Patenting medical treatments in the US and Europe – a guide for practitioners

Lawyers at Maiwald and Sterne Kessler analyse how patents with claims directed to medical treatments are handled in the US and in Europe

The new EU clinical trial regulation (**EU No. 535/2014**) in force since January 31 2022, and its revised transparency rules in force since June 18 2024, can demand an early and far-reaching disclosure of clinical study information.

This disclosure may become prior art to later-filed patent applications claiming medical treatments such as specific dosing regimens, administration routes, patient populations, or combination therapies.

Because such disclosures may constitute prior art world-wide, patent practitioners globally must understand their implications for highly valuable medical treatment patents.

This article compares US and European patentability requirements for such inventions.

Medical treatment claims

In the US, medical treatments can be claimed in the form of method claims, the eligibility of which was **reconfirmed** by the Supreme Court in *Mayo Collaborative Services v Prometheus Laboratories*, 566 U.S. 66, 2012; 35 U.S.C. § 101.

In contrast, the European Patent Convention (EPC) excludes from patentability methods for treating humans by therapy (Art. 53(c) EPC) but does not

prohibit patenting products for use in such methods (Art. 53(c), 54(4), 54(5) EPC).

Such purpose-limited product claims are construed to include the therapeutic effect as a functional technical feature and are therefore limited to achieving such an effect. G 6/88, Headnote and reason 9, G 2/88, Headnote III and reason 9, G 2/21, reason 74.

In contrast, method of treatment claims are not necessarily construed to require the claimed treatment to be effective, in **which case** the claims may encompass a method designed to treat, potentially impacting patentability criteria such as enablement, written description, and novelty. *United Therapeutics v Liquidia Techs*, 74 F.4th 1360, 1369 (Fed. Cir. 2023), *Eli Lilly and Company v Teva Pharmaceuticals*, 8 F.4th 1331, 1340-43 (**Fed. Cir. 2021**).

Acceptable format for medical treatment claims

US	Europe
A method for treating disease X comprising administering compound Y to a patient in need therof.	Compound Y for use in a method for treating disease X in a patient in need therof comprising administering compound Y to the patient.

Novel subject matter

In either jurisdiction, a wide range of treatment-related features can confer novelty, such as the specific patient population, administration route, or dosing regimen. But claims directed to a new technical effect (e.g., mechanism of action, safety, or efficacy) can be more challenging to obtain.

In Europe, a new technical effect may confer novelty if it leads to a "new clinical situation" going beyond the mere discovery of a mechanism/effect underlying a previously disclosed therapeutic use. A new clinical situation may arise from the opening of a new field of clinical application such as treating a different pathology or creating a new subject group. T 1031/00, T 486/01, T 1020/03, T 1642/06.

In contrast, in the US, the inherency doctrine makes it challenging to establish novelty of claims reciting new technical effects arising from previously disclosed treatments. A limitation—or even the entire invention—may be deemed inherently disclosed if it is the natural result flowing from the explicit disclosure of the prior art. Contemporaneous recognition by a person of ordinary skill in the art (POSA) or actual reduction to practice is not required. *Schering v Geneva Pharm,* 339 F.3d 1373, 1376-80 (**Fed. Cir. 2003**), *Bristol-Myers Squibb v Ben Venue Laboratories*, 246 F.3d 1368, 1371, 1376 (**Fed. Cir. 2001**).

However, in the context of inherent obviousness, unexpected properties may render the invention patentable. Honeywell Int'l v Mexichem, 875 F.3d 1348 (**Fed. Cir. 2017**).

Sufficiency/enablement and written description

In the US, a patent specification must contain "a written description of the [claimed] invention" and disclose how to "make and use the same." 35 U.S.C. § 112(a) (written description and enablement). In Europe, the "patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." Art. 83 EPC (sufficiency of disclosure).

