



involved are highly technical in nature, but that does not mean that the approach to construing the language in dispute, which is after all in the English language, must be as artificial as the constructs proposed by LTC.

It is too often the case in patent litigation that the adversaries' competing contentions can resemble theological disputations akin to the classic debate about how many angels can dance on the head of a pin. In such circumstances it frequently pays to take the figurative step backward to survey the scene and reach a common-sense resolution of the issues.

That is certainly true, for example, of the first issue on which the litigants cross analytical swords -- the meaning of "after the final thaw" in the '929 Patent's Claim 1<sup>2</sup> at Col. 19:61. For a full understanding of the issue, those words must be placed in context, so here are lines 57 through 61:

A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes, being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw. . . .

LTC urges that the earlier-quoted phrase "after the final thaw" must be construed to mean "several hours after the hepatocytes preparation is thawed for the last time" (Dkt. 140 § XIII at 20-21 and Dkt. 209 § I at 3-5), while Celsis rejects that "several hours" approach in favor of "a reasonable time period after thawing the hepatocytes."

Celsis has the better of the argument. "Viability" as a concept clearly connotes something other than evanescence, but to inject the kind of temporal notion for which LTC contends is uncalled for. Here the method taught by the '929 Patent is intended to produce a result that is

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<sup>2</sup> All four of the subjects dealt with in this opinion relate to Claim 1, although the last subject has to do with the effect of language in the patent's preamble on the scope of Claim 1.

usable for the purpose for which particular hepatocytes are needed, and that is best reflected by the concept of "reasonableness" advanced by Celsis. That is a matter that can be dealt with at trial, based on the evidence that has been placed before the trier of fact -- and the law looks to juries every day to make determinations of reasonableness in the context of the cases before them.

Next the litigants dispute the construction to be given to the word "plated" as it appears at '929 Patent Col. 20:16-20:

wherein the hepatocytes are not plated between and the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

Here too LTC would render that term essentially meaningless in context by failing to attach it (bad pun intended) to the idea embodied in the invention.

As LTC would have it, the disavowal of the need for plating is totally without a purpose related to the invention itself -- it would simply mean "placed in a container having a surface coated with any extracellular matrix protein, such as collagen" (Dkt. No. 140 § V at 13-17 and Dkt. No. 209 § II at 5-6). But that turns matters on their head, because it ignores the fact that the '929 Patent teaches that its method is performable without rather than with plating.

By contrast with LTC's proposal that finds no anchor in reality, Celsis' construction gives the term "plated" its normal meaning and purpose: "to have placed hepatocytes on a plate containing attachments substrates (e.g., collagen or extra-cellular matrix proteins) for the purpose of allowing the viable hepatocytes to attach to the plate" (Dkt. No. 172 § D at 19-20). That version explains that the customary function of plating -- the provision of a surface to which the viable hepatocytes can attach -- is not needed to practice the method taught by the '929 Patent.

So LTC is a loser on this second term as well.

Third among the four issues singled out for construction is the phrase "between the first and second cryopreservations" found in the language quoted earlier from '929 Patent Col. 20:16-20. True to form, LTC's counsel proffer a proposed construction that is wholly artificial, divorced from the common-sense meaning and purpose of that aspect of the '929 Patent.

It must be remembered that the patent's teaching is the previously unknown phenomenon that its method can produce a high percentage of viable hepatocytes even though the cells had been frozen, thawed and frozen again, and that the just-completed discussion here confirms that plating for purposes of cell attachment is not needed to bring that about. That being so, the quoted language simply conveys the idea that the absence of a plating step after the initial cryopreservation applies to any group of hepatocytes that are then subjected to a second cryopreservation.

As LTC would have it (Dkt. No. 140 § VI at 17-18 and Dkt. No. 209 § V at 10-11), the language at issue means "after the hepatocytes are cryopreserved the first time ever but before any second cryopreservation." But that formulation impermissibly changes the obvious significance of the disclaimed need for plating. Conversely, that disclaimer is given full meaning by Celsis' proposed construction (Dkt. No. 172 § E at 21-22), which gives the patented method its full scope by construing the phrase to mean "between the first cryopreservation of at least some of the hepatocytes in the second cryopreservation of those same hepatocytes." That construction tracks several express disclosures in the '929 Patent specification (Col. 12:15-24):

Most preferably, the pooled hepatocyte preparations of the invention will

comprise at least one population of hepatocytes that were cryopreserved prior to pooling. For example, a pooled hepatocyte preparation may comprise one or more hepatocyte specimens that were cryopreserved prior to pooling with one or more freshly isolated hepatocyte specimens. Alternatively, a pooled hepatocyte preparation may comprise only hepatocyte specimens that were previously cryopreserved.

It could not be more clear that several embodiments of the invention are given as examples there, none of which would conform to LTC's distorted definition.

Last among the disputed matters is a question whether a portion of the '929 Patent's preamble to Claim 1 -- the term "desired preparation of multi-cryopreserved hepatocytes" (Col. 19:56-57) -- serves as a claim limitation that limits the body of Claim 1 (as LTC contends at Dkt. No. 140 § IX at 21-23 and Dkt. No. 209 § III at 7-8) or does not do so (as Celsis urges at Dkt. No. 172 § G at 24-25). To that end LTC advances a sort of poison-pill argument under which the patent's later use of the word "said" somehow taints the words in the preamble by converting them into a limitation on the claim. Unlike the three earlier-construed terms, the meaning of which was readily resolved on the basis of logic and common-sense English usage without having to resort to general principles of claim construction, this issue poses a question of law on which caselaw may provide some value.

On that score, two Federal Circuit decisions provide a useful guide. Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F. 3d 1279, 1288 (Fed. Cir. 2008) (citations and internal quotation marks omitted) serves as a general guide:

In general, a preamble is construed as a limitation if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. A preamble is not limiting, however, where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.

Perhaps more to the point, Schumer v. Lab. Computer Sys., Inc., 308 F. 3d 1304, 1310 (Fed. Cir. 2002) (citations and internal quotation marks omitted) teaches:

It is well settled that if the body of the claim sets out the complete invention, and the preamble is not necessary to give life, meaning and vitality to the claim, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

In this instance the body of Claim 1 surely sets out the complete invention, and the presence of the identical reference to a "desired preparation of multi-cryopreserved hepatocytes" in the preamble neither adds to nor subtracts from the claim itself. And that being so, as Schumer has put it, "the preamble is of no significance to claim construction." Once more LTC has failed in its effort "to make the worse appear the better reason."<sup>3</sup>

### **Conclusion**

LTC has gone 0 for 4 on the claim construction issues coming out of the Markman hearing. This action is set for a status hearing at 8:45 a.m. December 3, 2012 to discuss the future course of this litigation.



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Milton I. Shadur  
Senior United States District Judge

Date: November 26, 2012

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<sup>3</sup> John Milton, Paradise Lost book II, line 113.