Marquette Intellectual Property Law Review

Volume 18 | Issue 1 Article 3

# Ancillary Orders of Compulsory Licensing and Their Compatibility with the TRIPS Agreement

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# ANCILLARY ORDERS OF COMPULSORY LICENSING AND THEIR COMPATIBILITY WITH THE TRIPS AGREEMENT

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## I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) is one of the key international conventions in the field of intellectual property (IP). It is the first international treaty that lays down the mandatory minimum standard of patent protection for nations across the world. Given the comprehensive coverage of WTO membership,[1] the TRIPS Agreement has effectively established an international standard for IP protection in member states. With respect to copyright and patents, this Agreement expressly allows for compulsory licenses to be granted by competent authorities, with an aim to facilitate an adjusting mechanism to balance IP protection, on the one hand, and social or economic policy goals in general, on the other.[2]

Specifically, Article 31 of the TRIPS Agreement authorizes WTO members to issue compulsory licenses on patents to address national emergencies, extreme urgency, or other socioeconomic issues arising at the domestic level, subject to the procedures and limitations stipulated in the same article.[3] Through Article 9.1, one of the incorporation clauses in the TRIPS Agreement, the compulsory license scheme as to the author's translation and reproduction rights for developing countries, as provided in the Appendix of the Berne Convention (1971), essentially merges into and becomes an integral part of the TRIPS Agreement. This involuntary license regime affords developing countries leeway to adapt the level of copyright protection to address local economic, social, or cultural needs.[4]

In light of the important role that compulsory licensing could play in contemporary IP systems, the WTO reaffirms the members' right to grant such licenses in the Declaration on the TRIPS Agreement and Public Health, adopted in November 2001 at the Doha Ministerial Conference (Doha Declaration).[5] One of the main themes in the Doha Declaration is that patent protection should be implemented in a manner that permits WTO members to protect public

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1. As of November 25, 2013, the WTO has 159 members.

2. *See, e.g.*, CARLOS M CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 242–43 (2000); ANA MARIA PACÓN, *What Will TRIPs Do for Developing Countries?*, FROM GATT TO TRIPS—THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 339–40 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996); JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 319 (2001).

3. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, prem. & ¶ (a)–(c), Apr. 15, 1994.

4. Berne Convention for the Protection of Literary and Artistic Works app. art. I, ¶ (1), July 24, 1971.

5. World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, ¶ 5(b).

health and to promote access for the general public to essential medicines. For that purpose, WTO members may use, to the full extent, the flexibilities as set forth in Articles 30 and 31 of the TRIPS Agreement.[6]

Following the guidance of the Doha Declaration, WTO members have made use of the compulsory license scheme to address their domestic issues, particularly in meeting the demands of public health. For instance, Brazil,[7] India,[8] Taiwan,[9] and Thailand[10] have issued compulsory licenses on pharmaceuticals essential for treating deadly diseases in recent years. Even so, relative to the large number of patents now in effect for WTO members, the frequency and number of compulsory licenses to date have been low.[11]

## II. CONDITIONS FOR COMPULSORY LICENSING TO BE EFFECTIVE

The compulsory license does not exist in a vacuum. Rather, the success of a compulsory licensing regime depends on the industrial and technological contexts that the licensee encounters. For a compulsory license to be effective, a number of conditions must be present. First of all, licensees with sufficient capacities are indispensable.[12] The lack of technical sophistication and ability to learn has been a significant detriment to technological transfer in developing

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6. *Id.* at ¶ 4.

7. Brazil issued a compulsory license against Merck & Co. for its HIV/AIDS drug, Efavirenz, in May 2007. Riadh Quadir, *Patent Stalemate? The WTO's Essential Medicines Impasse Between Pharmas and Least Developed Countries*, 61 RUTGERS L. REV. 437, 459–60 (2009).

8. On March 9, 2012, the Indian patent authority granted generics manufacturer Natco Pharma Ltd. the right to produce and sell Bayer's Sorafenib, a patented medicine that is useful in treating liver and kidney cancers at an advanced stage. Enrico Bonadio, Comment, *Compulsory Licensing of Patents: The* Bayer/Natco *Case*, 34 EUR. INTELL. PROP. L. REV. 719, 719 (2012).

