Paper of Prior User Rights B+ Sub-Group on Patent Harmonization Workstream on Prior User Rights May 10, 2016

Members of the Workstream:

Australia, European Patent Office, France, Germany, Japan, South Korea, Sweden, Switzerland, United States

[NOTE: This document has been agreed by the member delegations of the Workstream, who expressly reserve their positions with regard to the substance discussed therein. The support expressed in the options part of the paper is at working-level only.

Whilst some delegations stressed the importance of progressing issues as a package, with emphasis on best practice, other delegations are open to dealing with issues separately.]

I. Introduction

1. Outline of the Paper Concepts

A prior user right is the right of a party to continue the use of an invention where that use began before a patent application was filed for the same invention.¹ The main purpose of prior user rights is to strike a balance between the interests of the prior user, on the one hand, who may have made a decision not to seek a patent on an invention – for instance, to keep the invention as a trade secret –and the patentee on the other, who deserves to be rewarded for disclosing the subject matter to the public.²

Prior user rights are provided for by the different national patent legislations and such provisions in national legislation only have national effect. However, whilst the national provisions on prior user rights have some commonalities, there are also differences in the

¹ In the United State, prior user rights aren't "rights" per se. Instead, the Leahy-Smith America Invents Act (AIA) provides for a "prior use defense," which is a limited defense to patent infringement.

² Cited from page 76 of the "Consolidated Report on the Tegernsee User Consultation on Substantive Patent Law Harmonization" issued in May 2014; hereinafter referred to as the Tegernsee Report)

conditions under which they may be acquired.

Based on this, users of the patent system are in favor of having the rules on the scope and availability of prior user rights harmonized worldwide. In fact, page 96 of the Tegernsee Report shows the results of the questionnaire surveys. The vast majority of respondents in all three regions (Europe, Japan, and U.S.) consider the harmonization of the rules on prior user rights to be either critical or important (84% of respondents to the Japan Patent Office (hereinafter "JPO") survey, 81.7% of respondents to the United States Patent and Trademark Office (hereinafter "USPTO") survey and 74% of respondents in Europe).³

2. Summary of works that have been done at the Group B+ Meetings

At the B+ Plenary Meeting in Geneva on October 6, 2015, Mr. John Alty, Chief Executive Officer of the United Kingdom Intellectual Property Office (UKIPO) and Chairperson of the Group B+ Meeting, proposed that the ways of advancing discussions on patent system harmonization and practices should follow those indicated in the Chair's Note on Patent Harmonization (B+/PL/11/1), and the proposal was agreed by the participating countries. Also, in this Chair's Note, there are the following descriptions: (a) with regard to the issue of prior user rights, together with the other issues of patent system harmonization, i.e. the grace period (GP), conflicting applications, and options for implementation, discussions should be further advanced at the workstreams, which were set up to address these four specific issues, based on the "OBJECTIVES AND PRINCIPLES, WITH COMMENTARY ON POTENTIAL OUTCOMES" (the "Objectives and Principles") that was prepared by the B+ Subgroup members; and (b) the Workstream on Prior User Rights (hereinafter referred to the Workstream) should discuss prior user rights per se, while the Workstream on Non-prejudicial disclosures / Grace period (hereinafter "GPWS") should address the relationship between third party rights and the grace period.

In the "Objectives and Principles," the following principles governing prior user rights were agreed by the B+ Sub-Group:

(i) A third party who has started using an invention in good faith prior to the filing of a patent application for that invention by another party should have a right to continue to use that invention.

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³ Nonetheless, please note that, in the Tegernsee Report, there is a description stating that one should be cautious in interpreting the results of the questionnaire surveys.

(ii) The circumstances under which prior user rights arise, including the extent to which they rely on actual use having taken place, should balance the interests of third parties to protect their investments with the interests of the inventor/applicant.

Also, in the "Objectives and Principles," a consensus was reached on the following two items:

- Prior user rights should not arise through mere possession or knowledge of an invention by a third party.
- Prior user rights should be limited to the territory in which the activity giving rise to prior user rights has taken place.

3. Summary of Works by the Industry Trilateral

Along with the ongoing efforts of the B+ Subgroup members to prepare the "Objectives and Principles," the Industry Trilateral also prepared and submitted the "Policy and Elements for a Possible Substantive Patent Harmonization Package (hereinafter referred to as the Industry Trilateral Paper) in May 2015, dealing inter alia with prior user rights and containing: (1) elements to be included as part of a package when discussing each of the topics; (2) issues under discussion; and (3) various options for addressing these issues.

In the "Industry Trilateral Paper," with regard to prior user rights, the elements to be included as part of a package are:

A. AVAILABILITY OF RIGHTS

Rights should be available.

B. SCOPE OF RIGHTS

Prior user rights permit continued use or use envisioned by such preparations. No exceptions.

C. PREPARATIONS

Effective and serious business preparations for use before the filing date of the application will qualify for Prior User Rights.

D. TIMING

Prior to filing date, or priority date where claimed.

E. CONDITIONS FOR RIGHTS ACCRUING

Activities based on independent development qualify for PUR. Activities based on abuse/breach of confidence do not qualify for PUR.

4. Meeting of Trilateral Industry and Workstream

On February 22, 2016, a Group B+ Harmonization Subgroup Meeting with Trilateral Industry was held at Alexandria, the United States. At the Meeting, the Trilateral users, namely, the American Intellectual Property Law Association (AIPLA), BUSINESSEUROPE, the Intellectual Property Owners Association (IPO), and the Japan Intellectual Property Association (JIPA), gathered and discussed the grace period, conflicting applications, and prior user rights with the respective members of each workstream.

At the Meeting, the Trilateral users reported that, while in the future a review of this issue may be desirable, but at least for the present, it was agreed among them that prior user rights should be on a national basis. In addition, on February 23, 2016, at the Meeting of the Trilateral Offices with the Industry Trilateral, the Trilateral users reported on the further progress achieved at the meeting they held on February 22, 2016 in the afternoon. They reported that they reached consensus that "there needs to be a proper balance of third party prior user rights versus patentee rights". They also reported that, "Possible alignment" and "Elements to be Included as a part of a Package" are subject to review of all elements as a full package, and subject to the final approval by the competent bodies of each Industry Group organization.

Also, at the Afternoon Session of the Meeting that only the Workstream member offices attended, the members shared in the understanding that, although discussions should be advanced under the premise of reaching consensus on all of the issues outlined in the Paper below, there is an order of priority for discussing the issues. In other words, we will give a higher priority to issues on which no consensus was reached in the "Objectives and Principles" as well as to issues to be considered based on both the "Objectives and Principles" and the "Industry Trilateral Paper."

5. Issues to be Discussed in relation to the "Objectives and Principles" and the Industry Trilateral Paper

When considering the basic policy of this Workstream that, based on the "Objectives and Principles," and the Industry Trilateral Paper, discussions should be further advanced in the Workstream, it might be natural for the present Paper to review and consider discussion points organized as follows:

In both the "Objectives and Principles" and the Industry Trilateral Paper, prior use by a third party in good faith based on knowledge derived from a graced disclosure by the inventor/applicant" is indicated as an issue. However, this issue is dealt with in the Grace Period Workstream Report.

- A) Issues to be Discussed, on which consensus was not reached in the "Objectives and Principles"
- (i) Requirements of Use/Preparation for Accrual of Prior User Rights

In the "Objectives and Principles," we find that some member countries hold a view about activities which should give rise to prior user rights, stating "When third parties make effective and serious preparations in good faith to use their inventions, prior user rights could arise." On the other hand, at least one member country argues that, "prior user rights should arise only when the actual use of the inventions has taken place."

For this issue, about what kinds of activities could serve as the basis for availability of prior user rights, the Industry Trilateral Paper suggests that such activities are either "effective and serious business preparations for use" or "activities done for actual use" and are not limited to "actual use only."

(ii) Critical Date for Accrual of Prior User Rights

The "Objectives and Principles" include several views about the date on which prior user rights are provided: (1) "it was noted that in most, but not all jurisdictions, prior user rights can arise up until the priority date of the invention"; and (2) "the sub-group recognized the benefits of harmonizing the point in time by which prior user rights could arise." However, some member countries set the date other than priority dates.

In the Industry Trilateral Paper, there is an agreement that the critical date should be "prior to filing date or priority date," excluding a view that the date can be other than filing or priority date.