Required level of evidence

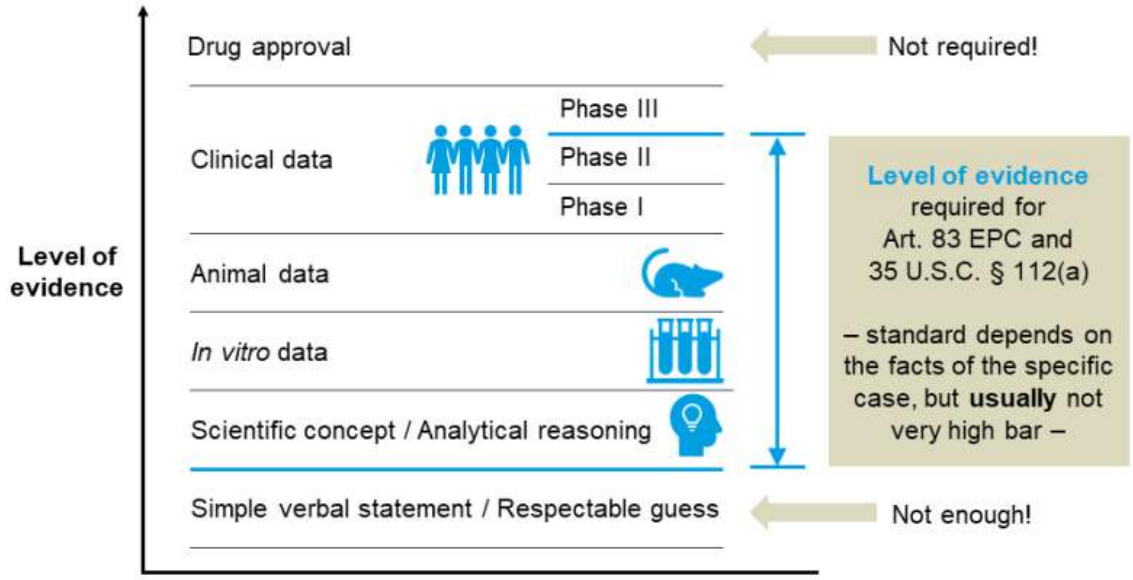
Under 35 U.S.C. § 112(a), the "how-to-use-prong" requires the specification to disclose a practical utility for the invention (e.g., sufficient therapeutic utility). Failure to comply may result in rejections for lack of enablement (35 U.S.C. § 112(a)) or lack of utility (35 U.S.C. § 101). *Rasmusson v SmithKline Beecham*, 413 F.3d 1318, 1323 (**Fed. Circ. 2005**), *In re '318 Pat. Infringement Litig.*, 583 F.3d 1317, 1323-25 (Fed. Circ. 2009).

In Europe, the EPO's Enlarged Board of Appeal (EBoA) confirmed that, to fulfill the requirements of Art. 83 EPC, a patent application directed to a medical treatment must render it credible for the skilled person that the claimed drug is suitable for the claimed treatment. G 2/21, reasons 74 and 77, and the landmark decision T 609/02, reason 9.

An important question in this context is: how much evidence is required to fulfill the enablement and sufficiency requirements? Given the intrinsic difficulties for a medicinal product to be officially certified as a drug, neither the US nor European patent system requires regulatory approval of a drug or human clinical trial data. *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995), *In re '318 Pat. Infringement Litig.* at 1324-26, T 609/02, reason 9. The level of evidence required is (usually much) lower.

In principle, practical utility and credibility can be inferred from the prior art both in the US and in Europe while this prior art does not necessarily need to represent common general knowledge. *In re '318 Pat. Infringement Litig.* at 1325, Rasmusson at 1323, 1324, T 728/21, reason 3.3, T 609/02, reason 9. Relying on prior art, however, may create tension in establishing non-obviousness and inventive step.