9. In the wake of the avian flu crisis, Tamiflu was considered an effective remedy for the H5N1 virus. Failing to secure sufficient supply from F. Hoffmann-La Roche Ltd., the Taiwanese Government granted a compulsory license on Tamiflu in December 2005. *See* Kung-Chung Liu, *Rationalising the Regime of Compulsory Patent Licensing by the Essential Facilities Doctrine*, 39 INT'L REV. INTELL. PROP. & COMPETITION L. 757, 760 n.12 (2008); Eileen M. Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1167 (2009).

10. Thailand granted a couple of compulsory licenses in 2006 and 2007, including the patented HIV/AIDS drugs Efavirenz (from Merck) and Kaletra (from Abbott), and Plavix, which is used for treating heart disease. Kristen Osenga, *Get The Balance Right!: Squaring Access with Patent Protection*, 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 309, 319–20 (2012).

11. *See* Kung-Chung Liu, *The Need and Justification for a General Competition-Oriented Compulsory Licensing Regime*, 43 INT'L REV. INTELL. PROP. & COMPETITION L. 679, 681 (2012); Getachew Mengistie, *The Patent System in Africa: Its Contribution and Potential in Stimulating Innovation, Technology Transfer and Fostering Science and Technology: Part 2*, 16 INT'L TRADE L. & REG. 175, 178 (2010).

12. Mengistie, *supra* note 11, at 178; Richard Li-dar Wang, 從 TRIPS 協定與公眾健康爭議論專利強制授權之功能與侷限 [*Functions and Restraints of Compulsory Licensing: Perspective from TRIPS Agreement and Public Health*], 1 TECH. L. REV. 215, 235–36 (2004) (Taiwan).

countries.[13] Existing manufacturing capacity also matters with respect to the quantity and speed at which the compulsory licensee could put the patented technology or copyrighted work into production. The more qualified capacity that is in place, the faster the licensed IP can come into mass production and fulfill the underlying goal of individual compulsory licenses—whether it is working the technology locally, treating a public health crisis, disseminating advanced knowledge and fostering higher education, or any other social or cultural need.

Notably, the required capacity is not limited to those located within the issuing country. If the scope of the compulsory license includes importation, the issuing government could utilize competent manufacturers located overseas to exploit the licensed IP and produce targeted products to fulfill domestic needs. This practice is allowable under the TRIPS Agreement. No provision in the same Agreement stipulates against non-voluntary import licenses. The key is that the expected foreign supplier must have the right to produce in its own country, and be able to legitimately export the products at issue. There are a couple of situations where those conditions will be met and it is entirely lawful to practice the subject matter and export the product there: when the term of the intellectual property protection covering the licensed subject matter has expired, or when no pertinent IP protection has been secured in the specific foreign country. Supply from abroad may also be possible when a compulsory license is in place in the exporting country. However, Article 31(f) of the TRIPS Agreement requires that each of the non-voluntary licenses be granted predominantly for the supply of the domestic market, which does not prohibit the licensee from exporting the product so long as the exportation constitutes a minor portion of the total production.[14]

Under the Guidance of the Doha Declaration, the WTO General Council established a waiver system in 2003 to soften the ban on production predominantly for exportation.[15] Under the waiver system, compulsory licenses predominantly for exports are permitted, with the condition that the importing WTO member has no pharmaceutical manufacturing capacity, grants such a waiver, and notifies the WTO Secretariat.[16] In December 2005, the General Council of the WTO formalized the waiver system, adding Article 31*bis* to the TRIPS Agreement.[17] This amendment is now waiting to take

13. Mengistie, *supra* note 11, at 179.

14. WATAL, *supra* note 2, at 325.

15. Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Decision*, WT/L/540 and Corr.1 (Sept. 1, 2003), *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

16. *Id.* ¶ 2.(a).

17. Decision of the General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 8,

effect.[18] This waiver system, however, is limited to exporting pharmaceuticals to WTO members, and to date only Rwanda has filed one request for importation.[19]

Historically, a number of governments have authorized importation of generic pharmaceuticals to address domestic health problems.[20] For instance, the government of Ecuador granted a compulsory license in 2010 on Ritonavir, an antiretroviral drug, to the local distributor of Cipla, an Indian company producing a generic version of the same drug.[21] Moreover, in the case of Efavirenz in Brazil, before local manufacturers could successfully provide this antiretroviral medicine, the Brazilian government included importation in the compulsory license and counted on several Indian generic producers to supply the medicine at a lower price.[22]

The second critical condition is the size of the market, which is a decisive factor for the sales revenue that a licensee may reasonably anticipate from practicing the patent or copyright. The potential magnitude of the market closely relates to whether the licensee would recover the necessary cost for employing the IP, benefit from economy of scale, or even make a profit.[23] If the market size is narrowly restrained and only a very limited amount of revenue could be generated from the compulsory license, even manufacturers or publishers with adequate capacity to practice the patent or copyright may stay away from taking it.

