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**United States Court of Appeals for the Federal Circuit**

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2015-1570

RAPID LITIGATION MANAGEMENT LTD., formerly Celsis Holdings, Inc.,  
IN VITRO, INC.

*Plaintiffs-Appellants,*

v.

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

*Defendants-Appellees.*

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Appeal from the United States District Court for the Northern District of Illinois  
in No. 1:10-cv-04053, Senior Judge Milton I. Shadur

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**Brief Of *Amicus Curiae* National Venture Capital Association  
In Support Of Appellants**

Lynn H. Pasahow  
Michael J. Shuster  
Carolyn C. Chang  
FENWICK & WEST LLP  
801 California Street  
Mountain View, CA 94041-2008  
Telephone: (650) 988-8500  
Facsimile: (650) 938-5200

*Attorneys for Amicus Curiae*  
National Venture Capital Association

## CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* National Venture Capital Association

certifies the following pursuant to Federal Circuit Rule 47.4:

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

National Venture Capital Association

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

As indicated in item 1.

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

There are no parent corporations or any publicly held companies that own 10 percent or more of the stock of any *amicus curiae* represented by me, except as indicated above.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this case are:

Law Firm

Fenwick & West, LLP

August 28, 2015

Partners and Associates

Lynn H. Pasahow, Michael J. Shuster,  
Carolyn C. Chang

By: /s/Carolyn Chang

Carolyn Chang

*Counsel for Amicus Curiae*  
National Venture Capital Association

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## **STATEMENT OF *AMICUS CURIAE***

### **I. IDENTIFICATION OF THE *AMICUS CURIAE***

The National Venture Capital Association (NVCA), with more than 400 members, is the venture community's preeminent trade association, advocating for policies that encourage innovation and reward long-term investment. NVCA's mission is to foster greater understanding of the importance of venture capital to the U.S. economy and support entrepreneurial activity and innovation. Venture capitalists are committed to funding America's most cutting-edge entrepreneurs, working closely with them to transform breakthrough ideas into emerging growth companies that put innovation in the hands of the public and drive U.S. job creation and economic growth.

### **II. STATEMENT OF INTEREST OF THE *AMICUS CURIAE***

NVCA and its members have an interest in preserving the patent rights that have created and continue to sustain innovation. The issue under review has far-reaching implications for the health, medical, and broader life sciences industries. Patent protection for new and innovative research tools incentivizes investment in the long and expensive research and development process endemic to the life sciences, in particular the medical and biotechnology industries. Denying patent eligibility to such tools threatens

not only important medical and biotechnological breakthroughs that are founded upon use of these novel techniques, but also the overall economic growth spurred by venture capital investment in the life sciences.

**III. AUTHORITY TO FILE**

Pursuant to Federal Rule of Appellate Procedure 29(a), all parties have consented to the filing of this brief of *amicus curiae*. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* or their counsel made a monetary contribution intended to fund its preparation or submission.



## SUMMARY OF ARGUMENT

Venture capital plays a vital role in bringing to market important and ground-breaking technologies that otherwise would have been left on the drawing table. It is often a key source of funding for companies developing technologies that have a long or uncertain path to market. Thanks to venture funding, companies such as Amazon.com, Biogen, Facebook, Genentech, Gilead Sciences, Google, and Twitter have been able to bring technological advances to the public, while driving economic growth. Indeed, venture capital has had a disproportionate impact on the U.S. economy. Ates, S. T., “*Beyond Cash: Venture Capital, Firm Dynamics, and Economic Growth*,” Job Market Paper, University of Pennsylvania 2 (Nov. 2014). While venture capital investments amounted to less than 0.2% of US GDP in 2010, revenues from venture-backed companies accounted for 21% of US GDP and 11% of private sector employment. *Id.*

Nowhere is the impact of venture capital felt more strongly than in the life sciences industry. In 2013, for instance, two of the largest drivers of growth in biotech – Biogen and Gilead Sciences – were venture-funded companies. Ernst & Young, *Beyond Borders, Unlocking Value*, Biotechnology Industry Report (“*Beyond Borders 2014*”) 39 (2014). That same year, venture capital investment in the larger life sciences industry

(which includes biotech, pharma, medical devices, therapeutics, and healthcare services) totaled \$6.9 billion. National Venture Capital Association, Yearbook 12 (2014). Such funding is vital to an industry mired by long development times, unpredictable science, government regulations, uncertain industry adoption, and a complex healthcare reimbursement system. This process can cost hundreds of millions of dollars and take several years before any return on investment is realized. *See e.g.*, HHS, *Personalized Health Care: Pioneers, Partnerships, Progress* 132 (2008) (“HHS *Personalized Health Care*”); Biotechnology Industry Organization, *Guide to Biotechnology* 77 (2008) (“BIO Guide”). The continued growth of the life science industry – an industry that creates hundreds of thousands of jobs, generates billions of dollars in revenue, and makes life-saving innovations available to the public – depends on the venture community’s willingness to invest in the face of such risk and uncertainty. *See* Ernst & Young, *Beyond Borders*, Global Biotechnology Report (“*Beyond Borders 2011*”) 39 (2011).

