Intellectual Property Advisory:

The Federal Circuit Establishes the 'Final Rule' for Determining Infringement of a 'Product-by-Process' Claim

By Ernest V. Linek[1]

On Monday, May 18, 2009, the Court of Appeals for the Federal Circuit issued a divided en banc decision[2] in the case of *Lupin Ltd. v. Abbott Laboratories*. The en banc portion of the opinion (Section III.A.2) involved the issue of the proper infringement interpretation standard for evaluating product-by-process claims, that is, patent claims that are defined, at least in part, by the process used to make the product.

In *Lupin*, the Federal Circuit held that "process terms in product-by-process claims serve as limitations in determining infringement." In other words, if a product is defined in the claim by reference to a process, then that process must be used to make the product in order to infringe the claim. The court expressly overruled *Scripps Clinic v. Genentech*, 927 F.2d 1565 (Fed. Cir. 1991) which had held that a novel product, defined in product-by-process claim language, was for infringement purposes, not limited to the process recited in the claim.

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[2]The following judges joined in the en banc decision – Chief Judge Michel and Judges Rader, Bryson, Gajarsa, Linn, Dyk, Prost and Moore. Judges Newman and Lourie (both Ph.D. chemists) filed dissenting opinions. Judges Mayer and Lourie joined in Judge Newman's 37 page dissent. Judge Schall did not participate as a member of the en banc court.

This case was a consolidated appeal from two District Court decisions against Abbott regarding U.S. Patent No. 4,935,507 (the '507 patent).

In the first case, the United States District Court for the Eastern District of Virginia granted the summary judgment motion of noninfringement filed by Lupin. In the second case, the United States District Court for the Northern District of Illinois denied a preliminary injunction motion filed by Abbott.

Abbott is the exclusive licensee of the '507 patent. The claims of the patent cover the antibiotic product cefdinir, which is sold in the United States under the Omnicef brand for treatment of children's ear infections.

The '507 Claims

The '057 patent has five claims. Claim 1 defines crystalline cefdinir using its chemical name and defines the crystal structure by reference to particular powder X-ray diffraction peaks. This crystalline form of the compound is known as Crystal A. Another form is also known – Crystal B – which this claim does not cover.

Claims 2-5 of the '057 patent are product-by-process claims defining crystalline cefdinir without the X-ray diffraction peak limitations of Claim 1. Instead, these claims define the compound with reference to processes used to obtain the product.[3]

Claims 2 and 5 are the independent product by process claims:

> **Claim 2.** Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by acidifying a solution containing 7-[2-(2-

[3] According to Section 2173.05(t) of the M.P.E.P, a compound of unknown structure may be claimed by a combination of physical and chemical characteristics. See *Ex parte Brian*, 118 USPQ 242 (Bd. App. 1958). A compound may also be claimed in terms of the process by which it is made without raising an issue of indefiniteness. Also, the majority opinion of the Federal Circuit includes a three-page

aminothiazol-4-yl)-2- hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) at room temperature or under warming.

Claim 5. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by dissolving 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

The FDA had approved Lupin's generic version of the drug and Lupin sought a declaratory judgment in the Eastern District of Virginia that it did not infringe, arguing that it used a different process to make its drug. With respect to the product-by-process claims, the court ruled for Lupin because it used a different process than either of those recited in the patent claims. With respect to claim 1, the court also ruled for Lupin, finding that Crystal B was not equivalent to Crystal A and a majority of the product made by the Lupin process was Crystal B.[4]

In the Illinois case, Abbott sued Sandoz, Inc. and other generic drug manufacturers because they had filed abbreviated new drug applications (ANDAs) with the FDA seeking permission to market generic versions of Omnicef. Abbott sought a preliminary injunction in the case and the parties agreed to adopt the claim construction from the *Lupin* case in Virginia.

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discussion on the "obtainable by" language used in Claims 2 and 5 - deciding that the language used was no different than if the words "obtained by" had been employed.

[4] Literal infringement of claim 1 was not at issue in the case.

The Virginia court relied upon the Federal Circuit's opinion in *Atlantic Thermoplastic v. Faytex*, 970 F.2d 834 (Fed. Cir. 1992) which held (contrary to the earlier *Scripps Clinic* decision) that "process terms in product-by-process claims serve as limitations in determining infringement." Under Federal Circuit rules a later issued panel decision cannot overturn an earlier issued panel decision – so this matter has been ripe for en banc review since the *Atlantic Thermoplastic* in 1992.[5]

Dissenting Opinions

In a vigorous dissent, three judges chided the majority for "overturning a century of precedent and practice" and warned that the decision "is a change of law with unknown consequences for patent-based innovation."

Judge Newman took the majority to task for failing to understand that certain chemical and biological entitles are often not definable in patent claims by structure – which is typically how chemical and biological entities are defined in a claim. These new entities, whose structure is otherwise unknown – are instead protected by patent claims that rely upon the method used to create them – for definitional purposes only. The process is used in defining the product claimed; but at least for novel products, such process recitations have not in the past been intended to impart limitations to the scope of the claim defining the product. Product claims that define a novel product by reciting process limitations, which are not limited in scope by the process limitations, are now no longer possible. Issued patents that have such claims are no longer as broad as they were before the Lupin case was decided.

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[5] Judge Rich issued a strong dissent when en banc review of *Atlantic Thermoplastic* was denied by the court, describing the panel opinion as "insulting," "mutiny," "heresy" and "illegal." *Atlantic Thermoplastic v. Faytex*, 974 F.2d 1279, 1281 (Fed. Cir. 1992).

Food for Thought

New chemical and biological entities can be defined without specific structure definitions in patent claims. Partial structures can be used. Physical and chemical or biological properties can be recited in the claim. If a product-by-process format is the only way to define the entity – know that unless this case is overruled by the Supreme Court – the process limitations will be relied upon to determine infringement.

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