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Supreme Court Is Not Done Hearing Patent Cases

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This week the United States Supreme Court granted the petitions for writ of certiorari in two more patent cases, furthering its top-down review of patent law and more directly the Court of Appeals for the Federal Circuit and how it has handled such issues. The two petitions granted were in *Kappos v. Hyatt* and *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, and follows three decisions by the Supreme Court in the past two months.[1]

Kappos v. Hyatt

When the United States Patent and Trademark Office (the "PTO") denies an application for a patent, the applicant may appeal the PTO's decision to the Federal Circuit under 35 U.S.C. § 141 or, alternatively, commence a civil action against the PTO in federal district court under 35 U.S.C. § 145. In a 2010 *en banc* ruling, the Federal Circuit held that, in a section 145 action, the applicant may introduce evidence of patentability that was not presented to the PTO. *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010).

On June 27, the Supreme Court granted a petition for writ of certiorari filed by the Director of the PTO. The ultimate ruling by the Supreme Court will decide the circumstances under which new evidence may be introduced in a section 145 civil action.

The questions presented to the Supreme Court are as follows:

1. Whether the plaintiff in a §145 action may introduce new evidence that could have been presented to the agency in the first instance.

2. Whether, when new evidence is introduced under §145, the district court may decide de novo the factual questions to which the evidence pertains, without giving deference to the prior decision of the PTO.

Background:

Gilbert P. Hyatt is the sole named inventor of U.S. Patent Application No. 08/471,702 ("Hyatt's application"), which relates to a computerized display system for processing image information. *Hyatt* at 1322. After a final rejection of 177 claims in Hyatt's application, Hyatt appealed the examiner's rejections to the Board of Patent Appeals and Interferences (the "Board"). *Id*. at 1323-24. Although the Board reversed many of the examiner's rejections, the Board affirmed some of the examiner's written description and enablement rejections with respect to 79 claims. *Id.*

Hyatt commenced a section 145 civil action in the District Court for the District of Columbia. *Id*. at 1324. The PTO moved for summary judgment that the claims were invalid for failing to meet the written description requirement. *Id*. Hyatt opposed the motion by arguing that disputes of material fact exist and submitted a written declaration in support of his motion. *Id*. The District Court,

however, excluded the declaration because Hyatt did not explain why he could not have submitted the declaration during in the PTO proceedings. *Id*. The District Court then granted the PTO's motion. *Id*.

After a divided Federal Circuit panel affirmed the District Court, an *en banc* Panel reversed and remanded. *Id*. at 1322. The *en banc* Panel held that 35 U.S.C. § 145 does not impose a "limitation on an applicant's right to introduce new evidence before the district court." *Id*. The *en banc* Panel specifically rejected the position taken by the PTO that only "new evidence that could not reasonably have been provided to the agency in the first instance" is admissible in a section 145 action. *Id*. The *en banc* Panel also held that, when no new evidence is introduced in a section 145 civil action, the court must apply the Administrative Procedure Act standard of review (*i.e*., give deference to an agency's findings). However, if new evidence is presented, the *en banc* Panel held that the court must make de novo fact findings. *Id.* at 1336.

Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S

The Hatch-Waxman Act (the "Act") makes a Paragraph IV certification (*see* 21 U.S.C. §355(j)(2)(A)(vii)) an act of patent infringement. The Act also permits a generic manufacturer to assert a counterclaim challenging the accuracy of the "patent information" submitted to the FDA by the brand manufacturer. Specifically, the generic manufacturer "may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either--(aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. §355(j)(5)(C)(ii)(I).

On June 27, the Supreme Court granted a petition for writ of certiorari filed by Caraco Pharmaceutical Laboratories, *et al*. that may have a significant impact on the use of the counterclaim provision in ANDA litigation. That is, can the counterclaim provision be used to force a brand manufacturer to correct its use code narrative if it is too broad or is the provision just to correct an erroneous patent number and expiration date?

The question presented to the Supreme Court is as follows:

Whether the counterclaim provision applies where (1) there is "an approved method of using the drug" that "the patent does not claim," and (2) the brand submits "patent information" to the FDA that misstates the patent's scope, requiring "correct[ion]."

Background:

To obtain FDA approval for a new drug, a "manufacturer must file a new drug application ('NDA') containing clinical studies of the drug's safety and efficacy." *Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laborites, Ltd. et al*., 601 F.3d 1359, 1360 (Fed. Cir. 2010); *see also* 21 U.S.C. § 355. "As part of the NDA process, the manufacturer must also identify all patents that claim the drug or a method of use," including filing the patent numbers and the expiration dates of the relevant patents. *Novo* at 1360. If the patent claims one or more methods of using the NDA drug, a description, known as the "use code narrative," of each of those processes is required. *Id*. at 1361. The patented drugs and their use code narratives are listed in the FDA's Approved Drug Products With Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." *Id*.

A streamlined process, called abbreviated new drug application ("ANDA"), is available for generic drug manufacturers, under 35 U.S.C. § 355(j), in which the generic manufacturer relies "on the safety and efficacy studies of a drug already listed in the Orange Book upon a showing of bioequivalence." *Id*. To participate, the generic manufacturer makes a certification regarding its drug and the relevant patents identified in the Orange Book. *Id*. "Specifically, the generic manufacturer must select one of four alternatives permitting use of the patented product or process: (I) no such patent information has

been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug." *Id*.

After a patent on the composition expires, a generic manufacturer can seek FDA approval of non-patented uses of the composition under section 21 U.S.C. § 355(j)(2)(A)(viii) by making a "section viii statement" and submitting a label "that does not contain the patented method of using the listed drug." *Id*. The FDA approves the section viii statement after verifying that there is no overlap with the use code narrative. *Id.* at 1361-62.

On February 9, 2005, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed an ANDA for the drug repaglinide with a Paragraph IV certification for the patent-at-issue. *Id.* at 1363. On June 9, Novo Nordisk A/S ("Novo") sued for infringement. *Id*. In April 2008, Caraco stipulated that its ANDA would infringe and, around the same time, amended its ANDA to include a paragraph IV certification with a section viii statement based on Novo's use code narrative. *Id*. Novo opposed Caraco's "carve-out" and, apparently at the FDA's request (*Id*. at 1368), updated its use code statement – the new use code narrative being broader than the original narrative. *Id*. at 1359. Caraco then amended its answer and added a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii) requesting that Novo change its use code narrative to the original narrative because the new narrative covers all three FDA-approved methods even though Novo only claims one method under the patent-at-issue. *Id*. at 1363. The District Court granted Caraco's counterclaim. *Id*.

On appeal, the Federal Circuit reversed and held that the phrase "an approved method of using the drug" in the counterclaim provision means "any approved method" and not "all approved methods" as argued by Caraco. The Federal Circuit also held that the term "patent information" in the counterclaim provision refers to correcting or deleting "an erroneous patent number or expiration date" and "does not extend to the use code narrative." *Id*. at 1366.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

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[1] *Microsoft Corporation v. i4i Limited Partnership, et al.*, 180 L. Ed. 2d 131 (2011), *Global-Tech Appliances, Inc., et al. v. SEB S.A.*, 179 L. Ed. 1167 (2011), and *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al.*, 180 L. Ed. 2d 1 (2011).