- B) Issues to be Considered based on the "Objectives and Principles" and the Industry Trilateral Paper
- (i) The Requirement of "Good Faith"

In the "Objectives and Principles," it is stated: "[A] third party who has started using an invention in good faith ... should have a right to continue to use that invention". A consensus was reached on the idea that acting in "good faith" is a requirement for prior user rights to arise, although the concept was not further defined in the document. Also, even in countries in which the requirement of "good faith" is not clearly stated in their statutes, the courts of most countries require "good faith" or a requirement equivalent to acting in "good faith".

In the "Policy Issue" of the Industry Trilateral Paper, it is stated that "[I]t is considered an unfair application of the scope of the rights attached to a patent that someone, who would have started *in "good faith*" the exploitation of a product or process [in a non-public manner] before the effective filing date of a patent application to another that claims the subject matter of the exploitation, should be prevented from continuing the exploitation after a patent issues from the filed patent application." In other words, according to the Trilateral users, acting in "good faith" is considered to be a prerequisite for providing prior user rights.

Although the wording "good faith" can be found in the "Policy issue" part of the Industry Trilateral Paper, no such wording can be found in the "Elements to Be Included as a Part of a Package", but as stated above, it is stated that users have reached consensus that: "(1)Activities based on independent development qualify for PUR." and "(2) Activities based on abuse/breach of confidence do not qualify for PUR." On the other hand, in the Industry Trilateral Paper, it is stated that whether or not activity based on information derived from the applicant without breach of any duty or agreement (i.e. innocently) qualify for PUR is an issue open for discussion.

Neither the "Objectives and Principles" nor the Industry Trilateral Papers clearly state what the term "good faith" exactly means in this context. In other words, although, both in the "Objectives and Principles" and the Industry Trilateral Paper, consensus has been reached on the necessity of requirements to establish requiring "good faith," for prior user rights to arise, no consensus was reached on the exact meaning and details of the requirements.

(ii) Territorial Scope of Prior User Rights

With regard to the territorial scope where prior user rights are being used, the "Objectives and Principles" suggests a view, on which a consensus was reached, stating "[P]rior user rights should be limited to the territory in which the activity giving rise to prior user rights has taken place." On the other hand, in the Industry Trilateral Paper, there is a view that the "territory" in which prior user rights should have effect should be the entire world.

(iii) Exceptions to Prior User Rights depending on the Types of Patent Rights Holders

The "Objectives and Principles" document does not suggest anything about whether or not exceptions to prior user rights should be allowed for patent rights holders who are certain types of entities. However, the Industry Trilateral Paper suggests that the issue should be addressed as part of a package when conducting discussions, and that "there should not be exceptions" to prior user rights depending on the types of patent rights holders.⁴

C) Other Issues

Although these issues were not raised in either the "Objectives and Principles" or the Industry Trilateral paper, it may be appropriate for the Workstream to consider the following issues on prior user rights with a view to clarifying them.

(i) Acts for Prior User Rights to Accrue

With regard to the acts of working patented inventions, Article 28 of the TRIPS

⁴ The Industry Trilateral Paper does not clearly state the definition of "exceptions." Nonetheless, at the Meeting of Workstream with Trilateral Industry in Alexandria, the U.S., on February 22, 2016, when the JPO asked the users what this word "exceptions" exactly means in the Industry Trilateral Paper, they suggested that it means "exceptions to prior user rights based on types of patent rights holders."

Agreement stipulates that such acts are acts of "making, using, offering for sale, selling, or importing for these purposes that product." Based on this, most domestic laws of the WTO member countries indicate that prior user rights should be granted where such acts have been performed or prepared for prior to the critical date.

On the other hand, in some countries, acts for prior user rights to accrue are stipulated in regulations concerning prior user rights, so that the list of such acts may not be identical to the acts of working patented inventions listed above.

(ii) Changes in Volume of Use of the Invention, Modifications of Embodiments of Invention and Changes in Types of Acts Carried Out to Work Invention

With regard to changes in volume of use of invention, possible issues include, for example, whether prior user rights owners should be allowed to expand their volume of production or/and sales areas, after other parties filed patent applications for the same inventions. Concerning this issue, in some jurisdictions, prior users are allowed to change the volume within their business objectives. Meanwhile, in other jurisdictions, volume changes are limited to those that have been used or planned to be used before the critical date on which prior user rights accrue, and further changes are not allowed.

With regard to modifications of the embodiment of invention, possible issues include, for example, whether or not prior user rights owners can manufacture slightly different products after other parties filed patent applications for the same inventions. Concerning this issue, in some jurisdictions, embodiments of inventions used under prior user rights should be those used before the critical date. If, after the critical date, the embodiments are changed to those that are likely to infringe patent rights, prior user rights may not apply to such embodiments. Meanwhile, in some other jurisdictions, prior user rights may apply not only to the embodiments on the filing dates of patent applications but also to those being changed within a certain scope.

With regard to change in types of acts carried out to work invention, possible issues include, for example, whether prior user rights holders are allowed to change the types of their acts (e.g. manufacture, use, sale, importation, etc...) from one to another, after patent applications were filed. Concerning this issue, in some jurisdictions, no change in the types of acts carried out to work invention are allowed. Meanwhile, in some other jurisdictions, changes in the types of acts carried out to work invention are allowed.

Also, please note that the "prior user rights system" in this Paper include the following legal systems: (1) legislative texts granting non-exclusive licenses for inventions to parties based on their prior use of the inventions; (2) legislative texts providing a prior user defense against a patent infringement suit.

II. Outline of Laws and Regulations on Prior User Rights in the Member Jurisdictions and their Requirements to Apply Prior User Rights

Australia

1) Regulations

According to section 119 of the *Patents Act 1990*,⁵ prior user rights are available to a person, if the person immediately before the priority date of the relevant claim "was exploiting the product, method or process in the patent area, or had taken definite steps (contractually or otherwise) to exploit the product, method or process in the patent area". Prior user rights do not arise if, before the priority date, the person had stopped exploiting or abandoned steps to exploit the product, method or process, unless only temporarily. Prior user rights are also not available if the person derived the product, method or process from the patentee or the patentee's predecessor in title. However prior user rights do apply where the product, method or process is obtained from information made publicly available with the consent of the patentee (or predecessor in title) and the grace period provisions of the Act apply. Prior use rights may be assigned.

2) Concept of Regulations

A key concept of the Australia Prior User Rights system is to ensure a balance between patents right holders and third parties. Australia does this by providing a possible defense against infringement to a third party that immediately before the priority date, was exploiting or had taken definite steps to exploit a product, method or process that would infringe the patent.

It has long been held that a patent should not stop another party from continuing doing

⁵ Cited from "Patents Act 1990" on ComLaw AU website. (The same hereinafter) (https://www.comlaw.gov.au/Details/C2015C00484/Html/Text# Toc429123129)

what they were already doing before the patent was applied for (Bristol-Myers Co v Beecham Group Ltd [1974] AC 646 at 681). If the use of that invention was secret then section 119 provides a strong defence against any potential infringement action.

The defence may be considered limited in scope due to the prior use having to be semicontinuous (can only have stopped or have been abandoned temporarily). The Intellectual Property Laws Amendment Act 2006 clarified that prior user rights may be assigned but not licensed (Section 119 (4)). The explanatory memorandum explains the change "will permit assignment of the right per se thereby enabling Australian research-based organisations to assign their inventions to others to further develop and bring to the market⁶". Letting the rights only be assigned rather than licensed also means it consigned to a single entity and balances the patentee's right to exclusivity in the market.

3) Regarding Each Issue

(i) Requirements of Use/Preparation for Accrual of Prior User Rights

As discussed above under 1. Regulations, prior user rights can arise under Australian law where the third party, immediately before the priority date, was exploiting or had taken definite steps to exploit a product, method or process that would infringe the patent. Section 119(5) of the *Patents Act 1990*, provides definitions of the term "exploit" in relation to a product, and a method or process.

In 2001, the Federal Court of Australia observed that it is not sufficient to say that definite steps to exploit the product had been taken by the infringer if immediately before the priority date, he or she was still evaluating alternatives (*Welcome Real-Time SA vs Catuity Inc.* (2001) 113 FCR 110; 51 IPR 327 at [91-97])⁷.

(ii) Critical Date for Accrual of Prior User Rights

Under section 119 of the *Patents Act 1990*, the critical date for accrual of prior user rights is the priority date of the relevant patent,

(iii) The Requirement of "Good Faith"

 $^6\ https://www.comlaw.gov.au/Details/C2006B00048/Explanatory\%20Memorandum/Text$

⁷ Cited from AustLII website (http://www.austlii.edu.au/cgibin/sinodisp/au/cases/cth/federal_ct/2001/445.html?query=%5E%20welcome%20real%20time

Prior user rights are generally not available if the person derived the product, method or process from the patentee or the patentee's predecessor in title. Section 119(3) of the *Patents Act 1990* explains that prior user rights do not apply to an invention derived from a patentee or their predecessor unless the invention is derived from information made publicly available with the consent of the patentee (or predecessor in title) and in prescribed circumstances. This "good faith" provision reflects the grace period provisions of the *Patents Act 1990* which limit the prior art base relevant to a particular patent.

