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If a product has been put on the market but cannot be reproduced, then to what extent is it prior art in Europe? EPO practice following G1/23 and a comparison with the position in the Australia, Canada, China, Japan, Korea and the US.

Contents

Introduction

The EPO's Enlarged Board of Appeal (Enlarged Board) recently issued its highly anticipated decision in G1/23, which clarifies EPO practice on the prior art status of products that have been placed on the market but which cannot be reproduced exactly. In this article, Dehns Partner **Neil Campbell**, who represented the opponent, Borealis, in G1/23 and in the underlying opposition and appeal, and Dehns Associate **Matthew Sullivan** explore the impact of this decision on EPO practice. This is then compared to the position by expert attorneys in six key jurisdictions.

Summary Table

	EP	AU	CA	CN	JP	KR	US
Is there a reproducibility requirement for a product placed on the market to become prior art?	No	No	No	No**	No	No	No
Does the confidential sale or supply of a product have a prior art effect?	No	Yes, but a 1-year grace period applies	No	No	No	No	Yes – on sale bar
Do non-analysable features of the product placed on the market become prior art?	No	No	No	No	No**	No	N/A – on sale bar
Is there an applicable grace period*?	No	Yes – 1-year	Yes – 1- year	No	Yes – 1-year	Yes – 1-year	Yes – 1-year

*Grace period features/requirements vary between jurisdictions. Local legal advice should be sought if more detail is required on the applicability of grace periods.

** typically – see relevant country section for more detail

Europe

Summary - Europe

- Following G1/23, when a product is placed on the market the product and all of its analysable features become prior art in Europe. There is no reproducibility requirement for such products to qualify as prior art. The fact that the skilled person can obtain the product from the market means there has been an enabling disclosure of the product and all of its analysable features. Under EPO practice, it can no longer be argued that a product placed on the market is not prior art on the basis that the product cannot be reproduced.
- In most cases, this means that once a product has been placed on the market, it can no longer be patented in Europe because the product has already been disclosed.
- This applies to natural products as well as man-made products, and to products across all technical fields.
- Evidential issues still apply – the party raising objections based on the disclosure of the product placed on the market still bears the burden of proving *what* was disclosed, and *when*.
- In contrast to other territories, there is no applicable grace period in Europe.

Background to G1/23

Unclear EPO case law before G1/23

In their earlier decision G1/92, the Enlarged Board established the following requirements[1] for determining whether a product put on the market is prior art under EPO practice, including a requirement for "reproducibility":

1. *The chemical composition of a product is state of the art when the product as such is available to the public and can be analysed and **reproduced** by the skilled person, irrespective of whether or not particular reasons can be identified for analysing the composition.*
2. *The same principle applies mutatis mutandis to any other product.*

(emphasis added)

As summarised in G1/23[2], the reproducibility requirement in this context was understood in G1/92, and in subsequent decisions interpreting G1/92, as meaning the preparation of the product put on the market by a method that is different from simply obtaining it from the market in its readily available form.

[1] see the Headnote of G1/92
[2] see paragraph 37 of G1/23

In the years following G1/92, non-uniform case law developed on how to interpret the reproducibility requirement. For example, some EPO appeal decisions adopted a strict "exact reproduction" standard, finding that a commercially available product was only prior art if an identical product in all of its features could be reproduced. Other decisions adopted a more lenient standard, finding that a commercially available product is prior art if it could be determined that a product could be reproduced that fell within the scope of the claim of the patent against which the product was prior art, regardless of whether the product was exactly reproducible. In other decisions some Boards of Appeal found a product put on the market to be prior art without addressing the question of its reproducibility.[3]

Key facts from the referring decision

G1/23 stems from a referral to the Enlarged Board in EPO case T0438/19. In T0438/19 the validity of the opposed patent potentially turns on whether a commercially available product - "ENGAGE® 8400" - is prior art. ENGAGE® 8400 is a complex polymer product that was commercially available before the effective date of the opposed patent. It was common ground between the parties in T0438/19 that the method for making Engage® 8400 is not publicly available and that the exact reproduction of complex polymer products is not straightforward. It was also agreed that many of the features of ENGAGE® 8400 were known from publicly available data sheets or could be readily determined by analysis of the product itself.

