Grounds for Compulsory License with Selected Cases Granted for Pharmaceuticals

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I. INTRODUCTION

Out of a desire to foster and regulate international commerce by codifying certain principles of intellectual property law that would govern the international community, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was born.[1]

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1. "[A]dequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights." Agreement on Trade-Related Aspects of Intellectual Property Rights, pmbl. 1(a), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade

Ratified in 1995, this agreement sets forth the framework for an international intellectual property law requiring all members of the World Trade Organization (WTO) to adhere to the minimum standards contained therein.[2] As most countries were members of the WTO, the TRIPS Agreement effectively codified a global standard for the intellectual property regime.[3]

Although the TRIPS Agreement does oblige its signatories to adhere to these aforementioned standards, the agreement contains several crucial flexibilities (compulsory licensing, parallel importation, limits on data protection, use of broad research and other exceptions to patentability, etc.); in particular, the Preamble recognizes "the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base."[4] These flexibilities were clarified and detailed in the Doha Declaration[5] (TRIPS Agreement and Public Health) of 2001 and again in 2003 by the General Council in its Decision on the Implementation of Paragraph 6 of the Doha Declaration.[6]

Both the Doha Declaration and its decision were welcomed by the international community. The World Health Assembly has encouraged and urged all members to amend their national legislation as a means of utilizing all the flexibilities found in the TRIPS Agreement.[7]

Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1125, 1197 [hereinafter TRIPS Agreement]; *see also Overview: The TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Apr. 13, 2018) (discussing the Preamble's objectives in the context of articles 7 and 8).

2. "The TRIPS Agreement is a minimum standards agreement, which allows Members to provide more extensive protection of intellectual property if they so wish." *Overview: The TRIPS Agreement*, *supra* note 1.

3. *Id.*

4. "[T]heir need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application . . . ." TRIPS Agreement, *supra* note 1, art. 66.1 (expounding upon this flexibility by again recognizing the needs of lesser-developed countries).

5. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

6. Decision of the General Council, Implementation of Paragraph of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003); *see also Meaning of Flexibilities*, WORLD INTELL. PROP. ORG., http://www.wipo.int/ip-development/en/agenda/flexibilities/meaning_of_flexibilities.html (last visited Apr. 12, 2018) (discussing the effect of the Doha Declaration on the understanding of the flexibilities provided by the TRIPS Agreement).

7. Frederick M. Abbott & Rudolf V. Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision* 2 (World Bank Working Paper No. 61, 2005), http://documents.worldbank.org/curated/en/173701468337882214/pdf/334260rev0pub.pdf.

One important flexibility is the agreement's provision for a compulsory license, which is a "legal vehicle whereby a government grants to itself or to a third party the right to produce or to import a patented product without authorization of the patent holder or right holder."[8] The provision of compulsory licenses is a crucial element in a health-sensitive patent law.[9] Such licenses may constitute an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention.[10]

Compulsory licenses have two impacts; first, a wider availability of medicines at affordable prices.[11] Primarily, governments issuing compulsory licenses aim at reducing the prices of certain patented products, either semi-voluntarily by the patent rights holders themselves or through generic competition.[12] Under the pressure of the issuance of a compulsory license, the patent holders usually reduce the prices for their own products themselves. This can be observed both after or before a compulsory license is issued.[13] Often the threat of a compulsory license when backed up with political will and the capacity to procure the drugs in question through alternative means often is enough to persuade the patent holder to negotiate a significant price reduction.[14]

The second impact is for the promotion of the local generic industry.[15] Issuance of a compulsory license will give the chance for the local industry to manufacture the generic copy of the patented product before the elapse of the patent period.[16]

Article 31 of the TRIPS Agreement lists a set of mandatory conditions that must be fulfilled prior to the issuance of any compulsory license.[17] These conditions in the TRIPS Agreement operate as a floor, rather than a ceiling; that is, while signatory countries are obliged to enforce these conditions, they are free to impose additional conditions that must be met before a compulsory license will be issued.[18] For

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8. *Id.* at 7.
9. *Id.*
10. CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 94 (2000), http://www.eldis.org/vfile/upload/1/document/0708/DOC9006.pdf.
11. *Id.*
12. *Id.*
13. *Id.*
14. *Id.*
15. *Id.*
16. *Id.*
17. *Id.*
18. *Id.*

example, a country may enact national legislation that places obligations beyond those set forth in the TRIPS Agreement upon any entity seeking a compulsory license.[19] Similarly, bilateral agreements may impose supplemental preconditions upon the application process; indeed, many countries have entered into such agreements.[20] In most cases, these bilateral agreements have operated to limit the number of compulsory licenses issued.[21] The U.S.-Jordan Free Trade Agreement is one of these bilateral agreements.[22] In particular, article 20 of this Agreement has limited the grounds on which a compulsory license will be granted to those mentioned therein.[23] Based on that, article 22 of the Jordanian patent law was amended in 2001 to add language exclusively to limit the grounds on which compulsory license can be issued.[24]

This Article, first, discusses the international framework for compulsory licenses. Second, this Article discusses the most recognized grounds for issuing compulsory licenses and provides examples of countries that have implemented each respective ground in their national legislation with an emphasis on the Jordanian, Egyptian, and Indian patent laws. Third, this Article provides cases from different countries that have issued compulsory licenses for pharmaceutical products. Those cases will show the effectiveness of the compulsory licensing scheme in reducing the prices of the patented drugs or making available generic drug with affordable prices. Finally, this Article will emphasize the importance of reviewing Jordan's patent law to make full use of this flexibility and to learn from the experience of other countries in this

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19. *Id.*

20. *Id.*

21. *Id.*

22. Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free-Trade Area, U.S.–Jordan, Oct. 24, 2000, 41 I.L.M. 63 (2002) [hereinafter U.S.-Jordan FTA].

