IS IT DIVULGATION OR CAN YOU STILL FILE A PATENT APPLICATION?

A Comparison of Outcomes Under the EPC and US Laws

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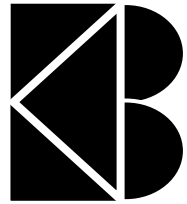

Ideally, an invention is created, a patent application is filed, and public disclosure or sale activity occurs – in that order. Unfortunately, we do not always live in an ideal world. Sometimes, disclosures or other activities occur before a patent application is filed. Those events may destroy the ability to protect valuable intellectual property rights.

Potential owners of intellectual property should be alert to differences in the legal systems of two of the most important economies in the world – the United States and Europe. This awareness is required to avoid the loss of valuable rights when an unfortunate disclosure happens.

This presentation will address some of the differences between Europe and the United States in the ability to file patent applications in certain circumstances when an invention has been disclosed, either by the potential patentee or by a third party. Many times, the answer with respect to the loss of rights is the same in both jurisdictions. Surprisingly, there are circumstances where rights are still available in one jurisdiction, but not in the other.

This paper will provide a summary of novelty concepts for the European and United States jurisdictions. A series of case samples is also provided to compare and contrast outcomes of actual cases with predictions of the outcome if the same case had been decided in the other jurisdiction under the same set of facts.

1. EUROPEAN PATENT CONVENTION summary

1.1. Legal Provisions

Novelty is one of the basic prerequisites for patentability as laid down in Arts. 52(1) and 54 of the European Patent Convention (EPC). Key provisions of the Articles to be discussed in this paper are as follows:

Art. 52

Patentable Inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

Art. 54

Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use or in any other way before the date of filing of the European patent application.

1.2. The "State of the Art" in Novelty Examination

1.2.1. What is meant by the "State of the Art"?

According to Art. 54(2) EPC, everything which is made available to the public before the date of filing of the European patent application is considered to belong to the state of the art. Written and oral descriptions and use are explicitly mentioned. This includes published patents and patent applications, scientific articles, dissertations, oral presentations (e.g. at scientific conferences) and public use.

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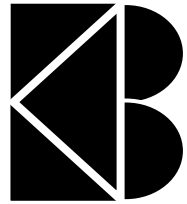

However, the state of the art is not limited to subject matter which is made available to the public by means of a written or oral description or by public use, but also comprises subject matter which is made available to the public in **any other way**, for example by the demonstration of subject matter during teaching lessons or on television.

The concept that everything which has been made available to the public is considered to be novelty destroying is called the "principle of absolute novelty." In this context, "absolute" means that no limits as to time (e.g. documents of the past 100 years) or place (e.g. only domestic prior use operations), as for example in the old German Patent Law, are intended.

1.2.2. The "Public" in Novelty Examination

There is no definition in the EPC for the term "public". An invention is usually addressed to a person skilled in the art, but according to the European Patent Office ("EPO") it is not necessary for a skilled person to actually take notice of an invention for the invention to be considered to have been "made available to the public." Information is considered to be publicly available if it was **possible** for members of the public at the particular date to gain knowledge of this information. It does not matter whether members of the public **actually obtained** the information. All that matters is that it was possible to obtain knowledge of the information. In principle, it is sufficient that it was possible for only **one** member of the public to obtain the information, provided that this particular person is not bound by a secrecy agreement.

If the particular information was made available to some selected members of the public on the condition that these members should not spread the information (secrecy agreement), the information is **not** considered to have **been made available** to the public.

It is important to note, however, that a secrecy agreement only provides *prima facie* evidence that the person to which the invention has been revealed has not spread this information ("made available to the public"). If, however, it can be proven that the person bound by the secrecy agreement has passed the information on to a member of the public despite the agreement, the information is considered **to have been made available** to the public.

1.2.3. What is required of a Disclosure to be Novelty Destroying?

In the examination of novelty it has to be established whether the state of the art is likely to reveal **the content** of the invention's subject matter to the skilled person in a technical teaching. See the decision "Thiochloroformates", T 198/84 (OJ EPO, 1985, 209, 213). Also, the decision "Spiro Compounds" T 181/82 (OJ EPO 1984, 401, 411) states:

"When the teaching from a citation is interpreted special attention must be paid to the material actually disclosed in the sense of a complete specific technical rule."

