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July / August 2023

A new dawn for patent law in Europe – can the UPC place European patent litigation on par with US patent litigation?

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Rachel Fetches, Partner & Head of Law at HGF, provides a first glimpse into the new UPC system, with summary of the unfolding patent actions that will influence the development of case law, to predict the success of the new system.

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CTC Legal Media

Jurisdictional Briefing, US: Federal Circuit cases provide enablement guidance following Supreme Court decision

Anne Maxwell, Ph.D. of Cantor Colburn LLP reports on the *Amgen Inc. v. Sanofi* case that has cemented enablement requirements drawn from the Wands Test and three recent biotech decisions.

Justice Neil Gorsuch's unanimous Supreme Court in *Amgen Inc. v. Sanofi* (May 18, 2023) carefully avoided citing or criticizing lower court case law on enablement. The Court agreed with the Court of Appeals for the Federal Circuit, the lower District Court, and Sanofi, that Amgen's patents US Patent Nos. 8,829,165 and 8,859,741 on its cholesterol drug Repatha, a monoclonal antibody, were invalid. The Court held that Amgen's patents did not provide adequate guidance to a person of ordinary skill in the art to make and use the potentially millions of monoclonal antibodies within the scope of Amgen's broad functional claims. This was the first time since 1928 that the Supreme Court ruled in a patent enablement case. Federal Circuit enablement case law remains intact following this decision and provides the best guidance for determining whether patent claims are enabled.

The Federal Circuit has long applied the eight factor "Wands Test" to ascertain whether claims are enabled as they did in their Amgen decision that was appealed to the Supreme Court. *Amgen Inc. v. Sanofi*, 987 F. 3d 1080 (Fed. Circ. 2021). *Wands* itself was an early monoclonal antibody case in which the federal circuit held claims were enabled, even though considerable experimentation was required, so long as the amount of experimentation was not undue. In *re Wands*, 858 F.2d 731 (Fed. Cir. 1988). The claims in *Wands* were directed to an immunoassay that used a monoclonal antibody rather than the antibody itself. The court held that the amount of experimentation required to produce the single monoclonal antibody needed to perform the claimed assay, though considerable, was routine, and therefore not undue.

Anne Maxwell

In applying the *Wands* test in the Amgen case, the Federal Circuit cited three of their more recent biotech decisions, *Wyeth&Cordis Corp. v. Abbot Laboratories* (2013), *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.* (2019), and *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc*. Following the Supreme Court's *Amgen* decision, these three cases provide the best guidance for determining whether pharmaceutical or biotech claims are patentable. These cases move beyond *Wands'* focus on whether the experimentation required to practice the claimed invention was routine. In *Wyeth* and *Idenix* the court has held claims invalid for lack of enablement, at least in part, due to the **quantity** of experimentation needed to practice the invention.

In *Wyeth* the Federal Circuit decided that claims reciting a method of using the compound class rapamycin to treat restentosis were not enabled because the patent disclosed only a single species, sirolimus. Even though the lower

court adopted a claim construction reciting some structural elements – "a macrocyclic triene ring structure produced by *Streptomyces hygroscopicus*, having immunosuppressive and anti-restenotic effects" – the Federal Circuit still held Wyeth's claims were not enabled because Wyeth did not provide any guidance as to which substituents on the rapamycin template structure were needed to treat restentosis. *Wyeth v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013).

The Federal Circuit also struck down Enzo's claims to labeled polynucleotides probes in *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*, 928 F.3d 1340 (Fed. Circ. 2019). In that case the court also noted that the claims required the labeled polynucleotides have two functional properties – to be hybridizable to another polynucleotide and be detectable upon hybridization. Yet, the application provided no guidance on the structure of the labelled polynucleotide needed to produce these functional properties. The label had to be attached on one of the many available phosphate groups in the polynucleotide but the nature of the label and the chemistry used to attach it were not specified. One had to make and test labelled polynucleotides at random to determine whether the functional requirements of the claims were met.

Idenix is the most concerning of the three cases the Federal Circuit relied on in its Amgen decision. Unlike the other cases, *Idenix's* US 7,608,597 claims recited only structural limitations and did not rely on functional language in its claims. Idenix's claims were directed to a method of treating hepatitis C (HCV) by administering a purine or pyrimidine -D-2'-methyl-ribofuranosyl nucleoside compound. Ribofuranosyl nucleosides are a broad class of compounds encompassing perhaps billions of molecules including competitor Gilead's HCV drug, sofobuvir (Solvaldi®). *Idenix* listed hundreds of compounds as falling within its claims but provided antiviral activity data for only a handful. In determining Idenix's claims were not enabled the court discussed the enormous number of compounds encompassed by Idenix's claims, the small number of working examples, and the lack of guidance as to which of the many possible compounds were useful for treating HCV infection.

Based on the claim language and scope, the Supreme Court held that the patents did not enable a skilled artisan to "make and use" the full scope of the invention, as required by § 112(a) of the Patent Act. The Court noted that if "a patent claims an entire class of . . . composition of matter, the patent's specification must enable a person skilled in the art to make and use the entire class." Applying this standard in view of Federal Circuit case law, the full scope of a broad claim must be supported by examples commensurate with its scope.

Patent applicants should understand the importance of including sufficient examples, direction, and guidance in the specification, and be wary of using functional claim language, particularly in the absence of any structural elements. Although structural limitations are not always sufficient, we recommend including claims that recite structural features. Where worked examples aren't available at the time of filing, inventors should consider adding detailed hypothetical examples and as much guidance as possible in the specification on how to make and use the invention. As Gorsuch's opinion explained, "[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class."

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Résumé

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Anne Maxwell, Ph.D., chairs the Pharmaceutical Patent Practice Group at Cantor Colburn. She provides all aspects of patent representation to clients working in chemical and life science research with a particular emphasis on the pharmaceutical and agricultural chemical industries. She has more than 20 years of experience drafting patent applications and prosecuting US and non-US patent applications in the areas of small molecule pharmaceuticals, drug delivery and formulations, biological therapeutics, chemical processes, medical diagnostics, biomaterials, and agricultural chemicals. She has extensive experience in rendering invalidity, patentability, and freedom-to-operate opinions.

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