23. *Id.* art 4.

> Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:
>
> (a) to remedy a practice determined after judicial or administrative process to be anti-competitive;
>
> (b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or
>
> (c) on the ground of failure to meet working requirements, provided that importation shall constitute working.
>
> Where the law of a Party allows for such use pursuant to sub-paragraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention.

24. *Id.*

field, which will benefit the local pharmaceutical industry and promote better access to medicine.

II. THE INTERNATIONAL FRAMEWORK

Under the Paris Convention for the Protection of Industrial Property, a country of the Union may provide for compulsory licenses to prevent the abuses that might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.[25] An applicant may not apply for a compulsory license on the grounds of failure to work or insufficient working at any time before either the expiration of the four-year period following the filing of the patent application or the three-year period.[26] This is subsequent to the date that the patent was granted, whichever period expires last.[27] Even where the requisite period has elapsed, the application for a compulsory license will be refused if the patentee is able to provide legitimate reasons justifying the inaction.[28] If the patentee is unable to provide legitimate reasons, then the application for the compulsory license will be granted; such a compulsory license must be nonexclusive and nontransferable.[29]

As discussed earlier, the provision of the TRIPS Agreement regarding compulsory licensing only sets up procedural minimum requirements that WTO members need to adhere to when issuing compulsory licenses on patented products and processes; thus, the grounds for issuing compulsory licenses that are mentioned under the TRIPS Agreement are not exhaustive.[30] They were incorporated in the TRIPS Agreement only in order to clarify that, in these cases, certain procedural requirements are relaxed.[31] For instance, article 31 makes specific reference to cases of national emergency and other situations of extreme urgency, and, in such cases, an applicant for a compulsory license may submit an application without having to conduct prior negotiations with the patentee.[32]

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25. "Failure to work: manufacture or to market the patented drug in the local market." Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305.

26. *Id.*

27. *Id.*

28. Id.

29. Coenraad Visser, World Intellectual Property Organization, Patent Exceptions and Limitations in the Health Context Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights, WIPO SCP/16/REF/SCP/15/3, Annex V, at 4 (Feb. 3, 2011), http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex5.pdf.

30. TRIPS Agreement, *supra* note 1, art. 31.

31. *Id.*

32. *Id.*

The Doha Declaration, an agreement designed to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the TRIPS Agreement, confirmed that WTO members have full freedom to determine the grounds for the grant of compulsory licenses.[33] Thus, countries can incorporate into their national laws other grounds as appropriate to protect public health and ensure access to affordable medicines, including grounds related to a specific public health concern.[34] With the Doha Declaration, WTO Member States further affirmed that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health—in particular, to promote access to medicines for all.[35] In this connection, they reaffirmed their right to use the provisions in the TRIPS Agreement to the fullest extent, which provide flexibility for this purpose.[36]

In the case of government use, in which governments permit them and their contractors to make noncommercial public use of the patents without the consent of the rights holders, it would appear that there is similar freedom to stipulate grounds for government use of patents.[37] The primary distinction between public sector and private sector compulsory licenses concerns the nature or purpose of the use of the patent.[38] Government use is confined to public, noncommercial purposes; however, since this term is not defined in the TRIPS Agreement, it has been suggested that omission allows for the policy space to interpret the term in favor of public health.[39] Under this approach, "public, non-commercial use" could be interpreted to allow for charging a private entity with exploiting a patented invention, where such a measure would benefit the public.[40]

Finally, the Doha Declaration addressed the problem that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.[41] They initiated the Council for TRIPS to find a prompt solution to this problem, which was

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33. Cecilia Oh, *Compulsory Licenses: Recent Experiences in Developing Countries*, 1 J. INT'L. PROP. MGMT. 1, 24 (2006).
34. *Id.*
35. *Id.*
36. *Id.*
37. *Id.*
38. *Id.*
39. *Id.*
40. *Id.*
41. Doha Declaration, *supra* note 5.

agreed upon in a 2003 WTO Decision and a 2005 TRIPS Amendment Decision to enable a compulsory licensee to export up to 100% of a production to a country that lacks manufacturing capabilities of medicinal drugs.[42]

III. CANADA

As a response to calls from Canadian civil society organizations and the United Nations Special Envoy on HIV/AIDS in Africa, the Government of Canada committed to enacting legislation implementing the WTO Decision through requisite reforms to Canadian law.[43] Subsequently, in 2005, Canada became the first country to pass legislation implementing the Waiver Decision, which permitted Canadian producers to acquire compulsory licenses in order to produce patented drugs for countries requesting these drugs.[44]

IV. GROUNDS FOR COMPULSORY LICENSE

The text of the Doha Declaration clearly allows an individual country to determine the substantive grounds for issuing a compulsory license: "[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[45] Nevertheless, this freedom has been limited under certain Free Trade Agreements (FTA), as in the FTA between the United States and Jordan (U.S.-Jordan FTA), in which the grounds for issuing compulsory licenses were limited.[46] Based on this agreement, Jordan amended its Patent Law Act to include the word "exclusively" in article 22.[47]

It is important to highlight that this right to grant compulsory licenses does not depend on a state of emergency or other circumstances of extreme urgency (in which case, a legislator may loosen the procedures so that a compulsory license can be granted more easily).