To be novelty destroying, a disclosure must disclose the claimed subject matter in a way which enables the person skilled in the art to carry out the invention. In other words, the reference must be enabling. See the decision "Overlapping ranges of

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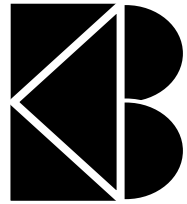


thickness", T 26/85 (OJ EPO 1990, 22, 27) wherein the Board of Appeal interpreted Art. 54 EPC

"... in the sense that anything comprised in the state of the art can only be regarded as having been made available to the public in so far as the information given to the person skilled in the art is sufficient to enable him to practice the technical teaching which is the subject of the disclosure, taking into account also the general knowledge in the field to be expected of him."

1.2.4 Prior Use

The determination of whether or not a public use of an invention is novelty destroying is the same as the determination of whether or not any prior art publication is novelty-destroying. In both cases, the invention must be **enablingly** disclosed to the public to be regarded as prior art. The only difference between these two categories of prior art is in the presentation of the evidence. In the case of a document, the disclosure content can easily be checked, and the only issue is the proof of the point of time that the document was made available to the public. In the case of an assertion of prior use, proof must also to be shown regarding the nature of the object that was used, and by whom it has been used.

It should be kept in mind that during public prior use, the public is only aware of that which it can learn from analyzing the product that was sold or from seeing the invention while in use. In the situation where an essential part of the invention is hidden, for example a specific use of a product, and that essential part would not have been obvious to a skilled person, this essential part does not become part of the state of the art. Such an invention can therefore, despite the public use of the product, still be novel.

2. US PATENT LAW SUMMARY

2.1 Statutory Provisions.

In the US, the concept of Novelty is defined in section 102 of Chapter 35 of the US Code. Key provisions for purposes of the discussion of this paper are as follows:

Sec. 102. Conditions for patentability; novelty and loss of right to patent

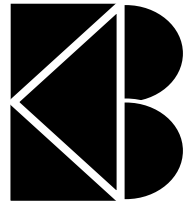
A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or...

(f) he did not himself invent the subject matter sought to be patented…

(g) ...(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable



diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

2.2 Policy Summary

To understand the law, it is important to know what the law is trying to accomplish. In brief, the law is trying to meet four important policy interests, which are:

1) to discourage removal from the public domain of inventions that the public reasonably has come to believe are freely available;

2) to favor the prompt and widespread disclosure of inventions;

3) to allow the inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent; and

4) to prohibit the inventor from commercially exploiting the invention for a period greater than the statutorily prescribed time.

These policies were described in the decision in the case of Tone Brothers v. Sysco Corp., 28 F.3d 1192, 31 USPQ2d 1321 (Fed. Cir. 1994).

2.3 Key terms in the US law

2.3.1 Patented or described in a Printed Publication

A claim will be held to lack novelty (or in other words be "anticipated") if the invention is disclosed in a patent or a printed publication. An invention may be anticipated if all elements of the claims are disclosed in a single reference. Titanium Metals Corp. v. Banner, 778 F. 2d 775, 227 USPQ 773 (Fed. Cir. 1985). The reference, however, must be enabling – that is, it must enable one of skill in the art to carry out the invention. Even though all of the elements of the invention have to be disclosed in a single reference to destroy novelty of the invention, additional references may be used to provide proof that this one reference is enabling. In re Donohue, 776 F. 2d 531, 226 USPQ 617 (Fed. Cir. 1985).

2.3.2 Public Use or Sale

Any public use or sale of an invention will act as a bar to obtaining a patent on that invention. A `public use' is defined as use more than a year before the patent filing date of a completed invention in public, without restriction.

There is an important distinction with respect to the need for enablement when the prior art is a public use or sale, as compared to enablement required when the prior art is a patent or printed publication as discussed above. The information disclosed in a public use or sale situation does not need to be enabling to destroy novelty. In re Epstein, 32 F.3d 1557, 31 USPQ 2d 1817 (Fed. Cir. 1994). This is because this type of disclosure relates to loss of right, and reflects the policies of prohibiting the inventor from commercially exploiting the invention for a period longer than the statutory period, and/or discouraging removal from the public domain inventions that the public reasonably has come to believe are freely available.

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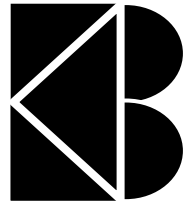


2.3.3 Experimental Use

There are circumstances where a public use is not a novelty destroying event, even when the event is earlier than the "critical date." These circumstances are when the public use is done within the context of an experimental purpose. Elizabeth v. Am. Nicholson Pavement Co., 97 U.S. 126 (1877). Even the sale of a product may be characterized as an experimental use, provided that there is control over the use of the product and evaluation of its performance. Monon Corporation & Rosby Corporation v. Stoughton Trailers, Inc., 57 USPQ2d 1699 (Fed. Cir. 2001).