Alternatively, *in* vitro or in vivo data in the application are usually sufficient. Even analytical reasoning or a sound scientific concept may be enough. T 609/02, reason 9, T 950/13, reason 3.6, *In re '318 Pat. Infringement Litig.* at 1324-26. However, "a simple verbal statement" (T 609/02, reason 9), or "little more than respectable guesses" (*Rasmusson* at 1325) may be insufficient.



For written description, the inventor must show possession of the invention, but actual reduction to practice is not required. The hallmark of written description is disclosure. The level of detail required depends on the nature and scope of the claims, the complexity and predictability of the technology, the existing knowledge in the field, and the extent and content of the prior art. *Capon v Eshhar,* 418 F.3d 1349, 1357-58 (**Fed. Cir. 2005**), *Nuvo Pharms. (Ireland) Designated Activity v Dr. Reddy's Laboratories,* 923 F.3d 1368, 1376-77, 1381 (**Fed. Cir. 2019**), *Ariad Pharm v Eli Lilly & Co.* 598 F.3d 1336, 1351-52 (**Fed. Cir. 2010**).

For instance, in *Nuvo Pharms*., the claims lacked written description because "the specification provide[d] nothing more than the mere claim that [the invention] might work, even though [POSAs] would not have thought it would work." A "mere wish or hope" for obtaining the claimed invention is inadequate. *Nuvo Pharms*. at 1381, 1382, 1384.

Relevant timepoint and extrinsic evidence

The requirements of 35 U.S.C. § 112(a) and Art. 83 EPC must be fulfilled as of the application's filing date (or any priority date sought). T 609/02, reason 13, *Rasmusson* at 1324, *Juno Therapeutics v Kite Pharma*, 10 F.4th 1330, 1341 (**Fed. Cir. 2021**), *Ariad* at 1351, 1355. A deficiency in this respect cannot be remedied by post-filing date evidence.

In Europe, consequently, reliance on post-filing date evidence in the context of sufficiency is only possible if the medical treatment has been rendered credible at the filing date. G 2/21, reason 77, T 609/02, reason 9.

Similarly, in the US, post-filing date evidence cannot render an insufficient disclosure enabling but can demonstrate that the disclosure was enabling when filed. *Application of Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974), *In re '318 Pat. Infringement Litig*. at 1325 including n.8, *In re Brana* at 1567 including no.19.

In contrast, post-filing date evidence was deemed "legally irrelevant" to establishing written description. *Juno* at 1341, *Ariad* at 1355.

While credibility and practical utility can in principle be inferred from the prior art, courts have held that extrinsic evidence can be used only as part of an objective inquiry into what the specification means and generally cannot establish written description where none exists in the specification's four corners. *Ariad* at 1351, *Nuvo Pharms*. at 1381, *Biogen Intl v Mylan Pharm*, 18 F.4th 1333, 1344 (**Fed. Cir. 2021**).

Novelty and obviousness

Grace periods and the assessment of prior art are important factors impacting novelty and obviousness.

While 35 U.S.C. § 102(b) provides a one-year grace period for disclosures made directly or indirectly by the inventor, there is no such general grace period under the EPC.

Non-prejudicial disclosure is limited to disclosure due to, or in consequence of, an evident abuse or displaying the invention at specific exhibitions no earlier than six months preceding the filing date (Art. 55 EPC).

In the US, anticipatory prior art must contain an enabling disclosure (*In re Donohue*, 766 F.2d 531, 533

(Fed. Cir. 1985). For obviousness, a reference need not be enabling if other prior art or evidence is enabling. *Amgen v Hoechst Marion Roussel*, 457 F.3d 1293, 1354 (**Fed. Cir. 2006**), *Raytheon Technologies v General Electric*, 993 F.3d 1374 (**Fed. Cir. 2021**).

