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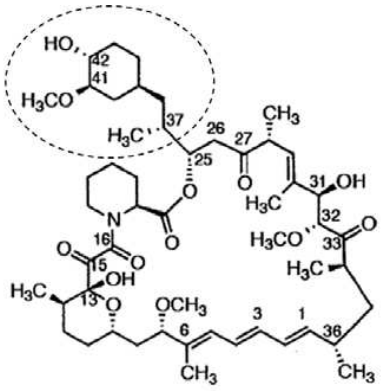
A SPECIFICATION MUST ENABLE ONE OF ORDINARY SKILL IN THE ART TO PRACTICE THE CLAIMED INVENTION WITHOUT EXCESSIVE OR UNDUE EXPERIMENTATION, PURSUANT TO 35 U.S.C. §112(a)

By: Donald W. Hanson

The U.S. Court of Appeals for the Federal Circuit (CAFC) case of *Wyeth and Cordis Corporation v. Abbott Laboratories*, decided on June 26, 2013, is an appeal by plaintiff Wyeth of a district court decision on summary judgment finding the claims of two U.S. patents of Wyeth invalid for non-enablement and thus not infringed. The district court held that the specifications of the two patents did not enable one of ordinary skill in the art to practice the claimed invention without undue experimentation.

The claims of the patents were directed to methods of treating or preventing retinosis in a mammal comprising the step of administering an effective amount of rapamycin to the mammal. Retinosis is the re-narrowing of an artery after a treatment to open the artery (such as, by implantation of a stent).

A species of rapamycin disclosed in the patents (sirolimus) has the following structural formula:



which has a macrocyclic ring of C1 to C36 and a substituent group at and beyond the C37 position, as shown by the circled portion. It was stipulated that it was known that proteins could be bound by the macrocylic ring and that the specification taught that sirolimus was effective in treating retinosis. Further, it was stipulated that four additional rapamycin compounds were known, all involving different substituent groups beyond the C37 position.

It is to be noted that the alleged infringing compounds differed from sirolimus only in that different substituents than OH were used at the C42 position.

The requirement of 35 U.S.C. §112(a) directed to enablement requires that the specification describe the invention in such terms that one of ordinary skill in the art can make and use the same. This requirement has been interpreted to mean that one of ordinary skill in the art could practice the invention **without excessive or undue experimentation**.

The district court characterized the invention as the use of any structural analog of sirolimus that exhibits immunosuppressive and antirestenotic effects. In finding that the subject patents were non-enabling as requiring excessive experimentation, the CAFC used the following two-part analysis:

(1) given the disclosure of the specifications as to a species of the claimed genus and the assumptions of the plaintiff Wyeth, there still would be tens of thousands of potential compounds with no clear guidance as to which would be effective for the stated use; and

(2) it was undisputed that it would be necessary to both synthesize each potential compound and then test that compound for the desired effects.

The court therefore concluded that practicing the full scope of the claims would require synthesizing and screening of each of at least tens of thousands of compounds.

Given the above, the CAFC then explored whether the facts of this case resulted in "undue experimentation."

It was declared that undue experimentation was a matter of degree in balancing between: (a) routine efforts with adequate guidance, and (b) iterative research in an unpredictable and poorly understood field. With the number of possible compounds, as discussed above, along with the above-mentioned fact that it would require an assay of at least several weeks to determine the effectiveness for each compound, it was found that the scope of the claims required undue experimentation and therefore were invalid for failing to provide an enabling disclosure.

Decision: AFFIRMED. Wyeth's patents are invalid for failing to meet the enablement requirement under 35 U.S.C. §112(a).

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