2.3.4 On Sale

The "on sale" bar applies when a) there is an offer for sale and b) the invention is ready for patenting. An invention is said to be ready for patenting when an embodiment has been reduced to practice or when there is sufficient information developed such that a patent application could be written. Pfaff v. Wells Electronics Inc., 525 U.S. 55, 48 USPQ 2d 1641 (1998). The on sale bar applied only to sales "in this country." The Federal Circuit has ruled that a bar is effective when it relates to offers for sale from outside the United States to a potential customer in the US. CR Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 48 USPQ 2d 1225 (Fed. Cir. 1998).

3. Cases and Discussion

3.1 "Plant Growth Regulating Agent", G 6/88 (OJ EPO 1990, 114, 124)

3.1.1 Question: Assume that a chemical compound is known for one use. A new use for this compound is discovered, but the new use would inherently happen when the compound is used for the old use. Is a claim directed to the new use novel?

3.1.2 Facts

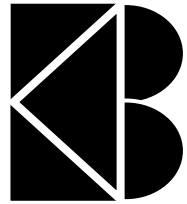
In a case decided by the European Board of Appeal, a compound (X) was known in the prior art. The known use of this compound was for controlling fungi on plants.

The claim under consideration was for the "Use of a compound (X) to regulate plant growth."

This fact scenario presents a difficult question, because when Compound (X) is used for the prior art purpose of fungi control, the compound automatically also is regulating plant growth.

3.1.3 European Decision

The argument that had been recited against novelty of the claim, i.e. that the person skilled in the art will recognize that an abnormal growth process was bound to occur as an unintended consequence of anti-fungal treatment of cultures with said compound, was not successful. The Board decided that if a skilled person unaware of the invention had in fact observed a culture exhibiting an uncharacteristic growth process, he could have sought the cause - had he reflected on the matter at all - among various factors such as the particular properties of the soil, the time or type of cultivation, climate, fertilization, etc. The public was thus unable - either by reading the prior art or by



executing its teaching - clearly to identify the essential character of the claimed invention, namely the growth-regulating effect of the above compounds.

In the course of examining and deciding upon the appeal in case T 208/88, Chemical Board of Appeal 3.3.1 of its own motion referred the following question of law to the Enlarged Board of Appeal:

Is a claim to the use of a chemical compound or class of compounds for a particular non-medical purpose novel within the meaning of Article 54 EPC, having regard to prior art which discloses the use of that compound (class of compounds) for a different non-medical purpose, if the two teachings are carried out by identical technical means and the only novel feature in the claim is the use itself?

In the decision, the Enlarged Board of Appeal answered this question as follows:

> ...under Article 54(2) EPC, the question to be decided is what has been "made available" to the public; the question is not what may have been "inherent in what was made available (by a prior written description or in what has previously been used (prior use), for example). Under the EPC, a hidden or secret use, because it has not been made available to the public, is not a ground of objection to validity of a European patent.
>
> * * *
>
> ...with respect to a claim to a new use of a known compound, such new use may reflect a newly discovered technical effect described in the patent. The attaining of such a technical effect should then be considered as a functional technical feature of the claim (e.g. the achievement in a particular context of that technical effect). If that technical feature has not been previously made available to the public by any of the means as set out in Article 54(2) EPC, then the claimed invention is novel, even though such technical effect may have inherently taken place in the course of carrying out what has previously been made available to the public.

3.1.4 European Conclusion

The patent will be granted. A newly found use of a known substance can be patentable although the technical effect that is achieved by the new use has already occurred in the use of a known compound in known applications without being recognized.

3.1.5 US Prediction

The US result is the opposite of the European result. No patent will be granted.

In the US, the discovery of a previously unrecognized effect that would be inherently happen when the compound is used in its previously described use is anticipated by the previous use. In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (Fed. Cir. 2002). However, for the new use to be anticipated by the inherent activity when used in the old way, there must be proof that the new result actually does occur when carrying out the old method. A mere probability that the new result occurs is not enough to destroy patentability of the new method claim.

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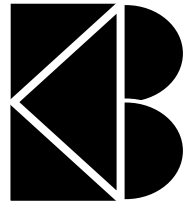

Electro Medical Systems S.A. v Cooper Life Sciences, Inc. 34 F.3d 1048, 32 USPQ2d 1017 (Fed. Cir. 1994); Glaxo, Inc. v Novopharm, Ltd. 52 F.3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995).