The following grounds for issuing compulsory licenses are widely recognized around the world, in one form or another, and they are all fully consistent with the TRIPS Agreement.

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42. Decision of the General Council, *supra* note 6, para. 6.

43. Richard Elliott, *Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export*, 1 J. INT'L. PROP. MGMT. 1, 96 (2006).

44. Visser, *supra* note 29, at 15.

45. Doha Declaration, *supra* note 5.

46. U.S.-Jordan FTA, *supra* note 22.

47. 1999 قانون براءات الاختراع رقم 32 لسنة [Law No. 32, OFFICIAL GAZETTE OF JORDAN], no. 4389, 4256 (11 Jan. 1999).

A. Control of Abuse and Anticompetitive Practices

A compulsory license is granted to control abuses of the patent holder's exclusive rights. The following are examples of the anticompetitive behavior of the patent holder:

- Excessive pricing;
- Preferential treatment regarding prices and conditions of sale;
- Failure to supply the domestic market with the patented product or supplying it on prohibitive terms;
- Stopping production of the patented product given the production capacity and market demand; and
- Exercising legally conferred rights in a manner that adversely affects the transfer of technology.[48]

If anticompetitive behavior has been determined by a judicial or administrative process, then the applicant for the compulsory license is not required to approach the patentee first in an effort to conclude a voluntary license on reasonable commercial terms and conditions.[49] Certain countries, such as India, permit the licensee to export the patented product.[50] Jordan has provided this ground in their patent law, in article 22.C: "[i]f it is decided judicially or administratively that the Patentee practices his rights in a manner that deters third parties from fair competition."[51]

Egypt also addressed this ground with examples of the cases that are considered anticompetitive practices of the patent holder:

> If it is determined that the patent owner has abused of or exercised the rights conferred by the patent in a manner that is contrary to fair competition, such as: a) Fixing exorbitant prices for the patented products or preferential treatment of agents with regards to prices and sales conditions. b) Failure to supply the local market with the patented product, or supplying it under prohibitive terms. c) Stopping the production of the patented item or its production in a disproportionate matter, given the production capacity and the market needs. d) Undertaking acts or practices which have adverse effect on the free competition according to the

48. WORLD INTELLECTUAL PROP. ORG., CDIP/4/4 REV./STUDY/INF/5, SURVEY ON COMPULSORY LICENSES GRANTED BY WIPO MEMBERS TO ADDRESS ANTI-COMPETITIVE USES OF INTELLECTUAL PROPERTY RIGHTS (Oct. 4, 2011), http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4_rev-main1.pdf.

49. Law No. 32 of 1999 (Jordan).

50. PATENT OFFICE OF INDIA, QUESTIONNAIRE ON EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS 13-14 (n.d.) (on file with author).

51. Law No. 32 of 1999 (Jordan).

> prescribed legal norms. e) Exercising of the rights conferred by this Law in a manner that adversely affects the transfer of technology.[52]

In addition to Jordan and Egypt, the following countries have applied this ground: Argentina, Bahrain, Brazil, Canada, Chile, Pakistan, The Philippines, Saudi Arabia, and Uruguay.[53]

B. National Emergency and Other Situations of Extreme Urgency

Compulsory licenses may be issued in cases of national emergency or other circumstances of extreme urgency.[54] In the case of national emergency, which is usually declared by the government in an official decree, such as when urgent public health needs arise as resulting from a natural catastrophe, war, or epidemics,[55] lack of access to medicine may represent the basis of extreme urgency.[56] Each country is free to expand the definition of national emergency and extreme urgency in their legislation.[57]

This ground is expressed in a detailed way in article 92 of the Indian Patent Act, in which cases emergency and extreme urgency may include "public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics."[58] Similarly, both Mozambique and Zimbabwe incorporated this ground in their national legislation[59] and utilized these provisions to issue compulsory licenses for HIV/AIDS products in 2004 and 2002, respectively.[60]

This ground is expressed in the Jordanian patent law as emergency only, thereby, excluding extreme urgency cases from consideration: "[i]f the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible."[61]

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52. Law No. 82 of 2002, AL-JARIDA AL-RASMIYYA, vol. 22, bis. 2, art. 23(5) (June 2002) (Law on the Protection of Intellectual Property Rights) (Egypt).

53. Visser, *supra* note 29, at 48.

54. Oh, *supra* note 33, at 25-29.

55. *Id.*

56. Id.

57. Id.

58. The Indian Patents Act, No. 37 of 1970, INDIA CODE (2017).

59. Mozambique Patent Law, art. 70.1 (b) (1999); Zimbabwe Patents Act, ch. 26:03, art. 34-45 (2002).

60. Oh, *supra* note 33, at 25-29.

61. 1999 لسنة 32 قانون براءات الاختراع رقم [Law No. 32, OFFICIAL GAZETTE OF JORDAN], art. 22(A) (11 Jan. 1999).

