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Thirty-Second Session Geneva, December 7 to 10, 2020

DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING PRIOR USE

Document prepared by the Secretariat

INTRODUCTION

- 1. At its thirty-first session, held in Geneva from December 2 to 5, 2019, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would continue working on a draft reference document on exceptions and limitations to patent rights in conjunction with patent protection, in accordance with the agreement reached at the twenty-eighth session of the SCP. In particular, it was agreed that, based on the agreement reached at the thirtieth session of the SCP, the Secretariat would submit a draft reference document on the exception regarding prior use to the thirty-second session of the SCP, taking into account any additional inputs from Member States for the preparation of the said draft reference document (see document SCP/31/9, paragraph 25, first bullet point under "Exceptions and Limitations to Patent Rights").
- 2. Pursuant to the above decision, the Secretariat invited Member States and Regional Patent Offices, through its Note C. 8940, dated January 10, 2020, to submit to the International Bureau any additional inputs for the preparation of the draft reference document on the exception regarding prior use.
- 3. Accordingly, Annex I to this document contains the said draft reference document for the Committee's discussions at its thirty-second session to be held in Geneva from December 7 to 10, 2020. As mandated by the Committee, in the preparation of the draft reference document, the Secretariat made use of information submitted by the Member States to the thirty-second

session of the SCP, available on the website of the SCP electronic forum at: https://www.wipo.int/scp/en/meetings/session_32/comments_received.html, as well as other information collected though the SCP activities, as indicated in document SCP/27/3. In addition, the Secretariat also consulted other sources of information in order to obtain supplementary material on the topic.

4. The reference document contains the following sections: (i) overview of the exception regarding prior use; (ii) objectives and goals of the exception regarding prior use; (iii) exception regarding prior use and international legal framework; (iv) provisions on exception regarding prior use in regional instruments; (v) national implementation of the exception regarding prior use; (vi) challenges faced by Member States in implementing the exception regarding prior use; and (vii) results of implementation of the exception regarding prior use. In addition, it contains an Appendix, in which various legal provisions on the exception regarding prior use are compiled.

[Annex follows]

DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING PRIOR USE

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APPENDIX

1. Overview of the Exception Regarding Prior Use

- 1. According to a general concept of patent law, a patent shall not be granted to an invention which already exists in the prior art. While the definition of the term "prior art" is not uniform, in many countries, it consists of all knowledge that has been made available to the public, anywhere in the world, prior to the filing or priority date of a patent application, whether it existed by way of written or oral disclosure or by way of public use.
- 2. There are cases where a patent is granted even if the patented invention had been used by a third party before the patent application was filed. Typically, this is the case where the third party was using the invention in its business prior to the filing date or priority date of the application or making substantial preparations to do so, but *in secret*. In reality, inventors may prefer not to seek patent protection for each and every invention because of various reasons of business and economic character. For example, this can happen when the inventor cannot afford to seek patent protection or has a business strategy that values secrecy over patent protection. According to the above definition of "prior art", a secret use of the invention which was not made available to the public prior to the filing or priority date would not be regarded as prior art.
- 3. In the first-to-file system under which most patent systems operate, where the same invention was made independently by more than one person, the person who filed first is entitled to obtain a patent. Since the public was not in possession of the details of the invention until the patent application was filed and published, it is considered appropriate that the applicant who filed first obtains a patent. However, it is also widely considered that allowing a patentee to enforce its rights against the third party who had been using the same invention secretly before the relevant application was filed would be unjust towards such a prior user. That would deprive the prior user the right to do what it had already been doing before the relevant patent application was filed. The economic consequences for the prior user may be too harsh if it has to renounce the continued use of the invention simply because it did not file a patent application.
- 4. Therefore, under a number of legislations, provisions exist allowing a third party to continue using a patented invention if it had used the invention for the purpose of its business in good faith before the filing date (or the priority date) or had made effective or serious preparations for that purpose.¹ The practical effect of such provisions is that the prior user can continue using the invention without liability, and without any remuneration to be paid to a patentee, subject to certain conditions, while the patentee enjoys exclusive rights against other parties except the prior user.
- 5. In general, the prior use exception aims to strike a balance between, on the one hand, the interests of the prior user, who may have made a decision not to seek a patent protection, and on the other hand, the patentee, who deserves to be rewarded for disclosing the invention to the public.
- 6. While national and regional law provisions on prior use exception have common aspects, the exact scope of the exception may differ from one jurisdiction to another, as discussed in subsequent sections of this paper.

See Appendix to this document.

7. Depending on the system established at the national level for safeguarding the activity of the prior user, the reference has been made to "prior use exception" or "prior user rights" or "prior use defense". While substantive nuances may exist between these systems, for the purposes of this paper, the terms "exception regarding prior use" or "prior use exception" are used as generic terms.

2. Objectives and Goals of the Exception Regarding Prior Use

8. In general, the public policy objectives of the exception are aimed to achieve a balance between the interests of the patentee and the prior user and to address inequity, which is inherent in the first-to-file regime, thereby to provide benefits to the society as a whole. While these objectives are described in this section under two headings, i.e., a balance of rights and fairness in the patent system, they both contain interrelated concepts and factors.

Balance of rights

- 9. One of the main objectives for provision of the prior use exception is to achieve appropriate balance of rights and interests between the right holder and the prior user. By allowing the prior user to continue using the invention, the exception protects the economic interests of the prior user which in the end benefits the society as a whole by encouraging the parallel creativity and competition.
- 10. Thus, in responding to a question on public policy objectives of this exception in the Questionnaire on Exceptions and Limitations to Patent Rights (hereinafter referred to as "the Questionnaire")² many Members States referred to the balance of rights and/or interests between different parties. For example, Canada, China, as well as the Eurasian Patent Organization stated that such exception was provided in order to "achieve an appropriate balance of rights" between patent holders and prior users, as defined in the applicable laws.

Box 1. Policy objectives of the prior use exception in China

"The purpose of the Patent Law to provide for such an exception is to balance the rights of right holders and the legitimate interests of third parties. Such limitation could help avoid unfairness that exists in real life, arising from the fact that the entities or individuals who have invested human and material resources in the creation of the invention are not able to exploit their own intellectual achievements just because they have not filed any patent applications before hand [...]."

- 11. In Spain, the aim of the exception is "to reconcile the interests of the patent owner with those of a prior user acting in good faith." With this exception, "the prior user is allowed to continue using or working the invention, albeit under more restrictive conditions than if he were the owner of a patent".
- 12. In the response from Australia, it was stated that "the grant of a patent should not deprive a party from continuing to do what they were doing before the patent was [filed]. On the other hand, an inventor should not be deprived of patent protection by the secret acts of third parties, of which they can have no knowledge." Further, it was stated that Section 119 of the Patents Act 1990 "provides a balance between the rights of the patentee and third parties who have independently used an invention before the priority date of a patent application". ⁴

The Questionnaire carried out within the WIPO Standing Committee on the Law of Patents (SCP), can be found at: https://www.wipo.int/scp/en/exceptions/.

³ See response from China to the Questionnaire.

See response from Australia to the Questionnaire as well as its response to the 32nd session of the SCP.

Box 2. Policy objectives of the prior user rights defence in the United States of America

"By allowing the earlier user/inventor to continue uninterrupted commercial use of the invention while also allowing the later inventor to obtain a patent enforceable against all others, the prior user right embodies a balance between the equitable economic interests of the earlier user and the larger goal of the patent system in incentivizing the enrichment of the fund of human knowledge. [...]."5

13. Other countries, focusing on economic aspects of the prior use exception stated the following: In Hungary, exception provides "protection of investments that were performed in *bona fide*"; In Italy, the relevant exception is provided in order to safeguard the prior user's economic status of possession. It is noted that "it is essential to avoid the legitimately created values are ruined. A later patent application cannot endanger prior user's investments."; In Romania, the prior use exception is "intended to protect the investments of a person done in good faith on the territory of Romania and to avoid the abuse of rights". Likewise, the response of Norway explains that if there were no exception on prior use, "the person who had used the invention secretly would have to stop using it, because the use would be in conflict with the patent right. The prior user's investments would be lost, and this is unfavorable in the light of community economy". Similarly, the response of Sweden states that the prior use exception is "reasonable" and "provides for economic benefits to the society as a whole". In the Russian Federation, the prior use exception is intended, *inter alia*, to protect the interests of third parties that have already invested capital in production and to incentivize parallel creativity of persons who, for some reason did not seek the patent protection.

Box 3. Policy objectives of the prior use exception in Germany

"The purpose of Section 12 German Patent Act is to ensure that the property of a third party acquired in good faith through use or through an event for use is not devalued by a later patent application. The right of prior use is intended to prevent the undue destruction of economic values created in the legitimate exercise of the right. The power, time and capital invested by the prior user in existing installations which either already exploit the invention or where the will to exploit it has been confirmed by events for use should not be spent in vain and such an asset should not be devalued by the patent application of another."

14. In Brazil, the prior use exception related to the "principle of acquired rights, which aims at avoiding unnecessary burden on good faith users who had been exploiting the invention before the date of deposit or priority of the patent application". Another explanation expressed by AIPPI French Group is that since the prior user did not learn from the disclosure made by the

See USPTO's response to a Report on Prior User Rights, available at: https://www.uspto.gov/sites/default/files/ip/global/prior_user_rights.pdf.

See responses to the Questionnaire received from these countries.

Ibid. It is to be noted that while the argument "protection of economic interest of the prior user" is recognized as legitimate in many countries, it does not apply in France since commercial working or serious preparatory steps are not required under French law. See AIPPI French Group submission Q228.

German Federal Court of Justice, BGH, Xa ZR 18/08 - Füllstoff, published in GRUR 2010, 47. See submission from Germany to the 32nd session of the SCP.

Furthermore, this principle was found in the Brazilian Constitution under Article 5. See a response from Brazil to the Questionnaire.

patentee and such disclosure "did not enriched the level of his/her knowledge", there is no justification for the exclusive rights of the patentee being enforced against such a prior user. 10, 11

Fairness in the first-to-file system

- 15. In addition to the above objectives, the prior use exception aims to provide fairness to, and mitigate effects of, the first-to-file system under which most patent systems operate. Under this system, where the same invention was made independently by more than one person, the person who filed first is entitled to obtain a patent. Eventually, in the absence of prior use exception, and in the absence of other legal remedies, 12 the patentee could enforce its rights against the prior user who had been using the same invention secretly before the relevant application was filed. Such a situation is not considered to be fair towards such a prior user. It is not only that the prior user would lose important investment he/she had made, but filing for patent protection would have become necessity and the rights of innovators to choose a secrecy over patent would be lost.
- 16. In this regard, for example, the response from the Netherlands, explains, inter alia, "whatever the reasons were for the prior user [...] to keep the invention secret (e.g. no interest in a patent, business strategy, etc.), it is considered unfair if the patent holder could maintain his rights against the prior user. Without a "prior use" provision, applying for a patent would be a necessity instead of a free choice." 13
- 17. Switzerland's response states that "this exception is aimed at limiting the consequences of the first-to-file system by protecting the investments made by the inventor of an unpatented invention that he has been keeping confidential since a date prior to the filing by a third party of an application concerning the same invention". In the United States of America "providing limited prior user rights in a first-inventor-to-file system addresses the inherent inequity such a system creates between an earlier commercial user of the subject matter and the later patentee". 14

Box 4. Policy objectives of the non-exclusive license on the patent right (prior user rights) in Japan

"[I]f the first-to-file system is strictly applied, it would not necessarily be fair that a party which had been working the same invention prior to the filing of a patent application by another party should be precluded from working the same invention of the patent right, just because the party was slightly behind in filing an application. Therefore, even if such a policy is applied, there remains a need to adjust the interests of the patent owner and any party already working the invention in question prior to the patent application." ¹⁵

¹⁰ AIPPI French Group submission Q228.

