Review of Granted Compulsory Licences

Chung-Lun Shen and Jyh-An Lee

Contents

Abstract Legislators recognise that exceptions and limitations may be established to help the achievement of the ultimate goal under patent law. However, exceptions and limitations are made to keep the interest balance between the patentee and the public, including the potential competitors of the patentee. Such interest balance would be obtained when patentees are restrained from asserting their exclusive rights against some acts that have no substitution effects on the patented products and, at the same time, are conducive to the disclosure of and access to the patent to enhance the technological development. This inference is supported by Art. 30 of the TRIPS Agreement, after which limited exceptions can be allowed in patent law provided that they "do not unreasonably conflict with a normal exploitation of the

C.-L. Shen is Associate Professor of Law. J.-A. Lee is Assistant Professor of Law.

C.-L. Shen
College of Law, National Chengchi University, Taipei, Taiwan
e-mail: clshen@nccu.edu.tw

J.-A. Lee
Faculty of Law, The Chinese University of Hong Kong, Hong Kong
e-mail: jyhan.lee@gmail.com

R.M. Hilty and K.-C. Liu (eds.), *Compulsory Licensing*, MPI Studies on Intellectual Property and Competition Law 22, DOI 10.1007/978-3-642-54704-1_15,

patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

In our opinion, "a normal exploitation" and "the legitimate interests" of the patent should be subject to the substitution effects of the products made under compulsory licence, and the legitimate interests of third parties should be measured by whether such interests benefit the ultimate goal of patent law. When the infringing acts have no substitution effects, "a normal exploitation" and "the legitimate interests" of the patent are not negatively impacted, and such acts may justifiably be named as exceptions and limitations.

The granting of a compulsory licence functions through the waiver of specific exclusive rights, to an extent. Therefore, the granting of a compulsory licence is among the exceptions and limitations under patent law. Based on our arguments about the exceptions and limitations, the granting of a compulsory licence should be tested by the criteria of Art. 30 TRIPS Agreement to secure its justification.

1 Introduction

A compulsory licensing provision is common in most countries' patent laws.[1] Nevertheless, compulsory licensing is not often instituted in these countries.[2] The practice of compulsory licensing varies from country to country. For example, in Brazil compulsory licensing is occasionally used by the government as a tool to threaten drug companies to reduce prices.[3]

In recent years, a number of Asian countries have granted compulsory licences, leading to considerable international controversy among local governments, patent holders, and their home countries. Most of these compulsory licences concern citizens' access to essential medicines, pharmaceutical companies' incentive to invest in research and development for new drugs, and the correct interpretation of relevant international treaties, especially the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a fundamental set of game rules established by the World Trade Organization (WTO) members. Because the practice of compulsory licence significantly affects patent owners' profits from the domestic market and control over their inventions, most of them are against such practices. On the other hand, increasing drug prices have troubled governments in

[1] Dutfield and Suthersanen (2008), p. 127; Correa (1994), p. 330; See chapter "The Use of Compulsory Licences in Latin America" by Carlos M. Correa, in this volume. It should be noted that the United States is one of the few countries that do not include compulsory licensing provisions in its patent law, and it has continuously discouraged other countries from resorting to compulsory licensing. *See id*, pp. 127, 314–316; Ford (2000), pp. 953–354.

[2] See chapter "The Use of Compulsory Licences in Latin America" by Carlos M. Correa, in this volume; Goldstein (2008), p. 476; Dutfield and Suthersanen (2008), p. 127; Ho (2009a), p. 1071.

[3] Dutfield and Suthersanen (2008), p. 319; Emilio (2011), pp. 69–70.

developing countries where lack of access to affordable medicines imperils the health and lives of their citizens.

According to Art. 31 (i) and (j) of TRIPS, the "legal validity of any decision relating to the authorization" of compulsory licensing and "any decision relating to the remuneration" of such licence should be "subject to judicial review or other independent review by a distinct higher authority". Among the patent law of most countries, compulsory licensing and any decision relating to the remuneration of such licence are subject to judicial review. Very few of them have "other independent review by a distinct higher authority". Therefore, this chapter will start with a short note on the meaning of "other independent review by a distinct higher authority" (Sect. 2) and focuses mainly on judicial review of compulsory licensing cases by two Asian countries, namely India and Taiwan (Sect. 3). Then an inquiry into Art. 30 of the TRIPS Agreement for criteria for judicial review will be made (Sect. 4), which will be followed by the conclusion (Sect. 5).

2 The Meaning of "Other Independent Review by a Distinct Higher Authority"

According to Art. 31 of TRIPS, in additional to judicial review, compulsory licensing and any decision relating to the remuneration of such licence may also be subject to "other independent review by a distinct higher authority". However, TRIPS does not provide a clear definition of what "other independent review by a distinct higher authority" is. We argue that "other independent review by a distinct higher authority" is supposed to be made by entities other than judicial bodies. But does that mean that such "higher authority" is an administrative agency? We believe so. Having said so, and acknowledging that members have flexibility in implementing the review scheme,[4] the design of such "distinct higher authority" should be different from that of a typical administrative body. The "distinct higher authority" should maintain a certain degree of institutional independence to prevent interference from the administrative body that grants compulsory licensing. Therefore, the "independent review" is not purely administrative in nature but rather comes with a "quasi-judicial" characteristic so that the legislative purpose of Art. 31 can be achieved.

In Taiwan, the Taiwan Intellectual Property Office (TIPO) is under the Ministry of Economic Affairs (MOEA), which has oversight over the legality and appropriateness of decisions made by the TIPO via the Administrative Appeal Review Committee (AAPC). According to Article 52(2) of the Administrative Appeal Act, the members of the AAPC under the MOEA shall be chosen from the agency's

[4] Gervais (2008), p. 390; Ho (2009a), p. 688 ('In addition, the negotiating history confirms that there should be no restrictions on the type of subject matter considered permissible since such restrictions were actually contemplated and specifically rejected').

senior staff, righteous gentlemen in the society, scholars, or experts; inter alia, the ratio of the righteous gentlemen, scholars, and experts shall be not less than one half. We therefore argue that the AAPC is "a distinct higher authority" as required by Art. 31 of TRIPS.[5] The AAPC of the MOEA upheld the decision made by the TIPO, which granted a compulsory licence against Philips (for more, see Sect. 3.2).