In calculating the size of a potential market for compulsory licenses, the basis for assessment in most cases would still be confined by the boundaries of the issuing country. Foreign markets are highly uncertain. The patent status of

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2005), *available at* http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

18. As of now about 70 WTO members have issued notification that they accept this amendment. Since less than two-thirds of the WTO members have formally accepted the amendment, Article 31*bis* has not yet taken effect and replaced the 2003 waiver. The deadline for WTO members to accept this revision has been extended to December 31, 2013. Decision of the General Council, *Amendment of the TRIPS Agreement – Third Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/829 (Dec. 5, 2011).

19. Council for Trade-Related Aspects of Intellectual Property Rights, *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*, IP/N/9/RWA/1 (July 19, 2007).

20. *See supra* notes 7–10.

21. *Leaked Cables Show U.S. Tried, Failed to Organize Against Ecuador Compulsory Licensing*, PUBLIC CITIZEN BLOG (May 10, 2011), http://www.citizen.org/leaked-cables-show-US-tried-failed-to-organize-against-ecuador-compulsory-licensing.

22. Keith Alcorn, *Brazil Issues Compulsory License on Efavirenz*, NAM (May 7, 2007), http://www.aidsmap.com/Brazil-issues-compulsory-license-on-efavirenz/page/1427206/. *See generally* Quadir, *supra* note 7 (explaining Brazil's compulsory license on Efavirenz).

23. Mengistie, *supra* note 11, at 178; Stacey B. Lee, *Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?*, 44 GEO. J. INT'L L. 1387, 1413 (2013); Wang, *supra* note 11, at 236.

the targeted products in foreign countries determines whether they could be produced or imported freely in those countries, whether a compulsory license for importation will be imposed, and whether those countries would utilize the waiver system to lift the limitation of Article 31(f) of the TRIPS Agreement. Though there might be opportunities for the licensees to export part of their production to countries granting compulsory licenses on importation of the same products, the chances are quite uncertain, and it may seem remote for potential candidates that are considering whether to take the compulsory license or not. As a result, countries that have only small populations or weak buying power will suffer from the constraint of market size,[24] and the function of compulsory licenses would be seriously curtailed.

A third precondition for an effective compulsory license concerns necessary know-how.[25] The patent law surely requires public disclosure of the claimed technology to enable persons skilled in the art to carry out the invention themselves,[26] but occasionally additional know-how is still necessary for them to put the claimed invention into industrial application on a commercial scale. IP licensing agreements, however, typically do not contain obligations regarding technical assistance or technology transfer from the IP owner.

In the scenario of compulsory licensing, it is implausible to expect right-holders to voluntarily provide any technical guidance to the licensee. If the licensee does not possess all the skills that are critical for practicing the licensed IP—such as the know-how on commercialization, improving the manufacturing process, optimizing the yield rate, etc.[27]—she will still be unable to duplicate the product of the right-holder successfully. When this situation arises, the compulsory license may not work as effectively as expected.

## III. ANCILLARY ORDERS TO ENSURE THE EFFECTIVENESS OF COMPULSORY LICENSING

If countries fall short of the essential conditions as set forth above, necessary measures should be taken to make up for the deficiencies. The first two conditions, however, are not so easy to restore. If competent licensees do not exist, the government could only choose to step in and practice the patent or copyright with its own facilities. Even so, the feasibility of this measure still

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24. *See* HANNAH E. KETTLER & CHRIS COLLINS, USING INNOVATIVE ACTION TO MEET GLOBAL HEALTH NEEDS THROUGH EXISTING INTELLECTUAL PROPERTY REGIMES 12–39, *available at* http://www.iprcommission.org/papers/word/study_papers/sp2b_kettler_study.doc.

25. Mengistie, *supra* note 11, at 178; Wang, *supra* note 11, at 236–37.

26. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 29, ¶ 1 ("Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art . . . .").

27. Wang, *supra* note 11, at 237.

depends on the presence of production facilities and technical sophistication of the country with regard to the licensed IP. Furthermore, factors affecting the magnitude of the market, such as population and national income, are difficult to change within a short period of time as well.

