IN THE UNITES STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
Appeal No. 2015-1570

RAPID LITIGATION MANAGEMENT LTD., FORMERLY CELSIS HOLDINGS INC. AND **IN VITRO, INC.,**
Plaintiffs-Appellants

v.

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

Appeal from the United States District Court for the Northern District of Illinois in Case Nos. 1:10-cv-04053, Judge Shadur.

BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* SUPPORTING NEITHER PARTY

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Dated August 28, 2015

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Biotechnology Industry Organization certifies the following:

1. The full name of every party or *amicus curiae* represented is:

   Biotechnology Industry Organization ("BIO")

2. The name of the real parties in interest (if the party named in the caption is not the real party in interest) represented by us is:

   None.

3. All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by us are:

   None.

4. The names of all law firms and the partners or associates that appear for the *amicus curiae* now represented by us in this court are:

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Biotechnology Industry Organization (BIO) is the world's largest biotechnology trade association, providing advocacy, development, and communications services for over 1,100 members worldwide. BIO members - many of whom are small, emerging companies-involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

BIO has no direct stake in the result of this appeal, nor does BIO take a position on the ultimate validity or infringement of the claims to a method of obtaining viable hepatocytes for medical uses. No counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the amicus curiae or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. This brief is solely the work of BIO and its counsel and reflects BIO's consensus view, but not necessarily the view of any individual member or client. BIO and its members are concerned that the development and commercialization of a diverse array of biotechnologies, including diagnostic testing and personalized medicine, will be hampered, if not precluded, if this Court does not address the mounting uncertainty currently afflicting patentable subject matter jurisprudence.

Unfortunately, the District Court's decision has done nothing to alleviate that uncertainty, but instead has exacerbated doubts as to whether meaningful patent protection remains available in the United States for many biotechnology inventions, and if so, the extent of that protection and the means to draft commercially meaningful method claims that meet the newly heightened standard for patent eligibility. The invention in this case would traditionally have been deemed eligible subject matter for patenting under 35 U.S.C. §101. It provides an excellent opportunity for the court to provide timely clarification on issues of critical concern to BIO and its members.

SUMMARY OF ARGUMENT

Further expansion of the scope of 35 U.S.C. § 101 as an exclusionary principle, and elimination of defenses against this rejection in *Celsis*, risks "swallowing up" method inventions in the biotechnology industry. The district court below characterizes the *Mayo*[1] and the *Alice*[2] decisions as "provid[ing] the road map for any determination of the validity of a process patent whose springboard is some law of nature." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 2015 WL 1523818, at *4, fn. 4 (N.D. Ill. Mar. 13, 2015). In practice, that "road map" is fast becoming a one-way street to invalidity. The Supreme Court has cautioned courts to "tread carefully in construing this exclusionary principle lest it swallow all of patent law," *Alice*, 134 S.Ct. at 2354, but lower courts seem to be struggling with the Supreme Court's admonition.

As of yet the Federal Circuit has given very little guidance with respect to how the excluded 'natural phenomenon' relevant to a particular claim is to be identified and defined. Any such definition is prone to being quite malleable, and without some meaningful constraints could be used to ensnare virtually any biotechnology invention.

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[1] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).
[2] *Alice Corp. Pty v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014).

A recent example of the consequence of this malleability can be seen in the present case, in which, on a motion for summary judgment, the court held that the capability of certain hepatocytes (i.e., liver cells) to be "frozen and thawed more than once" is "clearly" a "law of nature." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 2015 WL 1523818, at *7 (N.D. Ill. Mar. 13, 2015). *supplemented at* 2015 WL 1467188 (N.D. Ill. Mar. 16, 2015). Repeated freezing and thawing of isolated and viable human hepatocytes is certainly nothing that occurs "naturally," but the fact that a district court was able to come to this conclusion so easily, without any explanation, and on a motion for summary judgment no less, illustrates the need for guidance from this Court if Step I of the judicial "2 step" test for patent eligibility is to provide any meaningful gatekeeping function for innovations in biotechnology.