But that willingness to invest depends on the incentives created by patent protection in both end products as well as the research tools needed to bring those products to market. Removing patent eligibility for innovations used or realized at any point in the research and development process of a life sciences company – be it scientific research tools or end consumer products – threatens future investment and

the future of the life sciences industry.

## ARGUMENT

### I. CONTINUED INNOVATION IN THE LIFE SCIENCES DEPENDS UPON STRONG PATENT PROTECTION

While the opinion being appealed concerns a narrow invention, the district court's reasoning for invalidating the '929 patent – that it relies on applying a natural characteristic of hepatocytes (that they may repeatedly be refrozen) and therefore involves unpatentable subject matter – broadly applied would be very damaging to the life sciences industry. This is an industry highly dependent upon the ability to patent inventive compositions and processes that are based on *applying* natural laws and natural phenomena.

#### A. The Life Sciences Industry Is Marked by a Long and Unpredictable Development Process

The life sciences industry constantly seeks to forge new and disruptive ways of providing life-changing products and services to the public, whether in the form of biotech innovation or other medical and healthcare services. Thus, the industry's reach is far, ranging from new molecular-based therapies to biofuels to medical devices to new crops. But life sciences companies face a unique set of obstacles. *See* BIO Guide at 32-69. Unlike other industries, life sciences start-ups often tread into uncharted territory which requires overcoming unpredictable science, long development

timelines, and uncertain industry adoption.

Products in the life sciences often take more than ten years and hundreds of millions of dollars to develop and bring to market. *Id.* at 77. Research and development is expensive and challenging. The underlying laboratory science can be arduous and unpredictable, with the end result subject to significant regulatory hurdles. *See e.g. id.* at 39-40 and 44 (describing regulatory process for therapeutics and agriculture). And even after securing regulatory approval, market success still requires industry adoption.

For example, developing new biological diagnostics and therapeutics requires laborious work with respect to the underlying science, including ensuring sufficient sample sizes, quality control in the underlying biological samples, a rigorous statistical approach to analyzing data, and a consistent standard across the industry. President's Council of Advisors on Science and Technology, *Priorities for Personalized Medicine* ("PCAST Priorities") 29-30 (2008). And any end product is subject to significant and constantly changing regulations. Medical treatments are subject to long, expensive clinical trials, with new regulatory requirements put into place each year. There is also the practical necessity of convincing insurance companies, Medicare, and Medicaid to pay for these new tests, drugs, and therapies, all

of which require robust evidence supporting their safety and efficacy. *Id.* at 45-48. The process of bringing innovation in the life sciences to market “often takes 10 to fifteen years, costing an average of \$1.2 billion for a new drug and \$92 million for a novel medical device.” National Venture Capital Association, *Patient Capital 3.0: Confronting the Crisis and Achieving the Promise of Venture Backed Medical Innovation (“Patient Capital 3.0”)* 7 (2013) (internal citations omitted); *see also* Grabowski, H., *Follow-on Biologics, Data Exclusivity and the Balance Between Innovation and Competition*, 7 *Nature Reviews Drug Discovery* 479, 482 (2008) (“Grabowski 2008”) (bringing a single new test or therapeutic to market takes 15 years and costs over \$1.2 billion); BIO Guide at 38 (“It typically takes 10 to 15 years and an average of more than \$800 million (including the cost of failures) to develop a new therapy.”); *see also* PhRMA, *Key Industry and PhRMA Facts*, available at <http://www.phrma.org/news-media/related-resources/key-industry-factsabout-phrma>. And only an estimated 30 percent of biological therapeutics that make it as far as human trials succeed. Grabowski 2008 at 481.

