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U.K. Court of Appeal Aligns U.K. Sufficiency Standard with European Patent Office Standard and Sharpens Contrast with U.S. Practice

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On March 28, 2018, the U.K. Court of Appeal handed down its decision in *Regeneron v Kymab & Novo Nordisk* (found here), reversing a lower court decision that found two critical patents covering Regeneron's transgenic mice technology invalid for lacking sufficiency of disclosure. The rationale and analysis underlying the decision are significant because they align the U.K.'s approach to the assessment of insufficiency with that of the European Patent Office, and highlight, for U.S. life sciences and technology companies, the stricter standard to which patent specifications are subject in Europe.

The patents, EP 1360287 and EP 2264163, both disclose methods of producing transgenic mice possessing human antibody genes. These mice, and the technology used to produce them, have been highly valuable to Regeneron. These patents protect fundamental inventions behind Regeneron's *VelocImmune* humanized mice, which is considered one of the most valuable technologies in biotechnology history, helping to generate significant licensing revenues and blockbuster collaborations. The case was originally brought by Regeneron, which alleged infringement of the U.K. patents by Kymab and Novo Nordisk. The defendants counterclaimed that the patents were invalid for lack of sufficiency, novelty and inventive step. While the High Court rejected the lack of novelty and inventive step objections, it revoked the patents for lack of sufficient disclosure.

The claims at issue require "in situ replacement" of specific gene segments of the mouse with corresponding human gene segments. The High Court interpreted "in situ replacement" as covering the deletion of large mouse DNA sequences and the insertion of the equivalent human DNA sequences that were also relatively large. Specifically, the High Court found that the disclosure in the specification relied on a particular example, Example 3, which described replacement of large DNA segments, to disclose to the skilled person the method for producing the transgenic mice. However, experts testified that the skilled person lacked the knowledge to insert and delete such large pieces of DNA at the time of the priority date, and that the skilled person would have been unable to perform the invention by following the method disclosed in Example 3. Thus, the claims covered an embodiment that was not enabled for use by the skilled person, and the specification failed to enable the claims over their full scope. On this basis, the High Court concluded that the claimed method and mouse were insufficiently disclosed.

On appeal, Regeneron argued that the skilled person or team would have readily adjusted the method disclosed by Example 3, so that it used technology commonly known at the time of the application's priority date, and would put to the side the complex and less known technology set out in Example 3. Regeneron argued that the skilled person would still get Example 3 to deliver the invention, using the more commonly known technology. This modified approach, Regeneron asserted, would produce many embodiments of the invention as claimed and would provide the skilled person the benefit of Example 3, albeit by slightly different means. Thus, Regeneron argued that the disclosure was sufficient to enable the full scope of the claim, even under the court's broad construction.

The Court of Appeal agreed. In doing so, it relied heavily on the sufficiency jurisprudence of the European Patent Office (EPO). In particular, it analyzed and endorsed six decisions from the EPO Boards of Appeal, which set out the Board's view of the correct test for assessing the sufficiency of a patent disclosure in view of claim scope. In upholding the patents, the court emphasized that the assessment of insufficiency "must be sensitive" to the nature of

the invention, adding that inventions directed to "general methodology" or "general application" can be claimed in general terms even if not all embodiments covered by the claims are enabled. This represents a departure from the view of the High Court that found it improper to have claims covering embodiments that could not be put into practice by the skilled person as of the priority date.

While the patents in this case were ultimately upheld, for U.S. companies, the rationale and analysis of the Court of Appeal highlight the high bar that U.S.-originated patent applications must clear in Europe in order to withstand challenge. In the U.S., as in Europe and many important jurisdictions, claims must be enabled by the application as originally filed to allow a skilled person to put the invention into practice over the scope of the claim. The purpose of this requirement is to give effect to the legal principle that the monopoly granted upon the issuance of a patent must be justified by the technical contribution to the art of that which has been invented. This principle can be difficult to implement when the invention is a remarkable improvement over the art, as the Court found in this case. In such a case, a broad claim is justified, but the strict standard for disclosure must still be met. According to the EPO Boards of Appeal:

> "Even though a reasonable amount of trial and error is permissible when it comes to the sufficiency of disclosure in an unexplored field or…where there are many technical difficulties, there must then be available adequate instructions in the specification or on the basis of common general knowledge which would ***lead the skilled person necessarily and directly towards success*** through the evaluation of initial failures or through an acceptable statistical expectation rate in the case of random experiments."
>
> T 226/85 *Stable bleaches/UNILEVER* (emphasis added)

In this case, the Court found that Example 3 would be adapted by the skilled person and that the adapted process would still give the inventive result. Thus, the specification, under these facts, led the skilled person directly towards success over the scope of the claim. The fact that Example 3 was not enabled as described could be overlooked, because, according to the Court, the invention was so remarkable it was properly claimed using terms describing a "principle of general application". The Court found that such terms will always capture more than is explicitly disclosed in the application, and rightly so because the inventor should have rights to the embodiments disclosed and those embodiments, now unknown, but which are later built upon their invention. As the court deemed this invention such a significant technical contribution, the claim language using a general principle of application was proper and the disclosure still met the requirement that it must "necessarily and directly" lead the skilled person toward the successful implementation and use of the invention.

However, the requirement under European law that the patent disclosure must "necessarily and directly" lead the skilled person to success represents a higher bar than U.S. patent counsel may be used to, especially when viewed in conjunction with the distinct characteristics of the skilled person under European patent law. The "skilled person" under European law is a capable person with typical knowledge in the relevant field, but exercises no creativity. That skilled person will follow the instructions given in the disclosure and supplement that information only with information that is, without question, commonly known and immediately apparent to the skilled person. For example, the skilled person in Europe will be confused by contradictory statements in the disclosure and will draw little useful technical information from broad or general statements about possible features of the invention. However, under U.S. patent law, the person of ordinary skill is a capable person with typical knowledge in the relevant field and the typical creativity for a person in that field.[1] Under U.S. law on enablement, that skilled person, bringing his/her training and his/her general creativity, must be able to use the disclosure to put the invention to work. These differences in the characteristics of the skilled person (or person of ordinary skill in the art) can lead to instances where a patent application that meets the enablement requirement under the law of one jurisdiction fails to meet the requirement in another jurisdiction. This point may be further illustrated by the fact that in the U.S. litigation for Regeneron's counterpart U.S. patent, the defendants did not seriously challenge whether the U.S.

[1] See, *e.g.*, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

claims, which appeared to be just as broad as their European counterparts, were enabled by the disclosure.[2] While the enablement standards under both U.S. and European patent law do not require enablement of a commercially viable embodiment, or even disclosure of the best mode to practice the invention, they do require enough disclosure to actually put the invention in the public domain so that the skilled person (however he/she may be characterized in the relevant jurisdiction) can make and use the invention. Given this difference, patent applications that are intended for filing in Europe must more fully describe the invention and provide technical detail that clearly conveys how to put the invention into practice, than would be typically required in the U.S.

[2] In the U.S. case, the CAFC upheld a decision that the U.S. patent was unenforceable due to inequitable conduct. This issue is not considered under UK or EPO law.