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INTELLECTUAL PROPERTY ALERT

ABBOTT LABORATORIES V. SANDOZ, INC.: EN BANC FEDERAL CIRCUIT RESOLVES CONFLICT ON PRODUCT-BY-PROCESS CLAIM SCOPE

Inventor patents "compound X, obtained by process Y." Competitor makes "compound X by process Z." Is this infringement? Under a recent en banc Federal Circuit ruling, the answer is no—never. This ruling is significant because: (1) it resolves a long-standing conflict on the scope of product-by-process claims; and (2) the court's reasoning demonstrates that the U.S. Supreme Court has regained control of patent law in this country.

PRODUCT-BY-PROCESS CLAIMS ARE LIMITED TO PRODUCTS MADE BY THE PROCESS DESCRIBED

On May 18, 2009, the Federal Circuit handed down a decision in *Abbott Laboratories v. Sandoz, Inc*.[1] that settles a long-existing conflict concerning interpretation of product-by-process claims. The en banc portion of the opinion holds that product-by-process claims cannot be infringed by "products made by processes other than the one claimed."

But what if the inventor lacked the means to specifically identify the new compound other than by the means of its manufacture? What if the compound was so new or complex that current technology provides no means to describe it other than by the manner of its creation? As it stands now, such an inventor is out of luck—product-by-process claims now include the process as a limitation on scope.

The Federal Circuit has established a universal rule, apparently not subject to any exception for new, difficult-to-describe products. If claim language describes the product with reference to a process of manufacture, then that will serve to limit the scope of the claim to products made by that process. While an inventor is still free to describe new products by reference to their method of manufacture, protection will be limited to only products made by the claimed process, with no extension (save for potential equivalents of the process).

This holding alters what has been called the "rule of necessity," which in its previous form had sometimes allowed inventors to obtain general protection on the product itself based only on a claim describing the product as one obtained by specific means of manufacture. With this

[1] *Abbott Labs. v. Sandoz, Inc.*, Nos. 2007-1400, 2007-1446, 2009 WL 1371410, at*7 (Fed. Cir. May 18, 2009).

holding, the Federal Circuit adopts the rule for products-by-process laid out in *Atlantic Thermoplastics*[2] and overrules the conflicting decision in *Scripps Clinic & Research Foundation v. Genentech, Inc.*[3]

Given modern analytic methods, it may likely be a fairly rare event when the structure of a new chemical compound cannot be ascertained. Abbott, in fact, had claimed the compound in question in a separate, independent product claim by reference to certain objective measurements (x-ray diffraction) related to its structure. But the *Abbott* decision should still be kept in mind when drafting claims in the chemical, pharmaceutical or biotechnological fields, as the court appears willing to apply any language of description within a claim as a strict limitation on patent scope.

SUPREME COURT PRECEDENT HAS REEMERGED AS PRIMARY SOURCE FOR PATENT LAW

Of perhaps broader interest is the method the Federal Circuit used to reach its decision; *Abbott* is another in a string of recent decisions, such as *In re Seagate and In re Bilski*, in which the Federal Circuit relied on Supreme Court precedent to alter long-standing Federal Circuit patent doctrines.[4] Seagate and Bilski relied on modern Supreme Court cases, but here, in Abbott, the Federal Circuit relied heavily on 19th-century cases, while rather abruptly dismissing decisions by its predecessor courts—the Court of Customs and Patent Appeals (CCPA) and the Court of Claims.

Much of the court's analysis centered on a Supreme Court case from 1884 that had denied general product protection to an "artificial" version of dye compound previously known in naturally occurring form.[5] The artificial dye had been claimed as that produced by specific methods of manufacture, as well as more broadly by "any other method." The Court refused to construe the patent broadly and limited patent protection only to compounds made by the methods specifically claimed. The Federal Circuit highlighted the following quote from the 1884 decision: "Every patent for a product or a composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process."[6]

It may be that the *Abbott* decision is a reflection that the Federal Circuit has learned the lesson taught in Supreme Court in cases such as *eBay*[7] and *KSR*.[8] Those decisions were heavy-handed reminders that, while the Federal Circuit may have a special role in patent law, that role does not trump the Supreme Court's primacy over the judicial branch. As such, Supreme Court precedents, even very old precedents, cannot be ignored. A decade ago, few might have even bothered to cite the Supreme Court precedents on which the Federal Circuit now relies. This raises the question: what other "settled" patent doctrines might be overturned as conflicting with previously ignored Supreme Court precedents?

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[2] *Atl. Thermoplastics v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992).
[3] *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).
[4] *In re Seagate Tech., LLC*, 497 F.3d. 1360 (Fed. Cir. 2007), cert. denied sub nom., *Convolve Inc. v. Seagate Tech.*, LLC 128 S.Ct. 1445 (2008) (altering standard for willful infringement); *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)(altering standard for patentable subject matter).
[5] *Cochrane v. Badische Anlin & Soda Fabrik*, 111 U.S. 293 (1884).
[6] *Abbott Labs.*, 2009 WL 1371410, at *9 (quoting *Cochrane*, 111 U.S. at 310).
[7] *eBay v. MercExchange,* 547 U.S. 388 (2006).
[8] *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

CONTACT INFORMATION

If you have questions regarding this alert, please contact—

Gregory M. Hasley ..... ghasley@akingump.com ..... 713.220.8101 ..... Houston
David R. Clonts ..... dclonts@akingump.com ..... 713.220.5886 ..... Houston