2, https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/134826/q/IP/C/W610A3.pdf
information about such inventions, it is necessary to know about patents that have entered into the public domain. In a study by the WHO, it was mentioned that due to the lack of adequate administrative and legal infrastructure in developing countries, it is difficult to determine the patent status of pharmaceuticals.\textsuperscript{78} It is recommended that an authority, be it governmental (such as the DPDT) or non-governmental, be created or be given sufficient competence to search for expired patents and declare that such patents are freely available to interested parties for future exploitation. Such an authority should cooperate with other regional or international organisations (such as the WHO) to achieve the greatest possible advantage that an expired patent can bring.

It is recommended that a free online database be developed for all educational and research institutions in Bangladesh. The database should classify patented inventions, non-working patents and expired patents, and also provide information about the particular sector and about inventions. Such a database would provide local inventors with technical knowledge about different inventions, and allow them to make plans for the use of expired patents and non-working patents. Publication of non-worked inventions and expired patents enables various players and manufacturing companies in diverse industry segments to understand how and when they can make use of unused technology and expired technology, which may be more efficient and cost-effective for the industry and local population. During the author’s field research in Bangladesh, public health NGOs, pharmaceutical researchers and IP academics argued that this kind of database would help immensely with technological teaching and learning, and also with the immediate generic production of expired patented pharmaceutical products.\textsuperscript{79} Bangladesh may also need to develop a traditional knowledge database to encourage local inventors to exploit such knowledge further, and at the same time to prevent abuse.

\textit{Traditional Knowledge Database.} The Government of Bangladesh could develop a separate publicly accessible online database detailing available

\begin{itemize}
\item \textsuperscript{79} Based on interview data from IP academics, pharmaceutical researchers and public health activists involved with NGOs in Bangladesh.
\end{itemize}
traditional knowledge, medicinal plants and biological resources in Bangladesh to prevent bio-piracy and abuse of these resources for patenting. In this regard, Bangladesh could follow the existing models of India and China. China has developed a database on traditional Chinese medicines, and India has developed a broad-based traditional knowledge digital library derived from old scriptures and available archival information. Bangladesh may also need to take initiatives to inform different stakeholders regarding IPRs.

Considering the low level of IP awareness in Bangladesh, it is necessary to establish information centres around the country with support policies for SMEs.

Further, given existing workforce and technical resource issues in the patent area, Bangladesh should consider joining the PCT 1970 to outsource patent examinations. This would enable Bangladesh to extend patent protection for local inventions all over the world and would pave the way for foreigners to apply to Bangladesh through the international application system under the PCT. The advantage of relying on PCT preliminary examination reports to determine whether to award a national patent (as opposed to relying on foreign patent proxies under a re-registration scheme) is that developing countries are assured access to the underlying analysis on which the patentability was determined, as well as to the relevant body of prior work that was considered. However, Bangladesh could adopt the Brazilian model of forwarding pharmaceutical patent applications to any public health-related IP review body (as ANVISA was established under the Ministry of Health in Brazil) for review before pharmaceutical patents are granted in Bangladesh.

82 The PCT is a WIPO-administered treaty concluded in 1970. It provides patent applicants with the opportunity of filing an international patent application. Instead of filing separate applications in different countries, the applicant can file a PCT application with the International Bureau of WIPO, or any national or regional patent office. The date of this international filing is deemed as the date of filing in all national offices.
83 ‘Pharmaceutical Patent Protection’.
84 See ‘Intervention of Health Authorities in Patent Examination’.
To attain the optimum benefits of any patent information system, it is necessary to take steps for the promotion of R&D. Unfortunately, in Bangladesh there appears to be a lack of imperatives to increase and encourage investment in R&D. The DPDT could take initiatives to promote innovation and patenting practices among local SMEs and research institutions. One interviewee pointed out that there are no government initiatives in place to support or promote R&D. Another argued that the failure to support and promote R&D is a major barrier for the post-TRIPS survival of the pharmaceutical industry in Bangladesh. It is highly recommended that an ongoing policy for R&D based on domestic raw materials and traditional plant varieties be adopted. In this regard, one participant commented that it is important to establish new scientific research centres whose goal is to take part in modernising the domestic pharmaceutical industry and creating new pharmaceuticals for the public at reasonable prices. To promote R&D in local research centres and pharmaceutical companies, it is crucial to improve the quality of services at the DGDA.