Correlating with the above objectives, in the responses of other countries, the following public policy objectives were indicated: "not to prevent the prior user to make use of his achievement" (Austria); "not to make impossible continuing exploitation of a patented invention by a party who has not been aware of the existence of the patent" (Poland); "not to harm persons (inventors) who reached the same invention as described in the patent on their own at an earlier date" (Portugal). See the responses from these countries to the Questionnaire.

For example, in the United Kingdom, the 1949 Patents Act granted no protection to a prior user whose prior use began before the priority date of the invention; however, secret prior use was a ground for revocation. See response from the United Kingdom to the Questionnaire.

See response from the Netherlands to the Questionnaire.

Report on the Prior User Rights Defense, USPTO, January 2012, p.51.

See response from Japan to the Questionnaire.

- 18. AIPPI French Group also explains that "the "rights" of the third parties who made or had possession of the invention before the first person to file must be preserved so as to retain the possibility of selecting a policy of patenting or secrecy policy, in order to avoid a situation where a person who has chosen to keep an invention secret finds himself deprived of the right to work it on account of a patent subsequently being filed; any other arrangement would have the indirect result of making the filing of a patent obligatory". 16
- 19. While the response from Mexico underlined that the general legal principle was "first in time, first in right", it was also considered that the prior use exception, as defined in its legislation, sought "to protect users in good faith so that they may continue using their invention, although a third party not involved therein has obtained a patent for the said invention, in order to achieve fairness between two holders of an invention, even though only one of them has patented it". It was further explained that such an exception sought to protect the user in good faith, "provided that such a user may have invested economic, physical and intellectual resources in order to use the invention". The response from Japan, with respect to non-exclusive licenses granted to prior users in their law, also notes that such licenses are granted to ensure fairness in terms of the interests of both, patent holders and prior users.¹⁷
- 20. In Serbia, the prior use exception is "provided for the reasons of fairness and economic security necessary for investment and exploitation of the invention that was made before the filling of the application". In the United Kingdom, the exception exists to ensure that "the prior users are treated fairly with respect to patent holders". Whereas the responses from Indonesia, Qatar and Uganda also underline that the relevant exceptions are intended to provide protection for good faith prior users. ¹⁹

Exception Regarding Prior Use and International Legal Framework

21. No international treaty expressly addresses the exception regarding prior use. However, Article 30 of the TRIPS Agreement lays down general principles regarding the exceptions and limitations to the rights which may be provided by the WTO Members. Since Articles 30 is a permissive ("may") provision, Members are permitted, but not obliged, to provide those limited exceptions to the rights. The provision states:

"Exceptions to Rights Conferred

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."

¹⁶ AIPPI French Group submission Q228.

See the response from Japan to the 32nd session of the SCP.

The response further explains that when the Patents Act 1977 came into force "it deprived a secret prior user of his right to sue a patent holder for grounds of invalidity. To counter this deprivation it was thought only just to accord a right to continue his use, thus a secret prior user may continue his use without being sued on grounds of infringement subject to Section 64". See the responses from the United Kingdom to the Questionnaire

See responses from the respective countries to the Questionnaire.

22. While the wording of Article 30 does not expressly make any reference to the exception regarding prior use, the negotiating history of this provision shows that early drafts of this provision contemplated to include an illustrative list of exceptions which included a prior use exception. ²⁰ Specifically, Draft of July 23, 1990 (W/76) stated:

"[provided that legitimate interests of the proprietor of the patent and of third parties are taken into account,] limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as:

- 1.1 Rights based on prior use.
- 1.2 [...]"21
- 23. Ultimately, the illustrative list approach was abandoned in favor of a more general wording as provided in current Article 30 of the TRIPS Agreement and the negotiating records of the TRIPS Agreement provided no explanation of the reason for this decision.²²
- 24. The WTO Dispute Settlement Panel in *Canada Patent Protection of Pharmaceutical Product* case²³ provided some guidance with respect to the interpretation of Article 30 of the TRIPS Agreement, the summary of which has been provided elsewhere.²⁴ Although during the proceedings, parties had advanced their arguments about the consistency of the prior use exception with Article 30 of the TRIPS Agreement, this exception was not the specific focus of the dispute.^{25, 26}

4. Exception Regarding Prior Use in Regional Instruments

25. Several regional instruments provide for an exception regarding prior use. These are: Decision № 486 establishing the Common Industrial Property Regime for the Andean Community (hereafter "Andean Community Decision № 486"); Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (1999) (hereafter "Bangui Agreement",); Patent Regulation of the Cooperation Council for the Arab States of the Gulf; and the Patent Regulations under the Eurasian Patent Convention.²⁷

See Daniel Gervais, The TRIPS Agreement, Drafting History and Analysis, Third Edition, Sweet and Maxwell, 2008, p.380.

Composite Draft text (Informal Note No. 1404 of June 12, 1990) also lists "rights based on prior use" among limited exceptions. See WTO document WT/DS114/R, p.211.

See WTO document WT/DS114/R, p.165.

WTO document WT/DS114/R.

For the summary of the case, see document SCP/13/3, pp. 21 and 22, and document SCP/28/3, pp. 6-8.

See WTO document WT/DS114/R and document SCP/28/3.

For the parties arguments on the prior use exception, see WTO document WT/DS114/R, pp. 73, 74 and 85.

As regards Europe, Article 28 of the Unified Patent Court (UPC) Agreement provides for "Right based on prior use of the invention". In addition, Article 37 of the Agreement relating to Community patents (89/695/EEC) (adopted 15 December 1989) deals with "Right based on prior use and right of personal possession". As of January 15, 2020, both Agreements have not entered into force.

TABLE 1. REGIONAL INSTRUMENTS

Andean Community Decision № 486 ²⁸

Article 55:

"Article 55. - Without prejudice to the provisions stipulated in this Decision with respect to patent nullity, the rights conferred by a patent may not be asserted against a third party that, in good faith and before the priority date or the filing date of the application on which the patent was granted, was already using or exploiting the invention, or had already made effective and serious preparations for such use or exploitation.

In such case, the said third party shall have the right to start or continue using or exploiting the invention, but that right may only be assigned or transferred together with the business or company in which that use or exploitation is taking place."

Patent Regulation of the Cooperation Council for the Arab States of the Gulf ²⁹

Article 12(3):

"Despite the grant of the patent, an establishment that, in good faith, manufactures, uses an industrial manufacturing process of a product, or makes serious preparations therefor, before the filing date of an application by another person, or before the priority date of the application pertaining to the same product or process, shall have the right to continue such acts. Assignment or transfer of the said right is only permitted with the other elements of the establishment."

Bangui Agreement 30

Article 8(1)(d):

- "(1) The rights deriving from the patent shall not extend [...]
- (d) to acts performed by any person who in good faith on the filing date, or where priority is claimed, on the priority date of the application on the basis of which the patent is granted on the territory of a member State, was using the invention or making effective and genuine preparations for such use, in so far as those acts are not different in nature or purpose from the actual or planned earlier use.
- (2) The right of the user referred to in paragraph (1)(d) may not be transferred or handed on otherwise than with the business or company or the part thereof in which the use or the preparations for use were made."

²⁸ Andean Community comprises Bolivia, Colombia, Ecuador and Peru.

The Cooperation Council for the Arab States of the Gulf comprises the State of the United Arab Emirates, the State of Bahrain, the Kingdom of Saudi Arabia, the Sultanate of Oman, the State of Qatar, and the State of Kuwait.

Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization, 1999. Member States of OAPI are Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Togo and Comoros.

Patent Regulations of the Eurasian Patent Convention 31

Rule 20:

- "(1) Any natural person, legal entity, or organization assimilated thereto, which in good faith, before the filing date of the application or, where priority has been established, before the priority date of the invention, has been using an identical solution on the territory of a Contracting State, or has made the necessary preparations for such use, shall retain the right to proceed with that use free of charge, provided that the scope thereof is not increased. The right of the prior user may only be transferred to another natural person, legal entity, or assimilated organization, together with the production unit in which the identical solution has been used, or the necessary preparations for the use thereof have been made.
- (2) The right of the prior user shall apply only on the territory of the Contracting State in which such prior use has occurred."
- 26. The wording of the provisions relating to prior use exception under the regional instruments referred to in the above table show that there are certain common features among those provisions:
 - The date of prior use must occur prior to the filing or priority date of the relevant patent application;
 - The prior use must be performed in "good faith";
 - Assignment or transfer of the prior user right is possible only together with the business or company in which that use is made;
 - The scope of the exception includes use of the invention on or at the filing or priority date by the prior user as well as "effective", "serious" or "genuine" preparatory works for such use.
 - In Patent Regulation of the Cooperation Council for the Arab States of the Gulf and the Patent Regulations of the Eurasian Patent Convention, the exception is formulated as a "right" to continue prior use. Whereas in the Bangui Agreement, the legal effect of patent rights appears to be *priori* limited making it impossible to enforce a patent in case of prior use. In the Andean Community Decision № 486, both formulations are used.
- 27. As no extensive case law has been developed as regards the above provisions to date, it remains to be seen what are the exact boundaries of the exception for respective Member States. At least in one national case in Colombia, the territorial aspect of the exception has been discussed. In particular, Article 55 of the Andean Community Decision № 486 has been interpreted by the Superintendence of Industry and Commerce to mean that the scope of the prior use exception covered third parties' "effective and serious preparations" not only in Colombia where patent is in force, but also in any other jurisdiction.³²

Member States of the EAPO are Turkmenistan, the Republic of Belarus, the Republic of Tajikistan, Russian Federation, the Republic of Azerbaijan, the Republic of Kazakhstan, Kyrgyzstan and Armenia.

Landers & Cia S.A vs. Group Seb Colombia (2014)-Auto No. 31662, July 7, 2014. Delegatura para Asuntos Jurisdiccionales. Superintendencia de Industria y Comercio (Colombia). For the discussion of the case, see A.M.Castro and C. Hanssen "La Excepción del usuario anteriorde buena fe en materia de patentes: su objetivo y alcance en la Comunidad Andina", Derecho Farmaceutico y Propriedad Intelectual en America Latina, ASIPI, 2015, pp.283-298. Available at: https://www.munizlaw.com/e-mailing/PIntelectual/ASIPI/DerechosFarmaceuticosASIPI.pdf. The authors argue that as patent rights are territorial, so should be the exceptions to those rights.