The enablement standard for anticipation, however, differs from the enablement standard under 35 U.S.C. § 112(a) for a specification. Thus, prior art lacking a teaching of practical utility can be "entirely adequate to anticipate a claim… and, at the same time, entirely inadequate to support the allowance of such a claim". *Rasmusson* at 1325-26, *AstraZeneca LP v Apotex*, 633 F.3d 1042, 1055 (**Fed. Cir. 2010**).

Consequently, prior art references providing similar levels of disclosure as the challenged patent may meet the lower enablement standard for anticipation.

In Europe, a disclosure destroys novelty only if its teaching is reproducible by the skilled person (is enabling). T 1457/09, reasons 41 and 42, T 1437/07, reason 25, T 206/83, reason 2. There seems to be less clear guidance regarding enablement in the context of inventive step.

A pending referral (G 1/23) to the EBoA asks whether a physical product put on the market is excluded from the state of the art if it is not reproducible.

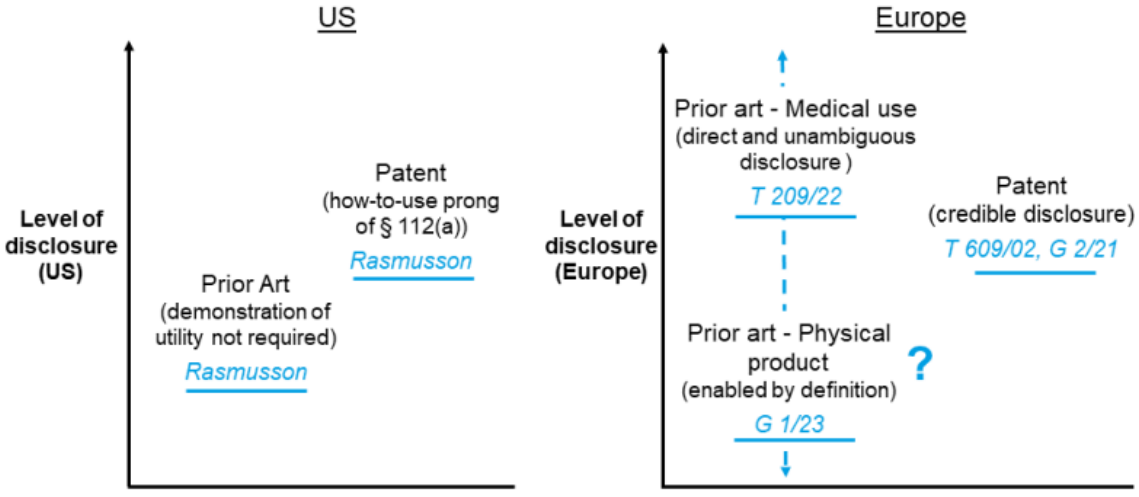
The referral does not distinguish between novelty and inventive step. An August 16 2024, preliminary opinion suggests that such product is, by definition, enabled, despite not being reproducible (reason 32). While the case's underlying facts relate to inventive step, its findings presumably may also be applied to novelty.

In Europe, it is also currently unclear whether the enablement standard for anticipation differs from the enablement standard for establishing sufficiency. Earlier decisions by the BoA established that the same standard applies. T 206/83, reason 2, T 576/91, reason 2.1, T 1437/07, reasons 25 and 26 in the context of medical use claims. More recently, the board in T 209/22, also relating to a medical use claim, stated that different standards apply to novelty and sufficiency of disclosure.

To be novelty-destroying, the prior art must provide a direct and unambiguous disclosure of the claimed treatment.

But, for sufficiency, the (lower) standard of a credible disclosure applies (reason 5.6). Other decisions rendered in the context of clinical trial protocol disclosures also seem to apply a higher standard concerning novelty than the "credible disclosure" standard concerning sufficiency. Without expressly mentioning a different standard for novelty and sufficiency, the board in T 239/16, for example, required a therapeutic effect to "arise with certainty" from the prior art (reason 5.2). Thus, while in the context of medical uses the enablement standard in Europe seems currently set higher for the prior art than for the patented subject matter, in the context of a prior art physical product, the standard might be set lower in the future (see above, "enablement by definition" as suggested by the preliminary opinion of the EBoA in G 1/23).

