The Place of Bolar Exception under Ethiopian Patent Law: The Need for Reform

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Abstract

The basic principle of patent law is that once the term of a patent has expired, the protected subject matter becomes part of the public domain. This allows competitors to enter the market immediately after such term expiry, eventually lowering prices for consumers and increasing welfare gains. However, Pharmaceutical products cannot be marketed without the prior authorization of a competent regulatory agency. This would negatively affect the right to public health (access to medicine). In response to such problems, many countries have recognized the Bolar exception that endows the third party with the right to use the patented invention without the right holder's consent before the patent expiry to develop information to get market approval. The purpose of this article is to ascertain whether the Bolar exception is recognized under the Ethiopian patent regime or the research and experimentation exception under the Patent Proclamation can be broadly interpreted to justify the Bolar exception.

To meet this objective, the study employed doctrinal research methodology along with comparative exploratory tools. The research findings showed that Ethiopia recognizes neither the Bolar exception nor the research and experimentation exception envisaged under the national patent regimes justifies the exception through interpretation. The historical, theoretical, and empirical lessons from other countries show that most countries facilitate access to medicine by incorporating a Bolar exception into their domestic law. Ethiopia should, therefore, incorporate in its pertinent legislation an exception that allows the competitors to experiment with a patented invention to achieve market authorization on the day of or immediately after the expiry of the patent protection.

Key words: *Patent, Bolar Exception, Human Rights, Public Health*

Introduction

Protections over one's innovation (patent protection) and the right to public health have long been recognized under different international and regional instruments such as the Universal Declaration of Human rights (UDHR)[1], International Covenant on

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[1] Universal Declaration of Human Rights (UDHR), United Nations General Assembly, (1948), (hereinafter, UDHR), Art.27 (1)).

Economic, Social and Cultural Rights (ICESCR)[2], Trade-Related Intellectual Property Rights (TRIPS) Agreement[3] And African Charter on Human and Peoples' Rights (ACHPR)[4]. Besides, the World Intellectual Property Organization (WIPO), United Nations Human Rights Council (UNHRC), the Committee on Economic, Social and Cultural Rights, the World Health Organization (WHO), and the Food and Agriculture Organization are now aware of the human rights dimension of the intellectual property, considering both patent rights and right to health as human rights.[5]

Despite the above facts, there were contentious relations between these two rights which can be traced back to the patent's historical background. For instance, recent studies by WTO, WIPO, and WHO have indicated that the essential but tricky balance between the two rights (patent rights and the right to health) is a contentious issue.[6] Patents are intended to offer some guarantee of a return on investment, but the patent system is also designed to balance the interests of inventors with those of the public. Balancing the interest of the patentee and the public is one of the legislative and policy imperatives for governments and this could be attained by ensuring access to medicine.

According to ICESCR, the right to health care includes the right to emergency care, health facilities, goods and services. Access to medicines is the core content of the right to health, both as the treatment for epidemic and endemic diseases and as part of the medical attention in the event of any sickness.[7] Consistent with these intents, General Comment 14, in interpreting Article 12 of the ICESCR, mentioned availability, accessibility (affordability), acceptability (medical ethics), and quality of medical services as four minimum elements to fulfill the right to health. Further, it embodies the provisions granting the right to essential medicines as one of the state's minimum core duties.[8] In addition, Resolution 12/24, adopted by the Human Rights Council in 2009, recognizes that "access to medicines is one of the fundamental

[2] International Covenant on Economic, Social and Cultural Rights (ICESCR), United Nations, 1976 (hereinafter, ICESCR), Art. 15 (1) (c).

[3] The trade-Related intellectual property rights agreement, world trade organization, 1994(hereinafter TRIPS), Arts.1 (1), 7 and 8.

[4] African Charter on Human and Peoples' Rights (ACHPR), Organization of African Unity, (1982) (hereinafter, ACHPR), Art.16 (1) & (2).

[5] Laurence R. Helfer, *Human Rights, and Intellectual Property: Mapping the Global Interface*, 1st edition, Cambridge University Press, 2011), p.1

[6] *Id.*p.21

[7] ICESCR, Art. 12.2(c)(d)

[8] General Comment 14 in interpreting Article 12 of the ICESCR, The Right to the highest attainable standard of health, UN Economic and Social Council, adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on August 11, 2000, available at https://www.refworld.org/pdfid/4538838d0.pdf,(last accessed on 30 June 2021)

elements in achieving the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[9] It particularly stresses the responsibility of States to ensure access to all, without discrimination, of medicines that are affordable, safe, effective, and of good quality.[10] With a consistent stance, the Doha declaration grants member states the right to make institutional moves targeting the protection of public health. As such, it re-affirms the right to establish or maintain marketing approval procedures for generic medicines or apply summary or abbreviated marketing approval procedures based on earlier marketing approvals for equivalent products for developing countries.[11]

While governments and the public are granted such space of right to such medicines, this is made with a reasonable protection of the rights of inventors (Patentees). Patentees enjoy an exclusive right of the monopoly of benefits from their invention for a specific time. The basic principle of patent law, regulating rights to benefit from such inventions, states that once the term of a patent has expired, the protected subject matter becomes part of the public domain. Hence, it can be freely used, including for commercial purposes, without interference by the former patent owner. This allows competitors to enter the market immediately after the expiry of such time limits, eventually lowering prices for consumers and welfare gains.[12]

Yet, it is important to note that pharmaceutical products cannot be marketed without the prior authorization of a competent regulatory body. Such authorization is conditional on submitting and approving an application that usually has to be accompanied by specific pieces of information.[13] Further, as the patent protection restricts the use of the relevant patent for clinical trials and tests, it would delay the release of generic medicines.

Hence, to balance patent protection and access to medicines by allowing the third parties to use the patented product for market approval before the expiry of the patent,

[9] Resolution on access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, UN Human Rights Council, A/HRC/RES/12/24, adopted by the Human Rights Council at 12th session,2009 available at https://digitallibrary.un.org/record/668398?ln=en(last accessed on 30 June 2021)

[10] *Id.*

[11] Anthony Tridico, Jeffrey Jacobstein & Leythem Wall, facilitating generic drug manufacturing: Bolar exemptions worldwide, WIPO Magazine, 2014, available at http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html(Last accessed on 13 August 2021)

[12] Carlos. M Correa, *the Bolar Exception: Legislative Models and Drafting Options*, research paper, south Centre, Switzerland,2016, p.1

[13] *Id.*

the "early working" or "Bolar exception has emerged."[14] The central idea of a Bolar exemption (also known as regulatory review exception)[15] is to allow competitors to experiment with a patented invention to achieve market authorization for a generic or biosimilar on the day of or immediately after the expiry of the patent protection. Looking into the Ethiopian legal regime, one could see that it recognized these rights at the constitutional level.[16] To this effect, the FDRE Constitution, under Articles 41(4) & 90(1), urges the government to provide all Ethiopians access to public health and education, clean water, housing, food, and social security.[17] It also entitles every Ethiopian citizen to the right to private property ownership, including any intangible product produced by the creativity of an individual citizen.[18]

Yet, balancing such rights to public health and patent protection remains one of the major duties of legislative bodies. The patent laws of Ethiopia have adopted various exceptions to balance the right to health and patent protection, and the emphasis of this paper is to assess whether the competitors are allowed to use the patented product to make an experiment to get the market authorization immediately after the expiry of patent protection. This would inevitably beg for such questions as: Is a Bolar-type exception recognized under the Ethiopian patent proclamation? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs, or does it also apply to other products, including biological products, research tools, etc.? Suppose, the Bolar exception is not recognized under the Ethiopian patent proclamation. Will the use of an invention without the patentee's consent to obtain approval of a generic product be covered by the research and experimentation exception?

