

**Keywords:** Construction of claims; literal infringement; intent; prosecution history; preamble

**General:** Claims for a method of “treating or preventing” pernicious anemia by administering folic acid and vitamin B12 “to a human in need thereof” are properly construed to require the compound be administered to a human with a recognized need to treat or prevent anemia.

**Jansen v. Rexall Sundown Inc.**  
**68 U.S.P.Q. 2d 1155 (Fed. Cir. 2003)**  
**Decided September 8, 2003**

## **I. Facts**

The alleged infringer marketed to the general public an over-the-counter dietary supplement that contained folic acid and vitamin B12. The alleged infringer’s product was labeled and advertised for maintenance of proper blood homocysteine levels. The holder sued the alleged infringer for inducement of and contributory infringement for his patent. In order to infringe on his patent, the human subject of the claimed method had to take the compound with the intent of treating or preventing macrocytic-megaloblastic anemia. Because the district court found no evidence of such intent or purpose on the part of the alleged infringer’s customers, the district court granted summary judgment of non-infringement. The appellate court found that the patent claims were properly interpreted to mean that the combination of folic acid and vitamin B12 had to be administered to a human with recognized need to treat or prevent macrocytic-megaloblastic anemia. It also found that the holder did not present genuine issues of material fact on the question of infringement. Thus, the district court did not err in granting summary judgment to the alleged infringer.

The independent claims read as follows:

1. A method of *treating or preventing macrocytic-megaloblastic anemia* in humans which anemia is caused by either folic acid deficiency or by vitamin B<sub>12</sub> deficiency which comprises administering a daily oral dosage of a vitamin preparation *to a human in need thereof* comprising at least about 0.5 mg. of vitamin B<sub>12</sub> and at least about 0.5 mg. of folic acid.
4. A method of *treating or preventing macrocytic-magaloblastic* [sic] *anemia* in humans which anemia is caused by either folic acid deficiency or by vitamin B<sub>12</sub> deficiency which comprises orally administering combined vitamin B<sub>12</sub> and folic acid *to a human in need thereof* in sufficient amounts to achieve an oral administration of at least about 0.5 mg. of vitamin B<sub>12</sub> and at least about 0.5 mg of folic acid within one day.

The issued patent was a seventh-generation continuation, and the original claim did not specify the type of anemia being treated, although it specified approximately the same amounts of folic acid and vitamin C. Eventually the Examiner agreed to allow the claims if the composition of matter claims were canceled and the method claims were narrowed by including a specific type of anemia.

**II. Issues**

- A. Whether the court improperly construed the claims by adding an intent element.
- B. Whether a genuine issue of material fact was raised regarding infringement.

**III. Discussion**

A. No. The claim recitation of a patient or human “in need” gives life and meaning to the preamble. Also the prosecution history indicates that both phrases were added simultaneously to overcome the same rejection and thus should be read together, meaning that the word “thereof” in the phrase “to a human in need thereof” should be construed to refer to the treatment or prevention of the specified anemia. Further, that “need” must be recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances of their addition suggests they carry.

B. No. The holder’s argument that some customers purchasing the over-the-counter product do knowingly take the product to treat or prevent the specified anemia. While theoretically possible, this assertion is quite weak evidence. In fact, as stated, it is a mere theoretical possibility or “metaphysical doubt.” Accordingly, the evidence is insufficient to create a genuine issue of material fact.

**IV. Conclusion**

The moral of this one is, once again, claim drafting. Be aware when you give life and meaning to the preamble. Also be aware of the scope of your language. In this case, it appears that the language implied a necessary intent.

February, 2004  
POW