PATENTS

INFRINGEMENT

PharmaStem Therapeutics, Inc. v ViaCell, Inc.
491 F.3d 1342 (Fed. Cir. 2007)
United States Court of Appeals for the Federal Circuit
Judges: Newman (dissent), Bryson (opinion), and Prost

PharmaStem brought a patent infringement action against six defendants asserting that they infringed two PharmaStem patents (US Patent Nos 5,004,681 ('the '681 patent') and 5,192,553 ('the '553 patent')) relating to compositions and methods for treatment based on hematopoietic stem cells found in a newborn infant's umbilical cord.

Claim 1 of the '681 patent recited a 'cryopreserved therapeutic composition comprising viable human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood ... or placental blood of a single human collected at the birth of said human, in which said cells are present *in an amount sufficient to effect hematopoietic reconstitution of a human adult*; and an amount of cryopreservative sufficient for cryopreservation of said cells' (*emphasis added*); and the '553 patent presented various method claims such as a 'method for hematopoietic or immune reconstitution of a human comprising ... introducing the blood components into a suitable human host, such that the hematopoietic stem cells are viable and can proliferate with the host'.

The defendants offered services to the families of newborns in which umbilical blood containing stem cells is collected and preserved for future use. The jury returned verdicts of infringement and that the patents were not invalid. The District Court subsequently vacated and reversed the jury decision on infringement. PharmaStem appealed the holding of non-infringement and the defendants appealed the holding of validity to the United States Court of Appeals for the Federal Circuit.

PharmaStem had the burden of proof to provide evidence that the defendants infringed one or more claims. An issue on appeal was whether PharmaStem had provided sufficient evidence that the alleged infringing compositions were 'in an amount sufficient to effect hematopoietic reconstitution of a human adult' (the '681 patent claims) and with respect to the '553 patent whether PharmaStem had sold or offered to sell cord blood units. Another issue on appeal was whether the claims of both patents were obvious or anticipated. In addition, whether the claims of the '681 patent were indefinite was also appealed.

Infringement

The '681 Patent

To establish infringement, PharmaStem relied on the promotional materials of the defendants and the testimony of an expert witness, Dr Hendrix. While the promotional materials stated uses that included adult uses, the Federal Circuit agreed that the District Court correctly overturned the jury's finding of infringement and concluded that promotional statements that said the product could be effective were insufficient. Moreover, the Federal Circuit also agreed that the District Court was correct to exclude Dr Hendrix's testimony. In doing so, the Federal Circuit found Dr Hendrix's testimony lacking because as a cell biologist, her expertise was not helpful in determining whether the defendants, through their promotional materials, admitted whether the defendants' product was 'in an amount sufficient to effect hematopoietic reconstitution of a human adult', particularly where the expert's testimony did not relate to whether the stored samples had sufficient cells.

The '553 Patent

PharmaStem asserted that the defendants infringed under the theory of contributory infringement as the defendants did not undertake all the recited method steps. The District Court held that the defendants sold a *service* because the client family, not the defendants, owned their sample and that the defendants did not sell cord blood units and that a sale or offer of sale was necessary under 35 USC §271(c). The Federal Circuit affirmed.

Obviousness

Citing the recent Supreme Court decision *KSR Int'l Co. v Teleflex, Inc.*,[17] the Federal Circuit stated that the patent challenger must show by clear and convincing evidence that a person of ordinary skill would have reason to attempt to make the invention and have a reasonable expectation of success. According to the Federal Circuit, there was not a serious question of whether a person of ordinary skill would attempt to carry out the process and, as such, it focused on the reasonable expectation of success. PharmaStem's expert testified that researchers were surprised when cord blood was successfully transplanted as it was not known that sufficient stem cells existed in cord blood. This evidence combined with evidence of long-felt need and commercial success was sufficient for the District Court to affirm the jury verdict. The Federal Circuit reversed, stating that the expert's testimony could not be reconciled with statements made in the specification which stated that it was known that stem cells existed in cord blood and that '[s]cientific confirmation of what was already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention'.[18] Judge Newman wrote a strong dissent on both the issues of infringement and invalidity.

17) 127 S.Ct 1727, 1740 (2007).

18) *PharmaStem Therapeutics, Inc. v ViaCell, Inc.*, Nos. 05-1490, -1551, Slip Op. page 36 (Fed. Cir. July 9, 2007). The majority did not address the defendants' motions on anticipation and indefiniteness.