

## Federal Circuit Patent Bulletin: *LifeNet Health v. LifeCell Corp.*

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September 16, 2016

*“Direct infringement of a method claim requires all steps of the claimed method to be performed by or attributable to a single entity.”*

On September 16, 2016, in *LifeNet Health v. LifeCell Corp.*, the U.S. Court of Appeals for the Federal Circuit (Prost,\* Reyna, Chen) affirmed the district court’s judgment entering the jury verdict that LifeCell infringed U.S. Patent No. 6,569,200, which related to plasticized soft tissue grafts suitable for transplantation into humans. The Federal Circuit stated:

LifeCell raises several issues on appeal. First, it submits that the district court erred by allowing the jury to resolve a dispute about the scope of the limitation “said one or more plasticizers are not removed from [an] internal matrix of [the] plasticized soft tissue graft” and that, because the accused products do not meet this limitation, JMOL of non-infringement is warranted. LifeCell also argues that JMOL of no direct infringement is warranted because, regardless of how the limitation is construed, LifeCell itself does not directly infringe; rather, independent surgeons or their assistants prepare the grafts for transplantation. LifeCell further argues that claims 1-4 are invalid as indefinite for covering both an apparatus and, through the non-removal limitation, a method of using that apparatus. Separately, LifeCell contends that the district court misconstrued “plasticized soft tissue graft” and that, under the correct construction, LifeCell does not infringe as a matter of law. Finally, it seeks JMOL of invalidity on grounds that the asserted claims are either anticipated by the Werner reference, U.S. Patent No. 4,357,274, or rendered obvious over Werner and the knowledge of a person of ordinary skill. In the alternative, LifeCell seeks a new trial on infringement or invalidity. . . .

Direct infringement of an apparatus claim “requires that each and every limitation set forth in a claim appear in an accused product.” Direct infringement of a method claim requires all steps of the claimed method to be performed by or attributable to a single entity. Although we may attribute a third party’s performance of method steps to a single entity in some circumstances, LifeNet did not pursue an attribution theory at trial.

LifeCell posits that the non-removal limitation cannot be met until an independent third party, such as a surgeon, actually prepares and uses the accused products, and it is unknown at the time that LifeCell sells a graft if and how that graft will be used for transplantation. LifeNet counters that “the final product that leaves LifeCell’s hands is complete and . . . infringes in that condition” without affirmative action by a third party. We

agree with LifeNet.

Functional limitations recited in the negative may describe a capability or structural element. Here, the preceding language in each asserted claim states that the relevant plasticizers are already part of the tissue graft. The non-removal limitation simply provides a negative limitation that those plasticizers remain in the internal matrix prior to transplantation. . . . [T]he non-removal limitation clarifies that the recited plasticizer has not been removed and, because the plasticizer is biocompatible, can remain in the internal matrix of the tissue graft during transplantation, i.e., it need not ever be removed. This limitation is met without action by a third party. It is satisfied by the graft from the moment it is manufactured unless and until the plasticizer is removed from the internal matrix before transplantation. Therefore, the non-removal limitation does not relieve LifeCell of direct infringement.

LifeCell also contends that because the non-removal limitation describes a method of use while the remainder of claims 1-4 describes an apparatus, those claims are indefinite for covering both an apparatus and a method of using that apparatus. [T]he non-removal limitation defines a property of the recited plasticizer in that the plasticizer is biocompatible and does not need to be removed from the internal matrix before transplantation in the context of apparatus claims 1-4, so no later action by a user of the tissue graft is necessary. Those claims therefore do not mix an apparatus with a method of using that apparatus, and the district court did not err in denying JMOL as to indefiniteness. . . .

Finally, we address LifeCell's argument that the asserted claims are either anticipated by Werner or obvious in view of Werner and the knowledge of a person of ordinary skill. . . . Werner is a patent that discloses a process for treating a soft tissue with hydrogen peroxide and other steps to increase biological stability. . . . A review of the record shows that there is substantial evidence to support a jury finding that Werner does not disclose a plasticized soft tissue graft under the district court's construction. . . . The ultimate issue on this record was a classic factual dispute that the jury was free to resolve in LifeNet's favor. Since there is substantial evidence to support a finding that Werner fails to disclose "plasticized soft tissue graft," we need not reach the "cleaned" limitation. The district court did not err in denying LifeCell's request for JMOL or a new trial with respect to anticipation.

LifeCell only argues obviousness on appeal with respect to the "cleaned" limitation. It does not point to any evidence that a "plasticized soft tissue graft," if not disclosed by Werner, would have been an obvious modification to a person of ordinary skill in the art. As LifeCell fails to provide a basis for disclosure of a "plasticized soft tissue graft" outside of Werner, the district court also did not err in denying JMOL or a new trial on obviousness.