Answering such questions would inevitably require further exploration. To the best of this author's knowledge and access, there is no research that explicitly answered the perplexities that underlie the Bolar exception. Yet, some authors have mentioned Bolar exemption issues in their works, though they failed to sufficiently explore it. For example, Fikre Markos, in one of the few works on the law of intellectual property in this country, demonstrated the instrumental role of Bolar exemption in ensuring the right to access medicine. The writer particularly stressed the WTO panel decision on

[14] *Id.*
[15] *Id.*
[16] The FDRE constitution has explicit provisions on both patent rights as property rights and the right to health. For patent rights, see Constitution of the Federal Democratic Republic of Ethiopia, Proclamation No 1/1995, *Federal Negarit Gazetta*, 1st Year No.1, 1995 (hereafter FDRE Constitution), Arts. 40 (1) & (2), 91(2), and for the right to health, see arts: 41 (4), 90(1) of the same constitution.
[17] *see* FDRE Constitution, Article 41(4) & 90(1)
[18] *see* FDRE Constitution, Article 40(1,2) & 91(2)

Canada pharmaceutical cases as a major illustration concerning Bolar exemption and stockpiling.[19] Yet, he left the issues open by questioning whether the Ethiopian regimes have the same exemption or not. In another work outlining the mechanisms of Ethiopia's Accession to the World Trade organization, Michael Tilahun pointed out that the country needs to use TRIPS flexibility as a way to facilitate access to medicine.[20] As such, he identifies the possible avenues to ensure access to medicine under WTO regimes and compares the Ethiopian patent regime in light of TRIPS flexibilities. However, his work has not ascertained whether Article 25 of Patent Proclamation No. 123/95[21] can be invoked to justify Bolar exemption.

Further, Israel Begashaw, in his work examining the compatibility between the Ethiopia patent regime and TRIPS Agreement, argues that the Bolar exception is not recognized under the patent regimes of Ethiopia. However, his work has not addressed whether the research and experimentation exemption may be interpreted to justify the Bolar exemption like the case in some countries which extend research and experimentation exemption to Bolar exception.[22] Further, his work does not show whether the Bolar exception may be a blessing or curse for Ethiopia and what ought to be done by Ethiopia to accommodate this exception in pertinent legislation.

Therefore, this article aims to examine and assess the place of the Bolar exception under the Ethiopian patent regime, identifying its shortcomings and exploring opportunities for proper regulation. To meet this objective, the study employed doctrinal research methodology along with comparative exploratory tools. Accordingly, the article investigates the pertinent provision of the Ethiopian patent proclamation with the primary objective of ascertaining whether the Bolar exception is recognized or the research and experimentation exception under the Ethiopian patent regime can be broadly interpreted to justify the Bolar exception. Finally, the paper explores the experiences of the USA, India, and South Africa to r draw a lesson for Ethiopia. These countries are purposively selected as they have good experiences in integrating Bolar exceptions to their domestic laws.

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[19] Fikre Markos Marso, The Ethiopian law of intellectual property rights: copyright, trademarks, patents, utility model and industrial designs, Addis Ababa University, school of law, 2012, pp. 255–257.

[20] Michael Tilahun, Ethiopia's accession to World Trade Organization (WTO): The Need to Reform Ethiopian Patent Law to Facilitate Access to Medicine, Abyssinia law,(March 14, 2018) available at https://www.abyssinialaw.com/blog-posts/item/1799-ethiopia-s-wto-the-need-to-reform-ethiopian-patent-law-to-facilitate-access-to-medicine (last accessed on June 20, 2021)

[21] A Proclamation Concerning Inventions, Minor Inventions and Industrial Designs, 1995, proc. No. 123, *Neg. Gaz*, Year 5, No. 25(hereinafter Ethiopian patent proclamation), Art. 25,.1(b)

[22] Israel Begashaw, The Ethiopian Patent Regime and Assessment of its compatibility with TRIPS Agreement, Unpublished LL.M thesis, Addis Ababa University, (2010), p.66

The article is organized into four sections. The first section uncovers the origin of the Bolar exemption and its compatibility with the TRIPS agreement. The second section presents the experiences of selected countries concerning the Bolar exception. The third section critically analyzes the place of the Bolar exception under the Ethiopian patent regime. Finally, the article ends with concluding remarks.

1. Origin of Bolar exception and its compatibility with the TRIPS agreement

Health has long been and is increasingly a concern of all people as citizens of the world and citizens of sovereign nations. The right to health is a fundamental part of our human rights and of our understanding of life in dignity. This has been recognized by several international human rights and policy documents. For example, the *Alma-Ata* Declaration, which was adopted nearly 30 years ago, noted that "Health for All" would contribute to both a better quality of life and global peace and security.[23] Consistent with this, the World Health Organization (WHO) Assembly has given legal recognition to the right to health as an indication for a government to improve access to essential medicine.[24]

Yet, people living with various diseases and other populations in desperate need of life-saving drugs are increasingly unable to access the existing preventative, curative, and life-prolonging treatments. The reasons behind the lack of access to medicines are numerous and include infrastructure, research and development, and the costs of medications.[25] Most of the findings indicate that the cost of medication has taken the lion's share as the high prices of patented drugs often make them unaffordable for the people and governments in the developing world.[26] In response to such a problem, the WHO recommends that generics competition and differential pricing contribute substantially to the affordability of medicines in low-income countries.[27] However, the medical patent right, which has been protected for decades as one of the Intellectual Property Rights, severely restricts generic manufacture and reverses the accessibility to

[23] World Health Organization, Report on health Systems Financing: The path to Universal Coverage, 2010, available at https://apps.who.int/iris/bitstream/handle/10665/44371/9789241564021_eng.pdf?sequence=1&isAllowed=y(last accessed on June 23, 2021)

[24] Hans V. Hogerzeil & Zafar Mirza, Access to essential medicines as part of the right to health,2011, available at http://digicollection.org/hss/documents/s18772en/s18772en.pdf(last accessed on June 23, 2021)

[25] *Id.*

[26] *Id.*

[27] World Health Organization, Report on Health Systems Financing: The path to Universal Coverage, 2010, available at https://apps.who.int/iris/bitstream/handle/10665/44371/9789241564021_eng.pdf?sequence=1&isAllowed=y(last accessed on June 23, 2021)

medicines. To overcome this problem, many countries have put the *Bolar exception* in place.