(iv) Territorial Scope

Prior user rights are limited acts done in the patent area. The "patent area" is defined in Schedule 1, Section 3 of the *Patents Act 1990* of Australia⁸ as: Australia; and the Australian continental shelf; and the waters above the Australian continental shelf; and the airspace above Australia and the Australian continental shelf.

(v) Exceptions to Prior User Rights based on Types of Patent Rights Holders

With regard to exceptions to prior user rights based on types of patent right holders, no exception exists in Australia.

(vi) Acts Giving Rise to Prior User Rights

To accrue prior user rights the person had to be exploiting the product, method or process or had taken definite step (contractually or otherwise) to exploit the product, method or process. Section 119(5) of the *Patents Act 1990*, provides definitions of the term "exploit" in relation to a product and a method or process. The term exploit in relation to a product can be defined; (i) as 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). The term exploit in relation to a method or process can be defined as: (i) use the method or process; and (ii) do an act described in subparagraph (a) (i), (iii), (iii) or (iv) with a product resulting from the use of the method or process.

(vii) Changes in Volume of Use of the Invention, Modifications of Embodiments of

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⁸ http://www.austlii.edu.au/au/legis/cth/consol act/pa1990109/sch1.html

Invention and Changes in Types of Acts Carried Out to Work Invention

In Australia, a prior user right is a defense against infringement. If a person was exploiting the patented "product, method or process" prior to the priority date then there is legislated a defense against infringement of the patent where person continues to exploit an "infringing" product method or process. There are no particular limitations to the activities or changes in types of working acts of the prior user in the Australian Legislation.

France

1. Legal provisions

The right of prior possession in France may benefit to anyone who was in good faith in possession of the invention.

According to Article of L.613-7 of the French Intellectual Property Code (IPC),⁹" "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. The right afforded by this Article may only be transferred together with the business, the enterprise or the part of the enterprise to which it belongs." ¹⁰

The right of prior possession is construed as an exemption to the rights conferred by the patent to the patent owner and is generally recognized as an "intellectual possession" of the invention.

Advantages of "prior possession": it protects third parties who have not necessarily made significant investments yet and prefer to protect their invention through secrecy (in favor of small entities).

Disadvantage of "prior possession": uncertainty, the extent of "possession of the invention" is not clearly defined either by the statute nor by case law.

According to the French law, intellectual knowledge of the invention is sufficient although this knowledge must be sufficiently comprehensive and complete to allow the implementation of the invention.

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Oited from "Laws and regulations of France for prior user rights" on JPO's website. (The same hereinafter) (http://www.jpo.go.jp/shiryou/toushin/chousa/pdf/zaisanken_kouhyou/h22_country/fr.pdf)

¹⁰ http://www.legifrance.gouv.fr/

2. Cases law on requirements to obtain PUR

The concept of "prior possession of the invention" is interpreted broadly by the French Courts.

In some cases law, an intellectual possession of the invention is sufficient and in other cases, evidence of acts of working or preparatory acts for working the invention are required:

- "Whereas article L 613-7 above is intended to give a right to work an invention to an inventor who did not choose to file a patent; that the text refers to "possession of the invention" and does not require, contrary to what is submitted by the appellant, that it has been establish acts of working or even serious and effective preparatory acts" (Paris, 17 avril 2015, SARL Balipro c. SA Vinmer)
- "whereas, for it to be possible to rely on intellectual possession of the invention, this must be complete, that is to say it must relate to all of the constituting elements of the patent as they are claimed" (Paris, 14 janvier 2004, paris fors france c.MW trading APS / Paris, 20 septembre 2006, SAS Kaufler c. SA Armor Inox)
- "the fact that the company vinmer offered its product unsuccessfully cannot be rebutted by the two declarations introduced into the proceeding by the applicant as proof of marketing of the products is not necessary" (TGI Paris, juin 2013, SARL Balipro c. SA Vinmer).
- "personal possession is established for legal purposes only when the person who pleads it is able to establish not that he is at the stage of studies and tests but that, if he has not actually worked it, then at least that he was in a position to do so without delay (Paris, 7 novembre 1966, Potez c. Airflam)

Concerning the condition related to the possession, the possession must cover the same technology as covered by the patent, the invention must be fully known. The possession must remain secret and it must be realized before the filing or priority date of the patent.

- 3. Regarding Each Issue
- (i) Critical Date for Accrual of Prior User Rights:

Under French law, the earlier of priority date or filing date is considered as relevant date to determine a prior user right.

(ii) The Requirement of "Good Faith"

The requirement of "good faith" is specified in article L 613-7 of the French Intellectual Property Code. The benefit of prior personal possession can be claimed by person who derived their knowledge of the invention from the patentee as long as they come into possession in "good faith" without breaching any statutory or contractual obligation.

According to case law, "the possessor acts in good faith when he has himself made the invention or when as in the present case, he has received it legitimately from its originator and has not been prohibited from using it". Good faith is excluded when the prior possessor is in contractual relationship with the patentee (employment contract, research agreement, licensing agreement...) or is aware of the invention by an illicit manner (stolen information, espionage ...).

(iii) Territorial Scope:

Under French law, territorial scope of prior possession is the French territory (article L 613-7 provides for that "any person, who, within the territory in which this book applies ..." According to case law, a prior possession acquired outside France does not confer any rights (research works, tests, trial should be carried out in the French territory).

(iv) Acts Covered by PUR:

Article L 613-7 of the French Intellectual Property Code allows the person benefiting from prior possession of the invention "to work the invention" without any particular limitation.

The beneficiary of prior possession may work the invention without being limited to the single embodiment of which he had possession (alteration or modification of embodiment of invention are allowed so long as these other embodiments are equivalent to the embodiments subject to prior possession).

French legislation and French case law have not fixed quantitative limits for the extent of

the working that can be realized by the beneficiary of prior personal possession. According to that, a beneficiary of prior personal possession can increase its production after the patent filing or can choose to manufacture the products after the patent filing, even if before the patent filing, he just sold the products.

However, the use of prior personal possession is limited to the trade or business of the person having a prior possession and according to article L 613-7 al 2 of IP code, "the right afforded by this article may only be transferred together with the business, the enterprise or the part of the enterprise to which it belongs". The benefit of prior possessions transferred only with the business to which it belongs and cannot be the subject of a license.

(v) Exceptions to Prior User Rights:

French legislation provides no exceptions to PUR which relate to technical field or nature of prior possessor.

Germany

1. Legal Provisions

According to Article 12, subsection (1) of the Patent Act of Germany, "The patent shall have no effect in respect of a person who, at the time the application was filed, had already begun to use the invention in Germany or had made the necessary arrangements for so doing. That person shall be entitled to use the invention for the needs of his own business in his own workshops or in the workshops of others. This entitlement may be inherited or sold only together with the business. Where the applicant or his legal predecessor has, before filing the application, disclosed the invention to others and, in so doing, has reserved his rights in the event of a patent being granted, a person learning of the invention as a result of this disclosure may not invoke measures referred to in the first sentence which he has taken within six months of the disclosure." 11

Relevant date for the accrual of prior user rights is the filing or - if applicable - priority date (Art.12, subsection (2), German Patent Act).

¹¹ http://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html#p0097

2. Case Law

Generally, in Germany, the prior user is grounded in considerations of both fairness and efficiency. On the one hand, it is considered unfair to stop a third party from doing that which he did before the critical date. On the other, it is considered not to be in the public interest to destroy existing commercial investments.

3. Prerequisites for obtaining prior user rights

(i) The Requirement of "Good Faith":

A general prerequisite, required by the courts, is good faith by the prior user ("Redlichkeit"), i.e. activities based on direct or indirect abuse or breach of confidence do not qualify. According to the German courts, the prior user is not in good faith if he knew, or was grossly negligent in not recognising that the invention originated with a third party, who would not consent to the sharing of the information about the invention or to its use. Thus, an employee will not acquire prior user rights if he has used his employee's invention prior to his employer's filing of a patent application. Moreover, generally, prior user rights are excluded where the third party and the inventor are parties to a contract, and the third party acquired knowledge of the invention through the fulfillment of this contract (see BGH, GRUR 2010, 47, 48 "Füllstoff"). Thus, where a person has been hired to build an embodiment of the invention, to test an invention or the like, the courts consider it impossible for the third party to be able to harbor an honest belief that he would be entitled to use the invention for his own purposes outside the confines of the contract. With regard to the issue of derivation from the applicant/patentee, in a case dating back to 1964 "Kasten für Fußabtrittsroste" (BGH, GRUR 1964, 673), 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, where he had acted in good faith.