The only way these important and life-saving innovations can reach the public is through the effort of researchers and entrepreneurs willing to dedicate the time and resources to overcome these challenges. But most of

the companies driving cutting-edge innovations in the life sciences are small. Without a significant source of capital, even when the technology is sound, these companies would run out of money before a product could ever be brought to market. BIO Guide at 77. Because of the nature of the industry, these companies require significantly more money, yet have significantly fewer funding options. See National Venture Capital Association, *Patient Capital: How Venture Capital Investment Drives Revolutionary Medical Innovation* (“*Patient Capital*”) 7 (2007) (“Because their capital needs are so large and their path to market so long and risky, it is difficult for life sciences startups to access bank financing or other more traditional sources of capital.”).

**B. Patent Protection at All Stages of the Development Process Incentivizes and Enables Venture Capital Investment**

Against this backdrop, venture capital has emerged as one of the sole sources of funding for these high risk ventures. Why has venture capital been willing and able to fund these early stage life sciences companies and their years-long high-cost development processes? The answer: patent protection. See Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission*, Chp. 3, p. 1 (2003) (“FTC Report”) (“Biotech representatives emphasized that patent protection is critical to attract the

capital necessary to fund this high-risk investment.”); PCAST *Priorities* at 21 (“The ability to obtain strong intellectual property protection through patents has been, and will continue to be, essential for pharmaceutical and biotechnology companies to make the large, high-risk R&D investments required to develop novel medical products”).

Any research tool or scientific advance that gives a life sciences company a unique advantage through this arduous R&D and product development process and in the market place is an indicator of likelihood of success. Patent rights are the main way in which potential investors, namely venture capitalists, can assess whether a company has such a unique advantage. Thus, in the life sciences, a company must have strong patent protection to secure venture capital investment. *Patient Capital* at 12 (“No other industry is as dependent on developing and protecting intellectual property as the life sciences industry.”); BIO Guide at 77 (noting that patents are “often the most important assets a biotech company has”); FTC Report at Chp. 3, pp. 1, 17-18 (2003) (“[b]iotechnology companies overwhelmingly underscored the importance of patents for attracting venture capital”); *see also* Hadzima, Joseph, et al., *IP in early stage commercial and investment success*, Intellectual Asset Management (“Hadzima”) 52, 55 (March/April 2010) (suggesting that high quality patents may be more important in the healthcare versus



information technology sector). As reported by the Federal Trade

Commission:

Patents . . . are particularly useful in enabling biotechnology companies, which are generally small in size, to attract capital investment and to contract with other firms for commercial development of their inventions. This capital is critical for ongoing R&D, because product commercialization in the biotechnology industry is particularly time-consuming and expensive.

FTC Report at Chp. 3, p. 29. Patents provide the incentive for venture capitalists to invest in the “incredibly risky, illiquid, and long-term investments.” *See* Hearing Before the Subcommittee on Courts and Competition Policy of the Committee on the Judiciary House of Representatives, *Biologics and Biosimilars: Balancing Incentives for Innovation* (“*Biologics Hearing*”) 182, 107th Cong., 1st Sess., Serial No. 111-73 (July 14, 2009).

Because life sciences start-ups face significant challenges at every stage in the development process, venture firms will evaluate what ability a company has to overcome the challenges presented at each stage. Typically, patents directed to the end product intended to be offered in the marketplace will provide a period of market exclusivity during which venture capitalists can recoup their investment. This makes potentially large rewards possible if a product can be brought to market. Merrill, Stephen A, et al., *Reaping*

*the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (“*Reaping the Benefits*”) 20, National Research Council of the National Academies (2006) (“patents provide a period of exclusivity with respect to the manufacture, use, or sale of the product”); *Biologics* Hearing at 182 (period of market exclusivity helps “produce a return that is much higher than you can get from less risky investments”).

These types of patents, however, do nothing to ensure that a product will, in fact, be brought to market. Accordingly, in the life sciences, patents directed to research tools and innovations made early in the research and development process are equally important. Such patent protection can signal that a company’s R&D efforts are likely to be successful or that a company has an advantage over competitors that do not have rights to such tools. Additionally, some life sciences companies focus on a market niche upstream from product development, where intellectual property rights to research tools are needed for market success and venture funding. *Reaping the Benefits* at 20 (explaining that companies in the market between fundamental research and applied product development rely on patents covering research tools).

Thus, strong patent protection – both in scientific research tools and consumer end products – enables life sciences companies to “increase their expected profits from investments in R&D, thus fostering innovation that would not occur without patents’ exclusionary rights.” Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition v* (2009).