The Bolar exception was first introduced by the US in Hatch Waxman Act, following a ruling by a US Federal Circuit court over *Roche Products, Inc. v. Bolar Pharmaceutical Co*.[28], one of the landmark cases in this regime of case law. The ruling which gave birth to the exception had the intent of striking a compromise between the so-called 'innovator' and generic pharmaceutical producers.[29]

The case involved a dispute related to the manufacturing of generic pharmaceuticals. Roche was a brand-name pharmaceutical company that made and sold Dalmane. This product was protected by patent. Bolar was a generic drug manufacturer and had an interest in manufacturing generic versions of Dalmane after the expiry of the patent. Before patent expiration, Bolar had used the patented chemical in experiments to determine if its generic product was bioequivalent to Dalmane to obtain food and drug authority (FDA) approval for its generic version of Dalmane. Then, the Roche pharmaceutical company took the issue to court for the infringement of patent protection. Bolar argued that its use of the patented product was not infringement under the experimental use exception to the patent law.

The Court of Appeals for the Federal Circuit rejected Bolar's contention holding that the experimental use exception did not apply as Bolar intended to sell its generic product in competition with Roche's Dalmane after patent expiration and, therefore, Bolar's experiments had a business purpose.[30] Bolar argued that public policy favoring the availability of generic drugs immediately following patent expiration justified the experimental use of the patented chemical because denying such use would extend Roche's monopoly beyond the date of patent expiry.[31]

Through the examination of the pertinent laws and the argument of the two parties, the court came to see an apparent policy conflict between statutes namely, the Food and Drug Act and the Patent Act. Further, the court held that disputes arising from such

[28] *Roche Products, Inc. v. Bolar Pharmaceutical Co*. United States Court of Appeals for Federal Circuit, No. CV 83-4312, (April 23, 1984)

[29] Christopher Garrison, An exception to patents in developing countries, UNCTAD – ICTSD, (October 2006),p.14, available at https://unctad.org/system/files/official-document/ictsd2006ipd17_en.pdf
(Last accessed June 25, 2020)

[30] Reference document on the exception for obtaining regulatory approval from authorities, WIPO, 2017, available at https://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_3.pdf (Last accessed June 25, 2020)

[31] *Id.*

policy conflict should be redressed by Congress, not by courts.[32] Unfortunately, this decision delayed the entry of generic drugs into the marketplace by delaying the availability of generic drugs by allowing a patentee to maintain market exclusivity for some time after its blocking patent(s) expired.[33] While the court rendered its judgments, it recommended that Congress should make such policy decisions. Accordingly, Congress did pass a law permitting the use of patented products in experiments to obtain food and drug authority (FDA) approval through the Drug Price Competition and Patent Term Restoration Act of 1984, often referred to as the "Hatch-Waxman Act."

This marks the beginning of the Bolar exception. The general view of the congress was that it was not appropriate to prevent generic pharmaceutical manufacturers from starting to prepare and obtain regulatory approval for their generic products before the expiration of patent protection since it would delay the entrance of generic medicines on the market for a substantial period and extends the effective protection period beyond the patent term.[34] Following this, many countries of the world have incorporated the Bolar exception into their domestic patent regime.

Despite such moves of incorporating Bolar exception into domestic patent laws, the scope of the exception or the types of products upon which the exemption applies vary across jurisdictions. In many countries, the Bolar exception applies to "any products" that require regulatory approval. In Albania, Canada, India, South Africa, Hungary, Israel, Italy, Jordan, Malaysia, New Zealand, Pakistan, Portugal, and Vietnam, the Bolar exception applies to any products that need regulatory approval.[35] On the other hand, in some countries like Austria, Chile cost Arica, and Thailand, the scope of the Bolar exception exemption is limited to pharmaceutical products.[36] Further, in other countries like Bosnia Herzegovina, Netherlands, and Croatia, the scope of the bolar exception is limited to Human or veterinary drugs or medical products.[37] Again, in China, the scope of the Bolar exemption is limited to patented drugs or patented medical apparatus and instruments.[38] In Finland, Greece, Lithuania, Poland, Denmark, Kenya, Slovakia, and turkey, the scope of the Bolar exemption is limited to medicinal products. Finally, in countries like El Salvador, Peru, and Latvia, the scope of the

[32] *Id.*
[33] *Id*.
[34] *Id*.
[35] World intellectual property organization, Exception for obtaining regulatory approval from Authorities,https://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_3.pdf (last accessed on June 25, 2021)
[36] *Id*., p.10.
[37] *Id*.
[38] *Id*.

exemption is limited to pharmaceutical and agricultural chemicals or plant protection products.[39]

At this point, it is important to note that this variation in the scope of applying the Bolar exception is largely driven by the underlying purpose that the exception is supposed to serve in the respective national policy regimes. To this end in some countries, the Bolar exception is applied to acts that may be carried out for obtaining regulatory approval in their respective territory. In others, the exception is applicable for activities carried out in other countries as far as the purpose of the activities is for regulatory approval. The experiences of India, Brazil, and Germany can be a case in point in this respect. Further, the way countries of the world implement Bolar exception varies across jurisdictions. Many countries have specific statutory provisions for Bolar exceptions[40] while other countries have expressly combined the Bolar and experimental or scientific research exception into a single provision.[41]

Now we turn to the position of the TRIPS Agreement on this issue. Under the TRIPS Agreement, patents confer exclusive rights to the patentee for making, using, offering for sale, selling, or importing (except to the extent that parallel imports are allowed)[42] a protected product.[43] These rights, however, are subject to exceptions under the general requirements contained in Article 30 of the Agreement. It provides that Members may provide limited exceptions to the exclusive rights conferred by a patent, if such exceptions do not unreasonably conflict with a normal exploitation of the patent, do not unreasonably prejudice the legitimate interests of the patent owner, and take account of the legitimate interests of third parties.[44]

The most common exception to the patent holder's exclusive rights in pharmaceuticals is often referred to as the 'Bolar provision.'[45] A Bolar provision allows interested (generic) manufacturers to start producing test batches of a product before the patent expires to collect the necessary data for submission to the registration authorities. This will reduce the delay for generic products to enter the market after the patent has

[39] *Id*.
[40] Experiences of Egypt, the USA, South Africa, and India can be an example as the bolar exception is regulated under a separate statutory provision.
[41] The experiences of Argentina, Bosnia Herzegovina, Croatia, Hungary, Jordan, Portugal, Slovakia, and Spain can be mentioned as an example of the issues of bolar exception, and experimental or scientific research exception is provided by a single provision.
[42] Carlos. M Correa, *supra* note 12, p.5
[43] *Id*.
[44] *See* TRIPS Agreement, *supra* note 3, Art.30
45TRIPS agreement and pharmaceutical, WHO, 2012, available at http://digicollection.org/hss/en/d/Jh1459e/6.5.html#Jh1459e.6.5(Last accessed on August 25, 2021)

expired, and thereby enhance competition. Yet the text of the TRIPs Agreement does not explicitly address this issue.[46]