(ii) Possession of the Invention:

The prior user need not be an inventor. Knowledge of the invention can have been obtained from a third party or even, in certain cases, from the patent proprietor himself.

First, the prior user must be in "possession of the invention" before the relevant date. This

requires the invention to be complete and the prior user to understand the technical teaching in a way, which allows the invention to be carried out (but no knowledge of e.g. underlying scientific principles is necessary) (see BGH, GRUR 1965, 411, 423 "Lacktränkeinrichtung").

(iii) Prior Use or Necessary Preparations:

Second, prior commercial use or necessary preparations for a commercial use in Germany (not e.g. other EU-countries) are essential before the relevant date. "Prior use" comprises all uses mentioned in Article 9 of the German Patent Act (direct infringement: producing, offering for sale, putting on the market, using, importing, stocking etc. See BGH, GRUR 1964, 491, 493 "Chloramphenicol") and – in specific cases – uses according to Article 10 (indirect infringement) of the Patent Act.

For the establishment of "necessary preparations", the German courts have articulated a three-pronged test: (1) the serious preparations must objectively be of a nature to make the exploitation of the invention possible; (2) a definitive decision to undertake a commercial use of the invention must have been taken by the user and (3) the intention must be to start the exploitation of the invention in the immediate future.

Prior use or serious preparations must take place in the prior user's own interest and not on behalf of a third party. Thus, where the prior use of an employee's invention takes place, it will be the employer entitled to the invention who will have acquired prior user rights vis-à-vis the patentee.

Preparations may be of either a technical or a commercial nature (e.g. the drawing up of blueprints, a specific production plan, the conclusion of a contract with a manufacturer, the purchase or construction of machines and facilities, filing an application for a market authorization for a medical product, active searching for distributors or manufacturers who could deliver parts necessary for the manufacturing of the invention).

Once actual prior use has taken place, it is possible for the prior user right to accrue despite a temporary suspension of the use of the invention, However, if the third party relies on serious preparations to ground the rights, such preparations must be ongoing at the critical date, otherwise, the intent to begin actual use in the immediate future, a constitutive element of the right, will be missing, (see BGH, GRUR 1969, 35 "Europareise").

There are no limitations as to the availability of prior user rights with respect to the type of inventor, technical field of the invention or the nature of the invention, ie whether the invention is a process or a product.

A peculiarity of German Law in relation to prior user rights is the provision of Article 12, subsection (1), last sentence, which excludes the availability of prior user rights for a third party for six months where the applicant has disclosed his invention and thereby reserved his rights to the invention in case of a later patenting of his invention, if the third party learned about the invention through this communication, including the reservation. Some authors have questioned how a third party could be in good faith if he has knowledge of this reservation. However, curiously, what the clause provides is a lifting of any restriction on the third party once 6 months have elapsed.

(iv) Scope of Prior User Rights:

The scope of the prior user right is generally identical to that of the used invention, or to the use for which preparations have been carried out. However, German courts have recognized that a prior user right which would be frozen at the critical date would not be apt to carry out the policy function of the provision to protect existing investments based on the possession of the invention.

(v) Expanding into Other Acts of Use:

German courts have developed detailed rules on the scope of prior user rights. Where the prior user has manufactured or prepared to manufacture, he may carry out any act contemplated under Art, 9 of the Patent Act. Whoever has offered the invention—for sale, may also manufacture the invention. On the other hand, where the prior user has only imported or sold the invention without making any preparations to manufacture, cannot begin to manufacture the invention. An important criterion is that the nature of the prior user's business as it existed at the critical date cannot be essentially modified. Thus, for instance, a prior user in the import-export business cannot build a factory to manufacture after the critical date.

(vi) Quantitative Changes to the Use of the Invention:

In Germany, it is settled law that there are no quantitative limits on the use of the invention. Where products are sold or manufactured, the amount of sales or production levels can be increased and production facilities enlarged, provided such use of the invention remains for the needs of the prior user's own business. German caselaw even recognizes that the prior user may contract out to third parties the production or use of the invention, for the needs of his own business, provided he retains control over the nature and scope of such use. He may not, however, grant licenses to third parties to use the invention for their own purposes.

(vii)Qualitative Changes:

The prior user may modify the embodiment of the invention, but this is subject to certain rules. German courts approach this issue on a case by case basis. Modifications which are not contained in the patent specification, or which would be obvious to the average person skilled in the art are allowed. However, the courts have drawn a line: where the modification goes beyond the embodiment which was the object of the prior use or serious preparations, it cannot encroach further into the subject-matter protected by the patent (see BGH, GRUR 2002, 231, 234 "Biegevorrichtung"). In particular, the prior user will be barred from adopting any modification he has learned from the patent specification.

The prior user right is linked to the business or specific part of the business and can be transferred or inherited only with this business or part thereof in order to avoid multiplication of rights, on the one hand, whilst ensuring a continued protection of existing commercial assets on the other.

Prior user rights lapse where the prior user renounces his rights, where he definitively abandons the use of the invention, or where the prior user gives up or closes down his business in a final manner (see BGH, GRUR 1965, 411, 413, "Lacktränkeinrichtung").

The burden of proof to show entitlement to prior user rights is generally on the prior user. On the other hand, where bad faith is alleged by the patent holder, the burden lies on him to show such lack of good faith.

<u>Japan</u>

1. Regulations

Prior user rights are stipulated in Article 79 of the Patent Act of Japan as follows: "A person who, without knowledge of the content of an invention that has been claimed in a patent application, made an invention identical to the said invention; or a person who, without knowledge of the content of an invention that has been claimed in a patent application, learned the invention from another person (who made an invention identical to the said invention) and who has since been working the invention or preparing to work the invention in Japan at the time the patent application was filed, shall have a non-exclusive license on the patent right, only to the extent of the invention and the purpose of such business worked or prepared."

2. Concept of Regulations

The main purpose of the prior user rights system in Japan is to "fairly balance the interests of patent rights holders and prior users." Under the first-to-file system, when two or more parities independently make the same inventions, only the parties who filed patent applications earlier, i.e. prior applicants, are able to obtain patent rights. However, if this first-to-file system is applied in all cases, the earlier granted patent rights will prevent parties who first made the same inventions independently and have been actually conducting business activities connected with the working of their inventions, from using such inventions; or who began preparations to use them in their businesses before the prior applicants filed patent applications for these inventions, from continuing their preparations. As a result, they will not be able to continue using their inventions. This may lead to creating unfair outcomes.

Based on this, non-exclusive licenses are granted, to a certain extent, to prior users, i.e. parties who made the same inventions independently and have been actually conducting business activities in connection with the working of their inventions, or began preparations to use them in their businesses before patent applications were filed for the same inventions. This is done so that prior users can continue using the patented inventions at no cost and can continue their business activities using these inventions, in order to ensure fairness in terms of the interests of both patent rights holders and prior users.

3. Regarding Each Issue

(i) Requirements of Use/Preparation for Accrual of Prior User Rights:

In Japan, prior user rights are to arise for parties who have been actually conducting business activities as the working of their inventions or began preparations to use them. Also, as requirements for the "preparations to use inventions in businesses," the Supreme Court decision determined in the "walking-beam type furnace" case¹² that: requirements for "the 'preparation for business to work the invention' as provided by Article 79 mean that a person who made an invention, which is identical to the invention for which a patent application has been made, without knowing its content, or having acquired the knowledge from this person has an intention to immediately work the invention, although he 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."

(ii) Critical Date for Accrual of Prior User Rights:

Under Article 79 of the Patent Act, the date on which prior user rights are provided is stipulated as the dates "when patent applications were filed for the same inventions." These dates are considered to be the filing date of these patent applications or the priority date of these applications if priority rights are claimed.

(iii) The Requirement of "Good Faith":

As requirements for "good faith," Article 79 stipulates "[A] person who, without knowledge of the content of an invention claimed in a patent application, made an invention identical to the said invention, or a person who, without knowledge of the content of an invention claimed in a patent application, learned the invention from a person who made an invention identical to the said invention." Therefore, prior user rights are not granted to parties who learned knowledge of the contents of inventions from the applicant.

