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PATENTS

The authors compare prior user rights provisions of the new America Invents Act with prior user rights laws of other major jurisdictions, and they provide guidance on optimizing retention of documents or data at home and abroad.

If the Shoe Fits—Keep It: Document Retention Polices to Maximize Prior User Rights as a Patent Infringement Defense at Home and Abroad

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Most patent systems contain infringement defense provisions for innocent prior users of a later patented invention. The theory behind prior user rights is that someone secretly using a process or composition who either has no intention of patenting it or fails to win the first-to-file race should have some pro-

tection from an infringement suit by the eventual patentee. How far these rights extend varies greatly on a country-by-country basis.

In the United States, prior user rights have always been something of an enigma. They have existed for commercially used methods and activities at nonprofit research entities such as universities.¹ These rights, however, were severely limited in the commercial sense to methods of doing or conducting business only (i.e., a business method patent), with activities in the nonprofit area being further limited to uses for which the public was the intended beneficiary.² As a result of these limitations, and the defense's fairly recent addition to U.S.

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¹ 35 U.S.C. § 273 (2006), amended by 35 U.S.C. § 273 (Suppl. 2011).

² *Id.*

patent law (1999), judicial interpretation of prior user rights is limited.³

Prior user rights received a significant strengthening with the enactment of the Leahy-Smith America Invents Act of 2011, presenting a new wrinkle for internationally-based companies with respect to their policies for retention of documents or data. Prior user rights are well established in a number of other countries, which has enabled companies to craft their document and data retention policies to take advantage of those rights.

Will those policies be appropriate under the new U.S. law, or will modifications be needed? If the latter, is a global solution possible or will policies need to be customized by country?

In this article, we will compare key provisions of the new U.S. law with those of other major jurisdictions and provide guidance with respect to those questions.

Prior User Rights Under the America Invents Act

The new prior user rights, which are effective against any patent issued on or after Sept. 16, 2011,⁴ are no longer limited to business methods and now encompass “subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process”⁵ Additionally, the AIA contemplates that premarketing regulatory review for safety or efficacy is a commercial use entitled to the defense.⁶

The defense is somewhat restricted, however, against university patent owners depending on funding used by the university to reduce the claimed invention to practice,⁷ and an entity in privity with the patent owner as to the claimed subject matter cannot assert the defense.⁸ As with the previous statute, a commercial use is one that is connected to a commercial internal use or as part of an actual arm’s length sale, and in all circumstances must be performed in good faith.⁹

Prior user rights are personal to the entity that performed or directed the protected acts.¹⁰ The rights can be transferred, however, if they are ancillary and subordinate to a good faith transfer of an entire enterprise or the entire portion of a business to which the prior user rights relate.¹¹ If a party legally effectuates an assignment of a prior user right under this section, the right is limited only to sites where it is in use at the time of transfer.¹²

³ Indeed, the definitive treatise on U.S. patent law, Chisum on Patents, cites *no* case law interpreting prior user rights in the section devoted to 35 U.S.C. § 273. See 5 Donald S. Chisum, Chisum on Patents § 16.03[4] (Matthew Bender) (2010).

⁴ H.R. 1249, 112th Cong. § 5(c) (2011) (enacted).

⁵ 35 U.S.C. § 273(a).

⁶ *Id.* Section 273(c)(1)

⁷ *Id.* Section 273(e)(5)(A) (The university exception does “not apply if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government.”).

⁸ *Id.* Section 273(e)(2).

⁹ *Id.* Section 273(a)(1).

¹⁰ *Id.* Section 273(e)(1)(A).

¹¹ *Id.* Section 273(e)(1)(B).

¹² *Id.* Section 273(e)(1)(C).

The key change that the AIA provides for is the expansion of “subject matter” into areas well beyond claims directed to business methods. The term “process” is no longer defined, and machines, manufacture, and compositions of matter are now included so long as they are used in manufacturing or a commercial process.