5.5.2 Capacity Building in the Directorate of Drug Administration and Public Health-related Institutional and Infrastructural Issues

The incapacity of the DGDA to monitor properly the standard of pharmaceuticals in Bangladesh was revealed during the Rid Pharmaceutical scam in July 2009, when several people died from using low-quality medicines distributed by Rid Pharmaceutical, a local small company. The DGDA itself admitted that it has insufficient manpower and technical facilities to monitor all domestic manufacturers. Moreover, the industry is against taking strict action.

Considering the adverse opinion of rigorous measures and the low financial and technical strength of local companies, Bangladesh could

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85 Interview with a pharmaceutical researcher working in an MNC with a manufacturing plant in Bangladesh, 7 March 2012.
86 Interview with an IP lawyer working as in-house counsel for a local medium-sized pharmaceutical company, 8 March 2012.
87 Interview with an academic working on pharmaceutical technology at the Department of Pharmacy, University of Dhaka, Bangladesh, 27 February 2012.
88 See Azam and Richardson (2010b).
89 Ibid.
adopt the responsive regulations theory (RRT) in the enforcement framework of the DGDA in an attempt to encourage gradual development in the pharmaceutical sector and to fulfil the twin goals of promoting pharmaceutical innovation and safety, on the one hand, and banning counterfeit, fake and low-quality medicines on the other.\(^\text{90}\) This theory is based on allowing flexibility in the regulatory approach to promote gradual development and ensure continuous supervision; in other words, “soft words before hard words, and carrots before sticks”\(^\text{91}\). This approach recognises the need for a diversity of regulatory strategies and for all strategies to be practically grounded and context-appropriate.\(^\text{92}\)

The RRT proposes a Regulatory Enforcement Pyramid of Sanctions (REPS) that targets the achievement of a maximum level of regulatory compliance by persuasion and advice.\(^\text{93}\) Therefore, persuasion, motivation, education, advice, training and so forth are situated at the base of the pyramid. If this does not work, the regulators could proceed to an escalation in the pyramid and issue a warning letter for improvement as per required regulatory standards. If the warning letter also fails to secure compliance, the DGDA may then impose a civil monetary penalty in an attempt to prompt compliance. The next step is criminal prosecution. If all these steps fail, the DGDA can move to shut down a particular manufacturing plant or issue a temporary suspension of the licence for the pharmaceutical company concerned: it can order them to withdraw from the market all the low-quality pharmaceuticals.

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\(^{90}\) The responsive regulations theory was first developed by John Braithwaite and Ian Ayres in their book *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press, 1992). However, it is important to emphasise that the development of responsive regulation as a theory has been and continues to be a collective effort, contributed to by numerous scholars and institutions, the most important early development being by Neil Gunningham, Peter Grabosky and Darren Sinclair in their *Smart Regulation* (Clarendon Press, 1998), with further contributions by John Braithwaite, ‘Responsive Regulation and Developing Economies’, *World Development* 34.5 (2006): 884–98; John Braithwaite, *Regulatory Capitalism: How it Works, Ideas for Making it Work Better* (Edward Elgar, 2008); and Valerie Braithwaite’s *Defiance in Taxation and Governance* (Edward Elgar, 2009).


\(^{93}\) See ‘Designing Safer Health Care’.
they produce and supply. Finally, if the temporary suspension of licence does not work, the DGDA could escalate to the final step of the pyramid and revoke the licence of the pharmaceutical producer, prohibiting sales and distribution of their products. Figure 5.1 demonstrates the REPS under the RRT.

![Figure 5.1: Regulatory Enforcement Pyramid of Sanctions under the responsive regulations theory for application in the pharmaceutical regulatory sector. Source: Based on Ayres and Braithwaite (1992), pp.35–38.](image)

It is expected that the application of REPS may facilitate a gradual improvement in all manufacturing plants in Bangladesh. However, to apply REPS in the pharmaceutical sector of Bangladesh and to improve the capacity of the DGDA to deal with post-TRIPS challenges, the DGDA needs more manpower and technical facilities. The most pressing problem is one of manpower deficieny, which compromises to a great extent the DGDA’s ability to maintain regular inspections, and ensure the safety and efficacy of pharmaceuticals produced in Bangladesh.94 A large pharmaceutical industry requires a large DRA. The DGDA itself estimated that they need 700 staff members to adequately carry out the necessary work, and has requested the appointment and approval of a budget for this number of staff.95 However, as of 2012, they have

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95 Assessment of the Regulatory Systems.
only 370 approved posts, and of these only 135 are filled and 235 stand vacant. No clinical pharmacologists are employed. Thus, the DGDA must urgently hire qualified staff.