5. National Implementation of the Exception Regarding Prior Use

5.1 Legal Framework Regulating the Exception Regarding Prior Use

28. In total, 123 countries and territories have been identified to provide for the exception regarding prior use through a specific statutory provision within respective IP or patent legislation. Appendix to this document contains provisions of laws of those countries and territories on the exception regarding prior use.

TABLE 2. LIST OF COUNTRIES AND TERRITORIES WHICH PROVIDE FOR EXCEPTION RELATING TO PRIOR USE

Albania, Algeria, Andorra, Antiqua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahrain, Barbados, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Brazil, Botswana, Brunei, Bulgaria, Burkina Faso, Canada, China, Hong Kong (China), Cameroon, Central African Republic, Chad, Colombia, Comoros, Congo, Costa Rica, Côte d'Ivoire, Croatia, Cyprus, Czech Republic, Denmark, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Finland, France, Gabon, Georgia, Germany, Ghana, Greece, Guinea, Guinea-Bissau, Honduras, Hungary, Iceland, Indonesia, Ireland, Israel, Italy, Japan, Kazakhstan, Kenya, Kyrgyz Republic, Latvia, Liechtenstein, Lithuania, Luxembourg, Madagascar, Malaysia, Mali, Malta, Mauritania, Mauritius, Mexico, Montenegro, Morocco, Mozambique, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Republic of North Macedonia, Romania, Russian Federation, Saint Lucia, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Singapore, Slovak Republic, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, Thailand, Trinidad and Tobago, Togo, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, Uruquay, United States of America, Uzbekistan, and Viet Nam.

29. In general, the national law provisions are formulated in a way that, under the prior use exception a third party is allowed to continue using a patented invention if he had used the invention for the purpose of its business in good faith before the filing date (or the priority date) or had made effective or serious preparations for that purpose. While these are the essential features of the prior use exception found in many jurisdictions, there are differences among national laws in terms of the exact wording of those provisions and their interpretation and scope.

The formulation of the provisions on the prior use exception

30. The way the exception has been formulated under the national laws could be generally categorized in the following five types:

Type I

31. In some countries that provide this exception, the legal effect of patent protection is, *a priori*, "limited" or it is impossible to enforce a patent in case of prior use. In these countries, the wording of provisions would typically state: "patent shall have no effect on persons" or "the rights conferred by a patent cannot be prevailed upon against a person" who has used the invention prior to the filing date (or priority date), or such prior use are "not opposable" or "not deemed to be patent right infringement", in that jurisdiction.

32. For example, Article 37 of the Law No. 24.481 of Argentina states that:

"The owner of a patent shall not have the right to prevent those who, in good faith and prior to the date of the patent application, have exploited or made significant investments to produce the subject matter of the patent in the country from continuing such exploitation." 33

33. Similarly, the law of the Czech Republic states in Section 17:

"(1) A patent shall not have effect vis-à-vis a person (hereinafter referred to as "the prior user")

who has already exploited the invention independently of the inventor or proprietor of the patent

or who has made preparation therefore, that he can prove, before the priority right began [...]"34

Type II

34. In some other Member States, the prior use exception is formulated as a *right* to continued prior use. For example, the law of Georgia states:

"The right of prior use implies a right of a person to use an invention regardless of the effect of the patent, if such a person has been using the invention in good faith or conducted preparatory works for its use prior to the date of filing the patent application with Sakpatenti or the priority date." ³⁵

35. Other examples in this category of laws are the laws of Brazil and Dominica, which state, respectively:

"The person in good faith who, before the date of filing or priority of a patent application, exploited its object in the Country, shall be assured the right to continue the exploitation, free of charge, in the previous form and condition. [...]"36

"Where a patent is granted for an invention, a person who before the date of filing of the patent application or, if priority was claimed, before the date of priority, does in good faith in Dominica, an act which would constitute an infringement of the patent if it were then in force, or makes effective and serious preparations in good faith to do such an act, shall have the rights specified in subsection (2)."³⁷.

Type III

36. The third category of provisions combines the features of the above two types, i.e., limitation of the enforcement of rights against the prior user, and a prior user's entitlement to a right to continue prior use. For example, the provision of law of Bosnia and Herzegovina falls in this category of laws:

Non-official translation.

Section 17 of the Zákon č. 527/1990 Sb. ze dne 27. listopadu 1990 o vynálezech a zlepšovacích návrzích Zmena : 519/1991 Sb.

Article 53 Law of Georgia No. 1791 of February 5, 1999, on Patents (as amended up to Law No. 3235 of July 20, 2018).

Article 45 of the Patent Law № 9.279 of 14 May 1996 of Brazil, as last amended by Law № 10.196 of 14 February 2001.

Section 34 of the Patents Act, 1999 (Act 8 of 1999) of Dominica.

- "(1) A patent shall have no effect against a person who had, prior to the filing date or prior to the date of the granted priority of a patent application, exploited or manufactured in good faith and within his economic activities a product according to the protected invention or had made real and serious preparations for such an exploitation of the invention in Bosnia and Herzegovina.
- (2) The person referred to in paragraph (1) of this Article shall have the right to proceed, without the patent holder's consent, with the exploitation of the invention to the extent to which he had exploited it or prepared it for the exploitation up to the filing date of the patent application for the said invention."³⁸
- 37. Another example in this category of laws is the law of Uganda, which states:
 - "(1) Notwithstanding section 38, a patent has no effect against any person, in this Act referred to as "the prior user" who, in good faith, for the purposes of his or her enterprise or business, before the filing date or, where priority is claimed, the priority date of the application on which the patent is granted, and within the territory where the patent produces its effect, is using the invention or is making effective and serious preparations for that use.
 - (2) A person referred to in subsection (1) has the right, for the purposes of his or her enterprise or business, to continue the use or to use the invention as envisaged in the preparations referred to subsection (1)."³⁹

Type IV

38. The provisions of laws of Japan and the Republic of Korea could be placed in another category as formulation of relevant provisions implies that the use of the patented invention by a prior user is not an exception to the patent rights *stricto sensu*. In those countries, prior users "shall have a non-exclusive license on the patent right" without any remuneration to be paid to the patentee.⁴⁰

Type V

39. Yet different from the above approaches, in the United States of America, the prior user is "entitled to a defense under section 282(b) with respect to a subject matter [...], that would otherwise infringe a claimed invention".⁴¹

5.2 Scope of the exception regarding prior use

40. The analysis of provisions on the prior use exception as well as jurisprudence shows that there are similarities and differences as regards the scope of the prior use exception in various jurisdictions. The following paragraphs provides information on various aspects of the exception defining its scope.

(a) Persons entitled to invoke the exception

41. In many national laws, the prior user must be a "person" or "third party" using the invention for the purpose of his/her business, or be making serious preparations to use the invention for that purpose prior to the filing or priority date.⁴² In addition, another third party may become

Article 74 of the Law on Patents of 28 May 2010 of Bosnia and Herzegovina.

³⁹ Section 41 of the Industrial Property Act of 6 January 2014 of Uganda.

See Article 79 of the Japanese Patent Act and Article 103 of the Patent Act of the Republic of Korea.

Section 273 of the U.S. Patent Law, 35 U.S.C. §§ 1 et seq. (consolidated as of May 2015).

In France, the term used is "any person...in possession of the invention". See paragraph 59 of the document.

entitled to qualify for asserting prior users right as a result of assignment and/or transfer of prior user's right, which is possible under many laws, under certain circumstances.⁴³ The good faith requirement under the law of many countries, as discussed below, determines whether the party is entitled to invoke the exception.

- 42. In Japan and the Republic of Korea, the prior user can be not only a person who has made the invention by himself without knowledge of the contents of the invention claimed in a patent application, but also a person who, without knowledge of the contents of the invention claimed in a patent application, has learned the invention from another person who had made the invention.
- 43. In some countries, court decisions have further clarified who could be considered a prior user in those jurisdictions. For example, in Germany, the Federal Court of Justice reviewed the case where the prior user manufactured individual parts, which technically and economically can only sensibly be assembled to the entire device in accordance with the invention. However, the prior user did not itself assemble the individual components, but supplied a third party with them, who assembled them into the protected entire device. Under these circumstances, the manufacture and supply to a third party of the components of the patented device was seen as a direct prior use, allowing such a manufacturer to invoke the exception.⁴⁴

(b) Good faith use

- 44. Many laws require that the activity of the prior user to be carried out in "good faith" or "bona fide" to fall within the scope of the exception.⁴⁵ In general, these terms appear to mean that the invention should be developed by the prior user independently from the patent owner and without knowledge of the content of an invention claimed in a patent application.⁴⁶
- 45. In this regard, requiring the independent nature of the prior user's creativity, some laws expressly provide that the exception would not apply if the knowledge about the patented invention was obtained from the applicant or patentee. For example, in the Netherlands, the prior user shall "continue to have the right to perform the acts referred to in art. 53(1) NPA 1995, unless his knowledge was obtained from matter already made or applied by the applicant or from the applicant's descriptions, drawings or models".⁴⁷
- 46. In the United States of America, the general articulation of the good faith requirement is that a prior user must be "acting in good faith, [to] commercially [use] the subject matter in the United States." Specifically, "[a] person may not assert a defense [...] if the subject matter on which the defense is based was derived from the patentee or persons in privity with the

See section 5.4 of this document on the assignment of prior user rights.

German Federal Court of Justice, BGH, decision of 14 May 2019 – *Schutzverkleidung*, X ZR 95/18. Published by OUP and CH Beck on behalf of GRUR International, 69(2), 2020, 168–173.

⁴⁷ Article 55 of the Patent Act 1995 of Netherlands.

See, e.g., Section 23 of the Patents Act of Austria; Section 13(4) of the Industrial Property Act of the Kingdom of Bhutan; Article 16(1) of the Law on Patent of the Republic of Azerbaijan; Article 74 of the Patent Law of Bosnia and Herzegovina; Article 45 of Law n. 9.279 of Brazil; Article 10 of Decree Law No. (30) for the Year 2006 of Qatar; Article 8.4(d) and 8.5 of Law No. 4/2001 of Sao Tome and Principle; Article 23 of Law on Patents of Serbia; and Article 17(1) of the Patent Act of Slovakia.