Because of the pivotal role patents play in fostering innovation, predicting success, and facilitating return on investment, venture capitalists will often assess the value of a company’s entire patent portfolio before investing, employing professionals with direct technical expertise as part of their due diligence.

Schneider, Judith E., *Intellectual property: The driving force for growth and funding*, 8 *Journal of Commercial Biotechnology* 320, 324 (2002); *see also* Barfield, Claude, et al., *Biotechnology and the Patent System* 11 (2007) (“Investors believe that in order for the biotechnology sector to succeed, it is critical that biotechnology firms be able to obtain and enforce strong patents.”).

Venture firms undergo this exercise because strong patent protection is correlated with market success. A significantly higher percentage of venture capital backed companies that have succeeded (i.e., been acquired or gone public) have patent portfolios compared to those that have gone out of business. Hadzima at 52, 55. Strong patent protection correlates with the amount of R&D investments made

by companies, and weak patent laws engender poor investment in R&D, diminishing a company's probability of success. Grabowski, Henry, *Patents, Innovation and Access to New Pharmaceuticals*, 5(5) J. Int'l Econ. Law 849, 854 (2002).

With all the other uncertainties that exist in the life sciences industry, patent protection in all stages of the research and development process is needed to counterbalance the extremely high risk faced by startup companies. See Graham, Stuart J.H., et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24:4 Berkeley Tech. L. J. 1255, 1279 (2009) (venture-backed firms are much more likely to hold patents and venture-capital investors appear much less willing to fund companies that don't hold patents).

## **II. THE LIFE SCIENCES INDUSTRY AND U.S. ECONOMIC GROWTH DEPENDS ON STRONG PATENT PROTECTION AND CONTINUED VENTURE CAPITAL INVESTMENT**

The life sciences industry would not exist today if not for venture capital investment:

From 1980 to 2012, venture capitalists invested nearly \$108 billion into an estimated 4,600 startup life sciences companies, constituting 19 percent of all venture investment in the U.S. for that time period. This historical investment has resulted directly in the creation and growth of our country's biopharmaceutical, medical device, and diagnostic industries, comprising thousands of companies dedicated to saving and improving the lives of patients worldwide.

*Patient Capital 3.0* at 8. Venture capitalists invested more than \$35 billion

in biotechnology between 2002 and 2011, with more than \$4 billion invested in 2011. *See Beyond Borders* at 44. That figure continues to grow. In 2013, almost \$7 billion of venture money was invested in the life sciences. NVCA 2014 at 12. Thus, “[e]xperts agree that virtually the entire biotechnology industry. . . would not exist without the support of the venture capital industry.” *Patient Capital* at 3. Indeed, venture capital funds almost all emerging biotechnology companies. *See Biologics Hearing* (NVCA testimony that venture capital firms “supply nearly all of the capital for early-stage biotechnology companies”). And continued funding of life sciences companies will depend, as it has, on strong patent protection.

Life sciences is a \$100 billion industry. *Beyond Borders* 2014 at 37. Venture capital’s investment in new, cutting-edge high-growth life sciences companies means that it plays a leading role in creating new industries which hold the potential for unparalleled job and revenue growth. The biopharmaceutical industry, for instance, has an enormous ripple effect throughout the economy. The Milken Institute projects that for every job within biopharmaceuticals, an additional 6.7 jobs are created in other sectors of the economy. *Patient Capital* at 8, citing Milken Institute, *Biopharmaceutical Industry Contributions to State and U.S. Economies* (2004). A reduction of these jobs and the revenues generated by eliminating venture-backed

companies will have significant unintended consequences on the economy.

Moreover, venture-backed companies that succeed and go public often re-invest in and support new and further advances. These advances go on to feed the cycle of innovation, job creation, and revenue growth. Thus, supporting strong patent protection has supported venture investment and the resulting steady economic growth and development of new technologies and emerging industries.

### **III. LIFE SCIENCE RESEARCH TOOLS ARE NOT DIRECTED TO PATENT INELIGIBLE SUBJECT MATTER**

The Supreme Court recognizes that “all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” *Alice Corp. Pty. Ltd., v. CLS Bank Int’l*, \_\_ U.S. \_\_, 134 S. Ct. 2347, 2354 (2014) (internal citations omitted). It warns that an invention should not be rendered patent ineligible because it involves an abstract concept or law of nature and that too broad an interpretation could “swallow all of patent law.” *Id.*

The Court described one important example of such an improper, overbroad application in *Mayo Collaborative v. Prometheus Labs.*, \_\_U.S.\_\_, 132 S. Ct. 1289, 1293-94 (2012) (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981), and *Mackay Radio & Telegraph Co. v. Radio Corp.*, 306 U.S. 86, 94 (1939); citations omitted):

[A]ll inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, in *Diehr* the Court pointed out that “a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.” It added that ‘an application of a

law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” And it emphasized Justice Stone's similar observation in *Mackay Radio & Telegraph*: ““While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.””