A number of approaches have been used to try to obtain patent protection on compositions having a new use. One approach has been to simply attach a set of instructions to a bottle containing the composition for the newly discovered use. In a recent decision by the Federal Circuit, claims drawn to a kit comprising the product plus instructions for use were definitively determined to be not patentable. In re Ngai, 70 USPQ2d 1862, (Fed. Cir. 2004). An approach that does work in the US, for example in a new pharmaceutical use of a known pharmaceutical, is to draft method claims wherein the first step of the method is to "identify a patient in need thereof" to avoid anticipation. This limitation, of course will cut both ways, limiting the reach of the claims to methods that actually carry out this identification step. Jansen v. Rexall Sundown Inc., 68 USPQ2d 1154, Fed. Cir. 2003.

3.2 "Availability to the Public," G 1/92 (OJ EPO 1993, 277)

3.2.1 Question: If a product is sold, but the invention can only be determined by analyzing the product, is novelty destroyed even though there is no motivation to analyze this product?

3.2.2 Facts

In this case, the Enlarged Board of Appeal had to deal with two decisions of the Technical Board of Appeal which contradicted each other (T 93/89 (OJ EPO 1992, 718) and T 406/86 (OJ EPO 1989, 302)).

In one of these cases (T 93/89) the Board of Appeal 3.3.3 decided that the composition of a product was not made available to the public by virtue only of the availability of the product to the public. The Board held that a particular reason must be identified why the skilled person would have analyzed the product. In particular, the Board stated that the simple fact that a new product is introduced onto the market is not a reason for a competitor to analyze the composition of the product.

In contrast with this decision, Board of Appeal 3.3.1 held in case T 406/86 that the availability to the public of a product should be considered as also making its composition available when it can be determined without any difficulty by chemical analysis.

3.2.3 European Decision

The Enlarged Board of Appeal considered it appropriate to make some general remarks on the kind of information that can be derived from the public use of products for the purpose of the application of the requirement "made available to the public" in Article 54(2) EPC.

An essential purpose of any technical teaching is to enable the person skilled in the art to manufacture or use a given product by applying such teaching. Where such teaching results from a product put on the market, the person skilled in the art

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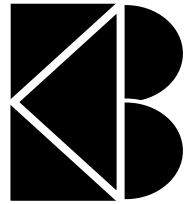


will have to rely on his general technical knowledge to gather all information enabling him to prepare the said product. Where it is possible for the skilled person to discover the composition or the internal structure of the product and to reproduce it without undue burden, then both the product and its composition or internal structure become part of the state of the art.

There is no support in the EPC for the additional requirement referred to by Board 3.3.3 in case T 93/89 that the public should have particular reasons for analyzing a product put on the market, in order to identify its composition or internal structure. According to Article 54(2) EPC, the state of the art shall be held to comprise everything made available to the public. It is the fact that direct and unambiguous access to some particular information is possible, which makes the latter available, whether or not there is any reason for looking for it.

3.2.4 European Conclusion

No patent will be granted.

The Enlarged Board of Appeal made clear that a chemical composition of a product belongs to the prior art if the product itself is publicly available and can be analyzed by a person skilled in the art. This decision is not based on whether person skilled in the art has a motive for analyzing the composition.

3.2.5 US Prediction

The result is the same in the US – no patent will be granted. But the reasoning is different.

As noted above, in the case of public sale, the sale itself triggers the statutory bar. There is no requirement for disclosure of the chemical content to the public, or enablement.

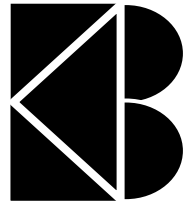
In fact, there is no requirement that the invention actually be in the hands of the customer and therefore available for reverse engineering. The offer for sale itself is the bar. JA LaPorte, Inc. v. Norfolk Dredging Co., 787 F.2d 1577, 229 USPQ 435 (Fed. Cir. 1986). In an interesting twist, a similar such discussion relating only to an offer to license the technology, rather than a formal offer for sale (i.e. offer, acceptance, price and quantity are all established), will NOT prevent the patent from being granted. An offer for license is not in the statute, and therefore doesn't affect patentability. Elan Corp. PLC v. Andrx Pharmaceuticals Inc., 70 USPQ2d 172 2, (Fed. Cir., 2004).

3.3 T 1054/92 (unpublished)

3.3.1 Question: If a product is tested in a study, with many people participating in the study (maybe under confidentiality), is a claim covering this product novel?

3.3.2 Facts

In the case which formed the basis for the decision T 1054/92, the Opponent asserted and also proved that the claimed invention which related to an absorbing structure for diapers was tested in a broad manner on some hundred persons during several weeks in various cities in the U.S.A. Appellant/Patentee admitted that he did not know for sure whether these tests were confidential.