For example, the response from Spain to the Questionnaire it was explained that good faith was required of the prior user, meaning that "the beneficiary of the right of prior use must be a third party who carried out the same invention as the patent owner prior to the patent owner, with no link or contact with the patent owner and having kept the invention secret. There shall be no good faith where the invention had been misappropriated or knowledge of the [...] inventor had been acquired unfairly." In the response from Poland, it was stated that "good faith of the user comes from either his developing of the same invention independently of the holder of the patent, or the user's belief that he can freely use a given technical solution." The response from the Russian Federation explained that "any use must be *bona fide*, i.e., the person who used the technical solution neither knew, nor should have known, about the essential features of the claimed protected solution." The responses to the Questionnaire can be found at: https://www.wipo.int/scp/en/exceptions/.

patentee".⁴⁸ In Sweden, the prior use exception exists provided "the exploitation did not constitute an evident abuse in relation to the applicant" or his predecessor in title.⁴⁹ In Portugal, the exception would not apply "if the knowledge is the result of unlawful or immoral acts against the patentee".⁵⁰

- 47. According to a French court, "the owner is acting in good faith when he or she has personally made the invention or when, as in this case, he or she has legitimately received it from its creator and has not been forbidden to use it". ⁵¹ In Germany, the Federal Supreme Court held that prior user rights accrued where the prior user had derived the knowledge of the invention from the later patent holder in good faith. ⁵²
- 48. With regard to the issue of derivation from the applicant/patentee, as stated above, the laws of Japan and the Republic of Korea state that the right to a non-exclusive license, in those countries, are not granted to parties who learned knowledge of the content of the invention from the applicant.
- 49. In some countries, it is clarified that a good faith may not be relied upon where the third party and the patentee are in the contractual relationship, i.e., the third party acquired the knowledge of the invention though fulfillment of the certain type of contract (e.g., work or research contract), or unlawfully (e.g., theft of information, espionage). In this regard, in Germany, the Federal Court of Justice held that "the prior user must act on the possession of the invention in his own interest. This means that acts carried out exclusively in the interests of another party do not form the basis of any right of prior use of the acting party itself." In China, while the relevant provision does not make the express reference to "good faith use", according to the commentators, the alleged infringer cannot claim the defense on the ground of right of prior use on the basis of illegally obtained technology or design.

(c) Permissible activities under the exception

The scope of "use"

50. As to the scope of the activities covered by the prior use exception under the applicable national law, the following can be observed.

51. In most countries, it is sufficient that the person "was using the invention" or "was making effective and serious preparations for such use" before the filing date (or the priority date). In relation to the scope of *use*, some countries' laws, including of Canada, the United Kingdom and the United States of America, clarify that the prior use exception/defense applies to acts

Article 105 of the Industrial Property Code of Portugal (approved by Decree-Law No. 110/2018 of December 10, 2018).

German Federal Court of Justice, *Kasten für Fußabtrittsroste* (BGH, GRUR 1964, 673). See Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights, May 2016. Available at:http://documents.epo.org/projects/babylon/eponet.nsf/0/A3EB2FE2F8A5AD71C1257E6D0057194A/\$File/b+sub-group_prior_user_rights_en.pdf, p. 16.

Liu Xiaojun, 'A Synopsis on Defenses to Patent Infringement', China Intellectual Property, available at: http://ipr.chinadaily.com.cn/2011-03/06/content_12124863.htm/.

Section 273 of the U.S. Patent Law, 35 U.S.C. §§ 1 et seg. (consolidated as of May 2015).

⁴⁹ Article 4 of the Patents Act (1967:837) of Sweden.

See submission from France to the 32nd session of the SCP.

German Federal Court of Justice, Füllstoff (BGH, Xa ZR 18/08 - published in GRUR 2010, 47). "Such is the case with workers, employees, managers and company organs that, to the extent that they have been working in the field assigned to them, are basically acting on behalf of their employer or the represented company (Kühnen, Patent Litigation Proceedings in Germany, 7th edition 2015, 6. Private right of prior use, Rn. 1741)". See submission of Germany to 32nd session of the SCP. See also response from Switzerland in the Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights, May 2016, p.28, as well as submission from France to the 32nd session of the SCP.

which would otherwise constitute an infringement of the patent.⁵⁵ Similarly, in Germany, the use of the invention comprises all uses stated in Section 9 German Patent Act (direct infringement: e.g. producing, offering, putting on the market etc.) and – in specific cases – uses according to Section 10 German Patent Act (indirect infringement).⁵⁶

- 52. In some countries, with respect to the prior use exception, the laws state that the following activities are not considered infringement of patent rights: "exploiting"⁵⁷, "commercially exploiting" ^{58,} "manufacturing"⁵⁹ or "commercial use" of the invention ⁶⁰, "creation and use of a similar solution"⁶¹, "[making] an invention identical to the said invention [...], and working the invention"⁶².
- 53. Some laws provide further clarifications with regard to permissible acts. For example, with regard to "exploitation", Section 119(5) of the Patents Act of Australia states that the "exploit" includes: "(a) in relation to a product: (i) make, hire, sell or otherwise dispose of the product; and (ii) offer to make, hire, sell or otherwise dispose of the product; and (iii) use or import the product; and (iv) keep the product for the purpose of doing an act described in subparagraph (i), (ii) or (iii); and (b) in relation to a method or process: (i) use the method or process; and (ii) do an act described in subparagraph (a)(i), (ii), (iii) or (iv) with a product resulting from the use of the method or process."63
- 54. In Spain, the Supreme Court ruled that the prior use exception is only invoked when products produced or marketed by the previous user are the same as those covered and protected by the patent. In addition, another court stated that: "[...] the recognition of the prior use rights is only possible when a person seeks to make or market products [...] protected by the patent. As for the "exploitation" of the invention, Spanish case law clarified that acts of exploitation performed by a prior user must be the same as those which require the [authorization from the patentee].

See, e.g., Section 56 of the Patent Act of Canada, Section 64 of the Patents Act of 2004 of the United Kingdom, and Title 35, Section 273 of the United States Code.

See the submission of Germany to the 32nd session of the SCP.

See, e.g., Australia, Israel, Norway and Montenegro.

Section 4 of the Patents Act of Finland.

⁵⁹ See, e.g., Algeria, Madagascar, Nicaragua and Nigeria.

Title 35, Section 273 of the United States Code entitles a third party to a defense under section 282(b) with respect to patented invention if, *inter alia*, "(1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use".

Article 14 of the Patent Law of the Kyrgyz Republic.

Article 79 of the Japanese Patent Act.

Article 2(3) of the Japanese Patent Act defines "working" of an invention as: "(i) in the case of an invention of a product (including a computer program, etc., the same shall apply hereinafter), producing, using, assigning, etc. (assigning and leasing and, in the case where the product is a computer program, etc., including providing through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc. (including displaying for the purpose of assignment, etc., the same shall apply hereinafter) thereof; (ii) in the case of an invention of a process, the use thereof; and (iii) in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc., exporting or importing, or offering for assignment, etc. the product produced by the process".

See decision no. 86/2006 of 13/02/2006, referred to in the submission of Spain to the 32nd session of the SCP. See decision 363/2014 of the Regional Court of Pamplona (Iruña), referred to in the submission of Spain to the

^{32&}lt;sup>nd</sup> session of the SCP.

Examples are those acts laid down in Articles 50 and 51 of the former Law of Patents no. 11/86 [rights conferred on the patentee]. See decision 726/2013, Section 9, Regional Court of Valencia, January 28, 2014, submission of Spain to the 32nd session of the SCP.

55. The French Industrial Property Code, on the face of it, does not require "using" the invention to enjoy the exception, but a person who was in "possession of the invention" shall have the personal right to exploit the invention⁶⁷. Prior possession is understood as an exception to the rights conferred to the patent holder and is generally recognized as "intellectual ownership" of the invention. Thus, under French jurisprudence, intellectual ownership of the invention is sufficient to benefit from the exception and the physical production of the invention, or its effective use, is not required. With respect to the condition of position, the possession must concern the same technology covered by the patent and the invention must be fully disclosed.⁶⁸ The most notable French jurisprudence is presented in Box 5.

Box 5. French case law on exception relating to prior use

- "In view of the fact that article L 613-7 [...] is intended to confer a right to exploitation of an invention to an inventor who has not chosen to apply for a patent; that the text refers to 'ownership of the invention' and, contrary to the assertions of the claimant, does not require acts of exploitation or even serious and effective preparatory acts to have been carried out" (Paris, April 17, 2015, SARL Balipro c. SA Vinmer).
- "Given that, for the intellectual ownership of the invention to be invoked, it must be complete, that is, concern all of the constituent parts of the patent as claimed" (Paris, January 14, 2004, paris fors france c.MW trading APS / Paris, September 20, 2006, SAS Kaufler c. SA Armor Inox).
- "Personal possession is only established for legal purposes when the person who invokes it is able to establish not that he or she is at the research or trial stage, but that, if he or she has not actually used it, he or she is at least able to do so immediately" (Paris, November 7, 1966, Potez c. Airflam).
- 56. In Germany, while Section 12 of the German Patent Act does not expressly refer to "possession" of the invention, the *intellectual* possession of the invention, *inter alia*, on the priority date is required. According to the German Federal Court of Justice, the possession of an invention is given if the technical teaching resulting from the task and solution is objectively completed and subjectively recognized in such a way that the actual execution of the invention is possible. The fact that the outcome according to the invention has been achieved purely by chance or in an unrecognized way is not enough for a right of prior use to be obtained. The section of the invention has been achieved purely by chance or in an unrecognized way is not enough for a right of prior use to be obtained.

Article L613-7 of the Intellectual Property Code of France states that "any person who, within the territory in which this Book applies, at the filing date or priority date of a patent was, in good faith, in possession of the invention which is the subject matter of the patent shall enjoy a personal right to work that invention despite the existence of the patent."

See submission from France to the 32nd session of the SCP.

⁶⁹ German Federal Court of Justice, BGH, X ZR 131/09 – *Desmopressin*, published in GRUR 2012, 895. See the submission of Germany to the 32nd session of the SCP.

⁷⁰ Ibid.

On the other hand, as far as repeatable knowledge of the technical teaching is concerned, neither the physical nor the chemical processes that are responsible for the advantage according to the invention have to be recognized, nor is it necessary for the prior user to be aware of the merits and characteristics that are objectively associated with the technical teaching put to prior use by it. The prior user only needs to be aware of such effects if they have been included in the claim as part of the inventive teaching (German Federal Court of Justice, BGH, X ZR 131/09 – *Desmopressin*, published in GRUR 2012, 895).

Possession of the invention must be acquired honestly, that is to say in such a way that the user must have considered itself authorized to use the invention permanently for its own purposes.⁷²

Preparatory works

- 57. The preparatory works for the use of an invention are included in the scope of the prior use exception in the most of the national laws. The terminology used to describe such works differs, which may consequently imply the differences in the scope of the exception in various countries. For example, the following wording are found in various national laws: "necessary preparatory works", 73 "necessary preparations" 74, "effective and serious preparations" 75, "real and serious preparations" 6, "considerable and serious preparations", 17 "substantial preparations", necessary arrangements", "actual preparations", and "required preparation" as defined in the applicable laws.
- 58. In this regard, the laws of Australia and New Zealand state that the prior use exception, *inter alia*, covers the activity of a person who "had taken definite steps (contractually or otherwise)" to exploit the invention in the patent area.⁸² The Federal Court of Australia clarified that if, immediately before the priority date, the alleged infringer was still evaluating alternatives, he/she could not assert that the definite steps to exploit the product had sufficiently been taken.⁸³
- 59. Some other courts have also provided clarification with regard to the scope of the exception in their respective countries. Thus, Spanish case law considers that the meaning of "serious and effective preparations" should be related to the concept of exploitation, referred to in Articles 83 and 84 of the Law on Patents (11/1986).⁸⁴ The Court stated the fact that the invention had already been imported to Spain and that all of the advertising material had been prepared, were indicia of "serious and effective preparations".⁸⁵ Additionally, preparations can only be considered as "serious and effective" if there is evidence that it was possible to exploit the invention forthwith. Neither the sole intent to exploit nor research nor experimentation can be construed as consisting of evidence of "serious and effective" preparations.⁸⁶ In another

German Federal Court of Justice, BGH, Xa ZR 18/08 - *Füllstoff*, published in GRUR 2010, 47. See the submission from Germany to the 32nd session of the SCP.