Instead of uncritically classifying a method claim as being "directed to" a "law of nature," just because biological material that is used in such a method is "capable of" responding to human manipulation, the court should consider the claim as a whole to decide what is being removed from the public domain by the patent. In the present case, hepatocytes are not being removed from access by mankind, nor are the methods of freezing cells, thawing cells, or separating viable from non-viable cells. Just like in *Diamond v. Diehr*, 450 U.S. 175 (1981)[3], it is

[3] In *Diamond v. Diehr*, the examiner determined that those steps in respondents'

the combination of steps, a combination developed by human ingenuity, not a natural law like gravity that would be protected by the patent. That combination is not a "natural law." It did not exist before the inventors assembled and tested it as a whole, to serve a useful purpose in medicine. Although all inventions involve laws of nature[4], in the sense they are subject to those laws, it will often be the case that an otherwise novel and non-obvious biotechnology invention can be deconstructed into a mere combination of natural phenomena and known techniques as the examiner did in *Diehr*. But as the Supreme Court decided, such a combination of claim elements should not be dismissed on that basis alone. Inventions of this type constitute much of the basis for advances in biotechnology, so benefit to the field should be considered.

An articulation of the doctrinal and policy bases for patent eligibility would provide a much needed anchor, without which there is a danger that the doctrine will creep and drift with each new decision, creating uncertainty and jeopardizing patent protection for meritorious inventions without any basis in statute or policy.

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claims that are carried out by a computer under control of a stored program constituted nonstatutory subject matter under this Court's decision in *Gottschalk v. Benson*, 409 U. S. 63 (1972). The remaining steps -- installing rubber in the press and the subsequent closing of the press -- were "conventional and necessary to the process, and cannot be basis of patentability."

[4] H.T. Markey, *Why Not the Statute?* 65 J.Pat.Off. Soc'y, 331, 333-34 (1983) ("Only God works from nothing, man must work with old elements," referring to obviousness).

STATEMENT OF THE CASE

Hepatocytes, a type of liver cells, are useful for experimental drug testing. Previously, usage of these cells was limited because hepatocytes have a short lifespan in the laboratory, and their availability was contingent upon a sporadic supply of donated liver tissue. Additionally, hepatocytes are especially desirable when pooled from multiple liver donors, but again, the cells' short lifespan made it difficult to accumulate sufficient fresh liver tissue from multiple donors such that cells could be pooled prior to freezing.

Prior to Celsis' invention, repeated cryopreservation was not viewed as a promising option because freezing the cells even once was known to significantly reduce cell health and viability. Prevailing wisdom taught that hepatocytes could be frozen at most once and then had to be immediately used or discarded..

Celsis claimed a method that provided a practical and simple solution for freezing hepatocytes multiple times without further significant loss of cell health and viability. The method has three steps: (1) previously frozen cells are thawed, (2) nonviable cells are separated from viable ones using a "density gradient fractionation," and then (3) viable cells are cryopreserved for later use. Thus, the claimed method requires the cells to be frozen at least twice, and for the final preparation of hepatocytes to meet a certain viability rate after the final thaw *without* a new density gradient step. The claim also includes an optional (4) step of

pooling the hepatocytes from different donors.

The district court invalidated these claims under §101 by applying the two-step test set forth in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289 (2012). *First*, it inquired whether the patent is directed to a non-patentable concept; and *second*, if so, whether it did something more than apply conventional solutions to that non-patentable concept.

As to the first inquiry, the district court found that the "patent is directed to an ineligible law of nature: the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles."

As to the second inquiry, the district court found that "the patented process lacks the requisite inventive concept." The freezing process used for the second time was, in itself, "well-understood." The density gradient fractionation and other limitations demonstrated that the claims are "more narrowly drawn" than those at issue in *Mayo* and *Alice*; they do "not lock up the natural law in its entirety." But the court feared that "if one were allowed to own a slice of the preemptive pie, that would pave the way for multiple others to claim the rest of that pie." Thus, despite uncontroverted evidence of non-infringing, practically feasible design-arounds of the claimed method, the district court felt justified in striking down Celsis's claims out of concern that otherwise the whole "preemptive pie" could be tied up slice-by-slice.

ARGUMENT

I. BOUNDARIES NEED TO BE CLARIFIED FOR THE SCOPE OF THE TERM "LAW OF NATURE."

In *Mayo* and *Alice*, the Supreme Court established a two-step framework for evaluating the patent-eligibility of process claims, requiring, first, a determination of whether the claim is "directed to" excluded subject matter, and second, an inquiry of "what else" there is in the claim to transform the claim into an inventive application of that law of nature or other excluded concept.