Though the TRIPS Agreement does not address the issues of the Bolar exception, the issue as to whether the Bolar exception is consistent with Article 30 of the TRIPS Agreement was tested in a case initiated against Canada by the European Communities and their Member States through which Bolar exception had been introduced in 1991.[47] The points of argument were related to the Canada Patent Act, Section 55.2(1) which explicitly allows a third party to use the patented invention to submit the information required for marketing approval (in Canada or abroad) and stockpile the product (for up to six months) for release immediately after the expiry of the patent. It provides that:

It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province, or a country other than Canada that regulates the manufacture, construction, use or sale of any product.[48]

This section pertains to activities reasonably related to developing and submitting the information required by a regulatory body (such as the health office of Canada, similar to the US Food and drug administration). Finally, it is also important to note that Section 55.2(1) relates to information that a regulatory body may require not only in Canada but anywhere in the world. Under the Manufacturing and Storage of Patented Medicines Regulations, "the applicable period referred to in under 55.2(2) of the Patent Act is the six months immediately preceding the date on which the term of the patent expires."[49]

In March 2000, the WTO panel concluded that Canada was not in violation of the TRIPS Agreement in terms of its practice of allowing the development and submission of information required to obtain marketing approval for pharmaceutical products carried out without the patent holder's consent. However, Canada's actions were found to be inconsistent with the Agreement in terms of its practice of manufacturing and

[46] TRIPS agreement and pharmaceutical, WHO, 2012, available at http://digicollection.org/hss/en/d/Jh1459e/6.5.html#Jh1459e.6.5(Last accessed on August 25, 2021)
[47] Carlos. M Correa, *supra* note 12, p.6
[48] Canada patent act of 1985, Section 55.2(1)
[49] Carlos. M Correa, *supra* note 12, p.6

stockpiling pharmaceutical products during the six months immediately before the expiry of the 20-year patent term.[50]

Based on this reasoning and other convergent arguments, the panel concluded that the Canadian Bolar exception was consistent with the TRIPS Agreement. The panel ruling dismissed the argument suggesting that the owner of an expired patent had a right to a *de facto* extension of its monopoly resulting from the delay in approving generic products. However, the panel found that the stockpiling provision was inconsistent with Article 30 of the TRIPS Agreement. Canada subsequently amended its legislation in this regard.[51] The panel has also concluded that stockpiling provision was inconsistent with Article 28.1, as it constituted curtailment of the exclusionary rights granted to the patent holders.[52]

As the TRIPS Agreement does not define the scope or nature of the permissible exceptions, countries are left with considerable freedom for doing so. In determining which other exceptions may fall within the ambit of Article 30, Paragraph 5(a) of the Doha Declaration provides guidance for the interpretation and implementation in stressing the importance of the object and purpose of the TRIPS Agreement. In the circumstances, exceptions crafted to achieve objectives related to the promotion of the transfer of technology, the prevention of abuse of intellectual property rights, and the protection of public health may well be justifiable.

Finally, from the analysis presented in this section, member states of the WTO from the developing world should be aware that TRIPS does not prohibit countries from permitting the regulatory approvals of generic drugs to occur before the patent term expires.[53] Many WTO Members have implemented this exception in their domestic laws to facilitate the early entry into the market by generic competitors.[54] Yet, nothing will hinder nonmember states from inculcating Bolar exceptions to patent regimes so that it will positively contribute to ensuring access to medicines at lower prices.[55]

2. Bolar Exception under National Laws

[50] *Id.*
[51] *Id*, p.9
[52] *Id.*
[53] Moni Wekesa and Ben Sihanya, *Intellectual property rights in Kenya*, Konrad Adenauer Stiftung, Berlin, (2009), p.32
[54] *Id.*
[55] *Id.*

Following the WTO panel decision favoring the Bolar exception, several countries have incorporated such trends into their national legislation.[56] Since it is one of the flexibilities allowed by the TRIPS agreement, it is recommendable for the least and developing countries that cannot afford to buy patented medicine to mitigate the negative impact of patents on access to medicines via the adoption of Bolar exception in their national legislation.[57] There are differences, however, regarding the scope of protection from infringement claims. The next sections explore such varying experiences of selected countries.

2.1. South Africa

While some African countries have introduced a Bolar exception, a number of others have done so lower than those in other regions of the world.[58] The Bangui Agreement Relating to the Creation of an African Intellectual Property Organization (OAPI), with 27 member states, does not currently include a Bolar exception among those provided for patent rights.[59] The 2007 review[60] of the national legislation in 39 (out of the 47) Sub-Saharan African countries found that, although most of them, including least-developed countries, provided patents for pharmaceutical products, the level of the incorporation of the flexibilities, including the Bolar exception, was inadequate. Only three countries (Kenya, Namibia, and Zimbabwe) expressly provided for the Bolar

[56]WIPO, Exceptions and Limitations to Patent Rights: Experimental Use and Scientific Research, A report prepared by the Secretariat of WIPO for the SCLP, Geneva, November 18, 2013, available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=256318(Last accessed on August 25 2021)

[57]Germán Velasquez, Carlos Correa and Xavier Scuba, IPR, R&D, Human Rights and Access to Medicines, research paper, South Centre, Geneva, 2012, available at https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2012_IPR-RD-HRs-Access-to-medicine_EN.pdf(Last accessed on August 25, 2021)

[58]WIPO, Regional Seminar on the Effective Implementation and Use of Several Patent-Related Flexibilities, Bangkok, Thailand March 29 to 31,2011, available at https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_bkk_11/wipo_ip_bkk_11_ref_topic3.pdf
(Last accessed on August 25, 2021)

[59] *Id.*

[60] Sisule F.Musungu, Access to ART and Other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislation, UNDP, September 2007,p.13, available at https://www.opensocietyfoundations.org/uploads/11027264-6d1f-4456-99fd-fa46b53730da/artafrica_20090313.pdf (Last accessed on August 25, 2021)

exception.[61] Since the review, however, some African countries have incorporated it. The Notable exceptions were Egypt, South Africa, and Nigeria.[62]

South Africa undertook the intellectual property amendment Act in 1997, and further amendments were made in 2002 and 2005.[63] The relevance of the South African experience with pharmaceutical patent issues goes beyond doctrinal matters as it used competition law and other governmental interventions for price bargaining. As such, the practice in this country brought the potential tension between patent protection for pharmaceuticals and public health concerns to public attention. triggering a debate about what should be allowed and what should be prohibited to preserve the incentives for investments in pharmaceuticals while still allowing the flexibility to respond to public health crises as deemed fit.[64]

Further, through a legislative amendment made in 2002, the South African patent act introduced a Bolar-type exception.[65] This exception allows a potential competitor to use an invention to undertake acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term without the patent holder's authorization.[66] This exception is provided in the Patents Act under Section 69A (Acts of non-infringement), which provides:

(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of, or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.[67]

From this provision, it is clear that the generic manufacturer can use the patented invention to obtain regulatory approval. It should be further noted that the generic manufacturer could not use the patented invention for any other purpose than obtaining market approval which in turn allows to put the generic product on the

[61] Carlos. M Correa, *supra* note 12, p.12
[62] Sisule F. Musungu , The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?, World Health Organization, April 2006,p.57, available at https://apps.who.int/iris/handle/10665/43503(Last accessed on August 25, 2021)
[63] Yu-Fang Wen & Thapi Matsaneng, Patents, Pharmaceuticals, and Competition: Benefiting from an Effective Patent Examination System, Competition Commission's 7th Annual Conference, China, (Sept.5, 2013). p.1
[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] South African Patent Act of 1978, as amended by Patents Amendment Act No. 58 of 2002, Section 69A

market on the day of or immediately after the expiry of patent protection. For instance, the generic manufacturer is not allowed to stockpile a product before the expiry date of the relevant patent protection.[68]

2.2. USA

As it has been mentioned, the Bolar exception was introduced by the US' Drug Price Competition and Patent Term Restoration Act of 1984.[69] Specifically, Section 271(e) (1) of this Act, widely known as safe Harbor in the USA[70], sets out stipulations that insulate certain activities from patent infringement. Evidencing this intent, it provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site-specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[71]

From these stipulations, it is clear that the generic manufacturer can use the patented products for regulatory procedures before the relevant patent(s) expiry if the use is solely related to the development and submission of information for the drug and administration approval process. Also, from this provision, one could see that in the United States, the Bolar exception is broadly applied to pre-clinical testing of drugs or potential drugs "at least as long as there is a reasonable basis to believe that the compound tested could be the subject of ... and the experiments will produce the types of information relevant to" an application for approval for clinical trials or marketing.[72]Yet its application is limited to drugs for human use; other biological products would only be covered to the extent that they are regulated as drugs. The exception does not

[68] Elijah Munyuki &Rangarirai Machemedze, Implementation of the TRIPS flexibilities by east and southern African countries: Status of patent law reforms by 2010, Southern and Eastern African Trade, Information and Negotiations Institute (SEATINI), 2010,p.15, available at http://www.equinetafrica.org/sites/default/files/uploads/documents/Diss80TRIPSupdate2010.pdf(Last accessed on August 25 2021)

[69] Carlos M. Correa, *supra* note 12, p. 2

[70] *Id*.

[71] Drug Price Competition and Patent Term Restoration Act, Public Law 98-417, 98th united states congress,1984, Section 271(e)(1)

[72] Sisule F. Musungu, *supra* note 60, p.56

apply if the drug is primarily manufactured using recombinant DNA or hybridoma technology or if the drug is a new animal drug or veterinary biological product.[73]

The Safe Harbor has been interpreted broadly by US courts and, as a result, exempts a wide variety of activities with the attendant commercial benefits provided that the conduct is reasonably related to gaining information relevant to the FDA approval process.[74] The courts stated that under certain conditions, the exemption could include: (1) experimentation on drugs that were not ultimately the subject of FDA submission; or (2) the use of patented compounds in experiments that were not ultimately submitted to the FDA.[75]

Looking into the literature on the welfare implications of the Hatch-Waxman Act", one can see that the source of significant potential positive gains of two types. First, it eliminated costly scientific testing, which served no useful purpose. Second, the Act lowered prices to consumers with some elimination of deadweight losses and large transfers from producers to consumers.[76] Similarly, the Bolar exceptions incorporated in modern patent laws serve the public's interest, governments, and social security systems that bear the cost of medicines. There is ample evidence that price is reduced after the first generic is introduced following patent expiration, albeit it may not be initially significant.[77] In the USA, for instance, the introduction of the second generic has been reported to reduce the price, on average, by half, and that when a more significant number of generic manufacturers enter the market, the average price may fall to 20 percent or less of that of the brand-name product.[78] Finally, USA law provides very little research or experimental use exemption concerning patented inventions. The exemption is so limited that it is limited to actions performed for "amusement, to satisfy idle curiosity or for strictly philosophical inquiry." [79]

2.3. India

[73] *Id*.
[74] Carlos M. Correa, *supra* note 12, p.2
[75] *Id*.
[76] Joseph E. Harrington, John M. Vernon & W. Kip Viscusi, *Economics of regulation and antitrust*, 2nd edition, Cambridge, The MIT Press, (1997), p.857
[77] Carlos M. Correa, *supra* note 12, p.5
[78] Lisa.Mueller, Understanding Bolar and Bolar-Like Exceptions in the US and Abroad, *National Law Review*, Vol.7, No.201,(2017) available at https://www.natlawreview.com/article/understanding-bolar-and-bolar-exceptions-us-and-abroad-part-1(Last accessed on 13 June 2021)
[79] *Id.*

Most countries in Asia provide for the Bolar exception, albeit with different scope.[80] In some countries, it is limited to marketing approval in its territory (e.g., Pakistan, Singapore). In others (India, Philippines, Israel), submissions in other countries are also exempted.[81]

India took a similar vision but a different path to balance pharmaceutical innovation with the public health concern of access to medicines.[82] To alleviate the problem, India reformed its patent policy in 1970, and this patent regime was also amended on January 1, 2002.[83] India introduced the Bolar exemption by the Patents Amendment Act of 2002 which amended the Indian Patents Act of 1970.[84] Section 107A of the Indian Patent Act of 2002 is known as India's Bolar Exemption. The fundamental objective of Section 107A is to delineate certain acts that are not to be considered an infringement. For this Act:

(a) any act of making, constructing, using, selling, or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or a country other than India, that regulates the manufacture, construction, use, sale or import of any product.[85]

Under this section, using a patent to develop and submit information for regulatory approval will not be considered an infringement of the patent right. Thus, in the new patent regime, as innovator companies introduce new drugs in India and enjoy exclusive patent rights, such Bolar provisions can introduce generics immediately after the expiry of patents.[86] Making, constructing; using; selling, or importing a patented invention are allowed in acts for obtaining regulatory approval from the concerned authorities.