See, for example, Section 23 of the Patents Act of Austria; Section 22 of the Patent Law of Latvia; and Article 16(1) of the Law on Patent of the Republic of Azerbaijan.

See, for example, Article 22(iii) of the Law on Industrial Property of Mexico, and Article 69(2) of the Patent Law of People's Republic of China.

See, for example: Section 13(4) of the Industrial Property Act of the Kingdom of Bhutan; Article 31 of the Law No. 20-00 on Industrial Property of the Dominican Republic; Section 83 of Patents Ordinance of Hong Kong (China); Section 21(4)(e) of the Patents, Industrial Designs and Trademarks Act of Mauritius; Article 55 of Law No. 17-97 on the Protection of Industrial Property of Morocco; Section 11(4)D) of the Industrial Property Rights Law 67/2008 of Oman; and Section 30(5)(d) of the Patents Ordinance of Pakistan.

Article 74 of the Patent Law of Bosnia and Herzegovina and Article 64 of the Patent Act of Croatia.

Article 31 of the Patent Law of Ukraine.

Section 4(1) of the Consolidate Patents Act (Act no. 91 of 28 January 2009) of Denmark, Section 4 of the Patents Act of Finland and Article 71 of the Industrial Property Law of Poland.

Section 12 of the Patent Act of Germany.

Section 53 of the Israel Patent Law 5727-1967.

Article 14 of the Patent Law of the Kyrgyz Republic.

The provisions further clarify that the exception would not apply if, before the priority date, the person: (a) had stopped (except temporarily) exploiting the invention; or (b) had abandoned (except temporarily) the steps to exploit the invention. See Section 119 of the Patents Act 1990 of Australia and Section 146 of the Patents Act 2013 of New Zealand. See "Abandonment of prior use" in paragraphs 78 to 80 in this document.

Welcome Real-Time SA vs Catuity Inc. (2001) 113 FCR 110; 51 IPR 327 at 91-97.

See decision no. 726/2013 (Section 9, Regional Court of Valencia, January 28, 2014), referred to in the submission of Spain to the 32nd session of the SCP.

⁸⁵ Ibid

Decision no. 375/2006 (Section 15, Regional Court of Barcelona, July 20, 2006). See submission of Spain to the 32nd session of the SCP.

case in Spain, where the alleged "serious and effective preparations" consisted in the filing of a utility model application six days after the grant of the patent, the Court affirmed that, in this case, the filing of a utility model application could not be considered as sufficient evidence of "serious and effective preparations" for exploitation of the patent-protected invention.⁸⁷

60. In Switzerland, in relation to Article 35A(1) of the Federal Act on Patents for Inventions, which grants a prior user right to a person who, *inter alia*, had made special preparations for commercially using the invention in good faith in Switzerland, the Federal Supreme Court clarified that, it is not enough to have a plan or a technical drawing to have a prior user right established.^{88, 89} Similarly, with respect to a provision on the prior user's right in the Czech Republic, it was explained that "[n]either the technical development plan nor the contract for work, which was designed to solve the same problem, are likely to be sufficient to prove such a right" and that "[p]roven preparations for exploiting the solution fallen within the scope of the patent in question must be of such a nature that they are indeed aimed at such a solution. It is not enough to have the same problem, nor evidence to solve such a problem."⁹⁰

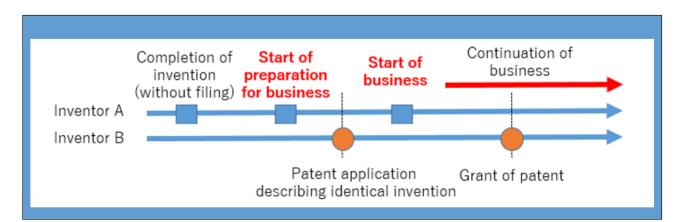


Figure 1: Conceptual image of prior user rights system in Japan⁹¹

- 61. In Japan, a non-exclusive license can be granted to a person who has been working the invention or engaging or preparing to engage in business that involves the working of the invention in that country at the relevant date. The Supreme Court determined that the requirements for the 'preparation for business' as working of an invention as provided by Article 79 could be met, where a person has an intention to immediately work the invention, although he/she has not reached the stage of implementation of the business, and such an intention has been expressed in a manner and to an extent which is objectively recognizable."
- 62. In Germany, the Higher Regional Court of Düsseldorf ruled that, while it is sufficient to invoke the prior use exception based on a single use of the invention, the prior user must show the seriousness of a commercial intention to use the invention into practice.⁹³ This is not given,

Decision no. 397/2012 (Section 28, Regional Court of Madrid, December 21, 2012).

⁸⁸ BGE 86 II 406 of 13 December 1960.

It is suggested that the special preparations for the commercial use of inventions may therefore include the purchase of equipment or material to manufacture products based on the inventions or the employment of people to carry out the invention. See Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights, May 2016.

See the submission by the Czech Republic to the 32nd session of the SCP.

See submission from Japan to the 32nd session of the SCP.

Judgment of the Supreme Court of Japan, 2nd Petty Bench, October 3, 1986 (Case number: 1986(O)454), available at: https://www.ip.courts.go.jp/app/files/hanrei_en/626/001626.pdf.

Higher Regional Court of Düsseldorf, I-2 U 109/03, published in BeckRS 2008, 5802. See submission of Germany to the 32nd session of the SCP.

for example, in the case of an unsaleable sample or a prototype still to be tested. 94 Furthermore, for the establishment of necessary arrangements for the use of the invention in Germany, a definitive decision for a commercial use must have been taken and serious preparations for the use of the invention in the near future must have been started. Acts which prepare for the possibility of a later, still uncertain use of the invention are not events within the meaning of Section 12 of the German Patent Act. The same applies to acts which are only intended to clarify whether the invention can and should also be used commercially, i.e. which serve to form the will directed towards commercial use in the first place. 95

Box 6. United Kingdom: Lubrizol Corporation v Esso Petroleum Co. Ltd. [1998] RPC 727

In the United Kingdom, the phrase "effective and serious preparations", as provided in Section 64 of the Patents Act, was analyzed by the Court of Appeal in Lubrizol Corporation v Esso Petroleum Co. Ltd. The Court ruled that, two customer trials by the defendant in the United Kingdom of small samples imported from the United States of America with a view to possible later manufacture in the United Kingdom but with no decision yet made, were not "effective", although serious, preparations. The Court stated that the primary meaning of the word "effective" are "having an effect" or "powerful in effect" and that it will be a matter for a court to determine in any given case whether "the serious preparations in question properly warrant the additional epithet "effective". The Court amplified is not "sufficient to show that the serious preparations, if pursued to finality, will have the requisite effect".96

(d) Extension of the scope of the business

63. The laws of many countries specify that the scope of the prior use exception does not allow for an extension of the business beyond its scope on the relevant date. For example, in China, the prior use exception allows the continuation of the manufacture of the products or use of the methods "within the original scope". In the Kyrgyz Republic, the prior user has the right to use the patented invention free of charge "without enlarging the scope of such use". In the Russian Federation, the prior user shall have the right to proceed with his activities, "provided that the scope thereof is not extended". In Vietnam, the prior user may continue using patented invention "within the scope and volume of use".

64. Likewise, in Brazil, prior users have the right to continue the exploitation, "free of charge, in the previous form and condition". Similarly, in El Salvador, the prior user "shall have the right to continue to manufacture the product or use the process as before". In Spain, the prior user is permitted to continue to work the invention "in the same manner or according to the preparations which had been undertaken until then or for the form in which preparations had been carried out. However, in both cases, this is restricted to such working having been carried out sufficiently to meet the reasonable needs of the enterprise". 97

Higher Regional Court of Düsseldorf, I-2 U 65/05, published in BeckRS 2008, 5814. See submission of Germany to the 32nd session of the SCP.

German Federal Court of Justice, BGH, X ZR 42/66 – Europareise, published in GRUR 1969, 35. See submission of Germany to the 32nd session of the SCP.

Lubrizol Corporation v Esso Petroleum Co. Ltd. [1998] RPC 727, p.785.

In this regard, the submission from Spain to the 32nd session of the SCP explained that; "Another aspect that may be controversial is the extent to which changes can be made to "meet the legitimate needs of a business," [...]. In Spanish case law, no decisions have been found stating what changes are permissible in relation to the volume of production that can be considered suitable to "meet the legitimate needs of a business".

- 65. In other countries, the prior use activities could be expanded beyond its scope on the relevant date. For example, in France, the law does not fix any quantitative limitations for the extent of exploitation of the invention by the prior user. Consequently, a prior user could increase its production after the filing (or priority) date. 98 In Japan, the Court recognized that the businesses can be justifiably expanded if this is within the scope of the businesses. Though the possible extent of expansion "within the scope of business objectives" may depend on the circumstances of the case. 99 In this regard, in the United States of America, the relevant provision states that "[t]he defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter for which it has been established that a commercial use [...] occurred." However, the provision goes on to state that "the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent." 100
- 66. Somewhat different from the above approaches, the laws of some other countries, such as Denmark, Iceland, Finland and Sweden require that the general character of prior use be "retained" or "maintained". In Sweden, this appears to allow extension of the business after the relevant date. ¹⁰¹ In Morocco, the rights granted by a patent do not extend to acts performed by the prior user, "provided that such acts do not differ, by their nature or purpose, from effective or expected prior use". ¹⁰²
- 67. In this regard, in the United Kingdom, the Court of Appeal ruled that the protection afforded by Section 64 of the Patents Act to the prior user is not strictly limited to acts identical to those which were performed before the priority date, but "cannot be a right to manufacture any product, nor a right to expand into other products". The Court of Appeal upheld the view that "if the protected act has to be exactly the same (whatever that may mean) as the prior art then the protection given by the section would be illusory. The section is intended to give practical protection to enable a man to continue in substance what he was doing before". 103

(e) Modifications to the embodiment of the invention

- 68. Related to the question on the expansion of the scope of the business, courts in some countries pronounced specifically on the issue as to whether a prior user could continue enjoy the prior use exception if he/she modifies the embodiment under prior use to another embodiment covered by the patent.
- 69. In France, the Intellectual Property Code permits a person benefiting from prior possession of an invention to exploit the invention without any specific restriction. He/she may exploit the invention without being limited to the sole embodiment of it that he/she possessed and modification of the invention is authorized as long as there is equivalence between the new embodiments and the initial embodiment.¹⁰⁴

See submission from France to 32nd session of the SCP, and Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights, May 2016.

¹⁹⁹ Ibid, Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights p.22.