Egyptian law provides for a compulsory license in "[c]ases of emergency or circumstances for extreme urgency."[62]

Bahrain, Brazil, Chile, China, Malaysia, The Philippines, Saudi Arabia, and Zambia are all among the countries, which expressly state this ground in their patent laws.[63]

C. Lack or Insufficiency of Working

Most often, the non-working ground is assessed after the elapse of a discrete period, such as the four-year period following the date of the application's submission or the three-year period since the grant of the patent.[64] The following are examples of how this ground is utilized in numerous patent laws, including the Indian Patent Act:

- The patented product has not been worked, or insufficient working by the patent holder in the country;
- The reasonable requirements of the public with respect to the patented product have not been satisfied; and
- The patented product is not available to the public at a reasonably affordable price.[65]

It is still debatable as to whether or not domestic demand should be met through local working (manufacture in the country) only, or whether meeting domestic demand through importation would be sufficient.[66] Some countries clearly require local manufacture, such as Egypt,[67] while others leave the matter open in their national laws,[68] with a minority, including Jordan, clearly stating that importation represents working.[69]

Adopting this latter perspective, in 2001, the United States Trade Representative (USTR) and the WTO jointly questioned whether certain provisions of the Brazilian patent law violated the TRIPS Agreement.[70] Under the Brazilian law, the patent holder is required to work the patented product locally within Brazil; otherwise the issuance of a

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62. Law No. 82 of 2002, AL-JARIDA AL-RASMIYYA, vol. 22, bis. 2, art. 23(1)(b) (June 2002) (Law on the Protection of Intellectual Property Rights) (Egypt).
63. Visser, *supra* note 29, at 15.
64. *Id.* at 11-13.
65. *Id.*
66. *Id.*
67. Law No. 82 of 2002, vol. 22, bis. 2, art. 23(4) (Egypt).
68. Visser, *supra* note 29, at 11-13.
69. *Id.*
70. *Id.*

compulsory license is based on the failure of working.[71] The USTR argued that the definition of failure to be worked as connoting a failure to manufacture or incomplete manufacture of the product or a failure to make full use of the patented process.[72] Eventually, both countries reached a settlement and the United States withdrew the complaints.[73]

Regarding this ground, Jordan's patent law holds that:

> [i]f the patentee doesn't exploit it or exploits it insufficiently before the elapse of 4 years as of the application date or 3 years as of the granting date, the period to be applied is the one that elapse later. However, the Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee exploitation. 2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the related International Conventions, the importation of the subject goods for the patent to the kingdom shall be deemed utilization of the patent.[74]

Jordan's law also states that importation is considered as working.[75] While, both Egypt's and India's patent law clearly delineate the cases that are to be deemed as non-working.[76] This clarity is illustrated in a 2012 case from India, discussed below, that a compulsory license was issued for the anticancer drug Sorafenib based on this ground.[77] In Egypt, patent law article 23(2) specifies that inadequate quantities is considered as failure to work and in subparagraph four of the same article mentioned that the exploitation of patent shall be through manufacturing.[78]

Additional countries providing for compulsory licenses on this ground include Algeria, Argentina, Bahrain, Bangladesh, Canada, Ethiopia, Ghana, Indonesia, Kenya, Lebanon, Malaysia, Mexico, Morocco, Nigeria, The Philippines, Qatar, Saudi Arabia, South Africa, Tanzania, Thailand, Tunisia, Uruguay, and Zambia.[79]

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71. Decreto No. 9.279, de 14 Maio de 1996, DIARIO OFICIAL A UNIAO [D.O.U.] Brazilian Patent Law on Industrial Property, Law No. 9,279, art. 68 (May 14, 1996).

72. *Id.*

73. Visser, *supra* note 29, at 11-13.

74. 1999 لسنة 32 رقم الاختراع براءات قانون [Law No. 32, OFFICIAL GAZETTE OF JORDAN], art. 22(b)(1) (11 Jan. 1999).

75. *Id.*

76. Law No. 82 of 2002, AL-JARIDA AL-RASMIYYA, vol. 22, bis. 2, art. 23(2) (June 2002) (Law on the Protection of Intellectual Property Rights) (Egypt); The Indian Patents Act, No. 37 of 1970, arts. 84-85, INDIA CODE (2017).

77. *Id.*

78. Law No. 82 of 2002, vol. 22, bis. 2, art. 23 (Egypt).

79. Visser, *supra* note 29, at 13.

D. Public Interest

Compulsory licenses may be issued in the public interest when they address environmental, public health, national security, or economic development concerns by promoting third-parties.[80] Many countries have used this ground to issue compulsory licenses; for example, Canada frequently used this ground to issue compulsory licenses with the objective of promoting its generic pharmaceutical industry.[81]

In Jordan's patent law, this ground is expressed in the following article: "[i]f the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible."[82]

Egypt, too, incorporates this ground in its national legislation, defining the public interest as "includ[ing] the preservation of national security, health, environment and food safety" and "[s]upport of national efforts in vital sectors for economic, social and technological development, without unreasonable prejudice to the right of the patent owner and taking into consideration the legitimate interests of third parties."[83]

The Indian Patent Act addresses the public interest criterion by pointing out how this interest could be infringed:

> that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India; (e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health.[84]

Other examples can be found in the patent laws of Algeria, Argentina, Brazil, Chile, China, Ghana, Japan, Malaysia, Morocco, Mozambique, Pakistan, The Philippines, Saudi Arabia, South Africa, Tanzania, and Uruguay.[85]

E. Government Use

Compulsory licenses may be imposed by governments to permit them and their contractors to make noncommercial public use of the