The '929 patent has been swallowed by just such an overbroad interpretation of the patent eligibility jurisprudence. The '929 patent does not seek to patent the fundamental natural phenomena that hepatocytes can be cryopreserved and thawed more than once. Rather, recognizing that natural aspect of hepatocytes, the '929 patent employs it in a very specific application – exactly what the Supreme Court has stated is patentable. The '929 patent does not simply recite a law of nature and add the words “apply it.” *See Mayo Collaborative Servs.*, 132 S.Ct. at 1294. It recites a method for subjecting hepatocytes to specific conditions to that do not occur in nature to create an unnatural composition highly useful for life science research. Whether this method is simply a recitation of conventional steps should not be the focus of a patent eligibility analysis here, particularly when the patent claims are not directed to natural phenomena. Patent eligibility is concerned with the improper monopolization of a fundamental principle. There is no such concern here.

Nor should there be any concern that patents directed to research tools stifle innovation by discouraging or prohibiting basic research; this concern does not

comport with reality. In practice, patents have a negligible effect on research, in part because ground-level scientists are not aware of patents and because ultimately their research pursuits are driven primarily by scientific importance or interests regardless of patents. Walsh, John P., *Patents, Material Transfers, and Access to Research Inputs in Biomedical Research*, Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions 2, 6, 13 (2005). It has been found that “few of the frictions [caused by patents] that had been anticipated had materialized,” and that “patents on research tools did not impede biomedical research as feared.” *Id.* at 6. Thus, in reality, there does not exist any evidence of the feared negative effects of patents on further research. What does exist, however, is the undeniable importance of patents to the life sciences industry and the entire U.S. economy in general.



## CONCLUSION

For the foregoing reasons stated above, the National Venture Capital Association supports a finding that life sciences research tools such as that at issue in this matter are eligible for patent protection.

Dated: August 28, 2015

Respectfully submitted,

FENWICK & WEST LLP

By: /s/Carolyn Chang  
Carolyn Chang  
*Counsel for Amicus Curiae*  
National Venture Capital Association

**CERTIFICATE OF COMPLIANCE**

The undersigned hereby certifies that the foregoing Brief of Amicus Curiae National Venture Capital Association contains 3,502 words and is in compliance with Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

Dated: August 28, 2015

By: /s/Carolyn Chang  
Carolyn Chang

*Counsel for Amicus Curiae*  
National Venture Capital Association

## CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 28, 2015, I electronically filed the foregoing Brief of *Amicus Curiae* National Venture Capital Association with the Clerk of the Court using the CM/ECF System, which will serve via email notice of filing to all counsel registered as CM/ECF. Counsel for Plaintiffs-Appellants and counsel for Defendants-Appellees were also served via Federal Express, Standard Overnight Service:

Andrew J. Pincus, Esq.  
Paul W. Hughes, Esq.  
MAYER BROWN LLP  
1999 K Street, N.W.  
Washington, D.C. 20006

*Attorneys for Plaintiffs-Appellants*  
In Vitro, Inc. and Rapid Litigation  
Management Ltd.

Laura A. Wytsma, Esq.  
LOEB & LOEB LLP  
10100 Santa Monica Boulevard  
Los Angeles, CA 90067

*Attorneys for Plaintiffs-Appellants*  
In Vitro, Inc. and Rapid Litigation  
Management Ltd.

Adam G. Kelly, Esq.  
John A. Cotiguala, Esq.  
LOEB & LOEB LLP  
321 North Clark Street, Ste. 2300  
Chicago, IL 60654

*Attorneys for Plaintiffs-Appellants*  
In Vitro, Inc. and Rapid Litigation  
Management Ltd.

C. Kevin Speirs, Esq.  
David G. Mangum, Esq.  
PARSONS BEHLE & LATIMER  
201 South Main Street, Ste. 1800  
Salt Lake City, UT 84111

*Attorneys for Defendants-Appellees*  
CellzDirect, Inc. and Invitrogen  
Corporation

Dated: August 28, 2015

By:           /s/Carolyn Chang            
Carolyn Chang

*Counsel for Amicus Curiae*  
National Venture Capital Association