3.3.3 European Decision

The Board was convinced in the light of common experience that it was very unlikely that tests carried out on such a scale were kept confidential, in particular since, as confirmed by the appellant, the used diapers (at least some of them) were not returned to the patentee. According to the Board it is understandable in view of the high number of tests, participants and testing areas why no documents concerning security precautions of these tests have been located. According to the Board it was very probable that no obligation of confidence existed. As a rule, Patentee has to bear the burden of proof for a claimed secrecy agreement.

The Board, having to decide on the basis of the available evidence what happened on the balance of probabilities, has found that the tests were not confidential. The prior use of the diapers thus was considered as public.

3.3.4 European Conclusion

No patent is granted. The person who asserts the secrecy agreement (here the Patentee) has to bear the burden of proof of such a claimed secrecy agreement (explicitly or implicitly). If a secrecy agreement cannot be proven and if it cannot be derived from the prior use that the invention was not available to the public, the invention is no longer novel.

3.3.5 US Prediction

More facts would be needed to determine the US outcome.

In the US, applicants can rely on the 1 year grace period. Assuming that the study was done prior to the grace period, the use could still be considered to be experimental - which is not by definition a public use. In order to determine whether the study was an experimental use, a court would look at a number of factors. Mere marketing evaluations are not experimental uses, but if for example there is a genuine evaluation of the technical success or failure of the product, and if the samples remain under the control of the experimenter, it is possible that the study could be found to be an experimental use. Monon Corporation.

In order for a study to be found to fall under the experimental use exception, the study must not only carry out a bona fide evaluation of the technical benefits of the product, but the property that is studied must be a claimed feature of the product. In a remarkable example, the patent covering the antidepressant Paxil® was held to be invalid for prior public use because the clinical testing of the product tested for safety and efficacy, and did not evaluate a claimed feature of the drug. SmithKline Beecham Corp. v. Apotex Corp., 70 USPQ2d 1737 (Fed. Cir. 2004).

3.4 T 381/87 (OJ EPO 1990, 213)

3.4.1 Question: If the invention is described in a publication mailed two days before the "critical date," and posted in a library one day prior to the "critical date," is it still novel? (The critical date is different for Europe vs. the US. In Europe, the critical date is the date of filing of the

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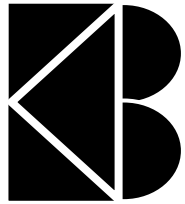

patent application. In the US, the critical date is one year prior to filing the application.)

3.4.2 Facts

The outcome of this case turns on the question of when a certain document was available to the public.

A European patent application was filed on 29 November 1982, and claimed priority from an application filed in the United States on 27 November 1981. (Note, November 27, 1982 was a Saturday, and thus the application could be filed in Europe the following Monday and still claim priority.) During examination of the application, an article by the three named inventors of the invention describing the subject matter of the application was cited by the Examining Division. The article was published in the Journal of the Chemical Society. The Examining Division pointed out that a note at the end of the article indicated that it had been received by the Chemical Society on 12 August 1981.

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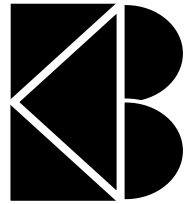

The following timeline chart identifies key dates in this case:

		12.08.1981	the article has been sent to the Royal Society of Chemistry, and received there to be published in one of the journals of the Royal Society.
		25.11.1981	the article has been dispatched by (second class) mail by the Royal Society to its subscribers
		26.11.1981	a single copy of the article has been delivered to and processed into the Library of the Royal Society of Chemistry
Priority date	27.11.81		
European filing	29.11.82		

It was undisputed that in general it would take two days for the post service to deliver the article to the subscribers. However, it was unclear whether, in isolated cases, subscribers nevertheless received the article **before** November 27, 1981.

A Decision of the Examining Division (first instance) was issued in which it was held that because the publishers of the article, the Chemical Society, lost control over the dissemination of their publication when it was dispatched on 25 November 1981, that date constituted the publication date.

3.4.2 European Decision

Due to the arguments put forward by the parties, the Board had no doubt that the article was received by the Royal Society of Chemistry in confidence, and that the Royal Society was obliged to keep the contents of the article secret prior to any publication. Therefore, August 12, 1981 could be ruled out as publication date.

With respect to November 25, 1981, the Board of Appeal explained that in the Board's view a document is not "made available to the public" for the purpose of Article 54(2) EPC merely by being addressed to a member of the public and placed in a post-box. It is quite clear that while such a document remains in the post-box, and at all times prior to its delivery to the person to whom it is addressed, it is not "available to the public." Accordingly, in the Board's judgment, the Examining Division was wrong to hold that document (A) was made available to the public on the day when it was posted to subscribers, i.e. 25 November 1981.