Section 273 of the U.S. Patent Law, 35 U.S.C. §§ 1 et seq. (consolidated as of May 2015).

See section on Sweden in the Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights, May 2016, p.27.

See Appendix to this document for the provisions of laws.

Lubrizol Corporation v Esso Petroleum Co. Ltd. [1998] RPC 727, p.770.

See the submission of France to the 32nd session of the SCP.

70. In Germany, the Federal Court of Justice stated that the prior user is not allowed to further develop the prior use device if the development exceeds the scope of the previous use and interferes with the subject of the patented invention. In 2019 decision, the Federal Court of Justice further defined the scope of the exception in Germany.

Box 7. Germany: The scope of the prior use exception

In a 2019 decision, 107 the Federal Court of Justice stated that the prior user can be banned from modifying the previously used embodiment not only when this interferes for the first time with the subject-matter of the invention protected by the patent, but also "when the prior user uses the invention to a greater extent than corresponds to the prior user's legal status, or when it uses the invention in a different way than before the filing or priority date. The right of prior use may not be interpreted so narrowly that the prior user can make no economically reasonable use of it. On the other hand, it must be taken into account that the technical teaching of a patent can include alternatives that realize the technical and economic virtues of the invention in quantitatively or qualitatively different ways. In any case, the legal status of the prior user, who has only recognized and used some of these alternatives, does not necessarily justify allowing the prior user access to all these alternatives to the detriment of the patent proprietor. The prior user can therefore be banned from modifying the previously used embodiment even when the technical teaching of the invention is realized by both the prior use and the embodiment used after the filing date, but the latter realizes the teaching of the patent claim in a different embodiment or method. If, however, two fully equivalent alternatives for a feature are named in a patent claim, the fact that the prior user only used one of these alternatives will as a rule not justify a corresponding limitation of that user's use right. It will likewise have to be assessed if, in the patent specification, a modification of the previously used embodiment is disclosed that is an obvious alteration that from the point of view of the skilled person is readily compatible with the prior user's possession of the invention at the date of filing or priority."108 [Non-official translation]

(f) Changes to the types of acts

71. As regards to a question whether it is allowed to change the type of acts from one to another after relevant patent application is filed, the following has been observed. In Sweden, the prior use "retaining its general character", has been suggested to mean that the use has to continue within the same framework, i.e., if for instance the use has been relating to "producing", the prior user right does not give a right to "importation". 109 Similarly, in Germany, according to case law, where the prior user has manufactured or prepared to manufacture, the claimed invention, he/she may carry out any act contemplated under Section 9 of the Patent Act. 110 However, where the prior user has only imported or sold the invention without making

The Court explained further "[t]his Court presumed such an intervention for the case in which the alleged infringing embodiment realizes all features of the patent claim, while this was not yet the case with the embodiment previously used due to a lack of one of these features." German Federal Court of Justice, decision of November 13, 2001, X ZR 32/99 – *Biegevorrichtung*, published in GRUR 2002, 231-234.

¹⁰⁶ See Box. 6.

German Federal Court of Justice, decision of 14 May 2019 – Schutzverkleidung, X ZR 95/18. Published by OUP and CH Beck on behalf of GRUR International, 69(2), 2020, 168–173.

The Federal Court of Justice also held that "the limits of the prior-use right can be exceeded if the modification realises an additional advantage that was not realised by the non-modified embodiment. This can be the case when an embodiment is used for the first time that is emphasised due to this additional advantage in a subclaim or in the patent's description." Decision of 14 May 2019 – *Schutzverkleidung*, ibid.

See Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights, May 2016, p. 27.

Section 9 of the Patents Act lists exclusive rights of the patentee.

any preparations to manufacture, he/she cannot begin to manufacture the invention. Thus, in these countries, the nature of the prior user's business as it existed at the relevant date cannot be essentially modified to be covered by the exception.¹¹¹

72. In France, the beneficiary of prior personal possession is entitled to change the type of act he/she was carrying out before the relevant date, i.e., he/she may choose to produce the product, even if before the filing of the patent application on the same invention by the third party, he/she was only selling the product.¹¹²

(g) Abandonment of prior use

- 73. In addition, some other limitations are provided to the scope of the exception under some laws. For example, in the United States of America, it is specifically clarified that a "person who has abandoned commercial use (that qualifies under this section) of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken on or after the date of such abandonment." 113
- 74. The relevant provisions of the laws of Australia and New Zealand state that the prior use exception does not apply if, before the priority date, the person: (a) had stopped (except temporarily) exploiting the invention; or (b) had abandoned (except temporarily) the steps to exploit the invention.¹¹⁴
- 75. A similar approach is taken in Germany: once actual prior use had taken place, a temporary suspension of the use of the invention would be allowed. Specifically, in 1965 case, the Federal Court of Justice stated that "[a] right of prior use does not arise when the prior user ultimately ceases preparations to use the invention before the registration date. If, however, the user has used the subject-matter of the invention in at least one instance, it is not necessary for the creation or the maintenance of the prior-use right for the use to be continued without interruption. In this case, rather, the prior-use right lapses only when the prior user abandons this right." In this regard, in 2019 case, the same Court stated that suspension of the use of the invention in question, which was due to fluctuating demand and required execution depending on custom orders, is permissible under the exception. 116, 117

See Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights, May 2016. Similarly, the paper suggests that, in Japan, it is not allowed to change the act of working from importing and selling to manufacturing and selling. See p. 23.

See the submission of France to the 32nd session of the SCP.

¹¹³ Section 273(e)(4) of the U.S. Patent Law, 35 U.S.C. §§ 1 et seq. (consolidated as of May 2015).

Section 146(2) of the Patents Act 2013.

Federal Court of Justice of Germany, decision of January 7, 1965, la ZR 151/63, GRUR 1965, 411, 413 – *Lacktrankeinrichtung.*

Federal Court of Justice of Germany, decision of 14 May 2019 – X ZR 95/18. Published by OUP and CH Beck on behalf of GRUR International, 69(2), 2020, 168–173.

In a commentary relating to prior use exception in Germany, it was stated, however, that if the third party relies on serious preparations to ground the entitlement to prior use, such preparations should be ongoing at the relevant date. Otherwise, the intent to begin actual use in the immediate future, a constitutive element of the right, will be missing. See Paper of Prior User Rights, B+ Sub-Group on Patent Harmonization, Workstream on Prior User Rights, May 2016, p.17., referring to BGH, GRUR 1969, 35 "Europareise".

(h) Date for establishing the prior use exception

- 76. To benefit from the prior use exception, the prior use activity must take place before a specific date related to a patent. The majority of national laws provide that the prior use shall take before the filing date of the application or, if priority is claimed, the priority date. While in some other countries, provisions on prior use refer to the filing date. 119
- 77. Some conditions may be applied in some laws with regard to the date for establishing the exception. For example, in Germany, prior use activity, as defined in the law, must take place "at the time the application was filed". If the patentee claims a right of priority, the prior use activity shall take place before the priority date and not at the time the application was filed. However, this rule does not apply to nationals of a foreign country that does not guarantee reciprocity in this respect. ¹²⁰ Therefore, foreigners from such countries are limited to the actual filing date of an application.
- 78. In the United States of America, a person is entitled to a defense based on prior commercial use if, *inter alia*, "such commercial use occurred at least 1 year before the earlier of either—(A) the effective filing date of the claimed invention; or (B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b)." Thus, the system established in the United States of America appears to be most restrictive for prior users with regard to when the prior use activity must take place.

(i) Territory in which prior use should take place

79. Many laws expressly state that the prior use activities must have been carried out in the territory of those respective countries to be covered by the exception. However, some countries' laws are implicit in that regard and do not make a reference to any territory. In the Philippines, the prior user has the right to continue its use "within the territory where the patent produces its effect". In addition, as mentioned above, in a decision relating to prior use exception in Colombia, it was ruled that the prior use should not necessarily take place in that country to be covered by the exception.

(i) Limitations on enforceability of the exception

80. In the United States of America, a prior user right defense does not apply in relation to patents owned by or assigned to universities or affiliated technology transfer organizations. Specifically, the provision states that the defense to infringement may not be asserted if "the claimed invention with respect to which the defense is asserted was, at the time the invention was made, owned or subject to an obligation of assignment to either an institution of higher education [...] or technology transfer organization whose primary purpose is to facilitate the

In some countries, the provision on the prior use exception refers to the "priority date", whereas the priority date is defined as the date of filing the application, or the date when the earliest application was filed. See, e.g., Section 43 of Patents Act 1990 of Australia; Section 5 of the Patents Act 1977 of the United Kingdom; or Article 16 of the Law of the Republic of Belarus No. 160-Z of December 16, 2002, on Patents for Inventions, Utility Models, Industrial Designs. In China, the provision on the prior use exception refers to the "filing date", which should mean the priority date, if the priority is claimed.

See, e.g., Bahrain, Bulgaria, Iceland, Japan and Thailand.

Section 12(2) of the German Patent Act.

Title 35, Section 273 of the United States Code.

For example, in Albania, Armenia, Australia, Azerbaijan, Bhutan, Croatia, France, Germany, Hong Kong (China), Japan, Kyrgyz Republic, Netherlands and Spain. In this regard, the submission from France to 32nd session explains that according to French jurisprudence, prior possession acquired outside France does not confer any right (research work and trials must be carried out in the French territory).

For example, laws of Canada, China, the Dominican Republic and Italy.

See section 4 of the paper on regional instruments.

commercialization of technologies developed by one or more such institutions of higher education."¹²⁵ This provision relates to the concerns expressed by the university community that such a defense may impair the ability of universities to license patents on upstream research results.¹²⁶ No similar provisions have been found in other jurisdictions.

(k) Protection of recipients of products disposed of in exercise of the prior user rights

81. In some countries' laws, it is clarified that the recipients of products disposed of in exercise of prior users rights are protected in such a way that such recipients may deal with those products in the same way as if they had been disposed of by the registered proprietor of the patent.¹²⁷

5.3 Prior use exception and grace period

- 82. Some national laws clarify the relationship of the prior use exception and the grace period provisions, ¹²⁸ where they are provided.
- 83. For example, Subsection 119(3) of Patents Act of Australia provides that the prior use exception "does not apply to a product, method or process the person derived from the patentee or the patentee's predecessor in title in the patented invention". The provision further states that the above does not apply in cases where "the person derived the product, method or process from information that was made publicly available: (a) by or with the consent of the patentee or the patentee's predecessor in title"; and "(b) in the prescribed circumstances mentioned in paragraph 24(1)(a)". Paragraph 24(1)(a) grants a grace period to the disclosure made by the patentee or the predecessor in title. 129 Thus, in accordance with Section 119(3), the prior use exception applies to a prior user who derived his/her invention from the information that had been made publicly available by, or with the consent of, the applicant (or his/her predecessor in title) during the grace period. In countries with this approach, the prior use exception is seen as an important balancing provision such that a prior user who relies on an unfettered disclosure remains free to exploit the invention despite the grant of a patent. 130
- 84. However, in other countries, the prior use exception does not apply to the disclosure made by the applicant/predecessor in title during the grace period. For example, Article 45(2) of Law n. 9.279 of Brazil provides that the prior use exception "shall not be granted to a person who gained knowledge of the object of the patent through disclosure, in accordance with Article 12, provided that the application has been filed within 1 (one) year of the disclosure".