3 Judicial Review of Granted Compulsory Licence in Certain Asian Countries

The Paris Convention and the TRIPS Agreement have not identified the legal substantive grounds upon which compulsory licences function, to allow flexibility for the granting authorities under national laws.[6] While Art. 5(A) of the Paris Conventions seems to position the prevention of abuse of patents as the justification for launching the compulsory licensing system,[7] Art. 31 of the TRIPS Agreement concentrates on the procedures that shall be followed prior to the grant of compulsory licences.[8] As a matter of fact, the Paris Convention attempts to exemplify "abuses of the patent" by using the terms "failure to work" or "insufficient working". However, the Paris Convention doesn't define what situations constitute the patentee's "failure to work" or "insufficient working". Furthermore, the assertion of the aforesaid two grounds shall be subject to "a grace period" for the patentee to work the patent to avoid the grant of compulsory licences.[9] It should also be noted that the grounds of "failure to work" or "insufficient working" merely form a prima facie of abuses of the patent. If the patentee could provide legitimate reasons for his inaction, "failure to work" or "insufficient working" would be justified.[10]

As we understand it, the possible grounds for the issue of compulsory licensing under the Paris Convention and the TRIPS Agreement should be read together with Art. 2(1) of the TRIPS Agreement.[11] Compulsory licensing functions as an exception or limitation to the exclusive rights enjoyed by the patentee. To secure the

[5] Mueller (2006), p. 583.

[6] Gervais (2008), p. 390; Ho (2009a), p. 688 ('In addition, the negotiating history confirms that there should be no restrictions on the type of subject matter considered permissible since such restrictions were actually contemplated and specifically rejected').

[7] *See* Art. 5(2) of the Paris Convention.

[8] *See* Art. 31(b) of the TRIPS Agreement.

[9] *See* Art. 5(4) ('A compulsory licence may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons') of the Paris Convention.

[10] Bonadio (2012), p. 722.

[11] Art. 2(1) of the TRIP Agreement states: 'In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)'.

correctness of the grant of a compulsory licence, a review by court is indispensable according to Article 31 of the TRIPS Agreement. Under the judicial review, the legal validity of and remuneration for a granted compulsory licence should be examined.[12] The review of the legal validity of a compulsory licence is conducted to ensure that such licence complies with the interest measure established by Art. 31 of the TRIPS Agreement, namely to balance the conflict of interests between the patentee and the public, including competitors of the patentee. Therefore, the legal grounds for a compulsory licence, the scope and duration of the licence, and the properties of the licence should be thoroughly reviewed to justify the grant of a compulsory licence. It is worth noting that the Doha Declaration and the pending Article 31*bis* of the TRIPS Agreement were proposed to take into consideration the lack of pharmaceutical manufacture capability in some members. In this aspect, the review of the legal validity of a compulsory licence, especially on the occasions where public health is threatened by an epidemic, shall factor in the new norms under the Doha Declaration and Article 31bis of the TRIPS Agreement.

Generally speaking, the grounds for a compulsory licence have often drawn the most attention during review. Other aspects of review in accordance with the TRIPS Agreement have generally been incidental to the authority's ultimate decision as to whether a compulsory licence should be granted.

3.1 India

According to Art. 84(1) of the Patents Act 1970, there are three legal and substantive grounds for the application for a compulsory licence on specific patents, which are that "the reasonable requirements of the public with respect to the patented invention have not been satisfied", that "the patented invention is not available to the public at a reasonable affordable price", and that "the patented invention is not worked in the territory of India", respectively. In addition, Art. 84(1) complies with the Paris Convention by setting up the time limitation for application for such a licence, namely the application must be filed at the earliest on the expiration of 3 years from the date of the grant of a patent.[13] These three grounds created the main disputes in the following case, namely whether they are endorsed by the Paris Convention.

[12] *See* Art. 31(i) and (j) of the TRIPS Agreement.

[13] Art. 84(1) of the Patents Act 1970 states: 'At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India'.

The patentee, Bayer Corporation (hereinafter "Bayer"), owns a patent on a drug "Sorafenib" used in treating liver and kidney cancers at an advanced stage.[14] Bayer was granted the "Sorafenib" patent in India on March 3, 2008.[15] Bayer also had the regulatory approval for importing and marketing this drug under the trade name "Nexavar", which is subject to the protection of the "Sorafenib" patent in 2008.[16]

An Indian generic drug manufacturer, Natco Pharma Ltd. (hereinafter "Natco" or "the applicant"), applied for the grant of a compulsory licence on the "Sorafenib" patent on July 29, 2011.[17] Basically, Art. 84(1) of the Patents Act 1970 is stipulated as the legal grounds for the grant of a compulsory licence. The time limitation is obviously not the issue the two parties would like to argue in this case. The applicant in this case negotiated with the patentee to seek a voluntary licence on the patented drug and failed to conclude the licence due to disagreement on the price.[18] Such negotiation for a voluntary licence on a patent will be taken into account in determining whether a compulsory licence will be granted under Art. 84 (1) of the Patents Act 1970.[19] From this point, it seems that the requirement of Art. 31(b) of the TRIPS Agreement that the applicant negotiated a voluntary licence first is also satisfied in this case.