Thus, an entity’s methods, as well as the tools that it uses to effectuate those methods, should be protected by the new prior user rights, so long as the entity was practicing the methods and using the tools at least one year before the earlier of the effective filing date of the patent at issue¹³ or the date on which an inventor of that patent disclosed the patent’s subject matter in a manner that affords protection under the newly defined novelty sections of the Patent Act.¹⁴

Prior User Rights in Foreign Countries Compared to the U.S.

Unlike the United States, many foreign countries have well established prior user rights.¹⁵ Such prior user rights are intertwined with the first-to-file patent systems commonly found in foreign jurisdictions and are considered a necessity to balance the race to the patent office created by such systems.¹⁶

Included within the AIA was the requirement that the Patent and Trademark Office provide Congress with a report on the operation of prior user rights in some of these foreign countries, including Japan, Canada, Australia, and members of the European Union.¹⁷ The PTO delivered this report to Congress in January 2012, with extensive sections devoted to prior user rights in requested, and additional, countries.¹⁸ Unsurprisingly, while the AIA’s prior user rights share some similarities to those in foreign jurisdictions, there are no exact matches to the U.S. rights.

The report concluded that activities qualifying as prior use can be divided into three categories: pure use, pure possession, and a hybrid of the two.¹⁹ Most coun-

¹³ The effective filing date of a patent application is “(A) if subparagraph (B) does not apply, the actual filing date of the patent or application for the patent containing a claim to the invention; or (B) the filing date of the earliest application for which the patent or application is entitled, as to such an invention” *Id.* Section 101(i)(1).

¹⁴ *Id.* Section 273(a)(2). New Section 102(b) allows for certain disclosures made by an inventor or a joint inventor to not be considered prior art against the inventor’s or joint inventor’s patent application if made within the year prior to the effective filing date of the patent application. See H.R. 1249, Section 3(b).

¹⁵ Though again there is very little case law on the subject. See, e.g., Fédération Internationale des Conseils en Propriété Intellectuelle, FICPI—Comments on the PTO Paper: Prior User Rights (Nov. 16, 2011), http://www.uspto.gov/aia_implementation/pur-2011nov16-ficpi.pdf.

¹⁶ *Id.*

¹⁷ H.R. 1249, Section 3(m).

¹⁸ David J. Kappos and Teresa S. Rea, Report on the Prior User Rights Defense (2012), http://www.uspto.gov/aia_implementation/20120113-pur_report.pdf.

¹⁹ *Id.* at 13. Brazil and Canada are pure use countries, while France is the only pure possession country studied. *Id.* at 13-14.

tries studied, including the United States, utilize the hybrid approach though the specifics vary.²⁰

Typically, a prior use is an exploitation of a product, method, or process, or taking definitive steps towards such exploitation.²¹ Such a definition is substantially shared by Japan, Australia, Denmark, South Korea, Mexico, China, and Russia, but other countries that use a hybrid system such as the United Kingdom and Germany have either a strict possession standard (United Kingdom) or lenient one (Germany).²²

The U.S. standard, though falling within the PTO's hybrid definition, does not exactly match any of the studied countries. Possession and use in the United States are subsumed by the requirement that the use be a commercial one and must occur at least one year before the patent's effective filing date or subject matter disclosure date.²³ So, while the U.S. prior user qualifications *relate* to those of the majority of the countries studied by the PTO, guidance from these countries as to whom actually qualifies is limited.

As to most other provisions in the AIA, the U.S. prior user rights sync with the majority of countries studied. For example, the United States and most of the countries studied require that a party asserting prior user rights to act in good faith.²⁴ Transferability of the right is recognized by all countries studied except Mexico, with most having similar transfer of entire entity or business to which the right relates requirements.²⁵

The United States and all countries studied, except Russia, permit assertion of the prior user right not just by the person actually performing the use, but also by an entity controlling or directing such person.²⁶ All countries studied including the United States restrict the prior use activity to that inside the country's borders.²⁷