As this case illustrates, courts must "tread carefully" when beginning their analysis under Step I because the process of identifying an implicated law of nature can lead to very malleable definitions of the excluded subject matter. Depending on what one defines the implicated law of nature to be, it is very easy to arrive at the conclusion that the claim is "directed to" it, and therefore meets Step I.

For example, under the district court's logic a supposed law of nature for the present case could variously be defined as:

"hepatocytes are capable of surviving freezing more than once;"

"hepatocytes are capable of surviving freezing;"

"hepatocytes are capable of surviving gradient centrifugation;"

"hepatocytes are capable of surviving freezing and gradient centrifugation;"

"hepatocytes are capable of surviving freezing, gradient centrifugation, fractionation, pooling, and refreezing."

Of course, assuming Celsis's method is operable as claimed, the hepatocytes subjected to it necessarily have the "capability" of surviving *any* of the claimed steps and *any* part of the claimed sequence of steps, such that under the district court's logic any number of laws of nature could be articulated. After all, if "hepatocytes [being] capable of surviving multiple freeze-thaw cycles" is a law of nature, then so is "hepatocytes being capable of surviving centrifugation," or plating for cell culture, or, frankly, any other manipulation. So why did the court below choose to define the implicated natural law as "hepatocytes are capable of surviving multiple freeze-thaw cycles" in order to get past Step I, when it equally validly could have defined the natural law as "capable of surviving gradient centrifugation," or any other step?

The facetious answer is: because any other possible and equally reasonable articulation of the implicated natural law would not have led to invalidity under §101. The claim would likely have survived the Step II analysis because the repeated freezing and thawing step, itself new and surprising in the art, would have supplied the requisite "inventive concept."[5]

[5] *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922 (Fed. Cir 2012) (affirming grant of motion for preliminary injunction, *inter alia*, because the prior art did not teach, and in fact taught away from, repeated freeze-thaw cycles, thus supporting likelihood of success on non-obviousness). Subsequently, the non-obviousness of the invention was also confirmed by a reexamination in the USPTO. *See* Appellants' Br. at 10-11.

This thought experiment highlights not just the perils and malleability of an incautious Step I analysis. In practice as was the case here decision makers who analyze a process claim under the *Mayo* two-step test will inevitably tend to first home in on those steps or elements of the claim that distinguish it over the prior art, and to then formulate an implicated natural law around precisely those features of the claim that the patentee views as its inventive contribution over preexisting technology. In this way, the same reasons that make the claim fit Step I doom it under Step II, since there is no other "inventive concept" in the claim.

Just as insidiously, the present district court decision expands the scope of *Sequenom* to suggest that any process claim that depends on the response of a biological material to human manipulation is "directed to" a "law of nature," even if the steps applied to the biological material and the product of the process would never be encountered in nature. After all, there is no logical boundary between saying "hepatocytes are capable of surviving multiple freeze-thaw cycles;" "cancer cells are incapable of surviving multiple cycles of camptothecin treatment;" and "the human body is capable of responding to aspirin." If any number of "laws of nature" could be so easily conjured, then potentially all method steps applied to a biological material will automatically meet the "step 1" criteria of the *Mayo/Alice* test for patent eligibility, and proceed down a one-way street directly to invalidation.

Inventors must, of course, necessarily work with the natural properties of materials biological or otherwise. But to say that it is a "law of nature" when such materials respond to human manipulation according to their properties would send the Step I analysis down the proverbial rabbit hole.

A more rational appraisal of the present claims leads to the conclusion that the present claims are not directed to a law of nature. The method claim central to the *Celsis* opinion recites three steps: subjecting frozen and then thawed hepatocytes to a density gradient centrifugation to separate the viable cells from the non-viable cells; recovering the viable cells, and then freezing the composition that have greater than 70% viable cells after a second thawing without requiring a density gradient step. Hepatocytes are not subject to repeated freezing in nature under the conditions of the claimed methods. And, liver cells do not survive multiple freeze-thaw cycles under naturally-occurring conditions – they display this "capacity" only in the hands of the skilled human technician. No process as claimed has been identified in nature wherein previously frozen cells thaw, the viable ones separate from the non-viable ones, and only the viable cells refreeze. The claimed process, and its result, is entirely artificial. The only "laws of nature" that could be said to be at work operate at a much higher level of abstraction such as the laws of thermodynamics which govern Celsis's freeze-thaw steps, or the law of gravity which governs the centrifugation step.