The pharmaceutical sector falls under the Ministry of Health and Family Welfare in Bangladesh; in other countries, the Ministry of Industry and Commerce or the Ministry of Science and Technology are responsible for this area. One option may be for the pharmaceutical sector in Bangladesh to be split between different ministries under a coordination cell, in order to meet the dual goals of technological development in the sector and societal demands for ensuring access to pharmaceuticals. In addition to this, the Government of Bangladesh should address the health-related institutional and infrastructural issues, for example by promoting investment in R&D and encouraging local pharmaceutical companies to develop an excipient-based industry.

Investment in R&D. As Bangladesh has an opportunity to manufacture patented drugs for its local needs as well as export them to other LDCs, the industry needs to invest in its R&D so that it can manufacture patented drugs by reverse engineering. Also, as it must follow TRIPS-compliant patent provisions after the expiration of the transitional period, Bangladesh needs to be well supplied with the entire range of patented drugs for this period, and will need to be sufficiently technologically developed to face the challenges after pharmaceutical patents are introduced. In the meantime, the country could contribute to the invention and discovery of new drug molecules on the basis of “learning by doing” during the transitional period. During surveys, 63% of participants strongly agreed and 32% agreed that pharmaceutical companies in Bangladesh should invest in R&D, whereas 5% disagreed. The Government of Bangladesh could follow the model of the Brazilian Health Ministry and invest in pharmaceutical research and production, with a concentration on local pharmaceutical needs and country-specific diseases.

In addition to investment in R&D, pharmaceutical companies need to develop standards.

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96 Ibid.
97 Based on the findings of survey data, small pharmaceutical companies argued that it is in fact not possible for them to make the huge investments required for new invention and basic pharmaceutical research.
Developing Standards for Pharmaceutical Companies. Many pharmaceutical companies in Bangladesh cannot boast of complying with GMP and other national and international standards. Modifications are essential for the development of manufacturing plants and infrastructure that would ensure the production of quality pharmaceuticals. One interviewee argued that maintaining GMP status is extremely important for the reputation of pharmaceutical products from Bangladesh and thus for expanding pharmaceutical exports. Another participant argued that maintaining standards is essential not only to the production of quality medicines and exports but also to competing with MNCs. Another participant remarked that the DGDA of Bangladesh does not regularly monitor standards of pharmaceutical companies, which the occurrence of low-quality cheaper medicines in the local market. The DGDA will need to strictly monitor modifications and improvements to seize the opportunity for export. The Government of Bangladesh may approach the WHO for assistance. Thus, there may need to be improvements in the DGDA. While improving standards in the pharmaceutical sector, the government may need to encourage the setting up of excipient-based pharmaceutical companies.

Setting Up Excipient-based Pharmaceutical Companies. One interviewee noted that at present, almost all excipients are imported to Bangladesh by local companies. Arguably, locally manufactured pharmaceutical excipients would be much cheaper, and the overall production cost for finished products substantially reduced. The setting up of the local pharmaceutical industry to produce excipients and other additives would be profitable for Bangladesh and would remove the deficiency of pharmaceutical excipients/additives that are most required for the production of finished products. Another issue for Bangladesh that needs attention is the lack of modern test facilities to facilitate international certificates for export.

International Certificates for Export, and Modern Test Facilities. One interviewee mentioned that to acquire export registration it is necessary
to have bio-equivalence, bio-availability tests and clinical trial reports.\textsuperscript{102} The costs associated with implementing such a testing and documentary system are high. One participant argued that this is a major drawback for pharmaceutical SMEs in Bangladesh.\textsuperscript{103} The availability of pharmaceutical-related testing facilities is an ongoing challenge that will need to be met before Bangladesh is able to engage effectively and competitively in a post-TRIPS environment.

Bangladesh has only two pharmaceutical testing laboratories: one in Dhaka and one in Chittagong. These two laboratories are not equipped with sufficiently modern instruments to carry out all the tests required for pharmaceutical products.\textsuperscript{104} Put simply, these two laboratories are insufficient to monitor and check the quality status of the products of a large number of pharmaceutical companies in Bangladesh, which is why most Bangladeshi companies are facing problems in undertaking such testing and export registration.\textsuperscript{105} The Government of Bangladesh needs to consider a programme of building these facilities, which are required not only for compliance but to maintain any momentum garnered as Bangladesh takes the opportunities afforded to it during the transition period.

