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IP monitor

A tearful conundrum: FCA affirms dismissal of infringement claim in patent suit regarding ophthalmic medical devices

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Patents

In *TearLab Corporation v I-MED Pharma Inc.*, the Federal Court of Appeal (FCA) upheld the dismissal of TearLab's patent infringement action against I-MED. The Federal Court judge committed no palpable and overriding error in concluding that the claims at issue were obvious.

The FCA confirmed the trial judge's conclusion that by construing the claims of the patent broadly so as to capture the i-Pen® Osmolarity System for the purpose of infringement, TearLab could not simultaneously restrict them in order to save them from invalidity due to obviousness and anticipation. The FCA approved the methodology employed by I-MED's expert to locate prior art used in the obviousness analysis. It also confirmed that secondary indicia of non-obviousness, such as commercial success, will not save an obvious claim, particularly where the evidence does not establish a nexus between the commercial product and the patent claims.

The 540 Patent

The 540 Patent relates to measuring the osmolarity of a sample of bodily fluid, particularly tear film, that is deposited on a chip, where the sample fluid operatively covers the sample region of the chip. Electrical, optical, or thermal energy imparted to the sample fluid is then detected to produce an output signal that indicates osmolarity of the sample fluid. The 540 Patent also discloses an osmolarity measuring system that receives an output from a reception device, then interprets it and displays an osmolarity value to the user.

The i-Pen® Osmolarity System and the single use sensors

The i-Pen® Osmolarity System measures the conductivity of the tear-soaked eyelid conjunctiva and correlates this measurement to osmolarity. A single use sensor, consisting of a pair of electrodes on a non-conducting substrate, is inserted into the i-Pen® Osmolarity System and placed against the moist tissue on the inner eyelid conjunctiva. The tear-soaked conjunctiva completes an electrical circuit between the electrodes when an electrical current is applied, and the conductivity is then measured by a microprocessor within the i-Pen® Osmolarity System. An osmolarity reading is then displayed on an LCD screen.

A conundrum at the heart of the claim construction

The trial judge agreed with TearLab that the asserted claims were not limited to *ex vivo* applications, despite the examples in the patent focussing on these types of applications. He concluded that by broadly claiming both *in vivo* and *ex vivo* applications, for any bodily fluids, TearLab invited the validity problems that could not be avoided.

The FCA agreed with I-MED that TearLab found itself in a conundrum. TearLab could not argue that the judge's findings on infringement were correct while disputing the claim construction upon which those findings were made.

Claim construction and inventive concept

The FCA confirmed the trial judge's analysis was consistent with its recent decisions that downplay the importance of the inventive concept as an analytical tool in an obviousness analysis. The trial judge correctly focused his analysis on the claims.

The FCA also observed that "volume independence," said by TearLab to be the inventive concept, is nowhere to be found in the claims at issue. While the inventor may have wanted to incorporate volume independence in one embodiment, the trial judge correctly pointed out this is not sufficient to make it part of the claims in the absence of clear language to that effect.

The prior art search

The FCA agreed the prior art search by I-MED's expert followed proper methodology. The expert found the prior art references he relied on as a result of his own search, without the assistance of counsel and without being provided with the patent beforehand.

Inclusion of secondary indicia of obviousness

The FCA confirmed that the commercial success of a patented product is never, in and of itself, a conclusive indicia of non-obviousness, and is not sufficient to save an obvious claim. It also agreed with I-MED that the evidence of commercial success claimed by TearLab was not related to the invention disclosed in the patent, but to TearLab's commercial product. Since no nexus was shown between the two, TearLab's argument was irrelevant to the obviousness inquiry.

Norton Rose Fulbright acted as counsel to I-MED Pharma Inc.

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