Based on Art. 84(6)(i) and 84(7)(a)(ii),[20] the Indian Controller of Patents favoured the applicant's arguments and thought that the insufficient quantum of the patented drug provided by the patentee through importation to the Indian market had never met the needs of patients despite the market statistical data supplied by the patentee.[21] The Controller also questioned whether infringing drugs marketed by M/s. CIPLA, another generic drug manufacturer in India, could effectively supplement the lack of the patented drug in market. After observing that the

[14] *See* Decision about Application for Compulsory License under Section 84(1) of the Patents Act, 1970 in respect of Patent No. 215758, at 4, the Controller of Patents, Mumbai, Compulsory License Application No. 1 of 2011, the 9th of March 2012 (hereinafter "Natco/Bayer C.L. decision").

[15] Natco/Bayer C.L. decision, at 5.

[16] *Id.*

[17] *Id.* On the review about the impact of compulsory licences on Indian markets and foreign investment, please see chapter "Economic and Procedural Constraints of Compulsory Licences for Medicines" by *Yugank Goyal*, in this volume.

[18] Natco/Bayer C.L. decision, at 6.

[19] *See* Art. 84(6)(iv) of the Patents Act, 1970.

[20] Art. 84(6)(i) of the Patents Act, 1970 states: (6) In considering the application filed under this section, the Controller shall take into account (i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention. Art. 84(7)(a)(ii) of the Patents Act, 1970 states:(7) For the purposes of this chapter, the reasonable requirements of the public shall be deemed not to have been satisfied (a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, (ii) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced.

[21] Natco/Bayer C.L. decision, at 21–24.

patentee sought remedies against the infringement of the patented drug, the Controller found that the infringing drugs were actually facing the risk of having an injunction sought by the patentee, and it was not suitable to ignore the limited distribution to the patients.[22] The Controller then emphasised that even by adding the volume of the infringing drugs into calculation of the availability of the patented drug, the reasonable requirement of the public for the patented drug had not been satisfied.[23]

Although the Controller agreed with the patentee's argument about the interpretation of "the public" under Art. 84 (1)(b) of the Patents Act,[24] he also desired that the patentee should have implemented price discrimination on the patented drug to ensure affordability to the public.[25] The failure to use price discrimination seems to affect the interpretation of "reasonable affordable price". Additionally, the Controller affirmed his position again that the infringing drug products have no influence over the determination of the reasonable affordable price for the patented drug.[26] Finally, based on the fact that the price of the patented drug was prohibitive for the public, the Controller concluded that the second ground for the grant of a compulsory licence had been satisfied.[27]

The third ground for the grant of a compulsory licence is whether the patented drug has not been worked in the territory of India. After hearing the arguments made by the parties concerned, the Controller supported the applicant's position to limit the interpretation of "is worked" to the supply of the patented drug by local manufacture in India. There are three main reasons to justify the decision of the Controller. Firstly, the Controller rebuked the patentee over the amendment, in its submitted materials, of the text of Art. 84(7)(a)(ii). The Controller especially noted that the elimination of the requirement of local manufacture was made merely to shift implicitly this requirement into Art. 84 (1)(a) for determination of "the reasonable requirements of public", having nothing to do with the interpretation of Art. 84 (1)(C).[28] Moreover, the Controller recognised that the development of international patent law tends to authorise the states to establish the legal grounds for the grant of a compulsory licence to cope with public health threats.[29] Reading

[22] *Id*. at 21.

[23] *Id*. at 23.

[24] *Id*. at 30–31. In respect of "the public" stipulated under Article 84 (1)(b) of the Patents Act, the patentee argued that "reasonable affordable price" of the patented drug should be subject to the paying capacity of specific public sections rather than that of all public sections. The patentee claimed that the grant of a compulsory licence doesn't purport to make the lower class of patients on the paying capacity afford the patented drug to have the treatment of liver or kidney cancer.

[25] *Id*. at 30–35. The patentee further argued that the grant of a compulsory licence doesn't purport to make the lower class of patients on the paying capacity afford the patented drug to have the treatment of liver or kidney cancer.

[26] *Id*. at 36.

[27] *Id*.

[28] *Id*. at 39–40.

[29] *Id*. at 41.

the text of the Paris Convention on compulsory licence, the Controller also found that "failure to work" is not defined. As a consequence, without any contradiction with the Paris Convention, the Indian legislators had the discretion to set up the special requirement of local manufacture of the patented products to define "failure to work" in order to assuage the effects of patent abuses.[30] Finally, the Controller stated that the requirement of local manufacture is conducive to transfers of technology promoted by the TRIPS Agreement, and its benefits would be palpable, especially when the term of the patent expires.[31]

After the decision of compulsory licence was made by the Controller of Patents, Bayer moved its appeal to the Intellectual Property Appellate Board (hereinafter "IPAB"[32]). The appellant mainly raised six points to question the legality of the grant of compulsory licences, among which there are at least four questions connected with the substantive issues of compulsory licence.[33] Firstly, the appellant

[30] *Id.* at 41–43.

[31] *Id.* at 43–45.

[32] According to Section 120 (1) of the Patents Act, the Appellate Board established under section 83 of the Trade Marks Act 1999 shall be the Appellate Board for the purposes of this Act. Indian Trademark Act, section 92: (1) The Appellate Board Shall not be bound by the procedure laid down in the code of civil procedure, 1908 but shall be guided by principles of natural justice and subject to the provisions of this Act and the rules made thereunder, the Appellate Board shall have powers to regulate its own procedure including the fixing of places and time of its hearing. (2) The appellate Board shall have, for the purpose of discharging its functions under this Act, the same powers as are vested in a civil court under the Code of Civil Procedure 1908 while trying a suit in respect of the following matters, namely: (a) receiving evidence, (b) issuing commissions for examination of witnesses, (c) requisitioning any public record and (d) any other matter which may be prescribed. (3) Any proceeding before the Appellate Board Shall be deemed to be a judicial proceeding within the meaning of section 193 and 228, and for the purpose of section 196, of the Indian Penal Code and the Appellate Board Shall be deemed to be a civil court for all the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure 1973. The IPAB is therefore judicial in nature.