Following the case law adopting an "exact reproduction" standard, the patentee's position in T0438/19 was that ENGAGE® 8400 should be disregarded as prior art entirely because its composition could not be exactly reproduced. Opponent Borealis argued that ENGAGE® 8400 was prior art and it would be perverse if the EPO had to pretend that manifestly known information about a commercial product placed on the market before the priority date was somehow invisible to the skilled person.

After analysing the conflicting case law on the reproducibility requirement of G1/92 (discussed above), the Board of Appeal referred the following questions to the Enlarged Board, aiming to clarify this point:

> *1. Is a product put on the market before the date of filing of a European patent application to be excluded from the state of the art within the meaning of Article 54(2) EPC for the sole reason that its composition or internal structure could not be analysed and reproduced without undue burden by the skilled person before that date?*
>
> *2. If the answer to question 1 is no, is technical information about said product which was made available to the public before the filing date (e.g. by publication of technical brochure, non-patent or patent literature) state of the art within the meaning of Article 54(2) EPC, irrespective of whether the composition or internal structure of the product could be analysed and reproduced without undue burden by the skilled person before that date?*

[3] See Reasons 14-17 of T0438/19

3. If the answer to question 1 is yes or the answer to question 2 is no, which criteria are to be applied in order to determine whether or not the composition or internal structure of the product could be analysed and reproduced without undue burden within the meaning of opinion G 1/92? In particular, is it required that the composition and internal structure of the product be fully analysable and identically reproducible?

EPO practice following G1/23 and practical implications

The heart of the Enlarged Board's decision in G1/23 can be found in paragraph 73. Here, the Enlarged Board explains that the reproducibility requirement established in G 1/92 includes the obtaining of the product from the market in its readily available form. In other words, the reproducibility requirement is inherently fulfilled by a product that has been put on the market. The Enlarged Board therefore reframed the test established in G1/92 as follows, without any reference to the "reproducibility" requirement:

> *"the chemical composition of a product is part of the state of the art when the product as such is available to the public and can be analysed by the skilled person, irrespective of whether or not particular reasons can be identified for analysing the composition".*

This means that when a product is put on the market, the product and all of its analysable features become prior art. Thus, for a product to become prior art in Europe, there is no requirement for a product to be reproducible by a different route (i.e. a route other than obtaining the product from the market).

Practically, this decision means that it can no longer be argued under EPO practice that a product put on the market is not prior art merely because it could not be reproduced. In other words, G1/23 has removed the defence that a product put on the market was not prior art in the first place because it was not reproducible.

Although the product in question in the case underlying G1/23 was a man-made product in the field of polymer chemistry, on the face of it, the decision in G1/23 also applies to natural products[4], and across all technical fields.

However, even after G1/23, there is still some room for choosing trade secret protection over patent protection for commercially available products. In rare circumstances, patenting a product after launch may still be possible.

For sale of a product to have a prior art effect, the circumstances of the sale must be such that a skilled person could access the product in order to analyse it. Thus, confidential sales or supply of a product may still not make the product prior art in Europe. Similarly, use of a product under controlled conditions, such as in a clinical trial, such that a skilled person cannot access and analyse the product may still not have a prior art effect in Europe.

Importantly, putting a product on the market still only discloses the *analysable* features of that product (this has not changed following G1/23). Thus, even following G1/23, non-analysable structural features of a product put on the market can remain hidden and do not form part of the prior art. For example, if the exact blend of perfume ingredients in a commercially available

[4] See paragraphs 26-30 of G1/23

shampoo is not publicly available knowledge and cannot be determined by analysis of the shampoo, then a new patent claiming a shampoo characterised by this non-analysable feature could still be novel in Europe despite the shampoo having been sold previously.