[80] Sisule F. Musungu, *supra* note 62, p.56
[81] Anthony Tridico, Jeffrey Jacobstein & Leythem Wall, *supra* note 11.
[82] Prabhu Ram, India's New Trips-Compliant Patent Regime between Drug Patents and The Right to Health, *Chicago-Kent Journal of Intellectual Property*, Vol.5, No.2, (2006), p.195
[83] *Id*.
[84] Ravindra K. Ahuja, *Intellectual property rights in India*, 2nd edition, New York, Lexis Nexis, (2015), p.557
[85] The Patents Act 1970, Intellectual property of India (hereinafter, Indian patent act of 1970 as amended in 2005) , section 107A (a) available at https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf(Last accessed on 13 August 2021)
[86] Ravindra K. Ahuja, *supra* note 84

In India, the Bolar provision is comparatively broader than its US counterpart.[87] While the US provision restricts the safe Harbour available to generic manufacturers to make, use, offer for sale, or sell the patented invention solely for uses that are reasonably related to the development and submission of information under US federal law in the United States only, its Indian counterpart does not specify such territorial limits.[88] Thus, even if outside India, a sale will fall within the sweep of Section 107A if it is reasonably related to the development and submission of information required for regulatory approval under the country's law in which the sale takes place.[89] Further, unlike US rule, which has specified that research exemption is to be provided only for drugs or veterinary biological products, Indian law has not created any such demarcation, and the research exemption is for any product.[90]

Generally, the Bolar exemption enables generic drug manufacturers to use an inventor's pharmaceutical drug before the patent expires, which aids in the early launch of generic versions of the drug once the innovator drug's patent term ends and promotes further R&D.[91] It is important to here that there is a lack of cases regarding Bolar exemption in India. India has only one case (Bayer Corporation vs. Union of India & Anr) [92] regarding this provision wherein clinical trials have been mentioned as part of the Bolar exemption.

3. The Place of Bolar Exception under the Ethiopian Patent System

In Ethiopia's context, the Ethiopian National Health Policy, which was launched in 1993, aimed at the development of preventive, promotive, and curative health; assurance of health care accessibility for all segments of the population in general, and the availability of drugs, vaccines, equipment, supplies, etc. in particular.[93] In line with this policy, the FDRE Constitution has also urged the government to provide all Ethiopians access to public health and education, clean water, housing, food, and social security,[94] At the same time, the government is taking steps to promote science,

[87] Diksha Dubey, Bolar exemption: Indian perspective, 2017, available at https://iprlawindia.org/wp content/uploads/2017/12/cipra-research-paper.pdf (Last accessed on 13 August 2021)
[88] *Id*.
[89] *Id*.
[90] *Id*.
[91] Aayush Sharma, Bolar Exemption in India,2018, available at https://www.mondaq.com/india/patent/691036/bolar-exemption-in-india(Last accessed on 13 June 2021)
[92] *Id*.
[93] Thige G/Mariam, Kedir Tahir& Solomon G/Amanuel, Bringing Industrial and Health policies closer: Reviving Pharmaceutical Production in Ethiopia, Springer, 2016, p.70, available at https://link.springer.com/content/pdf/10.1007%2F978-1-137-54647-0_5.pdf (Last accessed on 13 June 2021)
[94]FDRE Constitution, Art. 41(4) &90(1)

technology and innovation, including the promotion of traditional knowledge (TK)/traditional medical knowledge(TMK) to solve the country's needs by formulating a National Science and Technology policy in the same year which was later revised in 2012.[95]

Moreover, the FDRE Constitution entitled every Ethiopian citizen to the right to the ownership of private property, including any intangible product produced by the creativity of an individual citizen.[96] In connection with this, the 1995 Ethiopia's patent proclamation stipulates the objective of encouraging local innovation/creativity, transfer and adoption of foreign technology, and fulfilling the nation's multidimensional demand like public benefits, including public health.[97] Accordingly, this proclamation made patent protection available for products including pharmaceuticals.[98] Yet while the proclamation has tried to give a place for public health[99], Ethiopia couldn't be free from the controversial issues of the problematic relationship between patents, including pharmaceutical patents and access to medicines that ought to be resolved with such a decision. The next sections take the issues of contention in turn for detailed analysis.

3.1. The Two Competing Interests and Bolar Exception under the Ethiopian Patent Law

To clear the ground for detailed elaboration of the issues, we need to note that, under the Ethiopian patent regime, exclusive rights are given to the patentee for a specific time as a reward for the inventor's contribution. Exclusive rights of the patentee as enshrined under the patent proclamation are not absolute as they are subject to some limitations.[100] As stipulated under Articles 25 and 26 of the proclamation, third parties have a right to exploit patented inventions without securing the consent of the patentee and the payment of equitable remuneration.[101] In this instance, the patent owners cannot claim their exclusive rights to exclude third parties exploiting the patented inventions. Exclusive rights are given to the patentee to achieve some overriding public policy objectives. Similarly, in certain circumstances, the exclusive rights of the patentee are limited to achieving some objectives.

[95] Thige G/Mariam, et al, *supra* note 93, p .79
[96] *See* FDRE constitution, Art.40 (1, 2) and 91(2).
[97] *see* FDRE constitution, Preamble
[98] *see* FDRE constitution, Art 14 & 18
[99] *See* FDRE constitution, Arts. 4, 25(1) (a & b), 25(2), 29-33.
[100] Ethiopian patent proclamation, Art.22.
[101] Ethiopian patent proclamation, Arts. 25 & 26.

It is clear that giving exclusive rights to the patentee and limiting the same have different objectives. One of the policy objectives for liming the exclusive rights of the patentee is public health objectives. The right to patent is granted for the promotion of invention in general and the protection of the patentee in particular. Accordingly, a monopoly right is given to the patentees to incentivize them for their invention. On the other hand, the grant of a patent negatively impacts society's interests and needs as it excludes them from exploiting the patented product. The problem is how to minimize the negative impact of patent grants by permitting third parties to exploit patented inventions without the patentee's consent to achieve some overriding objectives. In doing so, the Ethiopian patent proclamation has provided various limitations on the patentee's exclusive rights. To this end, Articles 25 and 26 of the proclamation lay down different grounds for the limitation of the patentee's exclusive rights. This shows how much the Ethiopian government has made effort to balance the two competing interests. Yet one of the newly emerging exceptions that has a tremendous role in ensuring access to patented medicines without the patentee's consent is missing in the Ethiopian patent regimes. This exception is known as the Bolar exception.

The absence of a specific provision on the Bolar exception under the Ethiopia patent regime would inevitably beg other questions as to whether the Bolar or regulatory approval exception may be justified under other exceptions of patent proclamation or otherwise. A patent confers upon its holder the right to exclude others from making, using, possessing, or selling the protected product. The exceptions under Article 25 of the Patent Proclamation do not include any reference to the use of patented substances to request marketing approval before the expiry of the patent term. Concerning pharmaceutical products, such authorization may only be obtained from a specialized regulatory body in Ethiopia, the Ethiopian Food, Medicine, and Healthcare Administration and Control Authority. Obtaining approval for the marketing of a drug might take time, and this could extend the monopoly rights of the patentee over the product.[102] Since the approval process may take time, the generic drugs would be available long after the expiry of the patent. This would certainly have important implications to access to drugs at affordable prices. That is why making a specific exception to use the patented invention for requesting regulatory approval has become an important issue.[103]

Turning to the rights of the patentees, one could see that the Ethiopian Patent Proclamation grants them the right to preclude any person from, among others, using

[102] Fikre Merkos, *supra* note 19, p.186
[103] *Id.*

the patented product.[104] The term "using" could be construed to include submitting a patented substance to secure regulatory approval. This may become an important bottleneck for generic manufacturers. By implication, this suggests that the inclusion of this specific exception in the Patent Proclamation would be an important measure to promote access to affordable medicine in Ethiopia.[105]

3.2. Bolar Exception *Visa Vis* the Scope of Scientific Research and Experimentation Exception under the Ethiopian Patent Law

The other important question is whether the scientific research and experimentation exception can be construed to justify a Bolar exception. Research and experimentation exception is useful in fostering pharmaceutical technological progress by exempting from patent protection; experimentation acts for purposes such as inventing around the initial invention, improving the invention, or evaluating the invention and determining validity.[106] Research exemption permits the use of a patented invention for experimental purposes without infringing the holder's rights.[107] The objective is to promote research and development in the country and ensure that patent rights must not impede or hinder higher education and research.