The United States is in the minority, however, as to the breadth of the prior use right once it has been established. Over half of the countries studies limit prior use rights to activities commensurate with the activity that triggered the right.²⁸ The United States allows some expansion of activities "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."²⁹

The term "variations in the quantity or volume of use of the claimed subject matter" appears to permit scale-up of any processes or tools beyond initial bench testing. The improvement clause is interesting, and ap-

parently unique, at least among the countries surveyed.³⁰

Because an improvement implies a later-developed technology, and given the language in Section 273(e)(3) that provides for an extension of the general license granted for prior use right, improvements should not be subject to the in use for at least one year before the effective filing date of the patent requirement found in Section 273(a)(2). Prior users thus have a broad right to develop technology based on their prior use right, so long as any new developments do not infringe other claims in the patent asserted against them.

Planning for a Prior Use Defense

Prior user rights are often considered and analyzed as part of the realm of trade secrets, though such a classification is not entirely accurate. In the general sense, a trade secret is "information . . . that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."³¹

From this definition, we can conclude that *some* prior uses are trade secrets, and indeed many of the commercial uses contemplated by a large corporation may well fall into such a definition, but it is unlikely that a nonprofit institute conducting research would consider, and treat, all its activities as trade secrets within the legal definition.

A party asserting prior use as a defense has the burden of showing such use by clear and convincing evidence.³² This evidentiary standard is quite high on the scale, somewhere above the 50/50 standard of preponderance of the evidence, but below the criminal standard of beyond a reasonable doubt.

Thus, a party asserting the prior user defense must be prepared to provide a significant amount of evidence proving the existence of such right and that the party is properly using such right as a commercial internal use or as part of an arm's length transaction.³³ Information that an entity already manages as a trade secret is probably under sufficient document management to establish a prima facie case of prior user rights should the need arise; the concern here is with prior uses that are not trade secrets and thus not subject to rigid, internal document controls.

One problem with maintaining sufficient document control over information related to a prior use that is not a trade secret is that there is a likelihood that such information is not particularly valuable for preservation. Without perceived value, information is disposable.

Another problem is that a prior user right is an unknown until a patent actually issues, and even then, unless a party is subject to an infringement suit, one must actively search the PTO databases to determine whether any claims exist that could trigger the right. Treating every business activity as a trade secret is ob-

²⁰ *Id.* at 14.

²¹ *Id.* at 15.

²² *Id.*

²³ Comparatively, almost all the countries surveyed permit *preparations* for exploiting the claimed invention prior to the effective filing date of the patent to serve as sufficient evidence of prior use. See *id.* at 60 (column one of Appendix D to the PTO report).

²⁴ *Id.* at 18.

²⁵ *Id.* at 27.

²⁶ *Id.* at 18.

²⁷ *Id.* at 22.

²⁸ *Id.* at 23.

²⁹ 35 U.S.C. § 273(e)(3). A minority of the countries studied also permit broadening of prior use rights, but in varying scopes that differ from the U.S. approach. Kappos and Rea, *supra* note 16, at 23-24. Germany singularly *narrows* the scope of activities upon discovery of a prior use right. *Id.* at 24.

³⁰ Kappos and Rea, *supra* note 16, at 23-25.

³¹ Uniform Trade Secrets Act § 1.4 (1985).

³² 35 U.S.C. § 273(b).

³³ Unless the party is a nonprofit, which adds the research laboratory use.

viously unrealistic, so what approach should an entity take to ensure that its activities are protected by the prior user defense, yet are practical enough for easy implementation?

Because a prior user right is unknown until a patent claim covering such rights grants, actual preparation for the defense is more a product of maintaining a sound document retention policy before any prior user rights exist as opposed to measures being taken after discovery of the right's existence.

As the U.S. prior user rights are similar, but not quite synchronized, with those in other countries, a worldwide document retention policy for established prior user rights would be an ineffective approach unless a global entity takes the extreme step of retaining all records completely in all jurisdictions. For purposes here, however, we look only to an approach for the preparation of a U.S. prior use defense as the peculiarities in the U.S. law present some problems not found in other jurisdictions.