However, in most cases, G1/23 clarifies that once a product has been put on the market, it is no longer possible to patent it in Europe (even if the product cannot be reproduced). G1/23 will therefore crystallise the practice of filing a patent application before launching a product, even in technical fields where products are difficult to reproduce exactly.

Finally, even if G1/23 clarifies that putting a product on the market constitutes a disclosure, there will still be evidential issues with proving *what* became prior art by virtue of that disclosure and *when*. This is especially the case for commercial products that are discontinued or change in composition/structure over time[5]. For instance, if a product was launched 10 years ago, how can the features of the product at the time of launch be proven? All of the existing EPO case law on substantiating a public prior use will continue to apply in these circumstances, and G1/23 has not altered this. For example, the party raising objections based on the prior sale of a commercially available product will still have the burden of proving *what* was disclosed and *when*.

Europe commentary provided by:

Neil Campbell and Matthew Sullivan of Dehns

[5] See paragraphs 82-86 of G1/23

Australia

The recently issued decision in G1/23 aligns European Patent Office (EPO) patent practice on the prior art status of products released to the market more closely with the position adopted in Australia. In the Australian context, reproducibility is not a strict criterion for a marketed product to qualify as prior art. Instead, Australian law prioritises public availability and enablement in relation to public prior use. For a product's placement on the market to constitute prior art in Australia, it must enable a person skilled in the art to comprehend the invention by revealing each of its features—for instance, its internal mechanisms that may be hidden from view. Mere inspection of the product may not suffice as an enabling disclosure if all features are not apparent or publicly accessible. The leading Australia case in this area, *Damorgold Pty Ltd v JAI Products Pty Ltd* (2015) FCAFC 31, elaborates on the requirements for a prior use to be novelty destroying. In this case, a new blind mechanism was marketed by JAI (but not sold) to trade customers in a showroom. The inventive internal features of the blind mechanism were only discernible if the product was disassembled (which evidence showed could have been done without damage to the article) and the evidence showed that no customer examined the internal workings (although they could have done). The Court thus held that the public use of the invention was not novelty destroying. Additionally, this case was decided when prior public use was relevant to Acts done in Australia only, the law has since expanded to include anywhere in the world.

Had the product been sold and made available to customers, the decision would likely have been different because then the blind mechanism could more readily be disassembled. This would allow the customer to analyse the internal workings, providing an enabling disclosure of the invention.

Applying the fact situation from G1/23 to Australian practice, the public sale of ENGAGE®8400 would form part of the prior art base when assessing the patentability of a later filed patent. Thus, the analysable features of commercially sold product become prior art in Australia, however non-analysable features would not constitute prior art, as there is no enabling disclosure, consistent with EPO practice. This enablement requirement applies across all technical disciplines, encompassing both natural and synthetic products. In contrast to EPO practice, the disclosure resulting from an act and a document cannot be considered together when evaluating novelty since the *Patents Act 1990* expressly refers to prior art information made publicly available in a single document or through doing a single act. Thus a person skilled in the art could not look to publicly available data sheets or other technical documents when considering a commercially available product. These two types of prior art information are to be considered separately.

Engaging in undisclosed commercial use of an invention can invalidate subsequent patent applications. To prevent inventors from informally extending patent protection through such secret exploitation, Australia's Patents Act contains strict provisions prohibiting secret use. However, Section 9 of the Patents Act 1990 provides an exemption: if a complete Australian patent application or a PCT application designating Australia is filed within 12 months of the initial secret use, this prior use may be disregarded under the law.

The party raising objections based on a commercial sale of a product, whether during opposition or court proceedings, bears the onus of proof. This evidentiary burden is relatively high as it is necessary to establish that the product was freely accessible to at least one member of the public, resulting an enabling disclosure of all of the essential integers of the invention. The party would also need to establish when the disclosure occurred. It can be challenging to establish exactly what the properties of the product were at the time of the sale, which could have occurred many years ago.