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80. *Id.*
81. *Id.*
82. قانون براءات الاختراع رقم 32 لسنة 1999 [Law No. 32, OFFICIAL GAZETTE OF JORDAN], art. 22(A) (11 Jan. 1999).
83. Law No. 82 of 2002, art. 23(4) (Egypt).
84. The Indian Patents Act, No. 37 of 1970, INDIA CODE (2017).
85. Visser, *supra* note 29, at 29.

patents without the consent of the right holders.[86] Government use licenses differ from so-called ordinary compulsory licenses concerning the objectives of each license.[87] Government use licenses are exclusively granted to promote public interests either by the governments themselves or by third parties acting for or on behalf of the governments.[88] However, the private party acting for or on behalf of the government is not precluded from making profit; private operators cannot be expected to carry out their activities without any commercial benefits.[89] What is dispositive in this context is not the (commercial) intermediate activity required to produce the needed drugs, but instead the noncommercial end use of that product by the government, e.g., not-for-profit distribution of medicines through a public health program.[90]

Examples of express provision for government use can be found in the patents laws of Canada, India, Kenya, Lebanon, Mexico, Nigeria, Tanzania, Tunisia, United Kingdom, United States, Zambia, and Zimbabwe.[91]

F. Export Compulsory License

The decision adopted by the WTO General Council in 2003 implements interim waivers with regard to the obligations set out in the TRIPS Agreement.[92] In this decision, the Council approves a new compulsory license for the exportation of pharmaceutical products to countries lacking the capacity to manufacture needed drugs under their own compulsory licenses.[93] In 2005, Canada was the first country to amend its national Patent Act to implement this decision.[94] Article 21 of the Canadian Patent Act describes the conditions for granting such licenses; the content of the application; the form and content of authorization; the quantity; the disclosure of information on website; the royalty; the export notice' duration; the renewal; and the termination.[95] Also, Schedule 1 contains the patented products that can be authorized

86. *Id.*
87. *Id.*
88. *Id.*
89. *Id.*
90. *Id.* at 15.
91. *Id.*
92. CORREA, *supra* note 10.
93. *Id.*
94. Canada Patent Act, R.S.C. 1985, c. P-4.2011.
95. *Id.*

for this purpose, and Schedule 2 lists the countries to which they can export.[96]

From India's patent law:

> Compulsory license for export of patented pharmaceutical products in certain exceptional circumstances.—(1) Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.
>
> (2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory license solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.
>
> (3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to Pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.[97]

Jordan later added this ground to its patent law in 2007.[98]

G. Refusal to Deal

Refusal to deal arises when the patent holder refuses to voluntarily license its rights to a third party on reasonable commercial terms.[99] Generally such behavior on the part of the patent holder is not considered abuse.[100] U.S. case law has held that the patent holder is free to license or not, whether or not a third party offers commercially reasonable terms.[101] The European Court of Justice has issued a similar opinion, although it held that in certain exceptional circumstances this refusal could be considered as abuse[102]—a compulsory license will be issued if the refusal will negatively affect the availability of the patented product or when it would block technology transfer.[103] The latter justification for issuing a

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96. *Id.*

97. The Indian Patents Act, No. 37 of 1970, INDIA CODE (2017).

98. قانون براءات الاختراع رقم 32 لسنة 1999 [Law No. 32, OFFICIAL GAZETTE OF JORDAN], (11 Jan. 1999).

99. United Nations Conference on Trade and Development, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide*, chs. 3.4.2 to 3.4.3, UNCTAD/DIAE/PCB/2009/19 (2011), http://unctad.org/en/Docs/diaepcb2009d19_en.pdf.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

compulsory license is predicated on the idea that one of the central objectives of patent protection is to promote technological innovation and dissemination.[104] Under the U.S.–Jordan FTA, this option is no longer available.[105]

Egyptian patent law, however, does allow for refusal to deal, which is expressed as:

> (3) Where the patent refuses to grant license to a third party seeking the exploitation of the invention, whatever the purpose of the exploitation, and despite the offer of suitable terms and the lapse of reasonable negotiation time. In this case, the party requesting the non-voluntary license shall provide evidence that he has made serious efforts to obtain a voluntary license from the patent owner . . . (6) Where the exploitation of an invention by the legitimate patent holder requires inevitably the use of another invention, underlying concrete technical advance as well as technical and economic significance compared to the other, he shall be entitled to obtain a non-voluntary license for the exploitation of the other invention, in which case the other patent holder shall equally have the same right.[106]

Other examples of refusal to deal provisions can be found in the legislation of, amongst others, Argentina, China, Indonesia, Pakistan, The Philippines, Qatar, Saudi Arabia, South Africa, and Uruguay.[107]

V. CASES OF GRANTED PHARMACEUTICAL COMPULSORY LICENSE

The following examples show that not only developing countries but also developed countries have made and continue to make use of compulsory licenses to regulate competition, ensure affordable prices, and promote a group of national interests.

A. Canada

Prior to its accession to the North American Free Trade Agreement (NAFTA) in 1992, Canada systematically granted compulsory licenses to promote the establishment of a national generic pharmaceutical industry.[108] In total, pre-NAFTA, 1030 applications to import or manufacture medicines under compulsory licenses were filed, of which

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104. *Id.*

105. U.S.-Jordan FTA, *supra* note 22, art. 20.

106. Law No. 82 of 2002, arts. 3, 6, AL-JARIDA AL-RASMIYYA, vol. 22, bis. 2, (June 2002) (Law on the Protection of Intellectual Property Rights) (Egypt).