In the Board's view, it is clearly possible that a copy of document (A) was delivered by mail to a subscriber on the day after it was posted by second class mail in the United Kingdom, i.e. on 26 November 1981. However, having regard to the evidence presented, the normal time taken for delivery of second class mail within the United Kingdom is at least two days from posting, i.e. not before 27 November 1981. Accordingly, the Board is not satisfied that, on the balance of probabilities, any copy of the article was in fact delivered by mail to a subscriber before the priority date of 27 November 1981.

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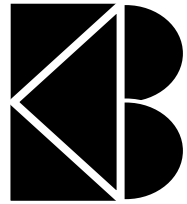


The article was placed on the shelves of the Library on 26 November 81. According to the Board it follows as a legal consequence of that fact that the article formed part of the state of the art for the purpose of Article 54 EPC on 26 November 1981. Furthermore, it was undisputed that "the journal containing the article would have been available on that day to anyone who requested to see it," and the Board further holds that on the balance of probabilities this is a true statement of fact. In the Board's judgment, such fact is also sufficient to establish that the article was "made available to the public" for the purpose of Article 54(2) EPC on 26 November 1981. It is not necessary as a matter of law that any members of the public would have been aware that the document was available upon request on that day, whether by means of an index in the Library or otherwise. It is sufficient if the document was in fact available to the public on that day, whether or not any member of the public actually knew it was available, and whether or not any member of the public actually asked to see it.

3.4.4 European Conclusion

A patent may not be granted in this case. A document is not "made available to the public" merely by being addressed to a member of the public and placed in a post-box. It is only "made available to the public" by its delivery to the addressee. The act that made this article available to the public was the placing of this article on the library shelves, not the mailing of the article.

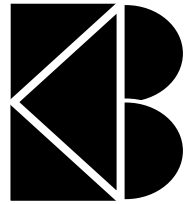
3.4.5 US Prediction

A patent will be granted in the US because the one year grace period. However, if the same facts occurred one year prior to the US priority date, the result would be the same in the US. Specifically, the patent will not be granted because of the library posting of the article. The mailing date of the article is not the effective date of the prior art.

An article is considered to be available when it is posted in the library, and is thereby accessible and available to the public. In re Hall, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986). A publication cannot be said to be published when it is still in the postal system. For defensive purposes, it is important to note that the burden of proof of the dissemination date is on the party that wants to characterize the reference as a printed publication. Carella v. Starlight Archery, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986). One can establish access to a publication by proving that the reference would have been available in the ordinary course of business through proof of the routine business practice. Constant v. Advanced Micro-systems, Inc., 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988).

3.5 Commercial exploitation of a secret process. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721. F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

3.5.1 Question: If the product of a secret process is sold (reverse engineering of the process is not possible from the product), is the process still novel?



3.5.2 Facts

Gore received a patent on a process for stretching highly crystalline, unsintered, PTFE. The district court found that claim 1 of the process patent was anticipated by Gore's use of its 401 machine, and all of the claims were invalid because of Budd's secret use of the Cropper machine.

3.5.3 US Decision

The Federal Circuit held that claim 1 was anticipated by Gore's use of his machine, but that Budd's use of the Cropper machine could not be held a bar to the grant of a patent to Gore on that process.

3.5.4 US Conclusion

No patent is granted if the secret exploitation is by the potential patentee. A patent would be granted if the secret exploitation is by a third party – not the potential patentee.

The confidential commercial exploitation of a process by a potential patentee is a bar to that user from obtaining a patent on that process. This is not, however, the case for any other party. In the US, a non-disclosing use of a process by a third party is not prior art against a party that separately invents and does not commercially exploit the process prior to the critical date. US law now provides for limited prior user rights in circumstances where a prior inventor has been commercializing a product made by a non-disclosing process, and a subsequent patent is granted drawn to that process. Specific advise of counsel in relying on this new right is highly advised.

3.5.5 European Prediction

A patent would be granted.

The secret use of a process is not a public use, and does not make the invention as claimed in a process claim available to the public. A patent can be granted on this process, regardless of whether the party that used the process is the potential patentee or a third party.

3.6 "Microchip," T 461/88 (OJ EPO 1993, 295)

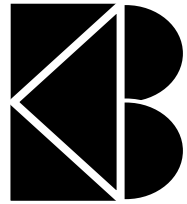
3.6.1 Question: If a product is sold that contains an invention drawn to a control method, and the invention can be reverse engineered only at great expense, is novelty destroyed?

3.6.2 Facts

In the decision "Microchip," the Technical Board of Appeal determined to what extent information that was only disclosed on a microchip is enabling and therefore forms part of the prior art.