Australia commentary provided by:

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Canada

Summary - Canada

- When a product is placed on the market anywhere in a way that makes it publicly disclosed, the product will become citable prior art in Canada. If it is the patent applicant's own product, then it only becomes citable prior art after one year from the public disclosure date. A third party product will immediately be citable prior art against a patent applicant.
- The citable prior art use or sale of a product is sufficient to bar patenting if the product actually discloses the claimed invention or makes it obvious. There is not a requirement to prove that the product can be reproduced. There is an exception to this bar for certain experimental uses.
- This public disclosure rule applies to products across all technical fields. It applies to natural products as well as man-made products.
- There is no patent opposition process in Canada. Re-examination is very limited. Challenges to patent validity are best brought in court. The party seeking to invalidate a patent based on the disclosure of the product on the market bears the burden of proving the invalidating public disclosure.

1 - Introduction

The prior art effects from use and sale of a product were set out in a Federal Court of Appeal decision (see *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd* and subsequent cases).

2 - Background

2.1 - Prior Use and Sale

The key case involved a Baker Petrolite patent for a method of selectively reducing the levels of undesirable sulfides in natural gas, known as sweetening or scavenging sour gas. The method contacted gas streams with a reaction product from a particular alkanolamine and aldehyde. The invention was really in the use of new chemistry in a known method. The defendant, Canwell, asserted that the patent was invalid because of non-confidential sales and deliveries by Baker Petrolite of the corresponding product mixture (called **W-3053**) to customers (s.28.2 of the *Patent Act*). The sales occurred a couple of years before the Canadian patent application was filed.

The principles relating to anticipation by prior publication were also applicable to anticipation by prior use or sale - whether a person skilled in the art would be led, without error, to the invention claimed. Canwell argued that W-3053 sales disclosed the invention to the public. Baker Petrolite argued that from a practical point of view, any reverse engineering by its customers would not be made public.

The patent was held by the Appeal Court to be anticipated and invalid. A defendant need only prove that the claimed invention was disclosed for there to be anticipation. A defendant does not have to prove that the sold product can be reproduced. In this case, a person skilled in the art

could have discovered the product through chemical analysis. As evidence, an expert witness conducted a blinded analysis that identified the major component of W-3053. Since the reaction product and its starting components were detectable, the invention was disclosed by the sale. While the evidence showed the analysis of the product disclosed the invention, it did not necessarily provide an ability to reproduce the product itself. There is no requirement to show that a particular purchaser did actually conduct an analysis to identify W-3053 components. These rules are applicable to anticipation by the patent applicant's own product disclosure or by third party product disclosures.

3 - Canadian practice and practical implications

When a product is put on the market, the product and all of its analysable features will become citable prior art. Non-analysable features of a product put on the market that can remain hidden will not likely form part of the prior art. In a court case, the patent challenger has the burden to establish that the commercial sales made the patented invention publicly available.

The decision applies to synthetic compounds, natural products, and all technical fields. The Baker Petrolite case was recently followed in a Federal Court of Appeal high tech decision.

Patenting a product after launch may still be possible if the Canadian patent application is filed within one year of the public disclosure by the applicant. In the case of third-party products as prior art, there is no grace period to file a patent application.

Confidential sales or supply of a product are not public disclosures in Canada.

Canada also has a limited exception to novelty for certain experimental uses.

The most cautious practice recommended for Canada is to file a patent application before launching your product, even in technical fields where products are difficult to reproduce exactly. This will preserve the patent applicant's rights in absolute novelty regions, such as Europe, where there is no grace period to file a patent application after a public disclosure. If a patent application is not filed before product launch, then file in Canada within a year of product launch to avoid arguing with a challenger about the prior art impacts of the prior use or sale.

Canada commentary provided by:

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China

China's Patent Law does not impose strict reproducibility requirements on products made available to the public to qualify as prior art. The focus is on whether the product was made public before the patent application filing date. However, determining whether a product constitutes prior art involves a comprehensive consideration of multiple factors. Below is a refined analysis based on China's Patent Law and related regulations:

1. Reproducibility Requirements for Prior Art

According to Article 22 of Chinese Patent Law, prior art encompasses any technology known to the public domestically or internationally before the filing date of a patent application. A product made available to the public before this date may constitute prior art. The law does not explicitly require the product to be reproducible in terms of composition, internal structure, or all technical features. Thus, even if a product cannot be fully analyzed or reproduced by a skilled person, it does not exclude it from being considered prior art.

