



UNIVERSITY OF
MARYLAND
SCHOOL OF LAW

**PATENT LAW
UPDATE**

Novartis Corp.
v.
**Ben Venue
Labs., Inc.**

No. 01-1122
Federal Circuit
Nov. 7, 2001

“Where . . . the theory of infringement relies on relatively esoteric and indirect means of proof, the patentee must also be prepared to provide the court with the theoretical and factual foundation underlying that proof, at least to the extent of presenting a genuine issue of material fact to avoid summary judgment.”

On November 7, 2001, the Federal Circuit affirmed the district court’s summary judgment that Ben Venue did not infringe U.S. Patent No. 4,711,880, which covers Novartis’ drug Aredia. The patented technology related to pamidronate disodium, a bone-resorption inhibitor used to treat disorders of bone metabolism, including bone metastases, cancer-associated hypercalcemia, and Paget’s disease. The Federal Circuit noted:

[T]he parties [dispute] whether the crystalline form of pamidronate disodium exists at any point during Ben Venue’s process for manufacturing pamidronate disodium in solution. Ben Venue asserts that the pamidronate disodium remains dissolved in solution throughout its manufacturing process, which would preclude the formation of any crystalline material. . . . Novartis contends that crystalline pamidronate disodium could form transiently . . . in Ben Venue’s process. . . .

Ben Venue submitted no evidence that would preclude a finding of infringement under Novartis’s theory. Of course, disproving the existence of a transitory product is not Ben Venue’s responsibility. Novartis must show that it could prove the existence of the infringing product at trial. Under its theory of infringement, Novartis would have to prove both that solid particles of pamidronic acid persist, and that the infringing crystalline material will form around them. [W]e conclude that Novartis has not introduced evidence from which a reasonable fact-finder could conclude that this proposition is true. The only support for this essential proposition is Dr. Nauman’s computer model. . . .

We believe the district court’s confusion over the basis of Dr. Nauman’s model was understandable, however, because the record is nearly devoid of any indication of what Dr. Nauman did base his model on. It is this deficiency that is fatal to Novartis’s case. Under modern summary judgment law, a patentee who fails to provide probative evidence of infringement runs the risk of being preemptorily nonsuited. Evidence from which a reasonable fact-finder could find infringement will forestall this possibility. However, a party does not meet this evidentiary threshold merely by submitting the affidavit of an expert who opines that the accused device meets the claim limitations. . . .

The necessity for such an explicit factual foundation should be self-evident. If all expert opinions on infringement or noninfringement were accepted without inquiry into their factual basis, summary judgment would disappear from patent litigation. [T]he factual predicate of an expert’s opinion must find some support in the record, and has emphasized that mere “theoretical speculations” lacking a basis in the record will not create a genuine issue of fact. Moreover, where an expert’s opinion is predicated on factual assumptions, those assumptions must also find some support in the record. [I]t was Novartis’s obligation to set forth the detailed basis of its evidence such that the district court could evaluate whether it could support a finding of infringement by a reasonable fact-finder. Without such basis in the record, we must regard Dr. Nauman’s opinion as no more than theoretical speculation raising, at best, a “metaphysical doubt as to the material facts.”