### *A. Know-How Transfer Orders*

The only condition that concerned authorities might be able to create in granting a compulsory license is the necessary know-how. Those authorities could issue an ancillary order to require the right-holder to provide additional know-how to the licensees.[28] In order to ensure the transfer of the licensed technologies, the order should obligate the right-holder to provide technical assistance, and hand over technical documents that contain the know-how or other technologies that the licensee identifies as necessary for implementing the compulsory license. If the right-holder obeys the order and conveys undisclosed know-how, the receiving licensee is obligated to maintain its secrecy and pay reasonable royalties for using the know-how, just as a voluntary trade secret licensee would.[29]

The licensee may encounter difficulties in identifying necessary know-how for transfers, but she does not have to recite the know-how item by item. Rather, the scope and content of the transfer order could be defined in categories with reasonable particularity, just as attorneys do in requesting opposing parties to produce documents or records in the discovery process of civil litigation in the United States.[30] In case of doubt, the granting authority of the compulsory license should adjudicate the dispute through adequate procedures, and determine the proper scope and content of the transfer. Where conflicts arise concerning whether the licensee has abused their rights in the know-how transfer and attained unreasonable advantages over the right-holder, the granting agency or a court should have the authority to decide whether the licensee is liable to pay compensation and refrain from further using a particular know-how.

Since IP right-holders will undoubtedly tend to be reluctant to transfer undisclosed know-how, other sources of such transfers should be secured to facilitate the implementation of compulsory licenses. For that purpose, the know-how transfer order could excuse persons that have access to the right-

28. Regrettably, the author has not found any national practice that adopts orders similar to what the paper proposes here.

29. RAYMOND T. NIMMER & JEFF C. DODD, MODERN LICENSING LAW § 7:3, § 17:16 (2013–2014 ed. 2013).

30. FED. R. CIV. P. 34(b)(1)(A) ("The request [to produce any designated documents or electronically stored information] must describe with reasonable particularity each item or category of items to be inspected . . . .").

holder's technical information or materials from their obligations under any existing non-disclosure agreement, thus enabling the licensee to get possession of necessary know-how. To alleviate any possible adverse impact on a business's honesty and integrity, this immunity could only be triggered at the time when the right-holder does not faithfully follow the transfer order and hand over all necessary technical information. The granting authority shall confirm that disobedience surely exists before issuing the transfer order through a formal adjudication process.

Such an exemption to the non-disclosure obligation might seem vulnerable to distortion and abuse, which could be difficult to redress once the trade secret was revealed. The primary function of the exemption, nevertheless, lies in deterrence. It is an enforcement measure of last resort, which should be administered cautiously and conservatively. Countries should not solely rely on the non-disclosure exemption, but should rather establish other remedies, such as fines and injunctive relief, to enforce a know-how transfer order. When those remedies fail and the exemption is granted, the competent authority should set up adequate rules and procedures to monitor the flow of trade secrets and prevent possible abuse. If executed appropriately, immunity from any existing non-disclosure obligation could confidently be a useful enforcement measure against the right-holder's resistance.

### *B. Goal-Attainment Ensuring Orders*

In addition to know-how transfer orders, there are still other types of ancillary orders that would help a compulsory license work effectively towards its contemplated goal. For those non-voluntary licenses granted on the grounds of unavailability of affordable drugs to the public, the manufacturer undertaking the license should be directed to distribute those drugs at an affordable price, or even provide them for free to especially needy patients.[31] In the same vein, in the case of compulsory licenses on the basis of nonexistent or insufficient local working, the licensee should be required to manufacture the targeted products within the country and should be restricted from importing from overseas.[32]

## IV. SIDE-EFFECTS PREVENTING ORDERS

Besides ancillary orders that serve to ensure the effectiveness of compulsory licensing, there is another type of order that is purported to prevent

31. *In re* Natco Pharma Ltd. and Bayer Corp., C.L.A. No. 1 of 2011, at 60–61 (Order item a & h) (Controller of Patents Mar. 9, 2012) (India), *available at* http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf.