[33] Review Order about Decision of Compulsory License under Section 84(1) of the Patents Act, 1970 in respect of Patent No. 215758, at ¶4, Intellectual Property Appellate Board, Chennai, Order No. 45 of 2013, OA/35/2012/PT/MUM, the 4th day of March 2013 (hereinafter "Natco/Bayer C.L. Review Order"):

Learned senior counsel Mr. P.S. Raman appearing for the appellant submitted that the compulsory licence order was vitiated by several errors;

(i) Under Section 87(1) where the Controller should have arrived at prima facie satisfaction that a case has been made out, notice was not given to the appellant herein, which is a grave miscarriage of justice;
(ii) (The compulsory licence application is not supported by any evidence;
(iii) The appellant had sought for adjournment to enable the invention to be worked to the fullest extent and this was not granted, which is against the law;
(iv) While deciding whether the reasonable requirement of the public has been satisfied, the Controller ought to have taken into reckoning the presence of another player, CIPLA (not before us) and the supply made by CIPLA and by totally ignoring its presence, injustice has been caused;
(v) The Controller ought to have ascertained what is the reasonable price and thereafter, decided the issue of granting compulsory licence; and

argued that it is necessary to consider the existence of the patentee's competitors in the market of the patented medicine to decide if the reasonable requirement of the public has been satisfied.[34] The competitors mentioned by the appellant included the infringer in this case. Since another firm, CIPLA, was an infringer of the patent, and marketed the infringing medicine with an affordable price, the appellant thought that the infringing medicines sufficed to meet the urgent needs of the public for treating the cancers specified in the case. However, this argument was rejected by the IPAB.[35] Affirming the position of the Controller on this issue, the IPAB emphasised that the grant of compulsory licence is merely relevant to patented inventions. Further, in terms of systematic interpretation on patent law, the meaning of patented invention indicates an invention protected by a patent that is reflected in the products the patentee or its licensees will sell in the market.[36] Under such interpretation, the infringing products never came from the patented invention, so the reasonable requirement of the public should not be considered. Certainly, even though CIPLA's infringing products might deal with the need of the public for treatment of cancers specified in the case, the risk of judicial injunction sought by the patentee over the infringing medicine should not be ignored.[37] As long as such an injunction was made, CIPLA's infringing products would be forced to leave the market.[38] The uncertainty of legal risk of injunction strengthened IPAB's conclusion that CIPLA's infringing products are not a leeway for the patentee to escape the responsibility of marketing sufficient medical products for the public.[39]

Secondly, the appellant contended that the requirement of working under Section 84(1)(c) of the Indian Patents Act that constitutes a ground for the grant of compulsory licence wouldn't be satisfied merely by the manufacture of the patented products in the territory of India.[40] According to the appellant's opinion, the importation of the patented products may also meet with the aforesaid requirement of working. The IPAB adopted a more flexible interpretation on the require-

(vi) The controller was in error in concluding that the manufacture in India was necessary to meet the "working" requirement under Section 84(1)(c) of the Act.

[34] The substantive issue is "(iv) While deciding whether the reasonable requirement of the public has been satisfied, the Controller ought to have taken into reckoning the presence of another player, CIPLA (not before us) and the supply made by CIPLA and by totally ignoring its presence, injustice has been caused", mentioned in note 1. *See* also Section 84 of the Patents Act 1970.

[35] Natco/Bayer C.L. Review Order at ¶¶23–29.

[36] Natco/Bayer C.L. Review Order at ¶28 ("Therefore, the words 'patented invention' can only mean what the patentee or his licensee markets and nothing else").

[37] Natco/Bayer C.L. Review Order at ¶29.

[38] Natco/Bayer C.L. Review Order at ¶29 ("While it is true that the injunction application was closed, if CIPLA had failed to file the accounts as undertaken, it was open to the appellant to move the Court for modification of the order").

[39] It's the author's observation in this case.

[40] The substantive issue is "(vi) The controller was in error in concluding that the manufacture in India was necessary to meet the "working" requirement under Section 84(1)(c) of the Act", mentioned in note 1.

ment of working than the Controller did in the first instance.[41] The IPAB never thought that the working of the patented products merely goes through manufacturers, nor did it give a necessary interpretation of "working" to include importation.[42] Based on the practical need for the patented products in the Indian market,[43] as the authors observe to have been the case, the IPAB seemed to prioritise the interpretation of working as local manufacture. If the patented products weren't made in the local market and were instead imported, the patentee should have provided sufficient evidence to show the reason why the importation occurred in the place of manufacture in India.[44] Otherwise, the requirement of working would not be satisfied, and thus the grant of compulsory licence was justified under patent law. Obviously, the patentee in this case failed to disclose the grounds for the importation of the patented medicine, so IPAB concluded that Section 84(1)(c) is applied to grant a compulsory licence.

On the third substantive issue, the appellant questioned the interpretation of Section 84(1)(a) and (b) about "the reasonable requirement of the public" and "a reasonable affordable price".[45] On the "the reasonable requirement of the public", the appellant argued that the postponed marketing of the patented medicine resulting from compliance with the related statutory requirements should be recognised in its definition.[46] In addition, it further argued that the Patient Assistance Program, a social benefit program in India, also contributes to the fulfilment of the reasonable requirement of the public and is among the factors influencing the requirement.[47] Shifting the focus to "a reasonable affordable price", the appellant thought that "a reasonable affordable price" should be decided as one reasonable to

[41] Natco/Bayer C.L. Review Order at ¶52.

[42] Natco/Bayer C.L. Review Order at ¶52 ("Therefore, we cannot decide that 'the working' totally excludes import, or that 'working' is synonymous to "import" and that if there is no manufacture in India, then there is no working").