(iv) Territorial Scope:

With regard to parties who have been actually conducting business activities as the

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¹² Judgment of the Supreme Court of Japan, 2nd Petty Bench, October 3, 1986 (Case number: 1986(O)454). Claim for the recognition of the right based on prior use and the counter claim for an injunction and compensation based on patent rights and exclusive license.

working of their inventions or began preparations to use them, such activities or preparations need to be conducted "in Japan." Therefore, any act of business activities or preparations to use the inventions outside Japan is not subject to prior user rights.

(v) Exceptions to Prior User Rights based on Types of Patent Rights Holders:

With regard to exceptions to prior user rights based on types of patent right holders, no exception exists in Japan.

(vi) Acts for Prior User Rights to Accrue:

As stipulated in Article 2 (3) of the Patent Act, the working of inventions mean the following acts: (1) in the case of the working of inventions of products: acts of producing, using, assigning, exporting or importing, or offering for assignment, etc. of the products; and (2) in the case of an invention of a process: the use of the process; and (3) in the case of an invention of a process for producing a product: in addition to the act of using the process, acts of using, assigning, exporting or importing, or offering for assignment, etc. the product produced by the process.

(vii) Expansion of the Business Activities:

It is considered that the scale of businesses can be expanded "within their business purposes." The Tokyo High Court determined in the "globe type radio¹³" case that "the scope of granting non-exclusive licenses for inventions to parties based on their prior use of the inventions is limited to the scope in which businesses, which are within businesses that prior users have actually conducted when applications for design registration were filed. However, the Court also recognized that the businesses can be justifiably expanded or strengthened if this is within the scope of these businesses. Nonetheless, the possible extent of expansion "within the scope of business objectives" may depend on the particular circumstances of cases.

Also, "within the scope of business objectives," the increase in import volumes can be regarded to be allowed. Nonetheless, the possible extent of increase may vary in cases.

In addition, "within the scope of business objectives" the expansion of sales areas by sales

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¹³ Judgment of the Tokyo High Court, September 29, 1966 (Case number: 1961(Ne)2881).

promotion may be allowed. Nonetheless, the possible extent of sales promotion may depend on cases.

(viii) Modifications of Embodiments of Invention:

Article 79 of the Patent Act states "within the scope of the invention and the purpose of the business worked or prepared." With regard to the interpretation of this sentence, the Supreme Court decision determined in the "walking-beam type furnace" case that: the "scope of the invention being worked or prepared" in this context "is not limited to the form of work which the prior user was actually working or preparing at the time of patent application (the Date of the Claim of Priority), but means the scope of the technical idea, i.e. the scope of the invention." Based on this, the Court also recognized that: the non-exclusive right to work the invention "extends" not only to the form of working the invention which the prior user had actually been working with or was preparing, "but also to the modified form insofar as it is identical to the invention as represented in the form of working." Nonetheless, the Court determined that, "if the invention as expressed in the form of working the invention corresponds only to part of the patented invention, the right of prior use extends only to this part of the patented invention," rather than to "the entire scope of the patented invention."

(ix) Changes in Types of Acts Carried Out to Work Invention:

With regard to an issue whether companies are allowed to change their acts of working inventions from importing and selling to manufacturing and selling in their own countries, this is basically not allowed. That is because it means that they change their acts that were being actually conducted.

However, based on some academic theories, if prior user rights are granted to the manufacturing, these companies may change their acts to other acts, when considering the Supreme Court decision in the "walking-beam type furnace" case, stating "within the scope of the invention and the purpose of the business worked."

South Korea

1. Regulations

The Patent Act Article 103 of South Korea (hereinafter "Korea") stipulates the following: "A person who has made an invention without having prior knowledge of the contents of an invention claimed in an patent application, or has derived the invention from the person and has been conducting or preparing business activity with the working of the invention at the time of the filing of the patent application, shall have a non-exclusive license on the patent right of the patent application. Such license shall be limited to the invention and the purpose of the business activity which is being worked, or for which preparations for working have been made."

2. Regarding Each Issue

(i) Requirements of Use/Preparation for Accrual of Prior User Rights:

According to the Article 103, in order for prior user rights to be granted, it is necessary that a person has been actually conducting or preparing business activities with the working (carrying out) of the invention.

Also, the "working" of invention is stipulated in Article 2 (3)¹⁴ of the Patent act and the "working the invention" means that there are objective circumstances under which the business operator has intention to continue the activity which is recognized to have worked the invention, at least preparation which is objectively recognized.

(ii) Critical Date for Accrual of Prior User Rights:

The date "at the time of the filing of the patent application" in Article 103 is considered to be the filing date of the patent application or the priority date of the application if a priority is claimed.

(iii) The Requirement of "Good Faith":

In Korea, prior user rights are granted to a person who is without prior knowledge of the contents of an invention claimed in a patent application. Prior user rights are not granted

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¹⁴ Patent Act Article 2(3)

The term "working" means any of the following acts:

⁽a) In cases of an invention of a product, acts of manufacturing, using, assigning, leasing, importing, or offering for assigning or leasing (including displaying for the purpose of assignment or lease; hereinafter the same shall apply) the product;

⁽b) In cases of an invention of a process, acts of using the process;

⁽c) In cases of an invention of a process of manufacturing a product, acts of using, assigning, leasing, importing, or offering for assigning or leasing the product manufactured by the process, in addition to the acts mentioned in item (b).

to parties who learned knowledge of the contents of inventions from the applicant.

(iv) Territorial Scope:

The business activities with working invention or the preparations need to be conducted "in Korea." Therefore, any act of business activities or preparations to use the inventions outside Korea is not subject to prior user rights.

(v) Exceptions to Prior User Rights based on Types of Patent Rights Holders:

There is no exception based on types of patent rights holders.

(vi) Acts for Prior User Rights to Accrue:

The acts for prior user rights to accrue are stipulated in Article 2(3). It corresponds to the acts constituting infringement.

(vii) Changes in Volume of Use of Invention, Modifications of Embodiments of Invention and Changes in Types of Acts:

The scope of the right is limited to the scope of the invention which has been worked or prepared, and to the purpose of the business activity. Although some changes may be allowable, the scope is not clear due to lack of case law.

Sweden

1. Legal provision

The Swedish Patent Act, para 4, stipulates the following:

"Anyone who, at the time when the application for a patent was filed, was using the invention commercially in this country may, notwithstanding the patent, continue such use while retaining its general character, provided that the use did not constitute evident abuse in relation to the applicant or his successor in title. The right to such use shall, on corresponding conditions, also be due to anyone who has made substantial preparations for commercial use of the invention in this country".

2. Regarding Each Issue

(i) Critical Date for Accrual of Prior User Rights:

At the time when the application for a patent was filed (i.e. the filing date), or, if there is a claimed priority date, the priority date.

(ii) Requirements of Use/Preparation for Accrual of Prior User Rights:

A condition for the prior user right is that the use did not constitute evident abuse in relation to the applicant or his successor in title.

It is necessary that the use is commercial and not private. Also the prior user right may accrue if substantial preparations have been made by the prior user. The prior user right is created automatically when the conditions for it are met. No registration or formalities are required.

(iii) The Requirement of "Good Faith":

It is not expressly stipulated that the prior user has to be in "good faith", but a condition for the prior user right is that the use did not constitute evident abuse in relation to the applicant or his successor in title. However, a prior user in good faith may have obtained his/her knowledge about the invention from someone who has obtained his/her knowledge (about the invention) in a way which constitutes evident abuse in relation to the applicant or from the one from whom the applicant derives his/her right.

(iv) Territorial scope of prior user rights:

The prior user right is limited to Sweden.

(v) Exceptions to Prior User Rights based on Types of Right Holders:

There are no exceptions.

(vi) Acts for prior user rights to Accrue:

The prior user right consists of the same use of the idea as with the invention so to speak, i.e. the same embodiment is necessary in principle.

The acts that constitute infringement of a patent might correspond to the prior user right, but it depends on what kind of use the prior user has made in the specific case. The prior user right can be more narrow than the patent right, depending on what use the prior user has made. Therefore it is not sure that all acts which constitute infringement of a patent also are covered by the prior user right concept in an individual case.

(vii)Changes in Volume of Use of the Invention, Modifications of Embodiments of Invention and Changes in Types of Acts Carried Out to Work Invention:

The prior user right can continue retaining its general character, meaning that the use has to continue within the same framework so to speak, i.e. if for instance the use has been producing, the prior user right does not give a right to importation and so on.

No limitations as regards the size of the enterprise which is the prior user i.e. it can grow. However the prior user right exists only within the same enterprise and no licensing is included in the prior user right.