2. Level of Reproducibility Required

For a product made available to the public to serve as prior art, it does not necessarily need to meet stringent reproducibility requirements. Generally, the cited prior art should disclose all technical features of the claimed product. If the cited prior art, combined with common knowledge in the field, enables disclosure of all technical features of the claimed product, it may be deemed to have rendered the claimed product's technical solution obvious.

3. Non-Analyzable Features of Products Made Available to the Public

If certain features of a product made available to the public cannot be analyzed or determined even by a skilled person using methods and means available before the patent application filing date, and the patent applicant subsequently discloses these features in the patent application, such features do not undermine the novelty of the patent application. However, if other technical information related to the product, e.g., technical brochures, data sheets, or other publications etc., was made public before the filing date, such information may still constitute prior art. Even if the product itself cannot be analyzed or reproduced, the technical information about the product most probably may constitute part of the prior art.

4. Natural Products vs. Man-Made Products

China's Patent Law does not differentiate between natural products and man-made products in terms of prior art determination. Whether a product is natural or man-made, as long as it was made available to the public before the patent application filing date, it may qualify as prior art.

5. Impact of Technical Field

The technical field of a product may influence the determination of prior art to some extent. For example, in Chemical field, Emphasis is placed on the reproducibility of components and manufacturing methods. Even if the product's components cannot be determined through conventional analytical methods, it may still constitute prior art if skilled person can infer the

components using known synthesis routes. In Mechanical field, If the technical solution of a mechanical structure can be clarified by disassembling the product, it may constitute prior art. Despite differences in the emphasis on reproducibility across technical fields, the core standard remains consistent in China, i.e., whether skilled person in the art can implement the technical solution based on publicly available information and address the technical problem.

6. Confidential Sales or Supply of Products

Under China's Patent Law, a product sold or supplied under confidentiality obligations before the patent application filing date does not constitute prior art and does not affect the novelty of the patent application. However, if the sale or supply of the product was not conducted under confidentiality obligations and the product was made available to the public through such transactions, it may qualify as prior art.

7. Burden of Proof

In patent infringement disputes involving prior art defenses, the alleged infringer bears the burden of proving that the technology or design used constitutes prior art. The alleged infringer must provide sufficient evidence to demonstrate that the technical solution of the claimed product falls within the scope of the cited prior art. If the cited prior art is a product made available to the public, the alleged infringer may need to provide evidence such as sales contracts, invoices, advertising materials, or user manuals to prove that the product was made public before the patent filing date. If the patentee or interested party challenges the prior art nature of the cited product, they must provide counter-evidence to refute the alleged infringer's claims. For example, they could argue that the cited product differs from the claimed product in technical features or that the cited product was not truly made available to the public.

Conclusion

Under China's Patent Law, the qualification of prior art primarily depends on whether a product was made available to the public before the filing date of a patent: strict reproducibility is not required. Reproducibility standards are not stringent, and publicly available technical information of the product may constitute prior art even if the product itself cannot be fully analyzed. Natural and man-made products are treated equally. Confidential sales do not qualify as prior art, while non-confidential sales may. Although prior art defense is permissible in China, the alleged infringer bears the burden of proof in related disputes.

China commentary provided by:

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Japan[6]

(1) As to Reproducibility

In Japan, there are no reproducibility requirements for products released on the market to be considered prior art.

For example, even if no one else can reproduce an item handmade by a craftsman, it is still considered prior art.

For your reference, the Supreme Court has ruled that “reproducibility” is one of the criteria for determining whether an invention is incomplete in Japan.

1) Veterinary Composition Case

Supreme Court Decision on October 13, 1977, 1974 (Gyo-Tu) No. 107

The court ruled that, in light of the purpose of the patent system, the technical content of an invention must be concrete and objective to the extent that a person with ordinary knowledge in the relevant technical field can achieve the intended technical effect through repeated implementation.

