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Don't Let a Disclosure or Sale Thwart Your Patent Protection

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One of the statutory bars to patentability in the United States prohibits a claimed invention from being described in a printed publication, being in public use or on sale, or being otherwise available to the public before the effective filing date of the claimed invention.[1] The first three restrictions are generally referred to as a bar on public disclosure, public use bar, and on-sale bar, while the last is a catch-all provision. The law does provide for a grace period if the restricted activity occurred one year or less before the effective filing date of a claimed invention (e.g., the filing of a patent application) and was done by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or joint inventor.[2]

While the text of the relevant section may seem straightforward, many real-world scenarios raise questions as to what constitutes a public disclosure, public use, sale, or public availability. Understanding what has been found to bar patent validity informs the type of dialogue needed with an inventor to assess whether patentability has been or may be affected. That assessment then guides next steps in protecting the inventor's intellectual property.

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WHAT MAY BE DEEMED PUBLIC DISCLOSURE

The Manual of Patent Examining Procedure (MPEP), which is published by the United States Patent and Trademark Office (USPTO) as guidance to patent examiners, expands on different aspects of the public disclosure bar and on-sale bar. For example, there is currently no geographic limitation on where prior public use or availability occurs under the September 2011 law established by the America Invents Act (AIA).[3] In addition, public use is clarified as referring to use by one who is under no limitation, restriction, or obligation of confidentiality to the inventor.[4] The on-sale bar is distinct from the bar on public disclosure in that even a sale made without public knowledge to a third party buyer under obligation to keep the invention confidential can disqualify an invention from patentability.[5] The U.S. Supreme Court set out a two-part test, referred to as the *Pfaff* test, to determine the applicability of the on-sale bar: whether the invention was ready for patenting, and whether the invention was subject to a commercial offer for sale. Both conditions must be true to apply the on-sale bar.[6]

On the other hand, sale or other use that is commercially exploited is distinguished from permissible experimentation. An inventor may conduct extensive testing without losing the right to subsequently obtain a patent, even if the testing occurs in the public eye.[7] The U.S. Court of Appeals for the Federal Circuit adapted the *Pfaff* test in the context of public use, rather than sale, such that the inquiries are: whether the invention was ready for patenting, such that the use was not experimental, and whether the use was public, which is only permitted when the use is experimental.[8] The answer to both inquiries must be positive for a claimed invention to be barred due to public use.

A 2016 decision from the U.S. District Court for the District of Delaware touched on both aspects of the two-part inquiry regarding public use. Sanofi had undertaken a clinical trial more than a year prior to the effective filing date of its 8,410,167 ('167) patent, and alleged infringer Glenmark used the clinical trial to assert public use by Sanofi that invalidated the '167 patent.[9] With regard to the second part of the two-part inquiry, Glenmark emphasized the lack of confidentiality restrictions on patients participating in the trial and the fact that the clinical trial protocol itself was not kept confidential.[10] However, the court found the clinical trial to be plainly an experimental use, citing Glenmark's failure to meet the heavy burden of demonstrating, by clear and convincing evidence, that the claimed inventions had been reduced to practice during prior clinical trials and before the critical date of one year prior to the effective filing date of the '167 patent.[11]

In addition, although concluding that the clinical trial was experimental use was sufficient to preclude the public use bar, the court also addressed whether the use was public.[12] The court noted that lack of confidentiality provisions for patients is not determinative on the public nature of use.[13] Additionally, in the Sanofi case, the investigators involved in the clinical trial, the physicians to whom a method of treatment would be most significant, were subject to confidentiality obligations, as were others overseeing and observing the trial, such as study managers contracted with oversight.[14] Thus, the court concluded that, even if the use had not been experimental, it was not public use that barred patent validity.[15]

While the Sanofi case involves a finding of patent validity based on the two-part inquiry indicating permissible experimental use and, although not additionally necessary, confidential use, a more recent case illustrates use that was found to be both commercial rather than experimental, and public rather than sufficiently confidential, leading to a finding of patent invalidity. Minerva displayed fifteen functional devices with technology claimed in its 9,186,208 ('208) patent at an industry event that occurred over a year prior to the priority date of the '208 patent.[16] A brochure dated a day after the presentation provided a detailed description of the device at issue and was consistent with previously made drawings of the device.[17]