If the enterprise which is the prior user is transferred because of assignment or succession, for instance, the prior user right will follow in its whole.

Switzerland

(a) Regulations

Article 35 of the Federal Act on Patents for Inventions (Patent Act) states that patent rights may not be invoked against any persons who, "prior to the date of filing or priority of the patent application," "were commercially using the invention in good faith or had made special preparations for that purpose" "in Switzerland."

(b) Concept of Regulations

Prior user rights aim at reducing the principle of the first-to-file system and at protecting investments made in good faith by third parties. The significance of prior user rights in Switzerland is essential for legal security reasons.

The concept of prior user right under Swiss law shall be rather seen as a sort of legal license (without counterpart) than as an exception to the exclusive right of the patent holder.

(c) Regarding Each Issue

(i) Requirements of Use/Preparation for Accrual of Prior User Rights:

According to art. 35 (1) Patent Act, a prior commercial use or special preparation in view of a future use prior to the filing or the priority date is a precondition for establishing a prior user right.

The special preparations in terms of future use must have been made to produce on a commercial scale. One should have had sufficient detailed knowledge about the invention to be able to carry it out. Furthermore concrete preparation should have been made to implement the invention. According to the Federal Supreme Court (BGE 86 II 406 of 13 December 1960), it is not enough to have a plan or a technical drawing to have a prior user right established. 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.

(ii) Critical Date for Accrual of Prior User Rights:

Under Swiss law, the earlier of priority date or filing date is considered as relevant date to determine a prior user right.

(iii) The Requirement of "Good Faith":

The commercial use of inventions or special preparations for that purpose shall have been carried out in good faith. This condition is essential to prevent people from taking advantage improperly or fraudulently of a prior use. Good faith may not be relied upon when the prior user become aware of the invention unlawfully, for instance in breach of an agreement with the patent holder or its licensee.

(iv) Territorial Scope:

It is necessary that the commercial use of inventions or special preparations for that purpose have been carried out in Switzerland or in the Principality of Liechtenstein. The prior use in a foreign country does not establish a prior user right. Nonetheless, the persons may learn of the inventions in foreign countries.

(v) Exceptions to Prior User Rights based on Types of Patent Rights Holders:

With regard to exceptions to prior user rights based on types of patent right holders, no exception exists in Switzerland.

(vi) Acts Giving Rise to Prior User Rights:

Prior use must be commercial. According to Art. 8 §2 of the Patent Act, the commercial use of inventions includes, in particular, manufacturing, storage, offering, placing on the market, importing, exporting and carrying in transit, as well as possession for any of these purposes.

(vii)Expansion of the Business Activities:

Pursuant to Article 35 § 2 of the Patent Act, the use of the prior user right is limited to the trade or business of the person having a prior user right.

In addition, this provision provides that the prior user right is only transferable together with the related trade or business. A prior user right is as a matter of principle not licensable.

Scholars interpret this provision so that the use may extend to all activities necessary to the continuation of the activities that the enterprise was carrying out at the filing or priority date of the invention.

However, art. 35\\$2 of the Patent Act does not prevent the geographic expansion of the activities.

(viii) Modification of Embodiments of Inventions:

The prior user right is limited to the scope of the prior use taking place before the filing or priority date of the invention. The prior use cannot be extended to the whole coverage of the patent. Consequently, the mere use of the invention before the filing or priority date of the invention does not allow the prior user to subsequently manufacture or put the subject matter of the patented invention into circulation. However, scholars consider that further obvious developments should be covered by the prior user right. To date, there is

no case law concerning this particular issue.

(ix) Change in Types of Acts of Working Inventions:

Under Swiss prior user rights, change in types of acts of working the invention is not allowed. The prior user rights are granted for the acts that were done at the date of priority of filing.

However, based on some academic theories, if prior user rights are granted to the manufacturing, the commercialization shall be also granted because one can presume that manufacturing is performed in view of a subsequent commercialization.

U.S.

(i) Requirements for Prior Use Defense:

Under section 273 of United States Code (U.S.C.) Title 35,¹⁵ a person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against a person if 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, and such commercial use occurred at least 1 year before the earlier of either the effective filing date of the claimed invention or the date on which the claimed invention was disclosed to the public by the patent rights holder during the grace period."

Before the Leahy-Smith America Invents Act (AIA) enacted in September 2011, the defense was only applicable with respect to business method patents. This restriction was withdrawn with the enactment of the AIA. However, 35 U.S.C § 273(e)(5)(A) provides an exception to the defense "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 an institution of higher education...or technology transfer

Lited from "Report to Congress January 2012 - Report on the Prior User Rights Defense" (http://www.uspto.gov/sites/default/files/aia_implementation/20120113-pur_report.pdf)

organization..."

(ii) Critical Date for Accrual of Prior User Rights:

35 U.S.C. § 273(a)(2) provides that in order to be entitled to a prior use defense the commercial use must have 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).

(iii) The Requirement of "Good Faith":

The AIA has both a general good faith requirement, and also an articulation of specific conduct that would defeat the prior user rights defense. 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." 35 U.S.C. §273(a)(1). In addition to this general requirement, the AIA goes on to further articulate a specific activity. More specifically, 35 U.S.C. §273 (e)(2) provides that a person may not assert a defense under this section if the subject matter on which the defense is based was derived from the patentee or person in privity with the patentee.

(iv) Territorial Scope:

In order to qualify for the prior use defense, the subject matter must have been commercially used in the United States. 35 U.S.C. §273(a)(1)

(v) Exceptions to Prior User Rights depending on the Types of Patent Rights Holders:

35 U.S.C. §273(e)(5) provides that a person commercially using the subject matter "may not assert a defense under this section 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 a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education."

(vi) Acts giving rise to Prior User Rights:

As mentioned above, the AIA provides that "a person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or commercial process, that would *otherwise infringe* (emphasis added) a claimed invention being asserted against the person..." 35 U.S.C. §273(a).

Further, 35 U.S.C. 271(a) defines acts that constitute infringement, which include making, using, offering to sell, or selling any patented invention, within the United States or importing into the United States any patented invention during the term of the patent.

(vii)Expansion of the Business Activities: Modification of Embodiments of Inventions; Changes in Types of Working Inventions

The AIA specifies that the prior user rights defense "extends only to the specific subject matter for which it has been established that a commercial use [...] occurred." 35 U.S.C. §273(e)(3). 35 U.S.C. § 273(e)(3) provides that the prior user rights 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.

III. Possible Options (Best possible solutions to the issues)

In this section, based on the summary of laws and regulations on prior user rights in the member jurisdictions and their requirements to apply prior user rights as stated in Section II, possible solutions to the two issues stated above are considered.

- A) Issues to Be Discussed, on which Consensus Is Not Reached in the "Objectives and Principles"
- (i) Requirements of Use/Preparation for Accrual of Prior User Rights

In the jurisdictions that were studied in section II, requirements for prior user rights to arise involve either "activities done for actual use and preparations done for use" or "activities done for actual use only." Both "activities done for actual use and preparations

done for use" are allowed in Japan, Germany, Korea, Australia, Sweden, and Switzerland. In the U.S., the requirements are limited to "activities done for actual use only".

Among the jurisdictions that were studied in section II, only in France do prior user rights arise when the inventions are in one's "possession." However, as stated above, in the "Objectives and Principles," there is a notion that a consensus was reached on the idea that "[P]rior user rights should not arise through mere 'possession' or knowledge of an invention by a third party." (Nonetheless, it should be noted that some voiced opinions that: any proof being submitted to the courts for supporting evidence of "possession" of inventions is enough to meet requirements for the acts of working inventions in other jurisdictions as well as for their serious and effective preparations.)¹⁶

Also, among the jurisdictions where "activities done for actual use and preparations done for use" allow prior user rights, in some jurisdictions, there are descriptions in their regulations in some way about the extent of these preparations (examples: "definite steps" in Australia; "special preparations" in Switzerland; and "necessary arrangements" in Germany). Meanwhile, in other jurisdictions, such as Japan and Korea, their regulations simply indicate "preparations." Thus, we find that the extent of preparations to use inventions differs among the jurisdictions in terms of their descriptive expressions. However, the extent of the preparations should be determined by the courts, depending on the facts and circumstances of individual cases.

According to the description on page 90 of the Tegernsee Report, most users in the U.S. supported the idea that actual use, i.e. "activities done for only the actual use of inventions" should be the minimum requirement for obtaining prior user rights. (87% of the respondents favored "actual use" while 45.3% responded that "preparations to use" would be sufficient to claim prior user rights.)