2) Yellow peach breeding and propagation method case

Supreme Court Decision on February 29, 2000, 1998 (Gyo-Ts) No. 19

The court ruled that reproducibility does not necessarily require a high degree of probability.

In the field of machinery, there is a ruling that feasibility is not a requirement in order to constitute prior art. (Conveyor Device Case, Tokyo High Court Decision on November 28, 1989, 1988 (Gyo-Ke) No. 275)

On the other hand, in the chemical and biotechnology fields, even if it is not easily implementable, it is required that it not be impossible to implement in order to constitute prior art. (Human Leukocyte Interferon Case, Tokyo High Court Decision on April 25, 2002, 1999 (Gyo-Ke) No. 285)

[6] In this section on the position in Japan, all but the Supreme Court cases are District Court cases.

(2) As to features of products released on the market that can't be analyzed

In Japan, whether a product can be analyzed or not doesn't change how prior art is judged.

In other words, even if there are features that can't be analyzed, it's still considered prior art.

In other words, if the product has existed since before, it is considered prior art, and whether or not it can be analyzed is irrelevant.

The reason for this is that analysis technology is advancing year by year, and even if it could not be analyzed in the past, it does not mean that it would not be considered prior art now that analysis technology has advanced.

On the other hand, there are also Decisions that determine that a product is not prior art when analysis is impossible.

The following Decision is an example thereof where novelty was recognized because product analysis was extremely difficult even using analysis techniques available to those skilled in the art.

・Branut Granules Case, Tokyo District Court Decision, 2003 (Wa) No. 19324

(3) In Japan, the determination of prior art does not vary depending on whether the product is natural or artificial, or the technical field of the product.

However, as in the above Decision in (1), compared to the mechanical field, where the predictability of the effects of technical means is high, in the chemical and biotechnology fields, where predictability is low, the feasibility of implementation has a greater impact on the eligibility of prior art.

(4) The burden of proof lies with the patent applicant in cases between the patent applicant and the Patent Office, and with the party seeking to invalidate the patent, such as the opponent, in cases of opposition, invalidation trials, and infringement litigation.

Japan commentary provided by:

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Republic of Korea

1. Marketed Products as Prior Art in Korea - No Reproducibility Required

Under the Korean Patent Act ("KPA"), once a product has been made publicly available and can be obtained and analyzed or utilized by a person skilled in the art through ordinary technical means, the product is sufficient to serve as prior art for negating novelty and inventive step of an invention. In other words, there is no reproducibility requirement beyond the product being publicly accessible.

It is well established by the courts that, even if the internal composition or structure of a product is not explicitly disclosed, the inherent features of the product are deemed to constitute prior art once the product has been made available to the public. Further, the Korean Supreme Court held that if a marketed product necessarily possesses the same structure or property as a claimed invention—even if such feature or property was not recognized at the time of filing—such features of the product may serve as prior art for the purpose of negating novelty of the claimed invention, and post-filing experimental data or scientific literature can be admissible to prove that the feature was inherently present in the prior product (*see* Supreme Court Case No. 2017 Hu 1304 rendered on December 30, 2021). That is, as in this European decision G1/23, the inherent elements or properties of the product are regarded as disclosed prior art.

Therefore, Korea does not impose a reproducibility requirement beyond public accessibility, and in this respect Korea's position is close to that taken by the EPO in G1/23.

2. Non-analyzable Features

If analyzing a product is extremely difficult such that its content or structure cannot be ascertained, such content or structure is deemed still novel.

Specifically, the Korean IP High Court held that, in chemical substances or pharmaceuticals, if a person skilled in the art could not have determined the composition or constituents of a product prior to the filing date by using ordinary analytical methods without undue effort, then—even if the product had been publicly sold—it would not be recognized as novelty-destroying prior art (*see* IP High Court Case No. 2017 Na 1247 rendered on January 11, 2018).