As one interviewee argued, in addition to building facilities, the government and the BAPI will need to work together to encourage local pharmaceutical companies to seek international certification, and assist them to understand the requirements of particular countries with the help of Bangladeshi foreign missions in those respective countries.\textsuperscript{106}

In addition to these technical and infrastructural initiatives, the Government of Bangladesh may need to adopt development-centred IP policies and national health strategies, and to promote university-industry-government cooperation and public-private partnerships to achieve its long-term goals of transforming into an innovative nation.

\textsuperscript{102} Interview with an official from a large local pharmaceutical company, 9 March 2012.

\textsuperscript{103} Interview with an official from a small local pharmaceutical company, 10 March 2012.

\textsuperscript{104} Such as bio-equivalency tests, bio-availability tests and the conduct of clinical trials.

\textsuperscript{105} It should be noted that among local pharmaceutical companies in Bangladesh, very few obtained export registration and only Beximco and Square have gained registration for export to highly regulated countries like the U.S., the UK, Austria and Australia.

\textsuperscript{106} Interview with an official from BAPI, in Dhaka, Bangladesh, 11 March 2012.
and securing proper healthcare and affordable medicine for the vast majority of its population.

5.6 Adopting a National Development-centred Intellectual Property Policy and a National Health Strategy Integrating Long-term Innovation and Access Objectives

Bangladesh could adopt a national IP policy in consultation with different stakeholders, integrating national developmental goals such as public health, unemployment and poverty reduction, climate change mitigation and adaptation. The ultimate objective of such a policy would be to promote innovation in sectors of vital importance for the country, by local universities and public and private institutions; develop technologies on country-specific needs; address local problems; and acquire affordable solutions. There are still no technology transfer offices in local universities and research institutions. As part of its IP policy, Bangladesh could adopt broader policy goals to promote IP creation and commercialisation through start-ups, venture capital, SMEs and university technology commercialisation centres. To do this, the government could adopt a special IP and innovation fund, incentives mechanism, patent fee waiver and reward schemes.

Lowering drug prices is crucial, but it is just one element. As the WHO’s director general stated, “It would be naive, however, to think that the cutting of prices of medicines is enough. The prospect of cheaper medicines stimulates demand for care, and this will actually increase the need for resources”. To ensure access to necessary drugs, countries need to formulate and implement national health strategies (NHSs), integrating long-term innovation and access objectives. The Government of Bangladesh should take initiatives for improving healthcare services and should give priority to building local innovation capacity, while considering long-term public health objectives and present and future access needs for medicines that treat country-specific diseases. An NHS to ensure regular access to essential drugs for the population and promote long-term innovation should include:

• Transparency and sustained participation of all stakeholders in the formulation, implementation and regular review of the NHS, considering unmet needs.

• Sound drug supply management and distribution systems, supported by strengthened human resources development. Rather than simply using a government-controlled top-down approach as currently employed in Bangladesh, a mechanism could be adopted for efficient drug supply using a mix of public, private and NGO sectors in the national drug supply and distribution systems.108

• Cost-effective selection of essential drugs and rational use of medicines. Many highly effective medicines are—or can be—made available at very low cost. Fully acceptable and affordable treatments can be found if one chooses well. Thus, the rational use of medicines is very important for improving the public health situation in a country. A rational selection of medicines includes defining which medicines are most needed and identifying the most cost-effective treatments for particular conditions while taking full account of their quality and safety, and ensuring that they are used effectively.109

• Use of generic names. It is crucial to ensure that the generic medicines on sale are of guaranteed quality and that the population is strongly aware of this. Typically, people who cannot afford high prices buy costly branded medicines in the belief that they are superior to generic equivalents.110

• Special investment protection measures for joint venture and the promotion of R&D by governmental investment for pharmaceutical research and production, utilising the experiences of Brazil and India.

• Centralised, pooled bulk purchasing of generic drugs through fully accessible and transparent international tenders.

• Effective drug pricing policies as explained in this chapter, giving due consideration to limitations.111

• National patent law and pharmaceutical regulation should include all the possible TRIPS flexibilities as outlined in this chapter.