[43] Natco/Bayer C.L. Review Order at ¶51 ["Section 84(7)(e) which refers to the working of invention in the territory of India and importation from abroad of the patented articles, clearly indicates different activities. In a given case there may be an invention which cannot be manufactured in India and it is also possible that there is an invention where the reasonable requirement of public itself is small in number and setting up a factory just for the said purpose is not practicable"].

[44] Natco/Bayer C.L. Review Order at ¶52 ("In any event, we are not furnished with any evidence regarding this aspect viz., whether the appellant in its facility in India, which admittedly the appellant does not deny, could not have manufactured this drug. So, with regard to Section 84(1)(c), we find that the word 'worked' must be decided on a case to case basis and it may be proved in a given case, that 'working' can be done only by way of import, but that cannot apply to all other cases. The patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient there must be evidence").

[45] The substantive issue is "(ii) The compulsory licence application is not supported by any evidence", mentioned in note 1.

[46] Natco/Bayer C.L. Review Order at ¶¶31–32.

[47] Natco/Bayer C.L. Review Order at ¶32.

the patentee and the public[48] and, consequently, that the R&D expenditure involved in the patent should be a significant factor in deciding what is a reasonable, affordable price for the patented medicine.[49] At the same time, the appellant was also concerned about distorting the market and opposed fixing the price for the patented medicine by the Controller through the grant of compulsory licence.[50]

The IPAB disagreed with the appellant on this issue and declared that the grant of compulsory licence is completely in accordance with public interest rather than exclusively with the patentee's interest or the licensee's interest.[51] The concept of public interest is a lever to check the affordability of the patented medicine. As to whether the reasonable requirement of the public was satisfied, IPAB resorted to assessing whether the commercial scale of the practising of the patented products had reached an adequate extent that is reasonably expected in the market.[52] Moreover, IPAB affirmed the Controller's position that the Patient Assistance Program would not work to satisfy the reasonable requirement of the public.[53] After considering the prohibitive price and insufficient quantity of the patented medicine in this case, the IPAB supported the Controller's opinion on the issue and held that Section 84(1)(a) and (b) applies to the grant of compulsory licence in this case.

According to the reviews about the aforesaid substantive issues, the IPAB affirmed the grant of compulsory licence in the appeal stage, except that IPAB modified the original order issued by the Controller about the royalty rate.[54] The case is worth observing further to see whether a motion of appeal will be made to the Indian Supreme Court.

[48] Natco/Bayer C.L. Review Order at ¶33 ("According to the appellant, the price of any product must be reasonable to the public and to the manufacturer/innovator").

[49] Natco/Bayer C.L. Review Order at ¶31 ("The affordability has to be decided considering the nature of the product and reasonably affordable price should be fixed taking into account the price at which the appellant can sell the product considering the expenditure incurred by them").

[50] Natco/Bayer C.L. Review Order at ¶35 ("Learned counsel submitted that in no case of compulsory licence anywhere, the authority had fixed the price and that fixing the price would actually distort the competition").

[51] Natco/Bayer C.L. Review Order at ¶43 ("Therefore, we must bear in mind that these proceedings are in public interest; they are neither against the inventor, nor in favour of the compulsory licensee").

[52] Natco/Bayer C.L. Review Order at ¶38 ("The reasonable requirements of the public would not be deemed to have been satisfied, if the patented invention was not being worked in the territory of India on a commercial scale to an adequate extent or on reasonable terms and was not being so worked to the fullest extent that is reasonably practicable [vide: Section 84(7)(d)]. The failure to meet the demand on reasonable terms must logically mean both quantity and price").

[53] Natco/Bayer C.L. Review Order at ¶42.

[54] Natco/Bayer C.L. Review Order at ¶54.

3.2 Taiwan

There were three recorded compulsory licences in Taiwan,[55] two of which had gone through judicial review, namely the Nippon Soda Topsin case and the CD-R case. The Tamiflu case was never appealed. However, the Nippon Soda Topsin case was based on a deleted provision and has no bearing on the current law. The following discussion will be limited to the CD-R case.

The TIPO raised five key reasons to justify its granting a compulsory licence in the proceedings before the Taipei High Administrative Court. Firstly, the TIPO asserted that "failure to conclude a licensing agreement having reasonable commercial terms and conditions in due time" can't be interpreted to have the precondition of "technological blocking" where the patentee fails to work the invention protected by the patent or to work the invention to the fullest extent in the market.[56] In the TIPO's position, "failure to conclude the licensing agreement" functions as an independent ground for the grant of a compulsory licence. Secondly, even though the applicant had practised the five CD-R patents prior to the grant of a compulsory licence, the TIPO opined that such practice never stops the applicant from applying for the compulsory licence over the same patents according to Art. 31(b) of the TRIPS Agreement, and as a consequence the compulsory licence granted by the TIPO doesn't contradict Art. 31(b).[57] Moreover, the TIPO concentrated solely on the calculation of royalties for the five CD-R patents to determine if the applicant had proposed reasonable commercial terms and conditions to the patentee for negotiation of the licensing agreement. The TIPO also set up the test of "a considerable period of time" by considering both the duration and terms of negotiation. After the interpretation of "the reasonable commercial terms and conditions" and "a considerable period of time", the TIPO concluded that the grounds for the compulsory licence have occurred in this case.[58]

Fourthly, the TIPO emphasised that the wording "such practice [under the compulsory licence] shall be mainly to supply the requirements of the domestic market" constitutes a condition attached to a compulsory licence rather than a ground for determining if a compulsory licence would be legally granted.[59] The applicant's exports involving the patented CD-Rs prior to the grant of a compulsory licence in this case seem to have nothing to do with the decision on a compulsory

[55] For more details, see the chapter "Compulsory Licence and Government Use in Taiwan: A Regress" by Kung-Chung Liu, in this volume.

