

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

CELSIS IN VITRO, INC. a Maryland Corporation,

Case No. 1:10-cv-004053

Plaintiff,

Judge Milton I. Shadur

v.

Magistrate Judge Martin C. Ashman

CELLZDIRECT, INC., a Delaware Corporation and wholly-owned subsidiary of INVITROGEN CORPORATION; and INVITROGEN CORPORATION, a Delaware Corporation.

Defendants.

MEMORANDUM OPINION AND ORDER (PUBLIC ACCESS VERSION)

At some point after this Court's July 15, 2010 issuance of a temporary restraining order that treated the method then being employed by defendants CellzDirect, Inc. and Invitrogen Corporation (referred to here as "LTC," treated as a singular noun¹) as having infringed United States Patent No. 7,604,929 (the '929 Patent), LTC returned to the laboratory and the figurative drawing board in an effort to design around the claims of the '929 Patent.² When LTC then returned with a claim that its efforts had been successful--that it had developed and was practicing a noninfringing method--this Court conducted a several-day evidentiary hearing earlier this month to address Celsis' Second Motion for Preliminary Injunction.

Now the litigants have complied with this Court's request to provide post-hearing supplemental submissions, without unduly overlapping the "mountains of paper" they had already tendered. As before, the parties have primarily focused on '939 Patent Claim 1, with

¹ Life Technologies Corporation is now the head of defendants' corporate group, so this opinion will follow the parties' lead in referring to "LTC" rather than the corporations named in the case caption.

² Meanwhile the parties crossed swords on Celsis' motion for preliminary injunction, which this Court granted in a September 8 order.

some attention also being given to Claim 10 (and Celsis has also referred a bit to Claim 2 as an asserted aid to the construction of Claim 1). Because all of the other claims are dependent on Claim 1, if it is not infringed the entire patent is not infringed.

For convenient reference, this Court attaches page 11 from Celsis' Corrected Memorandum in support of its current motion for preliminary injunctive relief. That sets out Celsis' own characterization, based on the Declaration of its opinion witness Dr. Stephen Strom, of a number of the patent's critical terms as they assertedly would have been understood by a person of ordinary skill in the art at the time of the invention. But as will be seen, the first bullet point in that listing presents a meaningfully different construct from the normal meaning of the corresponding language in the patent itself--a difference that is fatal to Celsis' current infringement claim.

This opinion will consider both sides' lawyers' treatment of the disputed issues to the limited extent needed to resolve the preliminary injunction question. Regrettably each side's post-hearing submissions reveal that both sets of lawyers have, at least in part, engaged in the Humpty Dumpty approach to language construction:³

There's glory for you!

I don't know what you mean by "glory," Alice said.

I meant, there's a nice knock-down argument for you!

But "glory" doesn't mean a nice knock-down argument, Alice objected.

When I use a word, Humpty Dumpty said in a rather scornful tone, it means just what I choose it to mean--neither more nor less.

Just one illustrative example on each side of the "v." sign will be referred to here.

2

³ Lewis Carroll, <u>Through the Looking Glass</u> ch. 6.

Thus LTC's counsel have bent the words "without requiring a density gradient step" (found in '929 Patent Claim 1 at Col. 20:14) out of shape, as though those words meant "without performing a density gradient step." But because it is Celsis' (and not LTC's) burden that is at issue in determining infringement, that distortion does not affect the result.

This opinion turns then to the first component of Claim 1, on which Celsis has performed similarly improper surgery. Here is the actual language of the '929 Patent (at its Col. 19:62-64) that sets out the first element of Celsis' method, with the emphasized words being those purportedly defined in Celsis' first bullet point in the attachment to this opinion:

(A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes. . . .

But Celsis' proposed construction in that attachment, which mirrors the position it urged during the hearing, deflects attention from the normal and obvious meaning of "density gradient," thus failing to explain away LTC's success in avoiding infringement via its revised method to separate hepatocytes.

Essentially all of Celsis' arguments equate to the impermissible device of reading the requirement of a "density gradient" completely out of its own chosen method. Before this opinion addresses that subject, however, mention should be made (if only briefly) of a subject to which the parties have devoted a good deal of attention but that this Court views as non-controlling here. That topic is LTC's emphasis on the fact that its new method causes hepatocytes to be separated into groups based on some other characteristic and not "based upon their density," as is the result of the use of a density gradient medium.

As LTC argues, the separation achieved by its new method is the consequence of the introduction of more than centrifugal force alone. Celsis responds by arguing that LTC's process eventuates in a result that still has a density-related factor as well.

But the parties' debate about the basis on which LTC's new method separates hepatocytes cannot be permitted to obscure the really dispositive issue: the requirement of a "density gradient" as an essential element of the '929 Patent's Claim 1. As that term itself necessarily imports, it must involve the use of a density gradient medium (30% Percoll is an example). By contrast, LTC's new method does not use Percoll or other density gradient medium.