In particular is the requirement that a defendant seeking to assert the prior use defense established commercial use at least one year before the effective filing date of the patent at issue or before the disclosure of invention date, whichever is earlier.³⁴

Perhaps the best structured method for retaining information related to a commercial use or a tool thereof is to consider such information prior art under the novelty sections of the U.S. Patent Act.³⁵ One of the requirements for patentability of an invention in the United States is whether such invention is novel over the prior art, with in most cases a novelty-destroying piece of prior art being a single reference containing all limitations of the claimed invention within the four corners of the reference and having a publication date at some point before the effective filing date of the subject patent.³⁶ While it is difficult to view a process or a tool for use in a process in terms of claim limitations in a patent in the absence of any such patent, it is possible to envisage that process or tool in terms of specific steps or components without the detail of legal claim language.

When the specific steps of your process or the components of your tool are defined, you need to evaluate whether you have sufficient, accessible information to enable one of ordinary skill in the art to practice your process or tool. Enablement and one of ordinary skill in the art are terms of art in the patent field, with both terms originating in Section 112 of the Patent Act.³⁷

While Section 112 applies to patentability of an invention, a prior art reference for novelty purposes must

³⁴ 35 U.S.C. § 273(a)(2).

³⁵ This is not to say that it will *actually* be prior art against the claimed invention, but organization of any documents related to the potential prior use should be thought of in the anticipatory sense.

³⁶ A patent claim can also be anticipated if the invention was "in public use, on sale, otherwise available to the public before the effective filing date of the claimed invention" 35 U.S.C. § 102(a).

³⁷ "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, 1st ¶.

also be enabling under the Section 112 definition.³⁸ What qualifies as an enabling disclosure is one that contains sufficient information such that the ordinarily skilled person can practice an invention without undue experimentation, with undue experimentation analyzed under the "Wands Factors."³⁹

What constitutes a skilled person to whom this undue experimentation analysis must focus is "a hypothetical person who is presumed to know the relevant prior art."⁴⁰ From these two concepts, one can readily review information related to a process or tool and determine whether such information is sufficient to be considered "anticipatory" of a future patent claim.

Additionally, once you have defined a process or tool similar to a patent claim, an actual prior art search may be useful. While not a nominal expense, a prior art search conduct by a professional search company, or in house for large entities, typically costs less than \$5,000. Outside of the cost, there are no disadvantages to a search, and the upside is quite high.

Information exchanged between you and the search firm should be subject to a confidentiality agreement, thus protecting its potential status as either a trade secret or patentable invention. Discovery of relevant, novelty-destroying art can be a great relief if you have no intent on patenting your process or tool as you now have access to the additional affirmative defense of invalidity should another party claim your prior used process or tool.

On the other hand, a clean search can lead you either to prepare your own patent application directed to the process or tool or to increase information retention around the process or tool in preparation for potential evidence in a prior use defense.

Summary

The AIA significantly expanded the scope of prior user rights to the point that such rights should be given serious consideration in an entity's document retention policies. Given that trade secrets should already be under strict document controls, most entities should be well prepared for a prior user defense of their trade secrets should the need arise.

Processes and tools that are not afforded trade secret protection, however, should be given a closer look as to value so that an entity can properly assess whether

³⁸ See, e.g., *In re Donohue*, 766 F.2d 531, 533, 226 USPQ 619 (Fed. Cir. 1985) ("[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling.").

³⁹ Factors to consider when deciding whether experimentation is undue include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400 (Fed. Cir. 1988).

⁴⁰ *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1108 (Fed. Cir. 1995). "In determining this skill level, the court may consider various factors including 'type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.'" *Id. quoting Custom Accessories Inc. v. Jeffrey-Allan Industries Inc.*, 807 F.2d 955, 962, 1 USPQ 1196 (Fed. Cir. 1986).

these unprotected assets should be subject to stricter document controls.