Enablement standard for a patent and prior art in the context of anticipation



Prior art disclosure on planned or ongoing clinical trials (including clinical trial protocols)

In *Montgomery*, the court found method-of-treatment claims to be inherently anticipated by prior art relating to an ongoing clinical trial (i.e., prior art representing an advanced stage of testing), even if the claims would be construed to require efficacy and even if the prior art would have only *proposed* administration of the drug for treatment without actually doing so. *In re Montgomery*, 677 F.3d 1375, 1381-82 (**Fed. Cir. 2012**).

In the context of obviousness in the US, the finding of a reasonable expectation of success may center, for example, around the stage of testing (Phase I, II, III), the level of skill in the art (e.g., availability of clinical, animal, and/or *in vitro* data), and the degree of predictability in a particular medical area, governed by the failure rate of prior drug developments. *Salix Pharmaceuticals v Norwich Pharmaceuticals,* 98 F.4th 1056 (**Fed. Cir. 2024**), *Janssen Pharm v Teva Pharm USA*, 97 F.4th 915 (**Fed. Cir. 2024**), *OSI Pharm v Apotex*, 939 F.3d 1375 (**Fed. Cir. 2019**), *Novartis Pharm v W.-Ward Pharm. Intl*, 923 F.3d 1051 (**Fed. Cir. 2019**), *Sanofi v. Watson Labs*, 875 F.3d 636 (**Fed. Cir. 2017**), *Eli Lilly and Co. v Teva Pharm. USA,* 619 F.3d 1329 (**Fed. Cir. 2010**).

In Europe, prior art disclosure relating to ongoing or planned clinical trials lacking results of such trials is regularly not considered anticipatory even if, on its face, such prior art discloses all claim features. However, such disclosure is regularly found to create a reasonable expectation of success leading to the finding of obviousness unless there was a dissuasion in the prior art that would lead the skilled person to expect that the described treatment would fail. T 158/96, T 715/03, T 239/16, T 1853/16, T 1123/16, T 96/20, T 108/21, T 1123/16, T 3165/19.

Filing considerations

Particularly when publications on ongoing or planned clinical trials such as clinical trial protocols are in the prior art, it seems more difficult to get patent protection in the US than in Europe, calling for a filing prior to such publications.

Disadvantages of such early filing are, however, the absence of the actual data obtained with the clinical trial, potentially creating issues under enablement and written description in the US or sufficiency in Europe, the lost opportunity to use surprising effects, and to file the strongest possible case. Whether the later obtained results can be used as post-filed evidence is also not guaranteed.

Filing after the trial data is available and with the clinical trial protocol in the prior art is likely riskier given the often potentially anticipatory character of clinical trial disclosures in the US and the high hurdles for showing lack of obviousness in view of such disclosures in Europe. The success of such later filing might depend on whether the data reveal a specific new and unexpected treatment opportunity (such as a new patient subgroup or dosing regimen) but is likely less useful for the broader basic treatment.

A further strategy might involve a first filing before the publication of the clinical trial protocol and a second filing once the clinical trial results are available. However, in this scenario the first filing becomes prior art for the later filing, in the US when filed after the one-year grace period triggered by the first filing, and in Europe either for novelty only or for novelty and inventive step when filed after the publication of the first filing. Any similarity in the claimed subject matter also mandates careful navigation between both cases during prosecution.

Neither of the discussed two time points nor filing at both time points is ideal and the filing strategy can only be optimised as much as possible. Additionally, all available measures to redact information from the early disclosures of clinical study information under the revised EU clinical trial transparency rules should be taken.

The opinions expressed herein are those of the authors and do not necessarily reflect the views of their firms/employers, its clients, or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

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