109 See Drugs and Money Prices.
110 Ibid.
111 See drug price control option in chapter 4 of this study.
• Elimination of tariffs, duties and taxes for certain periods: the WHO, the WTO and other public health organisations advocate the elimination of import duties (>30% in some countries) and the abolition of VAT and other national and local taxes (>20% of the final consumer price) for essential medicines, HIV-related medicines for example. In Bangladesh there is still a 15% VAT on pharmaceuticals (only pharmaceuticals produced exclusively for export are exempt) despite large numbers of people having access problems. This needs to be reduced or eliminated to increase affordability of medicines; most people bear the cost of their healthcare from their own pockets.

• Sustainable healthcare financing. Access to medicines must be viewed in the context of overall funding for healthcare, including financing for prevention and treatment of priority infectious diseases with a high public health impact. For decades, the public health sector in developing countries and the LDCs was mainly financed by the government, and it commonly provided medicines free of charge. Over the years, diminishing budgets have increasingly led to drug shortages in national health systems, particularly in rural areas, and to a widespread collapse of the free drug supply. In this regard, national health insurance schemes may be an option, though it may also be difficult to implement them in LDCs such as Bangladesh. Whereas social insurance schemes are common in Europe and are on the increase in Latin America and Asia, they are still quite uncommon in Bangladesh and need the attention of policymakers. Sustainable financing can also be achieved by a combination of several viable financing mechanisms, such as making provision for mandatory health insurance by public and private employers, reallocation of public funds, better use of out-of-pocket spending and international financing through grants, donations and loans in appropriate circumstances.112

• It may also be necessary to apply export restrictions to the local pharmaceutical company to prioritise supply in the local market. One interviewee argued that the local pharmaceutical market is dominated by 20 leading pharmaceutical companies, most of which are now more interested in exporting to make quick cash profits than in adequately supplying the local market.113 He further suggested that in future this may create a shortage of supply in the

113 Interview with a public health activist working in a local public health NGO, in Dhaka, Bangladesh, 11 March 2009.
local market, or an artificial supply crisis.\textsuperscript{114} Considering this, one participant suggested that the DDA, when giving drug registration and marketing approval, may include a condition that an “adequate supply to the local market needs to be ensured”. If it is not, upon the application of any person, the DDA would have the option of cancelling marketing approval and imposing export restrictions on the drugs concerned.\textsuperscript{115}

- Improved regulation, including improved enforcement and monitoring. It is important to ensure that the decisions adopted under an NDP are properly guided and supported by required national regulations, and are properly monitored and enforced.

It is suggested that Bangladesh could establish a national IP Institute to implement IP policy, and reorganise its existing National Public Health Institute to implement an NHS. As part of a pro-development IP policy and NHS, the Government of Bangladesh should establish cooperation between industries, universities and government institutions, as well as public-private partnerships.

5.7 Collaboration between Universities, Industry and Government and Public-private Partnerships

Universities in LDCs often face a host of problems: for example lack of funds, weak infrastructure, outdated reading and research materials, overcrowded classrooms, and overburdened and underpaid staff.\textsuperscript{116} Students in the basic and health sciences often graduate without being equipped to address critical tasks pertinent to the burden of disease and epidemiologic scenarios for which their service is needed. Both researchers and faculty struggle to find resources for substantive research projects. The overall lack of opportunity and career advancement results in low morale and provides little incentive to work in academia or the public sector, or even remain in the country.\textsuperscript{117} Therefore, strengthening universities, research centres and government institutes could have

\begin{thebibliography}{99}
\bibitem{114} Ibid.
\bibitem{115} Interview with a policy analyst working in a local public health NGO, in Dhaka, Bangladesh, 8 March 2009.
\bibitem{116} See John Ssebuwufu et al., \textit{Strengthening University-industry Linkages in Africa} (2012).
\bibitem{117} Ibid.
\end{thebibliography}
a direct effect on the ability of Bangladesh to muster the internal resources needed to boost local research and innovation with respect to country-specific diseases, and thereby the possibility to address its own public health problems. In particular, cooperation between industry, government and universities would help to develop an environment of self-reliance, confidence, entrepreneurship and experimentation that brings together researchers, practitioners and policymakers across disciplines to solve some of the pressing health problems facing Bangladesh.\textsuperscript{118}

Despite a lack of investment in basic R&D by the government and pharmaceutical companies in Bangladesh, one positive aspect is that there is a continuous supply of fresh graduates in relevant fields from local universities. Six public and 16 private universities in Bangladesh offer Bachelor of Science and Masters of Science courses relevant to the pharmaceutical sector. The total number of graduates each year is 860 in pharmacy, 1660 in chemistry, 650 in microbiology, 350 in applied chemistry and 250 in chemical engineering.\textsuperscript{119} The job opportunities for graduates are ever increasing, so more and more universities are offering relevant degrees.