On the other hand, Japanese users showed the same level of support. Namely, 77.4% and 75.8% of the respondents supported the actual use requirement and the preparation requirement, respectively. Nonetheless, based on the data on page 90 of the Tegernsee Report, it remains doubtful how Japanese users would have responded if the option of preparations to use the invention was specified as "substantial" preparations. Also, when reviewing the figures, substantial overlap clearly existed in the responses to the options by these two groups. As a result, due to the flaws in the design of the question, which

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¹⁶ Page 13 of "Report on Prior User Rights."

asked what the minimum requirement should be for rights to accrue, but then allowed multiple answers to be checked (p.88), as the Tegernsee Report indicates, the data does not allow any conclusion to be drawn, other than that a clear majority of respondents believed that mere prior possession of the invention should not suffice for prior user rights to accrue (p.91).

In Europe, the majority, i.e. 64.7%, of users responded that "preparations to use" would be sufficient to constitute the minimum requirement.

Based on the above, we present the following two options as possible solutions to the differences in the issue:

- Option 1: Actual use or [serious and effective] preparations for use
- Option 2: Actual use of the invention only

In the Industry Trilateral paper, Option 1 is supported.

Also, at the Meeting of Trilateral Industry and Workstream participants, Industry representatives and member offices, except for the United States, supported Option 1.¹⁷

(ii) Critical Date for Accrual of Prior User Rights

Based on the results of the reviews in Section II, in all of the jurisdictions, except the U.S., regulations clearly state that prior user rights are effective on the filing date of a patent application (or at the time of filing a patent application). And, when patent applications claims priority, the "priority date of the patent application" should be the critical date.

On the other hand, only the U.S. sets the critical date for accrual of prior user rights to be "at least one year before the earlier of either the effective filing date or the date of the first disclosure to the public." Based on page 93 of the Tegernsee Report, the vast majority of the respondents shared the view that the critical date for accrual of prior user rights should be the priority or filing date. (This view is held by 78.9% of respondents to the JPO survey,

¹⁷ France mentioned that, although both Option 1 and 2 do not reflect the current state of its system, "preparations" done for actual use of inventions are often applied as evidence to certify the requirements for "possession" of inventions.

65.5% of respondents to the US survey and 72.3% of respondents to the European surveys.)

In addition, on page 93 of the Tegernsee report, we find that: in the U.S., although the AIA set the critical date for accrual of prior user rights to be "at least one year before the earlier of either the effective filing date or to the date of the first disclosure to the public," 61.19% of US respondents to the US survey opposed the requirement that activities giving rise to prior user rights be required to take place before the grace period starts. Nonetheless, as described on page 92 of the Tegernsee report, given the overlapping nature of the possible responses, as well as the fact that the Tegernsee Joint Questionnaire allowed multiple answers, it must be stated that the reliability of this data may be questionable.

When reviewing Section II above, dates that can be selected as the dates on which prior user rights are provided may be firstly "the filing date of a patent application" and "the priority date of the application." Also, there is an idea that, like the U.S., taking into account disclosures during the grace period, the critical date should be the date prior to "the date of disclosure during the grace period." (The issue of the relationship between prior user rights and the grace period is not within the scope of this workstream. Nonetheless, please note that, when considering possible harmonization of the date on which prior user rights are provided," we need to consider the relationship with the grace period to some extent.)

Based on the above, we present the following three options as possible solutions to the differences in the issues with regard to the critical date for prior user rights to accrue:

- Option 1: Regardless of whether there are priority claims or not, the filing date of a patent application should be the critical date.
- Option 2: The filing date, or, if applicable, the priority date of the application should be the critical date.
- Option 3: The date prior to the earlier of either the effective filing date of a patent application (i.e. priority date or actual filing date) or the date of disclosure during the grace period should be the critical date.

With regard to Option 1, under Article 4 B of the Paris Convention, the effects of priority claim are stipulated as follows. "Any subsequent filing shall not be invalidated by reason of any acts accomplished in the period from the date of filing of the first application to one of the member countries of the Paris Convention to the date of filing of a subsequent application claiming priority to one of the other member countries, in particular, another filing, the publication or exploitation of the invention. And such acts cannot give rise to any third–party right." Based on this, if the filing date of a patent application is to be the critical date despite the existence of a valid priority claim, this will violate the Paris Convention. Therefore, Option 1 cannot be an effective option. Also, in the Industry Trilateral Paper, Option 2 is supported.

Also, at the Meeting of Industry Trilateral and Work Stream participants, Industry representatives and member offices, except for the United States, supported Option 2.

- B) Issues to be Considered based on the "Objectives and Principles" and the Industrial Trilateral Paper
- (i) The Requirement of "Good Faith"

Based on Section II above, whilst there appears to be a consensus amongst both the delegations and users that a prior user must be in "good faith" in order for prior user rights to arise to protect his investment, based on the above, among the jurisdictions reviewed, there seems to be two manners of approaching this issue: (1) The conduct of the prior user is assessed only in relation to the applicant/patentee; (in other words, whether or not knowledge of the invention is acquired independently from patent rights holders or their predecessors in title); and/or (2) the conduct of the prior user is assessed in absolute terms by whether the acquisition of the knowledge of the invention and the activities undertaken to use such invention have been carried out in "good faith", ie such acts are neither unfair, fraudulent, or in breach of any statute, duty or agreement, vis-à-vis any person, not just the applicant, so that the fact of prior user rights arising for this party does not breach elementary principles of fairness or equity. As can be seen from the statute in the U.S., these two approaches may be cumulative.

The issue is thus two-pronged:

(a) General Requirement of "Good Faith":

- Option 1: There should be a general requirement of "good faith", meaning that neither the acquisition of the knowledge of the invention nor the activities of the prior user have been carried out in breach of any statute, duty or agreement, so that the accrual of the prior user right is equitable under the circumstances.
- Option 2: There should be no general requirement of "good faith."
- (b) Derivation from the Applicant or the Legal Predecessors:
- Option 1: Activities based on information derived from the applicant in "good faith" as defined in the general requirement qualify for a prior user right.
- o Option 2: Activities based on information derived from the applicant in "good faith" as defined in the general requirement do not qualify for a prior user right.

(ii) Territorial Scope of Prior User Rights

Based on the results of the reviews in Section II, in almost all of the jurisdictions, as conditions required for accrual of user prior rights, their regulations clearly state that the acts of working inventions should be conducted "in their own countries" where patents rights are granted and registered.

In the Tegernsee Report, this issue is not discussed because page 76 states as follows: "Prior user rights are provided for by the different national patent legislations and such provisions in national legislation only have national effect."

On the other hand, in the Industry Trilateral Paper, as stated above, there is a view that the territory in which prior user rights are applied should be the entire world, although the Industry Trilateral has clarified since then that the issue of the territoriality of the scope of the prior user right, which has extremely complex ramifications, should be put aside for the time being, and other issues focused upon.

Given these facts, it may not be appropriate for this Draft Paper to discuss any best possible solutions with regard to this issue. Nonetheless, the possible options are as

follows:

- Option 1: Prior user rights have effect only in the country/region in which the prior qualifying activities took place.
- Option 2: Once acquired against a patent in one jurisdiction, prior user rights extend to all countries where the patent holder has obtained protection for that same subject-manner.

In the "Objectives and Principles" paper, consensus was reached by the B+ Sub-Group on Option 1.

Also, at the Meeting of Trilateral Industry and Workstream, all of the Workstream member offices supported Option 1. Moreover, as stated in Section I, Trilateral users reported that, at least for the present, they support Option 1.

(iii) Exceptions to Prior User Rights depending on the Types of Patent Rights Holders

Based on the results of the reviews in Section II, no jurisdiction except the U.S. provides for exceptions to the accrual prior user rights based on the type of patent holder.

The Tegernsee Report shows that, in response to a question as to whether or not exceptions to prior user rights should be granted to certain patents, the vast majority of the respondents in all three regions, i.e. Japan, the U.S., and Europe, were against exceptions being provided to prior user rights (82.3% of respondents to the Japanese survey, 87.4% of respondents to the European survey, and 92.7% of respondents to the U.S. survey,(Page 93-94.)).

Based on the above, we present the following two options as possible solutions to the differences in the issue:

- Option 1: Exceptions to prior user rights should be allowed for certain types of patent rights holders.
- Option 2: There should be no exceptions to prior user rights depending on the types of patent rights holders.

In the Industrial Trilateral Paper, Option 2 is supported.

Also, at the Meeting of Trilateral Industry and Workstream, all of the workstream member offices, except the U.S. (USPTO), supported Option 2.

