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***Sequenom* and Section 101 Challenges in
Diagnostics and Personalized Medicine**

Hans Sauer

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

CORRECTED

**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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Date: August 28, 2015

STATEMENT OF CONSENT

Both **RAPID LITIGATION MANAGEMENT LTD.** (*Plaintiff-Appellants*) and **CELLZDIRECT INC.** (*Defendant-Appellees*), have given BIO consent to file an Amicus Brief.

TABLE OF CONTENTS

	<u>Page</u>
CERTIFICATE OF INTEREST	i
STATEMENT OF CONSENT	ii
TABLE OF CONTENTS.....	iii
TABLE OF AUTHORITIES	iv
STATEMENT OF INTEREST OF <i>AMICUS CURIAE</i>	1
SUMMARY OF ARGUMENT	3
STATEMENT OF THE CASE.....	6
ARGUMENT	8
I. BOUNDARIES NEED TO BE CLARIFIED FOR THE SCOPE OF THE TERM “LAW OF NATURE.”	8
II. CAN ONLY COMPLETELY NOVEL STEPS APPLIED TO A “LAW OF NATURE” SATISFY STEP 2 OF <i>MAYO/ALICE</i> ?	12
CONCLUSION	18
CERTIFICATE OF COMPLIANCE.....	19
CERTIFICATE OF SERVICE	20

TABLE OF AUTHORITIES

	<u>Page(s)</u>
<u>Cases</u>	
<i>Alice Corp. Pty v. CLS Bank International</i> , 134 S. Ct. 2347 (2014)	3, 7, 8, 12, 13, 15
<i>Celsis In Vitro, Inc. v. CellzDirect, Inc.</i> , 664 F.3d 922 (Fed. Cir 2012).....	9, 16
<i>Celsis In Vitro, Inc. v. CellzDirect, Inc.</i> , 2015 WL 1523818 (N.D. Ill. Mar. 13, 2015), <i>supplemented at</i> 2015 WL 1467188 (N.D. Ill. Mar. 16, 2015)	3, 4, 6, 11
<i>Diamond v. Diehr</i> , 450 U.S. 175 (1981)	4, 12, 13
<i>Gottschalk v. Benson</i> , 409 U.S. 63 (1972)	5
<i>Mayo Collaborative Services v. Prometheus Laboratories, Inc.</i> , 132 S. Ct. 1289 (2012)	3, 7, 8, 10, 12, 13, 15, 18
<u>Constitutional and Statutory Provisions</u>	
35 U.S.C. §101	2, 3, 7, 9, 16, 17
35 U.S.C. §103	16, 17
<u>Other Authorities</u>	
Federal Rule of Appellate Procedure 29(b)	
Federal Circuit Rule 35(g)	
H.T. Markey, <i>Why Not the Statute?</i> 65 J.Pat.Off. Soc’y, 331, 333-34 (1983).....	5

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.

Also available as part of the eCourse

[Patent Eligibility: Section 101 Challenges and the New USPTO Guidelines](#)

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