Although there are more graduates, necessary steps should be taken to ensure that those graduates are recruited, deployed, trained and retained in the pharmaceutical sector. If graduates are given proper training and the opportunity to undertake research under the supervision of qualified and experienced experts, it would be an important step in the right direction for the transition of the pharmaceutical industry in Bangladesh beyond 2021. Bangladesh has great potential in this regard because infrastructure and labour costs are substantially lower than those for its competitors, such as China and India.

However, to date there has been little cooperation between government, industry and universities for R&D, and universities have little participation in national policymaking, resulting in fragmented, meaningless and bureaucratic national plans of action with no positive outcomes. On the other hand, the absence of national and university

\textsuperscript{118} For details on positive outcomes of this type of cooperation, see Henry Etzkowitz, ‘The Triple Helix-University-Industry-Government Innovation in Action’ (2008).

IP policies results in a lack of confidence and cooperation between industry and local universities. There is no evidence of public-private partnerships for R&D on country-specific technological needs and commercialisation.

Therefore, it is vital for Bangladesh to adopt IP policies at the national and university levels that will generate confidence and interest among faculty members, universities and industry partners for engaging in collaborative R&D. Such policies should indicate how to share the outcome of research or make it available to industry partners for the equitable sharing of royalties. An ideal policy would satisfy the faculty and student need for prompt publication to advance their research careers, and also satisfy the industry in the sense that firms will not have to pay royalties or unreasonable fees, nor risk infringement lawsuits to exploit the results of joint work. Finally, the government should address local problems such as the development and production of pharmaceuticals for some country-specific diseases.

It was suggested that the IP Institute and National Public Health Institute could identify priority areas for R&D in Bangladesh and then engage potential industry and university partners in generating local innovation in each particular sector. In this regard, Bangladesh could follow the U.S. model of the National Science Foundation\textsuperscript{120} and the \textit{Bayh–Dole Act, 1980}.\textsuperscript{121} Local universities in Bangladesh need

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{120} “The National Science Foundation (NSF), which was established in 1973 encouraged the creation of university-industry cooperative programs nationwide in a variety of technical fields. Again, the \textit{Bayh–Dole Act} of 1980 removed a major impediment for cooperation in fields such as pharmaceuticals and biotechnology, in which exclusive licensing of intellectual property is necessary. It transferred to universities rights, which reserved to Federal government agencies earlier. NSF expanded its commitment to cooperative research in 1985 with establishment of the Engineering Research Centers program. That program provides up to 11 years of NSF funding in partnership with industry”. See for details, ‘Working Together, Creating Knowledge: The University-industry Research Collaboration Initiative’, Business-Higher Education Forum of the American Council on Education and the National Alliance of Business (2001), http://www.bhef.com/sites/g/files/g829556/f/201604/BHEF_2001_working_together.pdf
\item \textsuperscript{121} The \textit{Patent and Trademark Law Amendments Act} (Pub. L. 96–517, 12 December 1980), or \textit{Bayh–Dole Act}, is the key piece of U.S. legislation dealing with IP arising from federal government-funded research. The \textit{Bayh–Dole Act} was designed to promote technology transfer by allowing universities, small business and research institutions to retain ownership of the patent rights resulting from federally-funded research, subject to an obligation to share royalties with the actual inventor.
\end{enumerate}
\end{footnotesize}
to establish innovation promotion and technology commercialisation centres to facilitate the establishment of start-up companies by students and faculty members, ensuring that advanced technologies are created to bring benefits to industry partners, and to facilitate the economic and technological development of society at large.\textsuperscript{122}

Despite the lack of R&D in most of the local research institutions, the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR-B) has made a remarkable contribution to improving public health in Bangladesh. This international health research organisation located in Bangladesh involves cooperation among research institutions around the world, and operates through the translation of research into treatment, training and policy advocacy. It addresses some of the most critical health concerns facing Bangladesh and the developing world.\textsuperscript{123} It has already made a considerable contribution in reducing the death rate due to diarrhoea and cholera, and has improved maternal health in Bangladesh. Bangladesh should perhaps consider engaging the international community and funding agencies and, through public-private partnerships, establishing additional research organisations to focus on the other most prevalent diseases in Bangladesh. This would have a real positive effect not only in terms of R&D but also in terms of improving public health in Bangladesh.