32. *Id.* at 61 (Order item i).

adverse side effects to the right-holder. For example, in the 2012 *Bayer-Natco* case in India,[33] the targeted product Sorafenib was a drug for treatment during the advanced stages of kidney and liver cancer. Bayer named it Nexavar and distributed it at a price of Rs.280428 (about US $5404) for one month's therapy.[34] Natco applied for compulsory licensing and proposed to sell the drug at one-thirtieth of the price.[35] The Indian government approved the application and required Natco to refrain from both representing its production of Sorafenib as Bayer's Nexavar drug, and from representing the two companies as associated in any aspect.[36] Furthermore, Natco's Sorafenib had to be visibly different from Bayer's Nexavar in color, shape, trade name, and outside packaging.[37]

Those mandates are quite similar to the special packaging and/or coloring/shaping requirements as stipulated in TRIPS Article 31*bis*.[38] The common goals of ancillary orders are to prevent possible confusion of the licensee's products with the right-holder's and to inhibit the pharmaceuticals manufactured under the license from being diverted into the stream of commerce outside of the granting country.

Another example of side-effect preventing orders can be found in the Berne Convention. Article IV(3) of the Appendix of the Berne Convention requires that copyrighted works translated or reproduced under a compulsory license have to contain indications of the true author and the title of the work.[39] This requirement protects the author's moral rights, including the right of attribution and the right to the integrity of the work, from being impaired. According to Article 6*bis*(1) of the Berne Convention, the author's right of attribution and the right to integrity of the work shall be independent of the transfer of the author's economic rights.[40] Consequently, those rights should stay intact even when the author is facing compulsory licenses.

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33. *Id.*

34. *Id.* at 5–6; Bonadio, *supra* note 8, at 721.

35. *In re* Natco Pharma Ltd. and Bayer Corp., at 6.

36. *Id.* at 61 (Order item k).

37. *Id.* at 61–62 (Order item k); *see also* Bonadio, *supra* note 8, at 726.

38. Decisions of the General Council, *supra* note 14, at Annex, ¶ 2(b)(ii).

39. Berne Convention for the Protection of Literary and Artistic Works, *supra* note 3, at app. art. IV(3).

40. Berne Convention for the Protection of Literary and Artistic Works, *supra* note 4, art. 6*bis*, ¶ (1).

## V. TRIPS-COMPATIBILITY OF ANCILLARY ORDERS

### *A. Know-How Transfer Orders*

The know-how transfer orders described above seem to be an ideal companion of compulsory licenses. Whether the transfer orders are in compliance with the TRIPS Agreement, however, is somewhat problematic. Since there is no general exception in the TRIPS Agreement for all types of IP, a specific exception is necessary for exempting any derogation of IP protection from the level as required in the same Agreement.[41] The first two paragraphs of Article 39 require WTO members to protect trade secrets, which cover undisclosed know-how.[42] Meanwhile, the same article, and even the same section of the Agreement, contains no exception to the trade secret protection it demands. This is not a coincidence. National trade secret laws of WTO members usually provide few exceptions as well. The United States' Uniform Trade Secret Act, for example, contains just one exception.[43]

The fact that no relevant exception to trade secret protection currently exists surely casts some doubts on WTO members adopting know-how transfer orders. But there is another avenue for justifying such orders under the TRIPS Agreement. In the first sentence of Article 39.1, the TRIPS Agreement articulates that the purpose of protecting trade secrets is to ensure "effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967)."[44] Article 10*bis*(2) of the Paris Convention defines the act of unfair competition as "[a]ny act of competition contrary to honest practices in industrial or commercial matters . . . ."[45] The issuance of a compulsory license, which grants the licensee court-ordered authority to request the right-holder to transfer know-how that is indispensible for fulfilling the license, should not in itself constitute an act of unfair competition contrary to business honesty. Compulsory licensing is a well-recognized mechanism to introduce adequate exploitation of patents or copyright to achieve public interest in various socioeconomic aspects.[46] The licensee here is just an undertaker of such a legitimate mechanism and does not come into competition with the right-

41. WATAL, *supra* note 2, at 309.

42. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 39, ¶ 1–2.

43. U.T.S.A. §§ 3(a), 3 cmt. (amended 1985) (The exception excludes from compensation damages accruing after the trade secret has been revealed or otherwise no longer sustains an advantage over competitors.).

44. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 39, ¶ 1.

45. Paris Convention for the Protection of Industrial Property art. 10*bis*, ¶ (2), July 14, 1967.

46. World Trade Organization, *supra* note 5, ¶ 4 & 5(b).

holder for her own commercial interest. As long as the compulsory license and ancillary order are based on national laws, granted legally by the authority concerned, and the licensee faithfully secures the secrecy of the know-how, there should be no offense to Article 10*bis*.