That distinction, strongly supported by the evidence before this Court, is critical to the analysis. Thus Celsis' own opinion witness Dr. Strom acknowledged that nothing in the patent refers to "density gradient fractionation" other than in the presence of a density gradient medium. Likewise, all of the literature consistently distinguishes between density gradient fractionation and LTC's new method, recognizing them as distinct processes. Nor does any literature describe the method used by LTC as a form of density gradient fractionation—Celsis' other opinion witness Dr. Shekhar Gandhi himself confirmed that none of the literature in the field either supports or suggests that the method used by LTC is a subset of "density gradient fractionation."

In light of that strong evidentiary support for LTC's position, Celsis' efforts to emulate Humpty Dumpty and act as a revisionist reader (actually a revisionist rewriter) of the '929 Patent are entirely unpersuasive. First, its discussion of intrinsic evidence (Supp. Submission 2) begins in this fashion:

Claim 1 recites the purpose for performing this technique (i.e., separating viable hepatocytes from non-viable hepatocytes).

But of course it is the method, and not its purpose, that defines the scope of the patent.

In like fashion, Celsis' counsel really stretch Claim 2 beyond its boundaries by urging an inference that is too attenuated to carry weight. And they then contend that the "patent specification expressly discloses 'density gradient fractionation' as including other separate

techniques"--but having said that, they cite only this language from the specification (Col. 4:44-47) as purported support for that proposition:

(A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation (especially percoll density centrifugation) to separate viable hepatocytes from non-viable hepatocytes.

Not so--to read that language as though it embraces LTC's new process (as disclosed and described by the hearing evidence) again reads the words "density gradient" right out of the specification, just as Celsis would read them out of Claim 1 itself.

This opinion could go on to knock down all of Celsis' straw men that it has set up in attempted support of its claim of direct infringement, but that is unnecessary. And Celsis' effort to bring LTC within the doctrine of equivalents is equally unpersuasive, because the proof directly refutes the view of Celsis' opinion witness Dr. Gandhi that the two processes "perform substantially the same function of separating viable from non-viable hepatocytes in substantially the same way."

In a way, the thought process exhibited by Dr. Gandhi in dealing with that key issue has inadvertently demonstrated why, contrary to his conclusion, the doctrine of equivalents does <u>not</u> aid Celsis. As Dr. Gandhi would have it, the separation of hepatocytes through a density gradient medium (Celsis' method described in the '929 Patent) also encompasses the separation of hepatocytes through LTC's new method, which does <u>not</u> involve the use of a density gradient medium. Voila! "Density gradient fractionation" has somehow become "fractionation without a density gradient medium," assertedly dooming LTC's claim that its new process escapes the claim of infringement.

This Court is unpersuaded. That attempted parallel between the two methods, as urged by Celsis, improperly ignores the really different function performed by an integral part of LTC's new process.

Case: 1:10-cv-04053 Document #: 200 Filed: 03/24/11 Page 6 of 8 PageID #:7628

Patent noninfringement is a game in which one strike is out, and LTC has prevailed in that game. Hence Celsis' motion for a new preliminary injunction is denied. Because a <u>Markman</u> hearing has previously been set for March 29, counsel should also come prepared at that time to discuss the impact of this ruling on other pending issues in the litigation.

Milton I. Shadur

Senior United States District Judge

Date: March 24, 2011

Here, Celsis IVT has provided this Court with the evidence necessary to construe the exemplar claims 1 and 10 of the '929 patent from the perspective of one of ordinary skill in the art. In particular, that evidence is found within the Declaration of Dr. Stephen C. Strom,⁴ an admitted expert in hepatocyte-related technologies, such as those disclosed in the '929 patent. Dr. Strom is familiar with people of ordinary skill in the art at the time of the invention of the '929 patent. In his Declaration, Dr. Strom provides a claim construction chart⁵ detailing his opinion of how a person of ordinary skill in the art at the time of the invention would have interpreted various claim terms appearing in the '929 patent based on the plain and ordinary meanings of those terms, the claims themselves, the specification, and the prosecution history, as follows:

- "density gradient fractionation" means a technique for separating viable hepatocytes from non-viable hepatocytes through an isotonic fractionation buffer based on their density using centrifugal force.
- "without requiring a density gradient fractionation step after thawing the hepatocytes for a second time" means that the claimed process does not require a density gradient fractionation step after thawing the hepatocytes a second time.
- "plated" means to have placed hepatocytes on a plate containing attachment substrates (e.g., collagen or extra-cellular matrix proteins) for the purpose of allowing the viable hepatocytes to attach to the plate.
- "the hepatocytes of said preparation are viable after the final thaw" means the percentage of living hepatocytes relative to the total cell population in the preparation, when determined after the final thaw.
- "incubating" means simulating certain biological conditions,
- "xenobiotic" means a substance foreign to the body.
- "metabolic fate" means the modification of the chemical structure or the localization of the xenobiotic by the hepatocytes.

⁴ See generally Strom Decl.

⁵ Strom Decl. at Exhibit D.

Based on the evidence provided by Celsis IVT (including the patent and its file history), the Court may properly construe the scope of Claims 1 and 10 of the '929 patent.