[56] "The defendant's arguments (1)" under "the issues", Taipei Gao Deng Xing Zheng Fa Yan 95 Nian Du Su Zi Di 2783 Hao Pan Jue.

[57] "The defendant's arguments (2)" under "the issues", Taipei Gao Deng Xing Zheng Fa Yan 95 Nian Du Su Zi Di 2783 Hao Pan Jue.

[58] "The defendant's arguments (3)" under "the issues", Taipei Gao Deng Xing Zheng Fa Yan 95 Nian Du Su Zi Di 2783 Hao Pan Jue.

[59] "The defendant's arguments (4)" under "the issues", Taipei Gao Deng Xing Zheng Fa Yan 95 Nian Du Su Zi Di 2783 Hao Pan Jue.

licence made by the TIPO. Finally, the TIPO clarified that although the TRIPS Agreement has no self-executing effects over Taiwanese patent law, the ground for a compulsory licence under Art. 76(1) of Taiwan Patent Act doesn't violate Art. 31 of the TRIPS Agreement and Art. 5(A) of the Paris Convention.[60]

As a matter of fact, in this case, the real issue should be whether Philips's refusal to conclude a licensing agreement under Gigastorage's proposal of reasonable commercial terms and condition in due time would constitute an independent ground for the grant of a compulsory licence. This issue may be recognised further as whether failure to conclude a reasonable licensing agreement in due time would be considered a substantive ground for third parties to apply for a compulsory licence or just a necessary procedural step for the applicant to express its best efforts to seek a voluntary licence to avoid the distortion of compulsory licences, when the substantive grounds have been satisfied.

Unfortunately, the Taipei High Administrative Court didn't respond to the above-mentioned issue; instead, following the text of Art. 76(1) of the Patent Act, it merely reviewed what "reasonable commercial terms and conditions" means according to the provision. The Court found that the TIPO erred in evaluating "reasonable commercial terms and conditions" exclusively by royalty calculation and stated that it should be evaluated as a whole if the terms and conditions under a licensing agreement are reasonable.[61] As a consequence, the Court held that the compulsory licence granted by the TIPO should be revoked because the applicant failed to provide sufficient and convincing evidence to prove that the terms and conditions proposed are reasonable in the market.[62]

4 Criteria for Judicial Review of Compulsory Licence Under Art. 30 TRIPS

4.1 Whether There Is Deterioration of the Values Respected by Patent Law

Under the theory of utilitarianism,[63] there is a social contract between the patentee and the government on behalf of the public under patent law. On one hand, the government grants exclusive rights to the patentee to secure his future incentives for

[60] "The defendant's arguments (7)" under "the issues", Taipei Gao Deng Xing Zheng Fa Yan 95 Nian Du Su Zi Di 2783 Hao Pan Jue.

[61] *See* "the substantive issue (1)", paragraph 4, "the opinion", Taipei Gao Deng Xing Zheng Fa Yan 95 Nian Du Su Zi Di 2783 Hao Pan Jue.

[62] *See* "the substantive issue (1)", paragraph 6–21, "the opinion", Taipei Gao Deng Xing Zheng Fa Yan 95 Nian Du Su Zi Di 2783 Hao Pan Jue.

[63] *See* Dinwoodie et al. (2002), p. 49 ('Patent laws are intended to encourage the introduction of new technology and the public disclosure of new technological information by giving the owner of

innovation through adequate recovery of R&D expenditures and reasonable returns in practising the invention protected by the patent. On the other, the patentee shoulders the duty to provide the public with high-quality inventions such that the public can access those inventions for the purposes of learning, technological improvement, and even re-innovation. "High-quality" inventions are reflected in the eligibility and requirements of a patent under patent law, which include the subject matter of a patent, novelty, non-obviousness, utility, enablement, and written description.[64] It is worth noting that the requirements of enablement and written description further address the significance of invention disclosure for public notice due to intangible properties of a patent. According to the utilitarian theory, the granting of exclusive rights is merely the means to achieve the ultimate goal of enhancing technological development under patent law that is rooted in the disclosure of and access to the invention to be enjoyed by the public.

Certainly, legislators also recognise that exceptions and limitations may be established to help the achievement of the ultimate goal under patent law. However, exceptions and limitations are made to keep the interest balance between the patentee and the public, including the potential competitors of the patentee. Such interest balance would be obtained when patentees are restrained from asserting their exclusive rights against some acts that have no substitution effects on the patented products and, at the same time, are conducive to the disclosure of and access to the patent to enhance the technological development.[65] This inference is

---

the patent a limited right to exclude others from making, using, selling, or importing a product covered by the patent, in exchange for the patent owner disclosing the invention to the world').

[64] "Written description" came from the necessity of patent disclosure and public notice, the main purpose of which is to determine the scope and boundary of claims. This requirement has been admitted by U.S. patent case law. *See Regents of the University of California* v. *Eli Lilly & Co*., 119 F.3d 1559 (Fed. Cir. 1997); *Ariad Pharms*., *Inc*. v. *Eli Lilly & Co*., 598 F.3d 1336 (Fed. Cir. 2010); Crouch (2010), pp. 385–387; Schuster (2007), p. 491.