Furthermore, laws and measures that compel disclosure of trade secrets usually do exist outside the trade secret law. Mandatory disclosure is commonly seen in the fields of corporate auditing and marketing approval.[47] In the TRIPS Agreement, Article 39.3 authorizes WTO members to require submission of undisclosed test data for the purpose of reviewing the marketing application of pharmaceutical or agricultural chemical products that utilize new chemical entities, on condition that such data shall be protected against unfair commercial use.[48] The same disclosure requirement is present in the section of civil and administrative procedures and remedies of the TRIPS Agreement as well.[49] In Article 43.1, the Agreement stipulates that national courts shall have the authority to order specific evidence, including confidential information, to be produced by one of the parties, subject to conditions that could ensure the protection of its secrecy.[50] The two provisions comprise part of the treaty context that must be taken into consideration when interpreting the scope and content of trade secret protection mandated by the TRIPS Agreement.[51] Consequently, the fact that the trade secret law lacks any exceptions does not indicate that limitations on the trade secret right are prohibited. As long as adequate measures are adopted to warrant its confidentiality, well-grounded disclosure orders from other areas of law should be reasonably recognized by analogy.

The objective clause of the TRIPS Agreement further fortresses the same

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47. *See e.g.*, Frank H. Easterbrook & Daniel R. Fischel, *Mandatory Disclosure and the Protection of Investors*, 70 VA. L. REV. 669, 669–670 (1984); Allen Ferrell, *Measuring the Effects of Mandated Disclosure*, 1 BERKELEY BUS. L.J. 369, 371–72 (2004); Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 38 AM. J.L. & MED. 63, 81–91 (2012); Liora Sukhatme, Note, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process*, 82 N.Y.U. L. REV. 1210, 1213–25 (2007).

48. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 39, ¶ 3.

49. *Id.* at part 3, § 2.

50. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 43, ¶ 1 ("The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.").

51. *See infra* text accompanying notes 39–40 (explaining the significance of treaty context in construing disputed treaty terms).

position. In Article 7, the Agreement proclaims that the protection of IP rights should contribute to the transfer and dissemination of technology, "to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare."[52] Know-how transfer orders are purported to assist compulsory licensing to balance IP protection and the socioeconomic welfare of the public. By requiring transfer of critical know-how, those orders can ensure complete conveyance of all necessary technologies between IP right-holders and non-voluntary licensees, thus substantially enhancing the efficacy of technology dissemination that the compulsory licensing regime is aiming to achieve. Taking all the above analyses into consideration, know-how transfer orders in effect could not be sensibly characterized as TRIPS-incompatible.

### *B. Local Manufacturing Orders*

Article 5A(2) and 5A(4) of the Paris Convention (1967) expressly recognize failure to work a patent and insufficient working as legitimate grounds for granting compulsory licenses.[53] This is often regarded as a local working requirement imposed on patent owners. In his famous treatise, Bodenhausen described the prevailing view of the word "working" in the context of the Paris Convention:

> Normally, working a patent will be understood to mean working it *industrially*, namely, by *manufacture* of the patented product, or *industrial application* of a patented process. Thus, importation or sale of the patented article, or of the article manufactured by a patented process, will not normally be regarded as 'working' the patent.[54]

In 1994, Article 2.1 of the TRIPS Agreement further incorporated Article 5 of the Paris Convention.[55] WTO members would accordingly grant compulsory licenses for the reason of insufficient domestic working from patent owners. In order to achieve the goal of local working, the granting countries might additionally grant an ancillary order that requires the licensees to manufacture the targeted products domestically and forbids importing.

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52. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art.7.

53. Paris Convention for the Protection of Industrial Property, *supra* note 45, art. 5, ¶ A(2) & A(4).

54. G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 71 (1969), *available at* http://www.wipo.int/export/sites/www/freepublications/en/intproperty/611/wipo_pub_611.pdf.

55. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art.2, ¶ 1.

These types of goal-attainment ensuring orders, however, may be incompatible with the non-discrimination principle as stipulated in Article 27.1 of the TRIPS Agreement.[56] This clause demands that patent rights shall be enjoyable without discrimination as to, *inter alia*, whether products are imported or domestically produced. A WTO panel once ruled that Article 27.1 applies to Article 31 as well.[57] It follows that the granting authority of compulsory licensing might not be able to treat patent owners and the licensees in a different way on the basis of whether the targeted products are imported or locally manufactured.

