UNIVERSITY OF MARYLAND SCHOOL OF LAW

PATENT LAW UPDATE

Jansen v. Rexall Sundown, Inc.

No. 03-1069
Federal Circuit
Sept. 8, 2003

"[T]he claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose. The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated."

On September 8, 2003, the Federal Circuit affirmed the district court's summary judgment that Rexall did not infringe U.S. Patent 4,945,083, which related to methods of "treating or preventing macrocytic-megaloblastic anemia" by administering a combination of folic acid and vitamin B_{12} "to a human in need thereof." The Federal Circuit stated:

> [The claims require] that the method be performed on "a human in need thereof" and that the method be used "for treating or preventing macrocytic-megaloblastic anemia." [Thus, the crux is] whether such a human must know that he is in need of either treatment or prevention of that condition. [T]he claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone "in need." [T]he claims' recitation of a patient or a human "in need" gives life and meaning to the preambles' statement of purpose. The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed. [Here,] the "treating or preventing macrocytic-megaloblastic anemia" phrase and the "to a human in need thereof" phrase were added to gain allowance of the claims after almost twenty years of repeatedly unsuccessful attempts to gain allowance of claims without those phrases. [A]dministering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention.
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> Given that claim construction, we turn to the issue whether Jansen has raised a genuine issue of material fact regarding infringement. We conclude that he has not. Jansen has asserted indirect infringement by Rexall, premised on direct infringement by Rexall's customers. Jansen's theory of infringement is primarily based upon his construction of the claim that those who do not affirmatively know that they do not need to take steps to prevent or treat macrocytic-megaloblastic anemia are still "in need thereof." . . . While Jansen is correct that it is theoretically possible that some of Rexall's customers do take the Rexall product knowingly to treat or prevent macrocytic-megaloblastic anemia, and therefore directly infringe his patent, his evidence is quite weak. In fact, he has shown no more than a theoretical possibility or "metaphysical doubt," which is insufficient to create a genuine issue of material fact. . . .
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> Use of an over-the-counter product like Rexall's is quite different from the use of a product pursuant to a prescription from a medical doctor. In the latter case, a prescription is evidence of a diagnosis and a knowing need to use the product for the stated purpose. Jansen does not have evidence of that in this case. Rexall's product is provided with a label stating that the product can be used for maintenance of blood homocysteine levels, and purchasers do not necessarily know that they are in need of preventing or treating macrocytic-megaloblastic anemia. Instead, Jansen has only conjecture that some purchasers of the Rexall product might meet the claim requirements.

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