[65] For example, the exhaustion doctrine and the experimental exception under patent law. The substitution effects result from the infringer's unauthorised practice of a patent without any justified ground under patent law. Since patent infringement occurs through unauthorised practice of a patent, the marketing of infringing products often produces unexpected and unnecessary competition with patented products in the market. Such illegal competition launched by the infringer goes with the advantages of price due to lower cost sunk into patent infringement than new innovation. Therefore, as long as the quality of infringing products can follow that of patented ones, incentives may be created to attract consumers in the market to purchase the infringing products rather than the patented ones. This is called "substitution effects". The assessment of substitution effects has been playing a key role in the calculation of "lost profits" as patent damages. Substitution effects are also considered when the court interprets "fair use" under copyright law. Further, substitution effects are pivotal in the application of Art. 30 of the TRIPS Agreement. Canada—Patent Protection of Pharmaceutical Products, Report of the panel, WTO document WT/DS114/R, 17 March 2000, para. 7.55: The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation

supported by Art. 30 of the TRIPS Agreement, after which limited exceptions can be allowed in patent law provided that they "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".[66]

4.2 Whether There Are Substitution Effects

In our opinion, "a normal exploitation" and "the legitimate interests" of the patent should be subject to the substitution effects of the products made under compulsory licence, and the legitimate interests of third parties should be measured by whether such interests benefit the ultimate goal of patent law. When the infringing acts have no substitution effects, "a normal exploitation" and "the legitimate interests" of the patent are not negatively impacted, and such acts may justifiably be named as exceptions and limitations.

The granting of a compulsory licence functions through the waiver of specific exclusive rights, to an extent. Therefore, the granting of a compulsory licence is among the exceptions and limitations under patent law. Based on our arguments about the exceptions and limitations, the granting of a compulsory licence should be tested by the criteria of Art. 30 to secure its justification.[67]

Art. 5 of the Paris Convention, which was incorporated into the legal system under the TRIPS Agreement, is to be interpreted according to Art. 30 of the TRIPS Agreement. Under Art. 5(A) of the Paris Convention, the granting of a compulsory licence is to alleviate the effects resulting from abuses of a patent. "Abuses of a patent" may be understood as the occasions where the execution of exclusive rights over the subject matters has very limited economic benefits to the patentee but hinders the achievement of the ultimate goal under patent law, violates fundamental values in human society, or restrains third parties from competing with the patentee in the market.[68] However, on attempting to cure the negative effects due to patent

practices is a key element of the policy reflected in all patent laws. Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined.

[66] *See* Art. 30 of the TRIPS Agreement ('Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties').

[67] Gervais (2008), p. 381 ("Given the specific mention of this type of use in art. 31, art. 30 should not apply to those cases. Otherwise, there would have been no need to list specific conditions to be met in art. 31") (omitted note 612). But Art. 30 seems to be flexible in establishing the exceptions of the exclusive rights to achieve a balanced interest between the patentee and the public under patent law. See the chapter "Limiting Patents" by Lionel Bently and Brad Sherman, in this volume.

[68] *See* Liu (2012), pp. 690–692; Liu (2008), pp. 772–774.

abuse through the grant of a compulsory licence, Art. 30 of the TRIPS Agreement reminds us of the substitution effects of the products produced under compulsory licence in the markets. In other words, the grant of a compulsory licence works as interference into the marketing scheme of the patentee who is protected by exclusive rights, merely through supplementing the patented products to keep the public from the harm of patent abuse. It was never the original expectation of legislators that the Paris Convention or the TRIPS Agreement should allow the products made under a compulsory licence to compete directly with the patented products in the market. From this point, "failure to work" and "insufficient working" would be recognised as a necessary threshold to apply compulsory licensing to cure patent abuses even though such wording hasn't been presented in the TRIPS Agreement.

As a consequence, the judicial review over the legal validity of a compulsory licence should establish clear grounds justifying its granting, connected with the abuses of a patent, and make sure that the products under a compulsory licence work as complements to cure the patent abuses.

Taking the *Natco* case in India as an example, the interpretation of Art. 84(1) of the Patents Act ought to seek the real grounds on which the values pursued by the legislators are deteriorated by patent abuse, and secure that the compulsory licence will not substantially influence the normal exploitation and legitimate interest enjoyed by the patentee due to substitution effects in the market. In fact, Art. 84 (1) (a), (b), and (c) of the Patents Act merely cite inadequate or insufficient supplies of the patent products caused by abuses of a patent, which hinder attainment of a specific value that the legislators cherish and wish to ensure through patent law. The granting of a compulsory licence under such circumstances is expected to lead to more patented products to resolve the aforesaid inadequate or insufficient supplies. As mentioned above, the Doha Declaration authorises members to establish the grounds for granting a compulsory licence. And the legal ground in the case of *Natco* is undoubtedly related to public health. The Indian Controller's decision to grant a compulsory licence on the patented drug treating liver and kidney cancers does not seem to run counter to the TRIPS Agreement and the Paris Convention. However, the patented drug in *Natco* was not used to respond to an emergency in the form of a pandemic in India but was a long-term treatment to extend the lives of patients. Based on the therapeutic effect of extension of lives, the Controller in *Natco* did not seem to question further whether there were any alternatives having similar therapeutic effect, as well as acceptable price in the market.

On the contrary, if there are other similar qualified drugs serving as alternatives to the patented drug, the failure to ascertain the market share of the patented drug inevitably distorted the decision on granting a compulsory licence. Under such circumstances, the alternatives might work with the patented drug as complements to satisfy the adequate and sufficient requirement for patients suffering from liver or kidney cancer. As a consequence, when the compulsory licence was granted on the patented drug, the licensed products would compete directly with the patented drugs, rather than supplementing the inadequate and insufficient supplies to secure specific value protected under patent law. The substitution effects resulting from the direct competition with the patented drug do not justify the grant of a compulsory

licence. It is worth noting that in determining the market share of the patented drug, the infringing drug in the market should be ignored. The infringing drug could bring in a competitive and affordable price, but it is vulnerable to the risk of an injunction by the court and may lack sufficient authorised tests of its safety and therapeutic effect. Consequently, the infringing drug should not be counted into the assessment of the market share of the patented drug. Additionally, irrespective of importation from foreign markets or manufacture in India, the availability of the patented drug in the market should be evaluated in the overall market. Distinguishing the origin of the patented drug when deciding the grant of a compulsory licence might violate the principle of technological neutrality expounded by Art. 27(1) of the TRIPS Agreement.[69]