107. Visser, *supra* note 29, at 13.

108. JEROME H. REICHMAN & CATHERINE HASENZAHL, UNCTAD/ICTSD, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: THE CANADIAN EXPERIENCE 1, 6-7 (2002).

613 licenses were granted.[109] After 1992, however, Canada largely abandoned this system, as a result of a new political strategy adopted as being part of NAFTA and the TRIPS Agreement.[110]

Nevertheless, in 2005, Canada became the first country to pass legislation implementing the export Waiver Decision.[111] This legislation allowed Canadian producers to acquire compulsory licenses in order to produce patented drugs for countries requesting those drugs.[112]

In 2007, Rwanda and Canada utilized the export waiver decision, with both countries notifying the WTO of their intention to implement paragraph 2(A) of the 2003 Decision.[113] In its notification, Rwanda stated that it would for a two-year period import from Canada 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine, and Nevirapine.[114] Correspondingly, both countries announced that they would not enforce intellectual property rights granted in their territories with respect to the named product.[115]

B. India

Amendments to the Indian Patent Act provide for compulsory licenses at the expiration of three years from the date of the grant of a patent on any of the following grounds:

(1) Reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(2) Patented invention is not available to the public at a reasonably affordable price, or
(3) Patented invention is not worked in the territory of India.[116]

In 2012, based on the above amendments, the Indian patent controller issued a compulsory license to Natco Pharmaceutical to locally produce the anticancer drug, Sorafenib,[117] for Bayer Corporation of Germany in

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109. *Id.*
110. *Id.*
111. *Id.*
112. Elliott, *supra* note 43, at 96.
113. *Id.*
114. Rwanda Notification to WTO, *Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/N/9/RWA/1 (July 19, 2007).
115. Canada Notification to WTO, *Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/N/10/CAN/1 (Oct. 5, 2007).
116. The Indian Patents Act, No. 37 of 1970, art. 84(1), INDIA CODE (2017).
117. Natco Pharma Ltd. v. Bayer Corp., Compulsory License Application No. 1/2011 (Controller of Patents, Mumbai), 56 (India).

2008.[118] Subsequently, Bayer Corporation marketed Sorafenib worldwide under the brand name *Nexavar*.[119] The compulsory license was issued based on the following grounds:

(1) The public was not provided with sufficient quantities of the drug by the patent holder;
(2) The patented drug was not available at affordable prices; and
(3) The patent holder did not work the invention in the territory of India, it being understood that the importation of the drug is not considered local working as the patent holder has manufacturing sites in India.[120]

The Indian Patent Office, inter alia, ordered the following terms of the compulsory license:

(1) The price for a one-month treatment with the drug shall not exceed Rs 8880, as compared to Rs 280,000 charged by the patent holder;
(2) The licensee may not outsource the production to third parties;
(3) The license is nonexclusive and non-assignable;
(4) The licensee shall pay a royalty at the rate of 6% of the net sales of the drug on a quarterly basis;
(5) The licensee shall not have the right to import the patented drug;
(6) The license duration is for the balance term of the patent;
(7) The licensee's product must be visibly distinct from the patent holder's product (e.g., in color and shape); the trade name & packaging must be distinct; the licensor will provide no support (legal, regulatory, medical, technical, sales, etc.) to the licensee; and
(8) The licensor is free to compete with the licensee and license the patent to third parties.[121]

In May of 2012, Bayer appealed the Patent Office's decision before the Indian Intellectual Property (IP) Appellate Board, and in March of 2013,[122] the IP Appellate Board affirmed the Patent Office's decision, citing affordability and increased product access as reasons to dismiss

118. *Id.*
119. *Id.*
120. *Id.*
121. *Id.*
122. Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai) (India).

Bayer's appeal. As a result of this appeal, the royalty was increased from 6% to 7%.[123]

C. Brazil

The Brazilian Government utilized compulsory licenses as a means of reducing the price of the branded patented products, particularly anti-AIDS medicines.[124] Predicated on the ground of public interest, in September of 2003, the Brazilian Government issued a decree to produce or import generic anti-AIDS medicines without prior approval of the patent holder, rationalizing that they had already negotiated with these companies to get reduction of 40% but were not able to reach an agreement.[125] The decree was concerning lopinavir (Abbott), efavirenz (Merck), ritonavir (Abbott), and nelfinavir (Gilead).[126] In November of the same year, Brazil and Merck reached an agreement.[127]

In 2005, the Minister of Health issued two decrees stating that Kaletra (Abbott) and Viread (Gilead) are in the public interest, and thus, appropriate for compulsory licensing.[128] Following this decree, both companies agreed to reduce their prices; Abbott by 46% and Gilead by 50%.[129]

Similarly, a 2007 decree by the Minister of Health, declared efavirenz (Merck) to be in the public interest; a compulsory license for this product was granted in the same year after the Brazilian Government was unable to reach a settlement with Merck.[130] The Royalty was set as 1.5%, and it was imported from India.[131]

D. Thailand

The Thai Government followed the same policy of the Brazilian Government in using the pressure of a compulsory license in order to reduce the price of many patented products.[132] The below graph shows

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123. Mansi Sood, *Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India*, NAT. L. SCH. IND. U. (2013).