Gravity and entropy are laws of nature because they operate regardless of the hand of man. They equally bind man-made processes, biological processes, and the inanimate world. They cannot be altered through human manipulation. In contrast, the ability of hepatocyte cells to remain viable and useful despite multiple freezing and thawing does not exist other than under the artificial conditions created by the skilled experimenter. Unlike gravity, the rate of hepatocyte viability can be enhanced or decreased by systematically deviating from these conditions. If it can be described as a "law" at all, it is a law of man, not a law of nature.

II. CAN ONLY COMPLETELY NOVEL STEPS APPLIED TO A "LAW OF NATURE" SATISFY STEP 2 OF *MAYO/ALICE*?

Once the patentee's main contribution over preexisting technology was defined away as a mere discovery of a law of nature, the district court easily concluded that the remainder of the claimed method lacked the inventive concept required under *Mayo* and *Alice*. Referring to the Supreme Court's statement that the patent-eligibility inquiry focuses on "what else" is in the claim, the court felt justified in removing the surprising survival rate of the cryopreserved hepatocytes from all further consideration, leaving "not much" to support the patent-eligibility of what was left of the claimed method.

Yet, Supreme Court precedent does not support the proposition that claim element even those that are deemed directed at excluded subject matter can

effectively be excised and removed from consideration of the claim altogether. Indeed, the Supreme Court has identified the fallacy of doing so when it explained that an otherwise statutory process such as *Diehr*'s method for curing rubber does not become non-statutory just because an improvement, in the form of a computer-implemented mathematical formula, is incorporated into the claimed process. *Diehr*, 450 U.S. at 187 ("a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer.").[6] If it is true, as *Diehr* teaches, that one cannot "flip" a claimed process into or out of patent-eligibility by including a mathematical formula (or law of nature, or natural phenomenon), then it cannot be correct to analyze the patent eligibility of a claim in any way other than through scrupulous attention to all elements of the claim, the old ones and the new ones even those involving a law of nature or mathematical formula. Only if all claim elements are considered will a decision maker be able perform a Step II analysis that, consistent with the Supreme Court's directive, searches for an inventive application *of* a law of nature. To do otherwise would be to search for an inventive application *apart* from a law of nature.

[6] In the same vein, if it can be assumed that the prior art methods for *once* freezing and then centrifuging hepatocytes were and are statutory subject matter, *Diehr* reminds us that these methods could not have *turned into* nonstatutory subject matter when the inventors added an improvement step (re-freezing the cells) that involved a purported law of nature.

Unfortunately, some lower courts seem to understand *Mayo* and *Alice* to require precisely that: 1. the exclusion of nonstatutory subject matter from the claim and 2. an inquiry into whether the claimed method would be patentable or "inventive" without that subject matter. This approach is highly problematic because it would mean that a newly-discovered natural phenomenon could never support the patentability of a claim. In practice, the patentee would basically have to make a different kind of invention entirely instead of a diagnostic method, for example, the patentee would have to invent an independently patentable tool that may be useful for the desired diagnosis, such as new laboratory reagents or a new analytical apparatus. In this way patent law would systematically reward the invention of research tools, and deny rewards to those who use these tools to develop real-world diagnostic, prognostic or other socially beneficial biotech processes.

Overall, an approach that requires an undefined "something else," that cannot be satisfied by the application of known techniques and reagents to a newly recognized natural phenomenon, threatens the availability of patent protection for a host of important innovations spanning the length and breadth of biotechnology. It will often be the case that a truly beneficial and meritorious biotechnology invention can be deconstructed, after the fact and with the benefit of hindsight, into a mere combination of natural phenomena and known techniques. But inventions

of this type constitute much of the basis for advances in biotechnology, and have generally been viewed as eligible for patent protection prior to recent jurisprudential developments. These inventions often require a great deal of investment, not only for their initial development, but also to translate nascent technology into commercial products that provide meaningful benefits to society. Patents on diagnostic and prognostic tests, for example, play a critical role as the necessary incentive for the substantial investment required for commercialization activities such as clinical studies in support of regulatory approval, insurance reimbursement, and even the necessary studies to convince healthcare providers and patients to avail themselves of the technology.