### 5.8 Limitations and Further Research

How the TRIPS Agreement will be implemented in Bangladesh is yet to be finalised, but this study has presented a number of options for consideration. What is certain is that there will be a need for regulatory agencies and the pharmaceutical industry in Bangladesh to be ready, willing and able to deal with pharmaceutical patents. At the moment there is concern that the current regulatory agencies—the DPDT and the DDA—and the local pharmaceutical industry lack such capacity.

\textsuperscript{122} Presently, the idea of university technology transfer and start-up companies is completely non-existent in Bangladesh. For details on successful university start-ups and venture capital, see David A. Hodges, ‘Industry-University Cooperation, and the Emergence of Start-up Companies’, http://andros.eecs.berkeley.edu/~hodges/UIC&ESUC.pdf

\textsuperscript{123} See for details, the website of the International Center for Diarrhoeal Disease Research, Bangladesh (ICCDDR, B), http://www.icddrb.org
This study has identified policy options and institutional and infrastructural issues that should be considered by Bangladesh and other LDCs in balancing pharmaceutical innovation and access to medicines, and also in progressing towards TRIPS compliance. However, the links between TRIPS, legislative changes and their effect on various stakeholders require further consideration, given their complex histories and relationships. This necessarily gives rise to a study focused not only on doctrinal legal issues but also on the social and regulatory effects of those issues.

It would be a misjudgement to say that TRIPS is an exogenous imposition to be implemented by Bangladesh while ignoring the socioeconomic conditions in the country. The TRIPS Agreement itself states that “the protection and enforcement of intellectual property rights should contribute to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”. Therefore, future study in this field must explore the TRIPS compliance process not only in the context of legal norms, but also while giving consideration to the consequences of those legal norms on the various stakeholders involved. Issues with respect to change and transition also then need to be considered. Therefore, further empirical socio-legal study may investigate these issues in the context of the TRIPS Agreement.

Another area of further research is the effect of TRIPS on traditional medicines in the LDCs and what policy options may be taken to protect and enhance traditional medicine use in a post-TRIPS setting.

5.9 Concluding Remarks

Since the ratification of the TRIPS Agreement, its effects in developing countries and the LDCs have been relentlessly examined. The situation

124 Article 7 of the TRIPS Agreement.
125 A study by the WHO mentions that 80% of the global population uses traditional medicines at some point in their lives. It also claims that the protection of traditional knowledge can include IP-related measures as well as non-IP-related mechanisms. This study added that diverse objectives need to be considered for the promotion of public health goals by facilitating the use of and access to traditional medicines. However, the study did not examine the effects of TRIPS on traditional medicines. See for details, ‘Intellectual Property Rights and Access to Medicines’.
of LDCs has received special attention, and they have been granted extensions to the transition period for TRIPS compliance, up to 1 July 2021 and until January 1, 2033 for the introduction of pharmaceutical patents. Despite having a waiver for pharmaceuticals since the establishment of the WTO, little progress has been made by most LDCs in terms of both affordability and innovative capacity in the pharmaceutical sector. Therefore, simply blaming the patent system will not deliver meaningful suggestions for the LDCs to improve their fragile healthcare sectors and low technological capabilities. It is undeniable that the pharmaceutical industry has an important role to play in the future development of new pharmaceuticals, and a patent system provides a mechanism through which to encourage R&D. All agree that a patent system must not become overprotective and so create a barrier for access to pharmaceuticals. Therefore the use of TRIPS flexibilities and government intervention options as indicated in this study may help to improve the affordability of medicines and encourage the local generic sector, but over-use of those safeguards could affect the funding of future R&D.