The "Tamifu" case in Taiwan involved the issue of public health. As the purpose of grant of a compulsory licence was to combat the threat of Avian Influenza H1N1 under the circumstance of insufficient supplies of the patented drug, the ground for the grant of the compulsory licence is justified in terms of the Paris Convention and the TRIPS Agreement. The order issued by TIPO to use the patented drug as a priority over compulsorily licensed one may be inferred that the TIPO seemed to have recognised the substitution effects in determining whether a compulsory licence would be granted.[70]

Compared with the "Tamifu" case, the CD-R case in Taiwan was more controversial in terms of the grounds for the grant of a compulsory licence. In spite of never being addressed by the Taipei High Administrative Court, the issue should have been whether the refusal to issue a voluntary licence, or the failure to conclude a voluntary licence in due time, constituted an independent ground for the grant of a compulsory licence under Taiwanese patent law even though reasonable terms and conditions had been offered. As we discussed in this chapter, the grant of a compulsory licence is to assuage the negative effects caused by patent abuses. Prior to applying for a compulsory licence, the applicant is obliged to prove that a specific value that patent law is intended to foster has been deteriorated by patent abuses.[71] Then the applicant also needs to raise evidence that the products under a compulsory licence will work as complements, rather than substitutions, to secure the aforesaid value from the impact of patent abuses. However, in this case, it seems that the applicant neither clarified what value behind patent law is susceptible to patent abuses nor ensured that a compulsory licence will be indispensable to restore such value against patent abuses without delivering any unfair substitution effects on the patented products. We firmly believe that the simple refusal to grant a voluntary licence or the failure to conclude a voluntary licence in due time never constitutes an independent ground for the grant of a compulsory licence under

[69] *See* Bonadio (2012), pp. 722–724.

[70] TIPO, the decision of a compulsory license, Zhi Fa Zi no. 09418601149 (智法字第0941860114號).

[71] de Carvalho (2005), p. 320 ('Refusals to license patents violate the law only when they are accompanied by an otherwise unlawful conduct').

Taiwanese patent law. Otherwise, the provisions about the compulsory licence will forestall any possibility of voluntary licence. To grant a compulsory licence in place of a voluntary licence without any justification is certainly not the value the legislators sought.

5 Conclusion

The issue of compulsory licence has been among the most controversial ones under patent law. In view of the developments on the grant of compulsory licence in the global community, the grounds for the application of a compulsory licence usually are the basis for much dispute between the applicant and the patentee. While the textual indication of Art. 5(A) of the Paris Convention seems to consider "failure to work" the invention protected by the patent or "insufficient working" of such invention an independent ground for the grant of a compulsory licence, the TRIPS Agreement does not even clarify the grounds for the grant of a compulsory licence but merely addresses the negotiation obligation prior to applying for a compulsory licence. This chapter attempts to probe into the relation between patent abuses and the substantive grounds for a compulsory licence. We find that the real grounds result from the deterioration of the values behind patent law by patent abuses, for example anti-competitive effects, threats to public health, obstruction of the achievement of the ultimate goal of patent law, and so on. This is the first step for the judiciary to take when reviewing the justification for the grant of a compulsory licence.

Moreover, based on Art. 30 of the TRIPS Agreement, this chapter also argues that the judicial review should ascertain that the products made under a compulsory licence work as complements, rather than substitutions, to cure the negative effects caused by patent abuses. This is the second step for the judicial review to take when probing the justification for the grant of a compulsory licence. Ignoring these two steps of a review would deprive a compulsory licence of its justification and even impair the function of a voluntary licence under patent law. At the same time, such neglect will also run the risk of hindering compulsory licence from the adequate role of exceptions and limitations under patent law.

References

Bonadio E (2012) Compulsory licensing of patents: the Bayer/Natco case. Eur Intellect Prop Rev 34(10):719–728

Correa CM (1994) The GATT agreement on trade-related aspects of intellectual property rights: new standards for patent protection. Eur Intellect Prop Rev 16(8):327–335

Crouch D (2010) An empirical study of the role of the written description requirement in patent examination. Northwestern Univ Law Rev Colloquy 104:382–397

de Carvalho NP (2005) The TRIPS regime of patent rights. Kluwer Law International, Frederick

Dinwoodie GB et al (2002) International and comparative patent law. Lexisnexis, Newark
Dutfield G, Suthersanen U (2008) Global intellectual property law. Edward Elgar, Cheltenham
Emilio AB (2011) Tripping over TRIPS and the global HIV/AIDS epidemic: legislation and political decisions in Brazil and the United States. J Contemp Health Law Policy 28:57–85
Ford SM (2000) Compulsory licensing provisions under the TRIPS Agreement: balancing pills and patents. Am Univ Int Law Rev 15:941–974
Gervais DJ (2008) The TRIPS Agreement: drafting history and analysis, 3rd edn. Sweet & Maxwell, London
Goldstein P (2008) International intellectual property law: cases and materials. Foundation Press, New York
Ho CM (2009a) Unveiling competing patent perspectives. Houston Law Rev 46:1048–41114
Ho CM (2009b) Current controversies concerning patent rights and public health in a world of international norms. In: Takenaka T (ed) Patent law and theory: a handbook of contemporary research. Edward Elgar publishing, Cheltenham, pp 673–711
Liu KC (2008) Rationalising the regime of compulsory patent licensing by the essential facilities doctrine. Int Rev Intellect Prop Comp Law 39(7):757–774
Liu KC (2012) The need and justification for a general competition-oriented compulsory license regime. Int Rev Ind Prop Comp Law 43(6):679–699
Mueller JM (2006) Note: the tiger awakens: the tumultuous transformation of India's patent system and the rise of Indian pharmaceutical innovation. Univ Pittsburgh Law Rev 68:491–640
Schuster MI (2007) Sufficient disclosure in Europe, is there a separate written description doctrine under European Patent Convention? Univ Missouri-Kansas City Law Rev 76:491–504