The idea of non-discrimination and avoiding trade distortion is a cornerstone of the WTO. The most-favored-nation principle and national treatment principle, two overarching doctrines throughout the WTO, vindicate and exemplify the importance of this basic policy.[58] Article 27.1 of the TRIPS Agreement crystallizes and enshrines the same idea in the field of patent law.[59] Even though failure to work and insufficient working are explicitly acknowledged as grounds for compulsory licensing in the TRIPS Agreement,[60] the meaning of the terms must be interpreted according to the whole context of the Agreement, including Article 27.1.

Article 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) points out that when disputes arise, the provisions of WTO agreements will be clarified in accordance with customary interpretation rules of public international law.[61] The WTO Appellate Body has consistently held that Article 31 of the Vienna Convention on the Law of Treaties (VCLT), as a rule of treaty interpretation, has attained the status of customary international law.[62] Article 31.1 of the VCLT states, "A treaty shall be interpreted in good faith in accordance with the *ordinary meaning* to be given to the terms of the treaty in their *context* and in the light of its object and

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56. *Id.* at art. 27, ¶ 1.

57. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 7.91, WT/DS114/R (Mar. 17, 2000).

58. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 3 (National Treatment) & art. 4 (Most Favored Nation); *see, e.g.*, MICHAEL J. TREBILCOCK & ROBERT HOWSE, THE REGULATION OF INTERNATIONAL TRADE 28–30 (3d ed. 2005).

59. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, *supra* note 57, ¶ 7.94; *See also* Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, *in* FROM GATT TO TRIPS—THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 189–90 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996).

60. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 2, ¶ 1; Paris Convention for the Protection of Industrial Property, *supra* note 45, art. 5, ¶ A(2) & A(4).

61. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 3, ¶ 2, Apr. 15, 1994.

62. *E.g.*, Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, 17, WT/DS2/AB/R (Apr. 29, 1996); Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, 10, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Oct. 4, 1996).

purpose."[63]

Even though the requirement of working a patent is understood as a mandate of local manufacturing in the context of the Paris Convention, it may slightly change its meaning when migrating into another treaty context. As a transitive verb with an object, the ordinary meaning of the term "work" may include to "function," to "cause to be in operation,"[64] or "to fashion or create a useful or desired product by expending labor or exertion on."[65] The manner in which local working is proceeding, however, has not been specified. In light of the non-discrimination principle as to the place of production, to "work" a patent could and should be construed more broadly as to "practice" a patent. In this way, the local working requirement can avoid direct collision with the non-discrimination principle and fit into the new context of the TRIPS Agreement much more adequately.[66]

In the *U.S.—Copyright Act* panel report, a WTO panel held that when TRIPS provisions are incorporated from other international conventions, their original contexts in those external instruments could also be integrated into the Agreement as a basis of interpretation.[67] The "*acquis*" thus introduced from other international instruments, however, constitutes only part of the context when interpreting those provisions. The text of the TRIPS Agreement is undeniably another significant component of the context. For the same reason, the panel in *U.S.—Copyright Act* panel report recognized that Article 13 of the TRIPS Agreement applies to provisions incorporated from the Berne Convention, though no analogous exception clause to the author's public communication right is present in that Convention.[68]

Professor Carlos Correa has argued that the non-discrimination requirement of TRIPS Article 27.1 is targeted at infringing products rather than the patentee's products.[69] He indicates that since the language of Article 27.1 only states that "patent rights [are] enjoyable without discrimination as to . . .

63. Vienna Convention on the Law of Treaties art. 32, May 23, 1969, 1115 U.N.T.S. 331, 340, *available at* http://treaties.un.org/doc/Publication/UNTS/Volume%201155/v1155.pdf (emphasis added).

64. OXFORD AMERICAN COLLEGE DICTIONARY (2002), *available at* http://oxforddictionaries.com/definition/english/work?q=work (last visited June 6, 2013).

65. MERRIAM-WEBSTER COLLEGIATE DICTIONARY 1443 (11th ed. 2009), *available at* http://www.merriam-webster.com/dictionary/work (last visited June 6, 2013).

66. *See also* Joseph Straus, *supra* note 59, at 205.

67. *See* Panel Report, *United States—Section 110(5) of the US Copyright Act*, ¶ 6.92, WT/DS160/R (June 15, 2000).

68. *Id.* ¶ 6.94.