The Government of Bangladesh will need to promote R&D in its universities and research institutions and provide technical and financial assistance to support local pharmaceutical companies to develop innovative capacities that enable them not only to make pharmaceuticals relevant to country-specific diseases in Bangladesh, but also to export them to gain economies of scale and to continue further investment in R&D. Initially, LDCs such as Bangladesh could introduce process patent and utility model law along with institutional facilities (e.g. research incentives, technology transfer offices, patent fee waiver and patent application support, venture capital or start-up support) to encourage innovation by local companies. This in turn could help them to improve their innovative capabilities and increase competition among local companies, which might further generate research in sectors of vital importance in the country by way of cooperation between government, industry and universities, and public-private partnerships.

Therefore, further study is needed to explore the ways and means to encourage pharmaceutical companies in Bangladesh and in other LDCs to invest in R&D so as to develop new drugs for country-specific diseases (currently neglected by the developed countries’ pharmaceutical industries) and make them available for poor people at an affordable
price. However, it is difficult to resolve the conflicts between the two competing objectives—covering R&D costs and minimising consumer costs.

Within the present technological capabilities of the LDCs, it is difficult to predict more generally whether the IP system could play a role in stimulating the capacity of developing countries themselves to develop and produce drugs for neglected diseases. The R&D financing issue has a long history at the WHO, where it has been the subject of tough negotiations. Members generally agree that there is a market failure in which the financial incentive for companies to invest in research on neglected diseases is lacking, although members have spent years in disagreement over how to solve it. The WHO Commission on Macroeconomics and Health (CMH)\textsuperscript{126} stated that a large injection of additional public funds into health services, infrastructure and research was required to address the health needs of developing countries. It took the view that patent protection offered little incentive for research on developing country diseases, in the absence of a significant market.\textsuperscript{127} WHA 2012 welcomed a report from the CEWG to adopt a possible R&D treaty and sustainable financing for negligent diseases. However, disagreement between the parties on issues around adopting an R&D treaty meant that it slipped from the list of possible approaches. The CEWG resolution contains three areas of action: establishing a global health R&D observatory, setting up demonstration projects, and developing norms and standards to better collect data on health R&D.\textsuperscript{128}

Regarding access to medicines, a CMH–WHO study favoured coordinated action to establish a system of differential pricing in favour of developing countries, backed up if necessary by the more extensive use of compulsory licensing.\textsuperscript{129} However, extensive compulsory licensing may be counterproductive for encouraging investment and technology transfer in the pharmaceutical sector, and lack of innovative technological capabilities in most LDCs will prevent local pharmaceutical companies


\textsuperscript{127} Ibid.

\textsuperscript{128} See ‘WHO Experts to Narrow R&D Projects for Developing Countries at December Meeting’, \textit{Intellectual Property Watch} (6 November 2013).

\textsuperscript{129} \textit{Macroeconomics and Health}. 
from utilising compulsory licenses to produce cheaper medicines. Thus, the creation of sound competitive market structures through competition law and enforcement could be more effective in both enhancing access to medical technology and fostering innovation in the pharmaceutical sector.\textsuperscript{130} It can serve as a corrective tool if IP rights hinder competition, and thus constitute a potential barrier to innovation and access.\textsuperscript{131} While adopting TRIPS-compliant patent law, LDCs need to ensure that their IP protection regimes do not run counter to their public health policies, and that they are consistent with and supportive of such policies.

Apart from establishing mutually supportive IP and health rules, Bangladesh may need to use public awareness campaigns for improving drug quality and explaining the rational use of medicines. There is also a need to integrate pharmacies (retail suppliers of medicines at the grassroots level) and health professionals to ensure rational use and ethical prescription practices—as consumers in Bangladesh have a tendency towards self-medication—and to prevent unethical prescription practices by doctors. Bangladesh could also investigate the possibility of a campaign combined with a toll-free number for consumers to report bad quality and unauthorised drugs. These initiatives would also have a positive effect on the health sector in Bangladesh.

This study has analysed the pharmaceutical industry and the status of relevant laws and regulatory bodies in Brazil, China, India, South Africa and Bangladesh. Policy options explored in this study are expected to guide future capacity building in developing countries and the LDCs, in terms of legislative, institutional, infrastructural and broader policy goals to preserve local pharmaceutical industries and accomplish the twin aims of promoting local innovation and ensuring access to medicines. The outcomes of this research may also be helpful in addressing the competitiveness of the pharmaceutical sector and, with some modifications to other sectors of vital importance in the LDCs, in establishing a plan of action for progression towards innovation and TRIPS compliance.

\begin{thebibliography}{99}
\bibitem{Ibid} Ibid.
\end{thebibliography}