

NOVEMBER 15, 2006

## **Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.**

No. 06-1118, Federal Circuit (*Lourie, Plager, Rader*)

***[K]nown interchangeability is only one factor to consider in a doctrine of equivalents analysis. It aids the fact-finder in assessing the similarities and differences between a claimed and an accused element.***

On November 15, 2006, the Federal Circuit reversed the district court's judgment that Mayne literally infringed U.S. Patents No. 5,714,520, No. 5,731,355, and No. 5,731,356, which related to pharmaceutical compositions of propofol (2,6-diisopropylphenol) and edetate used in general anesthesia such as DIPRIVAN® and RAPINOVET®, but affirmed the judgment that Mayne infringed under the doctrine of equivalents. The Federal Circuit stated:

“Infringement may be found under the doctrine of equivalents if every limitation of the asserted claim, or its ‘equivalent,’ is found in the accused subject matter, where an ‘equivalent’ differs from the claimed limitation only insubstantially.” ... An accused device that “performs substantially the same function in substantially the same way to obtain the same result” as the patented invention may infringe under this doctrine ...

... [T]he district court concluded that calcium trisodium DTPA and edetate were equivalent after finding that the differences existing between the two were insubstantial. In reaching this conclusion, the court performed a function-way-result analysis. The court identified the “function” of edetate as “retard[ing] microbial growth in propofol oil-in-water emulsions.” ... The court then defined the “way” that edetate worked as by metal ion chelation and found that the result achieved was “retard[ing] microbial growth to the extent required by the microbiological test set forth in the claims.”...

“What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case.” ... “Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum.”



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Here, the district court properly assessed the “way” edetate works by referring to the patent and the evidence presented at trial. The record evidence supports the conclusion that the “way” in which both edetate and calcium trisodium DTPA perform as an antimicrobial agent is by metal ion chelation. Indeed, the patent specification describes edetates as “metal ion sequestering agent[s].” Moreover, Mayne itself argued to the FDA that calcium trisodium DTPA is an effective antimicrobial agent in its generic propofol formulation because “of its ability to chelate divalent metal ions.”

[W]e reject Mayne’s argument that, as a matter of law, it is impermissible for the meaning of edetate to extend to other polyaminocarboxylates by equivalence. Mayne contends that by claiming their invention narrowly, i.e., by limiting the claim to edetate, Abraxis is barred from capturing DTPA, or any other polyaminocarboxylate, as an equivalent.... Contrary to Mayne’s assertion, the inventors did not clearly disavow other polyaminocarboxylates, including DTPA, by claiming edetate. There is no evidence that the patentees made a clear and unmistakable surrender of other polyaminocarboxylates, or calcium trisodium DTPA in particular, during prosecution. Indeed, the district court found that “the antimicrobial activity of calcium trisodium DTPA was unforeseeable during prosecution.” Mayne itself acknowledged the unforeseeability of DTPA while prosecuting its own patent. Thus, a person of ordinary skill in the art reading the patent would not conclude that by claiming “edetate,” the patentees surrendered or waived coverage of all polyaminocarboxylates, including DTPA, as an equivalent, particularly in light of the unforeseeability of calcium trisodium DTPA as an equivalent....

Lastly, we reject Mayne’s argument that the lack of known interchangeability between edetate and DTPA as an antimicrobial agent mandates the conclusion that the accused product does not infringe under the doctrine of equivalents. Mayne’s theory is largely premised on the fact that Mayne was able to receive a patent on its generic propofol formulation. In fact, the absence of known interchangeability underscores that the patent applicant had no reason to foresee and claim DTPA in this combination. [K]nown interchangeability is only one factor to consider in a doctrine of equivalents analysis. It aids the fact-finder in assessing the similarities and differences between a claimed and an accused element. [T]he court made factual findings that insubstantial differences exist between calcium trisodium DTPA and edetate, and further found that the separate patentability of Mayne’s generic formula did “not outweigh the substantial evidence of equivalence between Mayne’s calcium trisodium DTPA and the claimed edetate.” We see no clear error in that finding.

For more information on these issues or other intellectual property law matters, please contact **Lawrence M. Sung, Ph.D.** at [lsung@nixonpeabody.com](mailto:lsung@nixonpeabody.com) or 202-585-8221.

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