This case referred to a control system, which corresponded to all features of the patent in suit and which, stored on a microchip, was installed into a printing machine. One of these printing machines had been sold without a secrecy agreement.

In the first instance of the opposition proceedings, the patent was revoked. In its written statement of reasons for the decision, the Opposition Division explained that, on the basis of the evidence supplied, it regarded the prior use as public, since



the control and monitoring system shipped with the machine had been unconditionally delivered and sold to a member of the public, thereby giving the purchaser unlimited access to all the knowledge which could be gained from this object.

3.6.3 European Decision

The Board of Appeal did not follow the decision of the Opposition Division. The Board decided:

When an apparatus which is the subject matter of an obvious prior use is a microchip containing a program which embodies a control method and is written in a computer language, said control method shall not belong to the state of the art specified in Article 54(2) EPC if the interested experts have no access to the function and connection diagrams specific to the program, if the principle of the control method is not phenomologically recognizable and, according to life experience, the program contained in the microchip could not have been determined directly in the particular circumstances, especially in light of cost and effect considerations although such a direct determination is technically possible

3.6.4 European Conclusion

A patent will be granted.

The above decision is an exceptional case. On one hand, the Board of Appeal acknowledged that the microchip could have been analyzed with a great effort of time and costs and thus, was made available to the public at the time of purchase. On the other hand, the Board of Appeal took into account in the decision that considering practical experience, it was unlikely that an analysis had taken place because of the necessary effort along with the very high cost of the analysis. The Board of Appeal concluded that in this case, the invention has not been made available to the public.

3.6.5 US Prediction

The result would be different in the US – no patent would be granted.

I have not yet found a case that factors in the difficulty or expense of reverse engineering. The US cases do not raise this issue in the circumstance where the product is sold by the patentee, because the sale of the product itself is the bar to patenting. This is based on the public policy of not allowing an extension of the term of exclusive commercial exploitation by the patent owner.

If someone could determine the method imbedded in the chip by performing a known test that costs a lot of money - I would predict that the invention would be considered to be reverse engineerable, regardless of cost.

3.7. Disclosure to a potential patentee under obligation of Confidentiality. Oddzon Products Inc. v. Just Toys, Inc., 43 USPQ 2d 1641 (Fed. Cir. 1997).

3.7.1 Question: If someone from another company shows you a design under a secrecy agreement, and you create an invention very similar to that design, is that confidential disclosure to you prior art?

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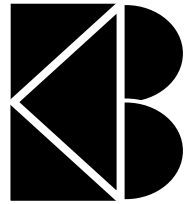


3.7.2 Facts

Designs were disclosed to a potential patentee of a toy under confidentiality agreement. The designs were not identical to any embodiments within the scope of the claims eventually obtained by the applicant.

3.7.3 US Decision

The designs that were disclosed under confidentiality agreements to the potential patentee are prior art, and may be used not only to show anticipation of the claim, but also obviousness.

3.7.4 US Conclusion

No patent would be granted.

Section 102(f) of the statute provides that a person shall be entitled to a patent unless "he did not himself invent the subject matter sought to be patented." It is now clear under the law that this section of the statute applies not only to situations where the exact subject matter of the claims was derived from another, but also in situations where obvious variations of the information that was learned from another.

3.7.5 European Prediction

The result would be different in Europe. A patent can be granted, but...

Information that is disclosed to a party under obligation of confidentiality, according to the EPC, is not considered as an anticipating disclosure. The obligation of confidentiality provides *prima face* evidence that the information was not available to an unlimited number of members of the public, i.e. was not available to the public. For this reason the information disclosed to a potential patentee is not prior art. Thus this information may not be used for novelty or inventive step considerations. The question of whether any patent that may issue is properly the property of the party that filed the application may be addressed in national vindication proceedings.

3.8 Sale between partners in a Joint Development Agreement. Brasseler USA I.L.P. v. Stryker Sales Corp., 60 USPQ2d 1482 (Fed. Cir. 2001).

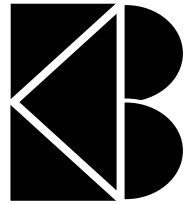
3.8.1 Question: Is novelty destroyed where a sale of goods falling within the scope of claims of an invention occurs between separate corporations in a joint development situation?

3.8.2.1 Facts

Surgical saw blades were invented by employees from two different companies. One company was obligated to manufacture all of the saw blades for the other company. The manufacturing company sold a large number of blades to the purchasing company before the critical date. The two companies were clearly separate corporate entities.