See, e.g., the provisions of laws of Antigua and Barbuda, Brunei, Dominica, Ireland and Trinidad and Tobago.

Section 273 (e)(5)(A) of the U.S. Patent Law, 35 U.S.C. §§ 1 et seq. (consolidated as of May 2015).

Report on the Prior User Rights Defense, USPTO, January 2012, p.7.

While the scope of the grace period provisions may differ under national/regional laws, in general, such provisions state that, in determining novelty (and inventive step in some countries), the disclosure made by, *inter alia*, the applicant or his predecessor in title shall not be taken into account, if it occurred within certain period of time before the filing or priority date (generally, six months or one year).

Paragraph 24 of the Patents Act entitled "Validity not affected by making information available in certain circumstances" states: "(1) For the purpose of deciding whether an invention is novel or involves an inventive step or an innovative step, the person making the decision must disregard: (a) any information made publicly available in the prescribed circumstances, by or with the consent of the nominated person or patentee, or the predecessor in title of the nominated person or patentee; [...]".

See response from Australia to the 32nd session of the SCP. Similarly, the Industrial Property Act of Kenya provided a grace period for disclosure of the invention by the applicant or predecessor in title, and the prior use exception was also seen as a "balancing provision" allowing a person who exploited the invention based on such disclosure to continue exploitation after the grant of a patent. See response from Kenya to the Questionnaire.

85. Yet, in the United States of America, where a grace period is validly invoked, a defense based on prior commercial use can be asserted, if such use occurred at least one year before the public disclosure is made under the grace period provision.¹³¹

5.4 Assignment of prior users right

- 86. With reference to assignment of prior user rights, most laws allow a prior user to assign and/or transfer its prior user's right to a third party. Some laws expressly state that the right could be assigned/transferred, but not licensed. Some laws were silent on the issue of transfer of the prior user rights.
- 87. In the vast majority of those countries that allow for assignment and transfer of the prior user's right, the condition is that the right has to be transferred together with the business where such use has been carried out. In that regard, Section 273 of the United States Code provides [e]xcept for any transfer to the patent owner, the right to assert a defense under this section shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates. In Brazil, the prior user's rights "may be assigned only by transfer or leasing, together with the business of the undertaking or the part thereof that has direct relation with the exploitation of the subject matter of the patent [...]." Romanian law clarifies that the transfer of prior user's rights is restricted to the assignment and inheritance. In the Republic of Moldova, the prior user's right may only be transferred "during the user's lifetime or by hereditary or testamentary succession together with his enterprise or business, or with that part of his enterprise or business in which the use or preparations for use have been made." In the Republic of Moldova to the succession together with his enterprise or business in which the use or preparations for use have been made." In the Republic of Moldova to the succession together with his enterprise or business in which the use or preparations for use have been made."
- 88. In addition, in the United Kingdom, a distinction is made between the prior user right of an individual, which can be assigned or transmitted on death, and the right of a corporate body which can be transmitted upon the body's dissolution. In Bulgaria, the prior user's right may be transferred together with the enterprise in which such rights have arisen and may be exercised, "subject to there being no increase in the volume of such use outside the enterprise". In Indiana, Indiana
 - 5.5 Related issue: Prior use after the invalidation or refusal of the patent, but before the restoration or grant of the patent
- 89. In some countries, a prior use exception applies in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent. 138

Section 273(a)(2)(B) of the U.S. Patent Law, 35 U.S.C. §§ 1 et seg. (consolidated as of May 2015).

For example, the following expressions are found in the laws: assignment and/or transfer are not allowed except together with "that part of the business", "the entire enterprise or business to which the defense relates", "the production unit", "the enterprise or business practice", "business where it originated or where the exploitation was intended to take place", "assignment or transfer of ownership of a company or its part", "business establishment in which use is made", "enterprise or its activities or with that part of the enterprise or its activities", "working process and production plant" or "firm or establishment in which such production or use was being carried out or had been planned".

Article 45 of the Patent Law № 9.279 of 14 May 1996 as last amended by Law № 10.196 of 14 February 2001.

Article 33(1) Law No. 64/1991 on Patents (as amended up to Law No. 83/2014).

Article 25 of the Law № 50-XVI of 7 March 2008 on the protection of Inventions.

Section 64(2)(b) of the Patents Act of 2004.

Article 21 and 23 of the Law on Patents and Utility Models Registration of 9 November 2006 as last amended by Law of 18 May 2012.

Countries which expressly provide this type of exception are: Armenia, Australia, Austria, Bulgaria, Finland, Georgia, Hungary, Israel, Japan, Latvia, the Netherlands, Norway, Pakistan, Portugal, the Republic of

- 90. Different titles were applied in various jurisdictions to such exception, for example, the right to "subsequent use" or "later use" or "further use" or "interim user". In many countries, the relevant provisions require that the activity of such a user has been carried out in "good faith" or "bona fide" to fall within the scope of the exception. ¹³⁹
- 91. Further, since laws differ in details on the grant/refusal, invalidation and restauration procedures, there are differences in the situations and timeframes applied to such exception. For example, the exception applies if the acts by third parties occur "after expiration of the time limit for reinstating a dismissed application or after a rejection has become final or a patent has lapsed but before such announcement is made"¹⁴⁰, "If a protective right has been refused, lapsed, expired, or otherwise became ineffective and is reinstated by the grant of reinstatement [...] after the lapse of the protective right and before the day of the official announcement of the grant of reinstatement or not later than on the day of entry of the request in the Register, in all other cases not later than on the day of receipt of the request at the competent authority [...]"¹⁴¹, "from the date of patent revocation [...] until its reinstatement"¹⁴², "period between a declaration of lapse of patent protection and restoration thereof"¹⁴³, "period between the loss of rights or means of redress and the restoration to the prior situation"¹⁴⁴ or "between the end of the period of six months beginning with the date when the patent concerned ceased to have effect and the date of the application" for restoration is made.¹⁴⁵
- 92. Further details on the scope of such exception were expressly provided in some national laws. In Armenia, the Republic of Moldova and the Russian Federation, such use was allowed "without extension of the scope of use", "within the limits of existing volumes" or "provided that the scope of such use is not expanded", respectively. In Austria, such person shall be entitled to exploit the subject matter for the requirements of "his own business in his own or in other persons' workshops". Similarly, the patent law of Serbia provides that such prior user is entitled to "continue exploiting the invention for production purposes only in his own production plant or in the plant of any other person for his own needs". In Finland, such a prior user may continue to exploit the invention provided "he maintains the general nature of the exploitation" and he should have begun to exploit an invention "commercially" and "in this country" to invoke the exception. In Romania, such prior user may continue to exploit the invention "to the same extent as on the date of publication of the mention of reestablishment of rights".
- 93. In some countries, the requirement is that such right can be transmitted only together with business by providing, for example, "this title shall be inherited or sold only in connection with the business"¹⁴⁷, "transfer of this right is permitted only together with the enterprise"¹⁴⁸, "the right [...] may only be transferred to another person together with the business in which it originated or in which exploitation of the invention was intended", or "[t]he right to exploit an invention [...]

Moldova, Romania, the Russian Federation, Serbia, Slovakia, South Africa, Spain, Sweden, Sri Lanka, Viet Nam, Tajikistan and the United Kingdom. Please see provisions of laws on this issue in WIPO Lex and the responses from these Member States to the Questionnaire.

See, for example, responses to the Questionnaire from Armenia, Finland, Georgia, Latvia, Romania, the Slovak Republic, Spain and Sweden.

Section 71c of the Patents Act of Finland.

Section 136 of the Patent Act of Austria.

Article 55 of the Patent Law of Georgia.

Articel 21 of Act XXXIII of 1995 of Hungary.

Article 23(5) of the Netherlands Patent Act of 1995.

Section 45(5) of the Patent Ordinance 2000 of Pakistan.

Similarly, in Sweden, the requirement is that the prior user may continue the exploitation of the invention "while retaining the general character of the exploitation".

Section 136 of the Patent Act of Austria.

Article 53 of the Patent Law of Georgia.

cannot be transferred, devolved or transmitted by inheritance, except together with the business in which that invention was used". 149

- 94. In Australia, where an application or patent ceases to have effect in certain circumstances but is restored, for example through the granting of an extension of a time limit, special provisions apply to allow a third party to apply to the Commissioner of Patents for a license to continue to exploit the invention. The person must show that they took definite steps to avail themselves of or exploit the invention as a result of the ceasing of the application or patent. 150
- 95. In some other countries, the prior use exception may be applied if the use takes place after invalidation but before the restoration of the patent term. For example, in Japan, a non-exclusive license on the patent right is available to a third party in situations where he/she has been, without knowledge, working the invention in Japan or has been making preparations for such use after the invalidation but before the restoration of the patent, as well as where a third party has made such use before invalidated registration of a patent term extension has been restored.¹⁵¹

6. Challenges Faced by the Member States in Implementing the Exception Regarding Prior Use

- 96. While no specific challenges have been reported from the Member States in the Questionnaire in relation to the implementation of this exception at the national level, 152 the following paragraphs indicate the issues which may affect the practical use of the exception by various parties.
- 97. First, in some countries, the exact scope of the exception is not clearly defined. This, coupled by the lack of court decisions, may create uncertainty for various parties. For example, no jurisprudence exist in majority of countries clarifying important constitutive elements of the exception such as what constitutes "use", "serious or effective preparations" or "good faith". In addition, the interface between the prior use exception and the grace period provision is not expressly defined in most of the laws, as discussed above. Likewise, in some countries, the relevant provision does not make it clear if transfer of prior users rights is possible at all.
- 98. Furthermore, another issue with regard to this exception relates to territorial limitation of its application. As discussed in the above paragraphs, the scope of the prior use exception in many countries is limited to the activities of the prior user taking place in those respective countries only. In this regard, at least with respect to the European Union, it was questioned whether such a territorial restriction is practical and/or reconcilable with the principle of free movement of goods in the European Union.153 It was also stated that clear guidance on this

See, for example, subsection 223(9) of the Patents Act of Australia. The terms of such a license are determined by the Commissioner (22.21(5)) taking into account the circumstance but the license is royalty free (See HRC Project Design PTY LTD v. Orford PTY LTD [1997] APO 12.)

See, e.g., responses from the Member States to question 41 of the Questionnaire found at: https://www.wipo.int/scp/en/exceptions/#F6.

Section 63 of the Israel Patent Law 5727-1967.

Article 176 of the Japanese Patent Act.