69. Carlos M. Correa, *The Use of Compulsory Licenses in Latin America*, *in* COMPULSORY LICENSING (Reto M. Hilty & Kung-Chung Liu eds., forthcoming 2014).

whether products are imported or locally produced,"[70] the provision could be interpreted as mandating that inventors shall possess equivalent rights of patents against infringing products, whether those infringing products are produced domestically or imported from abroad.[71] When the ordinary meaning of treaty language is vague, even in light of its context, the negotiating history could be instrumental in ascertaining its true intention.[72] During the negotiation process of the TRIPS Agreement, the local working requirement aroused heated debates among developed and developing countries.[73] The current language of Article 2.1 and 27.1 marks the compromise that the opposing parties eventually reached to resolve this deadlock when the negotiations concluded.[74] If we consider for now that the non-discrimination requirement as to the place of production is for infringing products rather than the patentee's products, the negotiating history will be neglected, and the intention of the drafter will be distorted. Even though Professor Correa refers to the *U.S.-Section 337* report of the GATT era[75] to illustrate possible discrimination between infringing products from importation and local production, the measures at issue in the same case—border measures that in essence only target imported goods—have also been expressly recognized in the text of the TRIPS Agreement as legitimate remedies against IP infringement.[76] It is thus unlikely for the agreement to institute a prohibition in Article 27.1 against such enforcement measures that are particularly authorized in the same instrument.

According to the analysis above, in light of the non-discrimination principle in Article 27.1, the local working requirement should not be interpreted as a local manufacturing requirement. Similarly, ancillary orders to secure local manufacturing on the side of the licensee may violate the same clause as well. When insufficient practicing of a specific patent is found, the non-voluntary licensee should be permitted to import, as well as to produce domestically, the targeted products to meet the local demand.[77]

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70. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 27, ¶ 1.

71. Correa, *supra* note 69.

72. Vienna Convention on the Law of Treaties, *supra* note 39, art. 32 (providing for supplemental means of treaty interpretation, "Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable.").

73. WATAL, *supra* note 2, at 317–18.

74. *Id.* at 318.

75. Panel Report, *United States—Section 337 of the Tariff Act of 1930*, L/6439 (Nov. 7, 1989).

76. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, Part III, § 4 (Special Requirements Related to Border Measures).

77. *See generally* Bonadio, *supra* note 7, at 723. *But see* Bryan Mercurio & Mitali Tyagi,

## VI. CONCLUDING REMARKS

Compulsory licensing is a well-recognized regime that strikes a balance between patent and copyright protection and socioeconomic goals. In order to make it work effectively, some ancillary measures are necessary. When the licensee lacks access to critical know-how for practicing the licensed technology, the granting authority of the compulsory license may require the right-holder to transfer such know-how to fill the gap. In addition, we might see the government authority require the licensee to manufacture the targeted product locally, or to provide the licensed medicine to the public at an affordable price, so as to ensure the compulsory licensing attains its contemplated goal.

On the other hand, the granting authority can issue a side-effect averting order to alleviate unnecessary impact that compulsory licensing may impose on the right-holder, so that the license does not become too intrusive. Those two types of ancillary orders are practical complements to non-voluntary licenses, and could be beneficial for the current regime of compulsory licensing, both nationally and internationally. They are undoubtedly worthy of consideration to be incorporated into national laws and international conventions.

The fact that no exception is expressly acknowledged in the trade secret section of the TRIPS Agreement casts some doubts on the legality of know-how transfer orders. These doubts are not well founded. Outside of the trade secret section, the TRIPS Agreement contains at least two provisions demanding submission of undisclosed information.[78] The objective clause of Article 7 also suggests against incompatibility of those orders with the TRIPS Agreement.[79] On the other hand, orders requiring local manufacturing are likely to contravene the TRIPS Agreement by violating the non-discrimination principle between imports and local production in Article 27.1. Even though the TRIPS Agreement expressly incorporates the local working requirement of patent owners from the Paris Convention, the meaning of "working" should be adjusted properly to reflect the change of treaty context, and is reasonably construed in this Agreement to encompass importation to avoid direct conflict with Article 27.1.

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*Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements*, 19 MINN. J. INT'L L. 275, 313 (2010) (the differential treatment resulting from local working requirements does not amount to an unjustified disadvantage, and hence is not a discrimination under Article 27.1 of the TRIPS Agreement).

78. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 39, ¶1 & art. 43, ¶ 1.

79. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 3, art. 7.