Looking into the Ethiopian Patent Proclamation in this light, it takes the position that the patentee's rights must not extend to "the use of the patented invention solely for scientific research and experimentation."[108] The justification for the existence of this exception is to facilitate the dissemination and advancement of technical knowledge.[109] It is argued that under the policy of the patent laws, both society and scientists have a legitimate interest in using the patent disclosure to support the advancement of science and technology, including pharmaceutical innovations.[110] The existence of this exception triggers further innovations by using patented inventions. However, the scope of this exception has been a subject of intensive policy debates

[104] *Id.*
[105] *Id.*
[106] MoniWekesa &Ben Sihanya, *supra* note 53, p. 32
[107] *Id.*
[108] Ethiopian patent proclamation, Art. 25.1(b)
[109] ". . . as an illustration, Article 30-type exceptions in national patent laws – the use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention is disclosed to the public."
[110] Israel Begashew, *supra* note 22, P.63

and litigation.[111] The scope of the exception remains unknown as it has never been subjected to interpretation in Ethiopia. In particular, it is not clear whether the exception is limited only to experiments or research of non-commercial nature or if it could, on a case-by-case basis, extend to experiment or research even with some commercial end.[112]

Again, the use of the term *"solely"* under the same provision tends to limit the scope of the exception only to scientific research and experimentation. Yet the objective of the scientific and experimentation exception is not clearly articulated, and this opens a room to invoke this room of using the exception for other extended purposes connected to research and experimentation. Accordingly, as the objective of the exception is not limited by patent proclamation, one can argue as though the use of the patented invention to get scientific information about the product, and ultimately to produce the product upon the expiry of the patent right over the product is covered under the research and experimentation exception. This may take us to the experiences of other countries.

Most countries of the world do not make a distinction between the applicability of research exceptions based on scientific purposes and research that have the immediate purpose of generating information for securing the marketing approval of the product.[113] This has been for example true in continental Europe. However, due to the confusion caused by such trends, the European Commission introduced directive 2004/27/ that exempts acts done for regulatory approval purposes.[114] In line with this, many countries have moved to adopt a separate exception in the context of pharmaceutical clinical trials.[115] For instance, under Article 25/1(f) of Botswana's industrial property Act, it is stipulated that rights conferred by a patent shall not extend

[111] For instance, *Roche Products Inc. v. Bolar Pharmaceutical Company* case can be a good example.

[112] Fikre Markos Marco, Ethiopia's World Trade Organization Accession and Maintaining Policy Space in Intellectual Property Policy in the Agreement on Trade-Related Aspects of Intellectual Property Rights Era: A Preliminary Look at the Ethiopian Patent Regime in the Light of the Agreement on Trade-Related Aspects of Intellectual Property Rights Obligations and Flexibilities, *The Journal of World Intellectual Property*, Vol. 15, No. 3, (2012), P.183

[113] Evans Misati & Kiyoshi Adachi, The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda, UNCTAD- ICTSD Project on IPRs and Sustainable Development policy, UNCTAD, March 2010, p.4, available at https://unctad.org/system/files/official-document/iprs_in20102_en.pdf (Last accessed on 13 June 2021)

[114] *Id.*

[115] *Id.*

to acts done regarding patented invention for purposes of compliance with pharmaceuticals regulatory marketing approval procedures.[116]

Further, countries that opt to regulate the Bolar exception under the research and experimentation exception have an express provision to that effect. Particularly, some countries have expressly combined the Bolar and experimental or scientific research exception into a single provision.[117] Coming back to the Ethiopian patent proclamation, nothing is provided as to whether the research and experimentation exception is applied to both research for scientific purposes and research that have the immediate purpose of generating information for securing the marketing approval of the product or otherwise. From the experiences of other countries, it is clear that the absence of clarification on the scope of application of the exception would inevitably create confusion on the practical implementation of the exception on pharmaceutical products. Hence, the use of the patented product for getting market approval may not be justified under the research and experimentation exception.

3.3. The Need for Integrating the Bolar Exception into the Ethiopian Patent Regime

As outlined in the last sections, the Bolar exception is an essential mechanism in facilitating the production and accelerating the introduction of generic substitutes on patent expiry.[118] Particularly, it has important implications for developing countries in two ways. First, it allows such benefits for countries that are currently or potentially producers of generic medicines. Second, even where they are not likely to be producers of medicines, the United Kingdom Commission on Intellectual Property Rights has recommended that developing countries to include a Bolar-type exception within their domestic law to enable the products of a foreign company to gain regulatory approval and, to enter the market soon after the expiry of the patent.[119]

Therefore, it is imperative for Ethiopia to incorporate Bolar exceptions to the substantive parts of the patent regime. This move can be justified on many grounds. First, the Bolar exception is important from the point of view of promoting access to affordable medicine. As far as granting a patent for pharmaceutical products is

[116] *Id.*, P.52.

[117] The experiences of Argentina, Bosnia Herzegovina, Croatia, Hungary, Jordan, Portugal, Slovakia, and Spain can be mentioned as an example as the issues of bolar exception, and experimental or scientific research exception are provided by a single provision.

[118] Integrating intellectual property rights and development policy, Commission on Intellectual Property Rights, London, September 2002, p.50, available at http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf(Last accessed on 13 June 2021)

[119] *Id.*

concerned, the government should not confine itself to encouraging research and development. It needs to see it from the perspective of making the pharmaceutical products or medicines affordable and accessible in the market to ensure the protection of public health. Suppose the manufacturer of generic products is allowed to get market approval before the expiry of patent protection. In that case, it will open a room for them to make it avail on the market immediately upon the expiry of the protection. This would inevitably lower product prices and enable the poor or needy parts of society to access medicine at lower prices. Contrary to this, if there is no bolar exception, it would take a long time to avail the generic drugs on the market even after the expiry of the patent protection as the approval process may take time. This would result in the de facto extension of patent protection and have important implications on access to drugs at affordable prices. Hence, providing Bolar exceptions concerning pharmaceutical patents sometimes becomes inevitable to save the lives of the populace by ensuring accessibility of drugs at affordable prices as it can be used to break up monopolies and cartels, which are some of the abuses of patents rights.