124. Visser, *supra* note 29, at 17-18.

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

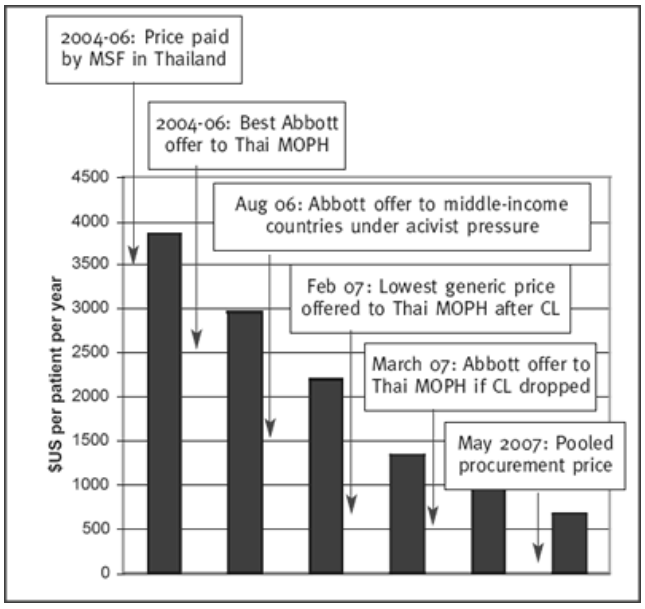
130. Visser, *supra* note 29, at 17-18.

131. *Id.*

132. DOCTORS WITHOUT BORDERS, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVS FOR DEVELOPING COUNTRIES, 10th ed. (July 8, 2007), https://www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW10_ENG_2007.pdf (referring to Nathan Ford et al., *Sustaining Access to Antiretroviral*

how Abbott, the patent right holder for Lopinavir/Ritonavir (Kaletra), reduced the prices for its medicine, a result accomplished by the issuance of the compulsory license issued by the Thai Government in January 2007.[133]

Abott Prices for Lopinavir/Ritonavir (Kaletra)
in Thailand (2004-2007)[134]



In January 2007, the Director General of the Department of Disease Control issued a compulsory license to manufacture a second line antiretroviral product used to treat HIV/AIDS patients, Lopinavir/ Ritonavir. The trade name of the patented product is Kaletra.[135]

The cited grounds for the issuance of this compulsory license were to protect public health; in particular, to promote access for medicines that constitute a national emergency or other circumstances of extreme urgency and of public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria, or other epidemics.[136]

Therapy in Developing Countries: Lessons from Brazil and Thailand, 21 AIDS 521, 527 (2007), https://www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_medjourno_ART-TherapyInDevelopingCountries_ENG_2007.pdf).

133. *Id.*
134. *Id.*
135. *Id.*
136. Visser, *supra* note 29, at 15.

The Thai Patent Act states that, for the public use, the ministry or department may exploit any patent without further negotiation with the patent holder.[137] This implication from this provision makes clear that, for noncommercial use, especially in public affairs of the government, such as public health services, the government is well within its rights.

The conditions of this compulsory license are:

(1) The use of the above patent rights are effective from today to the 31st January 2012.
(2) The use of the above patent rights will be limited to the provision of Efavirenz to not more than 50,000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social Security Act B.E. 2533, and the Civil Servants and government employees' medical benefits scheme.
(3) A royalty fee of 0.5% of the Government Pharmaceutical Organization's total sale value of the imported or locally produced Lopinavir+Ritonavir will be paid to the patent holder.[138]

The Department of Disease Control at the Ministry of Public Health will notify the patent owner and the Department of Intellectual Property at the Ministry of Commerce immediately.[139]

Another example in which a compulsory license was issued under the aegis of protecting public health in case of national emergency involved Clopidogrel (patented as Plavix), which is used to treat heart disease.[140] The requisite conditions to issue a compulsory license under this ground are:

(1) The use of the above Patent rights is effective from today until the patent expired or no essential need.
(2) The use of the provision of generic drugs of Clopidogrel is unlimited for patients covered under the National Health Security Act B.E.2545, Social Security Act B.E.2533 and Civil Servants and Government Employees Medical Benefit Scheme but is under doctors' judgment

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137. Thai Patent Act B.E. 2522, art. 1 (amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542).

138. *Id.*

139. Thawach Suntrajarn, Dir. Gen., Thai. Dep't of Disease Control, Decree of Department of Disease Control, Ministry of Public Health, Regarding Exploitation of Patent on Drugs & Medical Supplies by the Government on Combination Drug Between Lopinavir & Ritonavir (Jan. 29, 2007), http://www.cptech.org/ip/health/c/thailand/thai-cl-kaletra_en.pdf.

140. DOCTORS WITHOUT BORDERS, *supra* note 132 (referring to Nathan Ford et al., *supra* note 132).

(3) A royalty fee of 0.5% of the Government Pharmaceutical Organization's total sale value.[141]

E. Mozambique

A compulsory license was issued to produce a fixed-dose antiretroviral combination (lamivudine, stavudine, and nevirapine).[142] In April of 2004, this compulsory license was granted to local manufacturer Pharco Moçambique Lda, with the royalty set at a maximum of 2% of the total turnover.[143] This license was issued on the grounds of emergency, as per article 70.1 (b) of Mozambique's patent law, which permits the exploitation of a patent without consent of the patent holder in the case of emergency and extreme urgency,[144] "[i]n a case of emergency or in any other circumstances of extreme urgency, either of an economic or a social nature, or for the development of other sectors that are vital to the national economy, when the circumstances so require."[145] The license is valid until it can be found that the emergency created by the HIV/AIDs pandemic has ended.[146]