The Federal Circuit reiterated established factors that are considered as part of the *Pfaff* two-part inquiry in affirming the finding of invalidity for the '208 patent. With regard to an invention being ready for patenting, the court looked for a reduction to practice or the preparation of drawings or other enabling descriptions.[18] In the case of Minerva, the devices at the industry event were prototypes evidencing a reduction to practice.[19] Additionally, the prior drawings and their subsequent description in the brochure were found to be sufficiently enabling to constitute a reduction to practice.[20]

With regard to use that is deemed public, the court indicated that the nature of and public access to activities involving the invention, as well as confidentiality obligations imposed on observers, are all considerations.[21] A lack of secrecy obligations imposed on even one member of the public who understood the invention based on the inventor's use is sufficient to find public use.[22] A balance is struck between the level of disclosure and the skill of those to whom the invention was disclosed, so that even limited disclosure may be public use if made to those skilled enough to know, understand, and easily demonstrate the invention to others.[23] Thus, the court found that Minerva's pitch to sophisticated industry members who were allowed to see how the device operated, without confidentiality obligations, differed from a mere display of the devices and constituted public use.[24]

The catch-all provision of the bar on public disclosure prohibits availability to the public.[25] This provision puts the focus on public availability rather than on a particular mode of making information available, and can intersect with other prohibitions,

such as printed publication. Examples of modes describing an invention that were found to be publicly available include a student thesis in a university library, a poster display or other information disseminated at a scientific meeting, and a commercial transaction that did not qualify as a sale under the Uniform Commercial Code (UCC).[26]

The catch-all provision of the bar on public disclosure prohibits availability to the public.

A 2009 decision from the U.S. District Court for the District of Columbia provides an example of a reference found to be a printed publication based on public availability rather than on a traditional mode of publication. Dow Jones asserted a program, HTGrep, as prior art against Alblaise's 6,295,530 ('530) patent, because a link to the source code of HTGrep was posted on publicly available news groups over a year before the priority date of the '530 patent.[27] The court reiterated the established inquiry to determine whether a reference is prior art by stating that the reference must be made available to the extent that those interested and ordinarily skilled in the art exercising reasonable diligence could find it and recognize and comprehend the essentials of the claimed invention from it.[28]

The lack of evidence presented to dispute the testimony provided by the HTGrep developer and the three postings from newsgroup subscribers used to corroborate the testimony were found sufficient to meet Dow Jones' burden of proof.[29] The finding of HTGrep as prior art was additionally compelled by the fact that two of the known newsgroups to which the link to the source code was posted were for computer scientists and web programmers.[30] Despite being a pre-AIA case and despite the printed publication being of a reference used to allege anticipation (rather than the printed publication being of the claimed invention and resulting in invalidation), the case is instructive in emphasizing the breadth of publicly available media that can be problematic to patent validity.

WHAT QUESTIONS TO ASK AN INVENTOR

Unfortunately, inventors and companies do not always keep intellectual property rights in mind during each phase of the development of an invention, nor do they typically consult a patent professional prior to undertaking every activity. A patent attorney or agent may first come to know of planned or completed activities that involve an invention during an initial disclosure call with the inventors to discuss drafting a patent application for the invention. But, even at this stage, eliciting the necessary information about potentially problematic activities may require asking the right questions. One of the goals from the invention disclosure call with inventors is to determine whether a disclosure will be or has already been made. Generally, this determination begins with finding out whether any activity involving the invention has taken place with anyone other than the inventor(s) or outside the Assignee company. If it has, determining whether that activity meets the public disclosure bar or the on-sale bar involves using the *Pfaff* two-part inquiry to consider the activity: whether the invention was ready for patenting at the time the activity happened and whether the activity was public or constituted a sale. To this end, it is important to understand the timeline of an invention and ask questions according to the current stage of an invention.