In this regard, a response from Belgium to Question 228 on Prior User Rights, AIPPI, explains that in case *Centrafarm v Sterling* on patent exhaustion, the Court of Justice of the European Union held that "the exercise, by the patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that state, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the common market". The response further notes that "while clearly, the patentee's consent is not at issue in the case of prior use, it is difficult, taking into account the purpose of the EU Internal Market, to conceive why prior use in Belgium would lead to a right of prior use in Belgium, whereas use in Spain or other Member States would not [...]". See AIPPI, Question 228 on Prior User Rights, Belgium.

matter would enable a level playing field between EU Member States as locations to conduct R&D activities.154 Others note that while the territorial effect of prior user rights are of little use to companies operating multinationally, it is difficult to see, given the territoriality of patents, how it could be possible to expand prior user rights to encompass use outside the territory concerned.155

- 99. Lack of clear guidelines with regard to any of the above issues could pose practical challenges for taking business decisions, whether they are to be taken by a patentee, prior user or a third party. Therefore, call for the need to explore and clarify the above issues has been made in some fora. ¹⁵⁶ It was also suggested that, from the perspectives of global economic activities and industry, harmonization of the prior user right systems and practices would be desirable. ¹⁵⁷
- 100. Furthermore, at the practical level, one of the essential issues which need to be clearly established in order to successfully invoke the prior user rights/defense relates to the proof of "use". Under most of the laws, it is a prior user who has the burden of establishing its right to prior use by bringing the necessary evidence. 158 However, in some cases, this may not be an easy task as the facts that could justify a prior user right typically lie somewhat far in the past. At the time when the prior use started to use the invention, or was making effective or serious preparation for such use, it may also be not obvious for the prior user to decide on the extent and kind of evidence that might be needed, should he/she face a litigation in the future. Thus, it is paramount that the prior user ensures that evidence of prior use is properly recorded at the time the use is made so that when the dispute arises, the prior user would not face difficulties in presenting the required evidence. In practice, depending on the specificity of the case and the requirements of the law, continues recordation of a business activity may be desirable. In this regard, the submission from Japan notes that as the current business activities becoming more diversified and complex, more sophisticated ways for ensuring evidence is required. In particular, the digitization of evidence in such a business environment is noted to be necessary. 159
- 101. In this regard, some tools have been employed to secure electronic evidence of the existence of the information at a specific date and time, for example, Soleau envelope in France, ¹⁶⁰ or recent WIPO's new Digital Timestamping Service. ¹⁶¹ Furthermore, the notary system under which notary clarifies any legal facts and ensures the competence of evidence of

It is explained: "Suppose EU Member State A accepts that prior use in Member State B is sufficient to establish prior user rights in Member State A; but Member State B does not accept that prior use in Member State A is sufficient to establish prior user rights in Member State B. This could make Member State B a more attractive location to establish research facilities, because prior use in B would generate prior user rights in A and B, whereas use in A would only generate rights in A, but not B.". See AIPPI, Question 228 on Prior User Rights, Belgium, ibid.

See Report on Prior User Rights, Tegernsee Experts Group, 2012, available at: https://www.uspto.gov/sites/default/files/ip/global/prior_user_rights.pdf.

See AIPPI, Question 228 on Prior User Rights, Belgium; and Report on Prior User Rights, Tegernsee Experts Group, 2012, ibid.

See submission from Japan to the 32nd session of the SCP.

E.g., see the provisions of laws of Portugal, Sao Tome and Principle and the United States of America which explicitly state that the burden of proof lies with the person invoking the prior use exception/defense.

See submission from Japan to the 32nd session of the SCP.

The Soleau envelope (*Enveloppe Soleau* in French) is a sealed envelope serving as proof of existence of certain work and idea at certain date. See: https://www.inpi.fr/fr/proteger-vos-creations/lenveloppe-soleau/enveloppe-soleau.

WIPO's new Digital Timestamping Service is electronic signed certifications that will prove the existence of a digital file at a specific date and time. Presentation on WIPO Digital Timestamping Service can be found at: https://www.wipo.int/edocs/mdocs/govbody/en/wo_pbc_29/wo_pbc_29_presentation_on_wipo_digital_timestamping_service.pdf.

documents, and the writ of judicial order or any other equivalent form of evidence have been suggested as measures to establish evidence of prior use.¹⁶²

102. Furthermore, in order to assist users to utilize the prior user right system, the submission from Japan notes importance of awareness raising activities. Specifically, with that aim, the Japan Patent Office collects and publishes: (i) case studies and examples of prior user rights, which clarify the scope of the prior user rights and illustrate actual use cases; and (ii) major court decisions relating to the prior user rights (bibliographic data and an outline of the facts and decisions for each court case). 163

7. Results of Implementation of the Exception regarding Prior Use

103. As the exception relates to the secret use by a prior user and therefore such information is not recorded or publicly available otherwise, unless the relevant issues are brought to litigations and the decisions are published, there is very little statistical data on the frequency of use of this exception by the stakeholders. These make it inherently difficult to measure the full effect of implementation of the prior use exception at the national level.

104. As regards the litigations relating to this exception, their number appears to be relatively small and limited to several jurisdictions, and in most of the countries, there is no judicial decision on this exception. Warious reasons have been advanced to explain the low number of litigations on this exception. With reference to the United States of America, it was suggested that this could relate, *inter alia*, to the relatively high burden of clear and convincing evidence required for the use of the defense, on which many could be reluctant to rely. Another possibility is that the prior user rights defense could be the last option for the prior user to rely on, when actions based on non-infringement, invalidity or unenforceability are unavailable or the option to invent-around or licensing does not present a feasible alternative. With respect to the United Kingdom, it was reported that narrow and strict interpretation of the scope of the exception by courts makes it difficult to assert prior user rights in that country. Another explanation provided to the question why the exception is not often asserted in court cases is that the parties' arguments could be settled in the pre-litigation stage, the nature of which are confidential.

105. There is also limited economic research focusing specifically on the topic of prior use exception. One study using theoretical models to investigate impact of prior user rights concludes "[w]hen nearly simultaneous, independent invention occurs, awarding one inventor a patent and the other the right to use the invention has very attractive properties. Competition is enhanced, innovation is rewarded with relatively little deadweight loss, and the private and social incentives to be the sole versus joint inventor are generally better aligned than in the absence of such rights." Another study states that "[f]irst, the threat of entry by independent invention would induce patent holders to license the technology, lowering the market price.

See submission from France to the 32nd session of the SCP.

Japanese court decisions in English can be found at:

https://www.ip.courts.go.jp/eng/hanrei/judgments_list/150402/Vcms4_00000142.html.

See submissions by the Member States to the 32nd session of the SCP and their responses to the Questionnaire.

See, e.g, with regards to the US: Baker Donelson at: https://www.iam-media.com/prior-user-rights-defence-patent-infringement.

See a response from the United Kingdom in the Report on Prior User Rights, Tegernsee Experts Group, 2012.

See, e.g., a response from Germany and France in the Report on Prior User Rights, Tegernsee Experts Group, 2012.

Carl Shapiro, *Prior User Rights*, 96 America Econ. Rev.92, 95 (2006), p.4, available at: http://faculty.haas.berkeley.edu/SHAPIRO/prior.pdf. The author further concludes: "Prior user rights *automatically* reduce the rewards precisely for those inventions with a high profit-to-cost ratio, since these are

Second, a defense of independent invention would reduce the wasteful duplication of R&D effort that occurs in patent races. In either case, the threat of independent invention creates a mechanism that limits patent-holders' profits to levels commensurate with their costs of R&D." 169, 170

106. The number of scholarly publications exist, focusing on the prior use defense which was limited for business method patents in the United States of America before the amendment of the patent law in 2011.¹⁷¹ The most of the issues presented in those publications appear to boil down to a debate over the respective roles of patent and trade secret protection. In a nutshell. critics claimed that the prior use defense might weaken the patent protection by encouraging inventors to keep their inventions as trade secrets rather than disclosing them in patent applications; while the proponents argued that the patent system might not provide the right economic fit for each innovator and each type of invention, especially in case of SMEs and industries where innovation is incremental. 172, 173 In this regard, the report of the United States Patent and Trademark Office concludes that trade secret law and patent law can, and do, legally co-exist and that trade secret protection is of considerable value to United States businesses and the United States economy, and as such, there are compelling economic and policy justifications for providing a prior user rights defense to patent infringement. ¹⁷⁴ Further, with respect to the prior use defense specifically, the report concludes, inter alia, that the defense available historically in that country did not appear to have significant impact on innovation. In addition, the report concludes that there is no substantial evidence showing that the defense will have a negative impact on venture funding, small businesses, universities, or independent inventors and that the defense is pro-manufacturing and pro-jobs. 175

the inventions most likely to be discovered simultaneously. These are also the inventions that the patent system is most likely to over reward. From a Bayesian perspective, the fact that an invention was discovered independently by two or more parties is evidence that the profit-to-cost ratio for that invention was relatively high, so reducing the reward based on market power is attractive."

Stephen M. Maurer and Suzanne Scotchmer, *The Independent Invention Defense in Intellectual Property*, Economica, Vol. 69, pp. 535-547, 2002.

See also Vermont, S., *Independent invention as defense to patent infringement*, Journal of the Patent and Trademark Office Society, 90(4), (2008), 268-294. Though the publication is not specifically focused on the prior use exception, the findings of the author can be relevant to this topic. The author argues that "independent invention should be a defense, provided the independent inventor creates the invention before receiving actual or constructive notice that someone else already created it. The defense reduces wasteful duplication of effort and enhances dissemination of inventions without lowering the incentive to invent below the necessary minimum".

The Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), *inter alia*, revised 35 U.S.C. § 273 by expanding prior user rights defense to patent infringement. Prior to enactment of the AIA, section 273 provided for a limited prior use defense applicable to business method patents. Section 273 was enacted as part of the 1999 American Inventors Protection Act (AIPA) in response to the decision by the Court of Appeals for the Federal Circuit (CAFC) in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, which affirmed that business methods are eligible subject matter for patenting.
 It is explained that for certain types of business, such as SMREs prior user defense obviates the need to

patent every minor improvement, and that for industries where innovation tends to be incremental, such as electronics and communication areas trade secret protection are more economically rational. See, e.g., Barney, J. R. (2000). *The prior user defense: reprieve for trade secret owners or disaster for the patent law.* Journal of the Patent and Trademark Office Society, 82(4), 261-273., and Carl Shapiro, *Prior User Rights*, 96 America Econ. Rev.92, 95 (2006). The author notes that the effects of encouraging inventors to adopt trade secret versus patent protection are not well understood. See also Report on the Prior User Rights Defense, USPTO, January 2012.

While the issue of interface of patents and trade secret protection is beyond the scope of this paper, it should be noted that, conceptually, the subject matter to be protected under trade secret protection may not necessarily be the same as the subject matter eligible for prior use exception in many countries. This is because to qualify for protection under undisclosed information (trade secret), in addition to obligation to keep the information secret, other conditions needs to be respected (see Article 39 of the TRIPS Agreement) which do not apply for prior user rights context as discussed in the above sections of this paper.

Report on the Prior User Rights Defense, USPTO, January 2012.

¹⁷⁵ Ibid

107. While a generalized conclusion on the effect of the prior use exception in the different countries' context could not be made, as evidenced by the high number of countries having enacted this exception, the exception is presumed to be an important aspect of many patent regimes.

[Appendix follows]