Second, incorporating such kinds of exceptions is a practice of aligning domestic laws with the international patent regime. As it has been mentioned, the Bolar exception is consistent with Article 30 of the TRIPS agreement. Further, it is important to note in this connection that Ethiopia has been making moves to join WTO and the country despite the arguments against and in favor of joining WTO has resumed its journey to finalize the membership. As per the membership procedures of the WTO, a country that has applied for membership has to "bring its house in order" and ensure that its IP-related trade and legal regime is compatible with TRIPS. The patent is one of the areas of protection under the TRIPS Agreement. The experience of certain countries that had acceded to the WTO substantiates the argument that making national patent laws compatible with TRIPS is a prerequisite to the attainment of this goal.[120]

As the developed countries already had TRIPS standards and IP institutions in place, they did not need to make significant amendments or revise their domestic IP laws and administration to implement TRIPS.[121] On the other hand, implementing TRIPS in developing and least developed countries may require them to raise their IP standards (increasing the terms and scope of protection).[122] As such, it may involve complex reforms to update or redraft existing laws, adopt new laws, and promulgate new

[120] Abdulkader Mohammed Yusuf, Globalization of Patent Laws through Trade Agreements, and Pressures on Ethiopia's Patent Regime: The Passenger behind the Whee*l, Mizan law review*, vol.12, NO.1, (2018),p.86

[121] Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual property perform in developing countries*, (Oxford university press), (2009)

[122] *Id.*

administrative regulations and guidelines.[123] Thus, notwithstanding the special and differential treatment and certain flexibilities that Ethiopia is entitled to, its patent regime has to be consistent with TRIPS.[124] Hence, providing a Bolar exception would play its role in paving the way for the country to join WTO.

Third, providing such exceptions plays a vital role in developing and fostering a local generic pharmaceutical industry in Ethiopia. As it stands now, let alone the patented invention, the drug industries of Ethiopia have not been using the invention that entered the public domain. The development of the Ethiopian local pharmaceuticals manufacturing sub-sector has been very limited in production capacity, technology acquisition, employment opportunities, and investment.[125] Most local manufacturers are not in conformity with international good manufacturing practices (GMP), and no single product has prequalified for WHO standards.

Yet it is important to note that the Ethiopian government took several steps to incentivize the development of the local pharmaceutical industry during the past five years, with a noticeable positive impact.[126] One of such steps is the launching of a national strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (from 2015-2025).[127]This strategy has played an important role, including laying the groundwork for developing the Ethiopian pharmaceutical industry. Hence, since the patent owner's exclusive rights are not affected during the patent term, its incorporation into patent regimes is sufficiently justified.

Finally, sometimes delay in the development of important technological tools is caused due to deadlocks between the improver and the original patentee. In the absence of this exception, the patent holder will have the exclusive right to exclude scientific research, and in this case, the patent system by itself inhibits the progress of science and technological knowledge. Bolar exception can effectively resolve these deadlocks as it contributes to generating rapid technical progress.

Despite all these justifications for integrating the Bolar exemption into the Ethiopian patent proclamation, the mere adoption of the Bolar exception may not guarantee the attainment of its objective, i.e., ensuring access to medicine. Experiences from other

[123] *Id.*
[124] Abdulkader Mohammed, *supra* note 120, p.86.
[125] National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia(2015-2025), Developing the pharmaceutical industry and improving access, https://www.who.int/phi/publications/Ethiopia_strategy_local_poduction.pdf?ua=1.(last accessed July 25, 2021)
[126] *Id.*
[127] *Id.*

countries show that attaining this goal requires actual implementation of this exception. If we look at the experiences of Zimbabwe, early working of an invention is allowed as early as six months before the expiry of the patent.[128] In the absence of such stipulation, there may be a chance that a generic competitor would be able to start its bioequivalence and other testing/trials only after patent expiry. This, in turn, would result in a de facto extension of patent protection. Therefore, Ethiopia must provide a clear stipulation on the period from which the generic competitor would be allowed to start its bioequivalence and other testing or trials to obtain regulatory approval.

Concluding remarks

Protecting patients and facilitating adequate health services is one of the major governmental imperatives in modern policy moves. Such obligation is clear from various international treaties such as the Universal Declaration of Human Rights (UDHR) and the African Charter on Human and Peoples' Rights (ACHPR). However, the strict protection of patent rights may result in total denial of access to public health or be detrimental to the survival of human beings. Accordingly, there is a need to protect patent rights without affecting access to medicines. The extreme choice of protecting patent rights or public interest to access patented invention, especially medicines, would directly affect abrogating the protection given for either of the two interests. Thus, it would be better to find a solution that could balance two competing interests extensively discussed in this paper. One of the avenues by which the two extremes can be balanced is by incorporating the Bolar exception into domestic legislation.

Bolar exception is firmly grounded in WTO case law. This exception, among others, permits clinical trials and other preparatory activities "on" or "with" a patented pharmaceutical product before the expiry of the patent to enable generic competitors to apply for marketing approval of the competing product(s) as soon as possible after the expiry of the patent. This allows generic manufacturers to prepare production and regulatory procedures before patents expire so that products can be ready for sale as soon as the patent expires, rather than going through the lengthy preparatory process only after the patent expires. Owing to such advantages in ensuring access to medicines, a considerable number of countries in the world have integrated the Bolar exception into their domestic laws and benefited from such advantages of the exception. The experiences of South Africa, India, and the USA can be mentioned as examples.

[128] *See* Zimbabwe's Patents Act of 1996 as amended in 2002, Section 24 (3).

Turning to the context of Ethiopia, one could see that the FDRE constitution recognizes the right to public health and property right. Further, to balance the patentee's rights and public interest over health rights, the Ethiopian patentee regime sets various limits to the exclusive rights of the patentee. Yet, concerning the Bolar exception, the patent proclamation and its implementing regulations have no explicit provision. Further, the research or experimentation exception envisaged under Ethiopian patent regimes cannot justify the Bolar exception via interpretation. The historical, theoretical, and empirical lessons from other countries suggest that incorporating the Bolar exception could have an instrumental role in ensuring access to medicine.

It fundamentally balances two competing rights, namely the exclusive rights of the patentee and the right to public health recognized under the FDRE constitution. As such the patent owner's exclusive rights are not affected during the patent term and its incorporation into patent regimes is sufficiently justified. Further, the Bolar exception plays a key role in promoting technology transfer, preventing abuse of intellectual property, and protecting public health. Therefore, based on the conclusion drawn from the analysis., Ethiopia should reform its patent law and incorporate an exception that allows third parties to undertake without the authorization of the patentee acts in respect of patented products necessary for obtaining regulatory approval for the product just on the day of or immediately after the expiry of patent protection.

Particularly, the author would recommend Ethiopia to integrate into the patent proclamation, a provision that stipulates:

a) It shall not be an act of infringement of a patent to make, use or import the patented invention on a non-commercial scale and solely for uses reasonably related to the development and submission of information required under any law in Ethiopia or a country other than Ethiopia, that regulates the manufacture, use, sale or import of any product.

b) Notwithstanding what is provided under sub(a), the generic competitor shall not start early working on an invention as early as six months before the expiry of the patent protection.