Furthermore, meaningful innovation in personalized medicine typically focuses on the identification and clinical characterization of new biomarkers, not the development of new tools for analyzing DNA, enzymes or other patient-specific traits, which is an entirely different area of inventive activity. All this suggests that this Court must begin articulating limiting principles in order to achieve the Supreme Court's policy objective of preventing the building blocks of innovation from being tied up, while at the same time permitting reasonable scope of patent protection for important inventions in the life sciences.

As in the present case, it is particularly troubling when courts can look past the unconventional, even surprising attributes of the claimed process by the time

they reach Step II of the *Mayo*/*Alice* analysis. Earlier in this litigation, the district court and this Court both agreed that the evidence for non-obviousness of the claimed method was robust, and supported a likelihood of success on the merits sufficient to grant and sustain a preliminary injunction. Separately, the USPTO confirmed the non-obviousness of the claimed method once when it granted the patent and *again* upon reexamination. Clearly, there is something about the claimed process that would be deemed "inventive," and a real advancement, when measured against preexisting technology.

Yet, when this same question is now re-cast through the lens of §101, the very court that previously showed itself impressed by copious evidence of non-obviousness ("[N]ot a single one of that astonishingly large body of literature was devoted to the subject of *multi*-cryopreservation of hepatocytes." […] "Celsis has demonstrated more than a substantial likelihood of success on the issue.") now finds it easy to conclude that there is "not much" to support any inventiveness in Celsis's claim. *Celsis*, 664 F.3d at 927 (quoting district court hearing transcript).

From a business perspective, there can be nothing worse for investment in innovation. This case sends a clear signal that courts are free, even encouraged, to review the inventive merits of an invention under standards that are different from those that applied when the patent was granted and confirmed in prior adjudications. As here, the surprising advances on which a patent was granted,

reexamined, and upheld, can become fodder for a 101 attack that disqualifies these advances as non-statutory subject matter. In this way the same evidence that established the inventive merit of an invention under the rigors of a §103 analysis can lead to a diametrically opposite outcome under an untethered §101 analysis. What is an investor, or business decision maker, to conclude from all of this other than that they should have no confidence in a patent examiner's, or judge's determination that their invention is a nonobvious advance over the art? No business decision maker (whose mind hasn't been warped by law school) will be able to understand why large investments should be made in reliance on a patent that can at once be a non-obvious, surprising leap in technology and a routine, conventional application devoid of inventive merit.

Because of its well-developed record on the non-obviousness of the claimed invention, this case may present a good opportunity for this Court to clarify the interplay between §103 and Step II of the *Mayo*/*Alice* framework. To be sure, BIO believes that the district court's analysis under Step I was so flawed that Step II should never have been reached. But if this Court chooses to review the district court's "inventive concept" analysis, BIO submits that affirmative evidence of non-obviousness, such as surprise, skepticism, or teaching away in the art should not be discounted. To the discomfort of many in the patent bar, the Supreme Court in *Mayo* has stated that the inquiries under §§103 and 101 can sometimes overlap,

and this statement is often taken to mean that indicia that would tend to make a claim obvious can also point to a lack of an inventive concept under Step II. Until the Supreme Court provides further clarification, there is no reason not to take the Court by its word. If indicia of obviousness are fair game in an "inventive concept" analysis, then so should indicia of non-obviousness. If scrupulously applied to the claim as a whole, combined with a more rigorous Step I analysis, doing so would provide at least some helpful guidance to biotechnology patentees and applicants currently struggling in the face of unstable jurisprudence and ever-shifting patent examination policies.

CONCLUSION

For these reasons, this Court should grant en banc reconsideration of this case.

Respectfully submitted,

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August 28, 2015

United States Court of Appeals

for the Federal Circuit

Rapid Litigation Management, Ltd, f/k/a Celsis Holdings, Inc. and In Vitro, Inc. v. Cellzdirect, Inc. and Invitrogen, Corp.

No. 2015-1570

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing **Brief of the Biotechnology Industry Organization As *Amicus Curiae* Supporting Neither Party** was filed electronically using the CM/ECF system and was served via the CW/ECF system on counsel for the other parties as follows on this 28th day of August, 2015:

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