3.8.3 US Decision

The sale between the separate companies triggers an “on sale“ bar in the United States, whether or not it is a confidential



sale. There is no joint development exception to this rule. Sales activity kept secret from the trade still triggers the on sale bar.

3.8.4 US Conclusion

No patent will be granted.

3.8.5 EP prediction

A patent probably will be granted.

This case turns on whether there was an understanding of confidentiality between the companies, either express or implied, and whether confidentiality was in fact maintained. The joint development activity provides strong evidence of an intent to keep this information confidential, and it is likely that such an inference can be persuasive in Europe.

3.9 Secret unrecognized prior activity as prior art. Dow v. Astro-Valcour, 60 USPQ2d 1519 (Fed. Cir. 2001).

3.9.1 Question: Will the secret activity of a third party be prior art if the disclosure by the third party doesn't happen until after you have filed your application?

3.9.2 Facts

Inventors at one company developed a new process for blowing foams, and realized that it was a good process. They did not realize it was patentable. While the first company was working on commercialization, a second company also discovered this process, and filed a patent application. The first company's product came out later.

3.9.3 US Decision

Under 35 USC 102(g), prior activity by a third party inventor is prior art, even though this activity wasn't publicly known until after the filing date, so long as there is no abandonment, suppression or concealment. Active and continuous steps to commercialize the invention is all that is needed to avoid abandonment. That activity doesn't have to be the fastest possible course of commercialization, only reasonable efforts are required. The earlier invention is effective as prior art even though the inventor doesn't realize he has created a patentable invention. All he has to do is appreciate the fact that he has made something. This prior activity will destroy patentability in the US.

3.9.4 US Conclusion

No patent can be issued to the second company. The prior activity of the first company is a bar to patentability because they did not abandon, suppress or conceal the invention.

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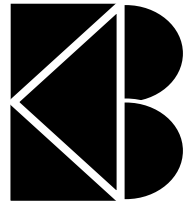

3.9.5 European Prediction

This early activity does not bar patentability in Europe. If the activity is not available to the public, there is no novelty destroying event.

3.10 Metabolite as prior art. Schering Corp. v. Geneva Pharmaceuticals, Inc., 67 USPQ2d 1664 (Fed. Cir. 2003)

3.10.1 Question: Will the metabolite compound that is necessarily produced in a patient's body upon ingestion of a drug be prior art against a patent claim of that newly identified compound?

3.10.2 Facts

Schering obtained a patent on its best-selling Claritin T antihistamine many years ago, for which the patent is now expired. Subsequently, Schering identified a metabolite of Claritin T and obtained a patent on it. Schering charged numerous defendants with infringing the metabolite patent by proposing to market generic versions of Claritin T. The metabolite is necessarily produced in the patient's body upon ingestion of ClaritinT.

3.10.3 US Decision

The Federal Circuit ruled that the ClaritinT patent "inherently" disclosed the metabolite, and so the compound itself was inherently anticipated. The decision was not limited to simply analyzing that the act that formed the basis of accusation of patent infringement (administration of the primary drug) was identical to acts described in an expired patent. The decision instead stated the broad rule above.

3.10.4 US Conclusion

Patent claims for a compound necessarily produced in the human body upon ingestion of a primary drug are inherently anticipated by the disclosure and sale of the primary drug.

It is not possible to claim the metabolite compound, but it is possible to get patent protection by careful claiming:

1. the metabolite may be claimed in its pure and isolated form
2. as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier).
3. as a method of administering the metabolite or the corresponding pharmaceutical composition

3.10.5 European Prediction

If one can assume that the claimed metabolite is a novel compound that has not been disclosed to the public before the filing day of the patent, there are chances to obtain a valid patent in Europe. A further prerequisite is that the metabolite is enabling disclosed, i.e. it can be produced and isolated. In order to overcome an inventive step problem it would be necessary that the metabolite can be administered to a patient and will show an effect.

The fact that the metabolite necessarily is produced in the human body upon ingestion of the primary drug does not

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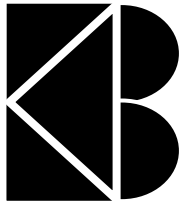

anticipate a claim on the metabolite, as long the knowledge of the metabolite was not available to the public.

CONCLUSION

This paper has been an attempt to illustrate the occasional but significant differences between the intellectual property rules in place in the United States and in Europe. It is hoped that this discussion creates an awareness of the types of questions that should be asked of intellectual property professionals when exploring the availability of rights in economically critical regions.

The foregoing is intended to provide you with helpful suggestions in protecting your organization from avoidable liability concerns in intellectual property matters. Each matter is different, and the advice of competent counsel in each situation should be obtained.