At the Meeting, the Trilateral users suggested that, as in the Industry Trilateral Paper, they reached consensus on this issue, supporting Option 2.

C) Other Issues

(i) Acts for Prior User Rights to Accrue

Based on the results of the reviews in Section II, in most of the jurisdictions, the acts of working patent inventions under Article 28 of the TRIPS Agreement are stipulated to qualify as acts for prior user rights to arise in their regulations. In the first place, prior user rights are exceptions to the prohibition for third parties to work inventions covered by a patent. Meanwhile, in some jurisdictions, specific acts of working inventions are defined as activities giving rise to prior user rights. Such definitions may not be identical to the definitions of the acts reserved to the patent holder post-grant, i.e. the definition of infringement. Where such differences arise and the definition of activities qualifying for prior user rights is narrower, then some prior activities will not be protected, and will have to be stopped by the prior user upon grant of a relevant patent.

Accordingly, when it comes to presenting possible solutions to the differences in the issues, the following two Options can be considered:

- Option 1: Acts giving rise to prior user rights should match the acts of working invention exclusively reserved to the patent holder post-grant (i.e. the acts that constitute infringement of patent).
- Option 2: Differences between the definition of acts giving rise to prior user rights and the definition of the acts of working an invention exclusively reserved to the patent holder post-grant are allowed.

At least within the Workstream member offices, Option 1 seems to be supported.

(ii) Changes in Volume of Use of the Invention, Modifications of Embodiments of Invention and Changes in Types of Acts Carried Out to Work Invention

Based on the results of the reviews in Section II, with regard to these issues, in some jurisdictions, there are descriptions in their regulations in some way about them. Meanwhile, in other jurisdictions, there is no binding regulation on them. However, in most jurisdictions, their specific rules seem to be determined by the courts.

As stated above, in some cases, these issues are to be determined by court decisions, depending on the facts and circumstances of individual cases. Accordingly, from the perspective of advancing harmonization, there are some voiced opinions that consensus should be reached on these issues.

In fact, some of the Workstream members and Trilateral user opines that this issue depends on individual law case and should be considered at a later stage.

However, in term of possible options toward harmonization, we may discuss at least whether or not these changes should be allowed.

Therefore, if we present possible solutions to the issues, the following can be considered:

- (a) Changes in Volume of Use of the Invention
- Option 1: Volume changes should be allowed.
- Option 2: Maximum production levels should be determined by the levels of use existing [or effectively and seriously prepared for] prior to the critical date.
- (b) Changes to Embodiments of Invention
- Option 1: Changes to embodiments of invention should be allowed.
- Option 2: Changes to the embodiments of the invention should be possible subject to well-defined conditions
- Option 3: No changes to the embodiment should be allowed.

- (c) Change in Types of Acts Carried Out to Work the Inventions
- Option 1: Prior users may change from one type of the act of working the invention to another without any limitations.
- Option 2: Prior users may change from one type of working the invention to another, subject to certain limitations, ie provided that the nature of their business is not thereby modified.
- Option 3: The scope of the prior user rights should be limited to the types of acts done [or seriously prepared for] prior to the critical date

IV. Conclusion

The purposes of the prior user rights system include elimination of adverse effects caused by the first-to-file system and relief measures for third parties who have made significant investments on the inventions for which patents are filed. In order to achieve harmonization of the prior user rights system, there are still some issues to be solved, including the stability of patent rights, the consistency of patentability, and appropriate balancing of the interests of patent rights holders and third parties.

As the reviews stated above, in the member jurisdictions that are studied in this Paper, a variety of measures are taken to deal with the issues.

For example, in term of the requirements for obtaining prior user rights, some jurisdictions are focusing on relieving third parties who have made significant investments on their inventions, while other jurisdictions are placing greater importance on avoiding legal uncertainties.

When conducting discussions on the harmonization of patent systems, it is essential to consider the best possible solutions in terms of achieving harmonization without imposing heavy burdens on the jurisdictions, while giving serious consideration to each solution from various perspectives.

V. Principles and Consensus

1. Objective and principles

- (i) A third party who has started using an invention in good faith prior to the filing of a patent application for that invention by another party should have a right to continue to use that invention.
- (ii) The circumstances under which prior user rights arise, including the extent to which they rely on actual use having taken place, should balance the interests of third parties to protect their investments with the interests of the inventor/applicant
- 2. Issues for which consensus has been reached by all the Workstream member offices:

Here, the issues which consensus has been reached by both Workstream member offices and Trilateral users are given in **bold**.

(i) Requirements of Use/Preparation for Accrual of Prior User Rights:

• Prior user rights should not arise through mere possession or knowledge of an invention by a third party.

(ii) Territorial Scope of Prior User Rights:

 Prior user rights should be limited to the territory in which the activity giving rise to prior user rights has taken place.

(iii) Acts for Prior User Rights to Accrue:

- Acts giving rise to prior user rights should match the acts of working invention exclusively reserved to the patent holder post-grant (i.e. the acts that constitute infringement of patent).
- 3. Issues for which consensus has not been reached by all the Worksteam member offices:

(i) Requirements of Use/Preparation for Accrual of Prior User Rights

Option 1: Actual use or [serious and effective] preparations for use

(Supported by AU, CH, DE, European Patent Office (hereinafter "EPO"), FR, JP, KR, SE)

 Option 2: Actual use of the invention only (Supported by US)

(ii) Critical Date for Accrual of Prior User Rights

- Option 1: Regardless of whether there are priority claims or not, the filing date of a patent application should be the critical date.
- Option 2: The filing date, or, if applicable, the priority date of the application should be the critical date.
 (Supported by AU, CH, DE, EPO, FR, JP, KR, SE)
- Option 3: The date prior to the earlier of either the effective filing date of a patent application (i.e. priority date or actual filing date) or the date of disclosure during the grace period should be the critical date.
 (Supported by US)

(iii) The Requirement of "Good Faith"

- (a) General Requirement of "Good Faith":
- Option 1: There should be a general requirement of "good faith", meaning that neither the acquisition of the knowledge of the invention nor the activities of the prior user have been carried out in breach of any statute, duty or agreement, so that the accrual of the prior user right is equitable under the circumstances. (Supported by AU, CH, DE, EPO, FR, KR, SE, US)
- Option 2: There should be no general requirement of "good faith."
 (Supported by JP)

(b) Derivation from the Applicant or the Legal Predecessors

o Option 1: Activities based on information derived from the applicant in "good

faith" as defined in the general requirement qualify for a prior user right. (Supported by AU, CH, DE, EPO, FR, SE)

 Option 2: Activities based on information derived from the applicant in "good faith" as defined in the general requirement do not qualify for a prior user right. (Supported by JP, KR, US)

(iv) Exceptions to Prior User Rights depending on the Types of Patent Rights Holders

- Option 1: Exceptions to prior user rights should be allowed for certain types of patent rights holders.
 (Supported by US)
- Option 2: There should be no exceptions to prior user rights depending on the types of patent rights holders.
 (Supported by AU, CH, DE, EPO, FR, JP, KR, SE)

(v) <u>Changes in Volume of Use of the Invention, Modifications of Embodiments of Invention and Changes in Types of Acts Carried Out to Work Invention</u>

(a) Changes in Volume of Use of the Invention

- Option 1: Volume changes should be allowed.
 (Supported by AU, DE, FR, JP, KR, US, SE)
- Option 2: Maximum production levels should be determined by the levels of use existing [or effectively and seriously prepared for] prior to the critical date. (Supported by CH)

At this time, due to differing views amongst its Contracting States, the EPO cannot express support for either of these options.

(b) Changes to Embodiments of Invention

Option 1: Changes to embodiments of invention should be allowed.

Option 2: Changes to the embodiments of the invention should be possible subject to well-defined conditions.

(Supported by AU, DE, FR, JP, KR, US, SE)

Option 3: No changes to the embodiment should be allowed.
 (Supported by CH)

At this time, due to differing views amongst its Contracting States, the EPO cannot express support for any of these options.

(c) Change in Types of Acts Carried Out to Work the Inventions

- Option 1: Prior users may change from one type of the act of working the invention to another without any limitations.
 (Supported by AU)
- Option 2: Prior users may change from one type of working the invention to another, subject to certain limitations, ie provided that the nature of their business is not thereby modified.
 (Supported by DE, FR, KR)
- Option 3: The scope of the prior user rights should be limited to the types of acts done [or seriously prepared for] prior to the critical date.
 (Supported by CH, JP, SE)

At this time, due to differing views amongst its Contracting States, the EPO cannot express support for any of these options. Further, at this time the US cannot support any of these options.