For example, if an invention is at a conceptual stage, the relevant questions may be whether the concept of the invention has been communicated through emails, talks, product announcements, or has been published in a paper. If an invention is incorporated into a prototype such that it would be deemed ready for patenting and its use would not be deemed experimental, a determination should be made as to whether the prototype has been shown or demonstrated in a trade show or appeared in advertising or marketing materials. If an invention has entered a manufacturing phase, it is important to understand whether only manufacturing services were permissibly contracted from the manufacturer or if the invention was commercially marketed, triggering the on-sale bar.[31] The UCC is generally used to guide an inquiry into whether communication rises to the level of a commercial offer for sale, and the absence of a title transfer for the product including the invention can support a conclusion that the product was not on sale.[32]

Because many of the cases involving public activity hinge on whether there was a duty of confidentiality in place, steps should be taken to determine whether any discussions or demonstrations

of the invention were undertaken without limitation, restriction, or obligation of confidentiality to the inventor.[33] And, where public activity has not already been undertaken, non-disclosure agreements should be suggested even for activity that may not be problematic. For example, some experimental use period of the invention (e.g., a software program) may have been performed or may be planned for testing purposes. The testing may be deemed experimental use that is not a public disclosure that might trigger a bar to patentability.

Nonetheless, if the testing has not already been undertaken, suggesting non-disclosure agreements for testers is still prudent in case the invention is ultimately found to have been ready for patenting at the time of the testing. When a disclosure has taken place, attorneys should obtain the requisite information to determine the nature of the disclosure to evaluate whether any barring activity may have occurred.

If there was a public disclosure, attorneys should take the extra step to determine what information was actually disclosed. Many times, the information disclosed is not to the level of detail that would be needed to understand the invention and is not the type of information that would eventually be provided within a patent application. Frequently, the inventor may have disclosed only a part of the invention, and other more important (and perhaps commercially valuable) portions may still be available for patenting. For instance, many times in software inventions, a product is publicly announced beforehand without disclosing some of its valuable features or underlying technology. In some cases, additional software functionality may be added at different points in time, and, therefore, different disclosure dates may apply to these added functions. Thus, in addition to the nature of the disclosure, the content of the disclosure should be well-understood. Further, to determine whether the one-year grace period available in the U.S. may be helpful, the exact dates of every disclosure should also be ascertained.

WHAT TO ADVISE – PATENT STRATEGY

The best situation to have from a patent filing perspective is that no disclosures of the invention were made by the time of the invention disclosure discussion with the inventor. That is, ideally, no activities involving the invention will have taken place with anyone other than the inventor(s) or outside the company such that no barring activity occurred. This is especially helpful because most foreign countries (e.g., European countries) have absolute novelty requirements and any public disclosure of the invention will bar the subsequent filing for a patent in those countries. In this case, practitioners should advise inventors not to disclose their inventions until a patent application (e.g., a provisional or non-provisional U.S. application) has been filed to preserve their foreign rights.

After at least one application has been filed, public disclosure of subject matter described in that application no longer threatens the validity of a patent stemming from the application. In addition, foreign rights can be pursued later by filing a Patent Cooperation Treaty (PCT) application, a direct national, or one or more regional cases within one year of filing the application and claiming priority to that first-filed application. The motto of "file early and often" is more relevant based on the fact that, post-AIA, the U.S. is, like many other countries, a first-to-file country. First-to-file means that the earliest filed application has priority, regardless of whether another may have reduced the invention to practice earlier. Thus, whether a disclosure has been made or planned, filing a patent application as early as possible is still advantageous. For example, the earliest filing date dictates whether the inventor has priority over the inventions of others, and whether public activity of others will bar the inventor from obtaining a valid patent.

Sometimes, inquiries made during the disclosure call with the inventor may reveal that, even if a disclosure has not already taken place, one is planned in the very near future. The disclosure may be in the form of a paper being prepared for submission to a conference or a planned meeting with a vendor or customer, for example. The planned disclosure may also be an upcoming announcement, upcoming Internet publication, software release, tradeshow, or other event that might bar one or more foreign patent applications from being filed.