F. Zimbabwe

In May of 2002, the Minister of Justice issued a notice declaring an emergency on HIV/AIDS, as a result of the rapid spread of this disease in their country.[147] Pursuant to sections 34 and 35 of Zimbabwe's Patents Act, this declaration enables any government department or a third party to produce or to import any generic drug used in the treatment of HIV/AIDS.[148] The aforementioned sections empower the Minister to authorize any government department or third party to make use of the patented inventions, including the power to make, use, exercise, and vend the inventions for any purpose the Minister states its necessary in case of emergency.[149]

Initially, the emergency period was declared[150] as six months and was later extended to five years.[151] In order to ensure competition in

141. Suntrajarn, *supra* note 139.
142. Oh, *supra* note 33, at 28-29.
143. *Id.*
144. *Id.*
145. Mozambique Patent Law, art. 70.1(b).
146. Oh, *supra* note 33, at 28-29.
147. *Id.* at 25-27.
148. Zimbabwe Patents Act, arts. 33-34 (2002).
149. Oh, *supra* note 33, at 25-27.
150. *Id.*
151. *Id.*

pricing the generic products, this compulsory license was granted to three companies. Varichem agreed to produce locally antiretroviral (ARV) products and to supply three-quarters of its produced drugs to state-owned health institutions in a differential price in comparison to the patented product; now it has seven generics of ARV products.[152] The other two companies were authorized to procure generic ARV products: Datlabs, a pharmaceutical company, imported ARV from Ranbaxy in India.[153] Omahn, an agent, was authorized to import Cipla products.[154]

VI. CONCLUSION

Jordan is well known for its pharmaceutical industry, which, as the second largest export industry after garment manufacturing, plays an important role in its economy.[155] Nevertheless, until now, it has not utilized the provisions of the compulsory license scheme, though there are opportunities to do so that would benefit the pharmaceutical industry, such as making use of compulsory licenses to export antiretroviral medicines (ARV) to East African Community, an area that is indeed of these medicines but has limited domestic production capacity.[156] The reason why Jordan has not issued any compulsory license derives from the limitations found in the provisions on the compulsory licensing in Jordan's patent law.[157] These provisions need more clarifications and details, such as those included in the Egyptian and Indian patent laws; both laws have elaborated extensively in the clarification of the patent holder abuse and failure to work.[158] An additional reason why Jordan has not made greater use of compulsory licenses is because of its FTA with the United States that limits the grounds for issuing a compulsory license to only those enumerated therein, prohibiting Jordan from utilizing some

152. *Id.*
153. *Id.*
154. *Id.*
155. Jordan's Top 10 Exports, WORLD'S TOP EXPORTS (Nov. 13, 2017), http://www.worldstopexports.com/jordans-top-10-exports/.
156. DOCTORS WITHOUT BORDERS, *supra* note 132.
157. قانون براءات الاختراع رقم 32 لسنة 1999 [Law No. 32, OFFICIAL GAZETTE OF JORDAN], art. 22(A) (11 Jan. 1999).
158. Law No. 82 of 2002, AL-JARIDA AL-RASMIYYA, vol. 22, bis. 2, art. 23(5) (June 2002) (Law on the Protection of Intellectual Property Rights) (Egypt); The Indian Patents Act, No. 37 of 1970, INDIA CODE (2017); Saad Abughan, The Protection of Pharmaceutical Patents and Data Under TRIPs and the U.S.-Jordan FTA: Exploring the Limits of Obligations and Flexibilities: A Study of the Impacts on the Pharmaceutical Sector in Jordan (Apr. 29, 2009) (unpublished SJD thesis, University of Toronto), https://tspace.library.utoronto.ca/bitstream/1807/32296/1/Abughanm_Saad_A_201203_SJD_thesis.pdf.pdf.

of the flexibilities granted by the TRIPS Agreement.[159] For instance, the FTA does not allow Jordan to issue a compulsory license in the case of a patent holder's "refusal to deal," and Jordan is considered one of the few countries that stated in its law that importation of the patented product is considered working of the patent.[160] In addition, article 8.A of the Unfair Competition Law and Trade Secret provides data exclusivity for five years starting from the date of approval of a pharmaceutical product, which may prevent our regulatory authority from granting marketing approval for a generic product before the elapse of the five years. [161]

Consequently, a review of Jordan's legislation including the patent law, the unfair competition law, and the bilateral agreement with the United States is necessary to ensure the implementation of all the flexibilities found in the TRIPS Agreement and the Doha Declaration and to reflect this in a way that would facilitate the use of these provisions in a speedy, transparent, and timely manner without any delays from any appeal or legal actions that could be raised by the patent holder.[162] Also, it gives the power to decision makers to issue compulsory licenses without fear of any international consequences, such as being added to the U.S. watch list or being brought to the dispute settlement before the WTO.

Jordan can, and should, benefit from observing the experience of other countries, such as India, Egypt, and Brazil, particularly, their approach to drafting national legislation, while still complying with the TRIPS Agreement. Finally, Jordan can learn from the practical experience of those countries that have issued compulsory licenses and how using this flexibility has served to promote better access to medicine and simultaneously developed their pharmaceutical industries.

159. U.S.-Jordan FTA, *supra* note 22.

160. *Id.*

161. 1999 لسنة 32 رقم الاختراع براءات قانون [Law No. 32, OFFICIAL GAZETTE OF JORDAN], art. 22(A) (11 Jan. 1999).

162. *Id.*; U.S.-Jordan FTA, *supra* note 22.