3. Confidential Sales or Supplies

Similarly to G1/23 decision, confidential sales or supplies of a product do not constitute prior art. Under the KPA, an act qualifies as "publicly worked" only if it is performed without restrictions such as confidentiality obligations. Where the contracting parties are subject to duties of confidentiality—whether expressly stipulated in the agreement or implicitly arising from a relationship of trust that precludes disclosure to third parties—the act cannot be regarded as publicly accessible.

For example, in a case concerning the delivery of prototypes and trial operations conducted prior to a patent application, the Supreme Court held that if a supply contract contained a clause

prohibiting disclosure to third parties and actual confidentiality measures were implemented—such as restricting attendance at the trial operation—an implied duty of confidentiality must be acknowledged even in the absence of a formal nondisclosure agreement relating to the prototypes, and accordingly, the prototypes could not be deemed to have been "publicly worked" prior to the filing date (*see* Supreme Court Case No. 2021 Hu 10732 rendered on January 13, 2022).

4. Additional Notes

Natural products, in the same manner as man-made products, serve as prior art once they have been made available to the public. No exception is recognized merely because the products originate from nature. For example, according to Korean court decisions and KIPO's Guidelines for Patent Examination, if a natural substance or its extract was publicly known and placed on the market, any subsequent invention directed to that substance—even if the invention discloses a novel effect or use—will be found to lack of novelty. (In this regard, a newly discovered use of a known compound need be claimed in a method or a composition claim format.)

Technical fields do not affect the criteria for assessing novelty under the KPA: irrespective of the field of technology, the inherent features embodied in a publicly available product are regarded as prior art.

The evidentiary burden, however, may vary depending on the technical field, while the substantive criteria are uniform across technical fields. In the chemical and biotechnological fields, where the determination of novelty often requires proof whether a prior substance necessarily possessed a particular property or structure, the Supreme Court has recognized that post-filing experimental data and scientific literature may be admissible to establish such inherency (*see* Supreme Court Case No. 2017 Hu 1304).

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US

In the US, the on-sale bar has been part of the patent code for almost 190 years. It prevents a patent applicant from obtaining a patent on an invention that was previously commercially exploited. The rationale behind the on-sale bar is to encourage early disclosure and to prevent one from commercially exploiting the invention and then continuing that exploitation through a patent, effectively extending the statutory term. The law surrounding the on-sale bar is, however, notoriously complex and fact specific. Advice should thus be taken about a particular situation from a suitably qualified US Attorney.

The current on-sale bar is codified in § 102(a)(1), defining prior art to include subject matter "in public use, on sale, or otherwise available to the public before the filing date of the claimed invention." 35 U.S.C. § 102(a)(1). The US courts have declined to read the word "public" before "on sale," meaning that private sales, e.g., sales where the terms and content are kept confidential, can qualify as prior art under § 102(a)(1). There is therefore no requirement of reproducibility in the US.

In general terms, a qualifying sale has occurred if there was a definite sale, or offer to sell, before the effective filing date of the U.S. application and the subject matter of the sale, or offer to sell, fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art. Mostly, whether a sale has occurred, and hence whether the product or process sold becomes part of the state of the art, will be easy to determine, but note that the on-sale bar applies to offers for sale as well as actual tangible sales. An important requirement for the application of the on-sale bar is that the subject matter being sold or offered for sale is "ready for patenting." That is, the subject matter is of sufficient detail to enable a person of skill in the art to make and use the invention. The Federal Circuit has also made clear that this on-sale bar analysis applies when a patentee later patents a process for making products that were sold before the critical date, in distinction to patenting the products themselves. The on-sale bar applies whatever the type of invention.

In the US, there is a one-year grace period for sales, or offers to sell, by the inventor or someone obtaining the subject matter directly or indirectly from the inventor under 35 U.S.C. § 102(b).

The most common fact pattern for the on-sale bar involves pre-filing sales by the patentee of the claimed invention, e.g. device or composition. Even sending a "quotation" letter to a potential customer in the US can be enough for an on-sale bar. The on-sale bar applies notwithstanding the patentee's ability to reject orders.

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