Here, practitioners should present the option of filing a provisional application which includes information that might be disclosed. Provisional applications may be used when an inventor wishes to preserve an early filing date for the invention but does not have the time or financial resources to

properly draft and file a regular (non-provisional) application. Many times, provisional applications are used to protect ideas at early stages when specific implementation details are not known or finalized (e.g., in the case of a commercial product), and the inventor has some impending disclosure where foreign rights would be lost.

In such cases, a provisional application can be drafted that includes a broad description of the invention and any foreseeable options or implementation details.

In such cases, a provisional application can be drafted that includes a broad description of the invention and any foreseeable options or implementation details. When more implementation details are known about the invention, additional provisional applications (if within one year of the first provisional application) or a regular (non-provisional) application conversion of the provisional application(s) can be filed which includes these details. Care should be taken, however, to ensure that the provisional application has enough information that might support claims to the commercially-valuable portions in a later-filed non-provisional application. This is because any subject matter in later applications that is not described in the earlier filed provisional application(s) will not benefit from the earlier filing date(s).

If a public disclosure of the invention was made without the benefit of confidentiality, the opportunity to file a U.S. application is still available if the disclosure occurred less than one year from the date when a (provisional or non-provisional) filing could be completed at the USPTO. If this is the case, the practitioner should advise that U.S. rights are still available if a U.S. application is filed within the one-year anniversary date of the disclosure event. Care should be taken to accurately document this event, and any disclosures in the form of printed publications should be cited by the practitioner to the USPTO in an Information Disclosure Statement that lists all art known to the inventor.

CONCLUSION

In summary, patent practitioners should be aware of any events that might be a bar to patentability due to public disclosure or being on-sale before filing a patent application on an invention. Even if some disclosure or on-sale activity has occurred, practitioners should identify opportunities to obtain some rights for their clients' inventions depending on the factual circumstances.

Notes

1. 35 U.S.C. § 102(a)(1).
2. 35 U.S.C. § 102(b)(1)(A).
3. MPEP 2152.02(c).
4. Id.
5. MPEP 2152.02(d).
6. Pfaff v. Wells Electronics, Inc., 525 U.S. 55,64, 119 S. Ct. 304, 142 L.Ed.2d 261 (1998).
7. Id.
8. Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1379 (Fed. Cir. 2005).
9. Sanofi v. Glenmark Pharms. Inc., 204 F.Supp.3d 665,698 (D. Del. Aug. 31, 2016).
10. Id.
11. Id.
12. Id at 699.
13. Id citing Bayer Schering Pharma AG v. Barr Labs. Inc., 2008 WL 628592, at *38 (D.N.J. Mar. 3, 2008).
14. Sanofi at 699.
15. Id.
16. Minerva Surgical, Inc. v. Hologic, Inc., No. 2021-2246 (Fed. Cir. Feb 15, 2023).
17. Id.
18. Id citing Helsinn Healthcare S.A. v. Teva Pharm. USA, INC., 855 F.3d 1356, 1372 (Fed. Cir. 2017) and Pfaff at 67-68.
19. Id.
20. Id.
21. Id quoting Delano Farms Co. v. California Table Grape Comm'n, 778 F.3d at 1247 (Fed. Cir. 2015).
22. Id citing Netscape Commc'ns Corp. v. Konrad, 295 F.3d at 1321 (Fed. Cir. 2002).
23. Id citing Dey, L.P. v. Sunovion Pharms., Inc., 715 F.3d at 1355-56 (Fed. Cir. 2013).
24. Id.
25. MPEP 2152.02(e).
26. Id.

27. Dow Jones Co., Inc. v. Ablaise Ltd., 632 F.Supp.2d 36,38 (D.C. July 15, 2009).
28. Id.
29. Id at 37.
30. Id.
31. Medicines Co. v. Hospira, Inc., 827 F.3d 1363, 119 U.S.P.Q.2d (BNA) 1329 (Fed. Cir. 2016).
32. Id at 1375.
33. MPEP 2152.02(c).