No. 12-786

In the Supreme Court of the United States

AKAMAI TECHNOLOGIES, INC.,

Petitioner,

v.

LIMELIGHT NETWORKS,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICI CURIAE MYRIAD GENETICS, INC. AND GENOMIC HEALTH, INC. IN SUPPORT OF RESPONDENT

BENJAMIN G. JACKSON*
MYRIAD GENETICS, INC.
320 Wakara Way
Salt Lake City, UT 84108
(801) 584-3600

Counsel for Myriad Genetics, Inc.
** Counsel of Record*

KATHLEEN DETERMANN
GENOMIC HEALTH, INC.
301 Penobscot Drive
Redwood City, CA 94063
(650) 569-2051

Counsel for Genomic Health, Inc.

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STATEMENT OF RELATED CASES

On April 20, 2011, the Court granted Akamai's request for rehearing en banc. (*See* Order of April 20, 2011, Granting En Banc Review, Case Nos. 2009-1372, -1380, -1416, -1417.) On May 26, 2011, the Court granted rehearing *en banc* in *McKesson Technologies, Inc. v. Epic Systems Corp.,* No. 2010-1291. (See Order of May 26, 2011, Granting *En Banc* Review, Case No. 2010-1291.) Both cases involve issues of joint infringement. Accordingly, the *McKesson* case may be affected by this appeal.

Myriad Genetics, Inc. and Genomic Health, Inc. respectfully submit this brief as *amici curiae* in support of Respondent.

INTEREST OF THE AMICI CURIAE

Myriad Genetics, Inc. is a pioneer and world leader in the new field of personalized medicine. Myriad's currently marketed personalized medicine products include innovative molecular diagnostic tests such as: Myriad myRisk™ Hereditary Cancer testing (for genetic predisposition to a variety of cancers); BRAC*Analysis*® testing (for genetic predisposition to breast and ovarian cancer); COLARIS® and COLARIS *AP*® testing (for genetic predisposition to colorectal, uterine and other cancers); Prolaris® (to predict a prostate cancer patient's risk of recurrence and disease-specific death); Myriad myPath™ Melanoma (to clarify the diagnosis of melanoma in ambiguous lesions); and Myriad myPlan™ Lung Cancer (to predict a lung cancer patient's risk of disease-specific death). Myriad's products are now used by more than 40,000 oncologists and Ob/Gyn physicians in the United States in the care of their patients.

Genomic Health, Inc. is a personalized medicine company committed to improving the quality of cancer treatment decisions through the research, development and commercialization of genomic-based clinical laboratory services. To that end, the company conducts sophisticated genomic research to develop clinically-validated molecular diagnostics which provide individualized information on response to certain types of therapy, as well as the likelihood of disease recurrence. Genomic Health's currently markets the Onco*type* DX® Breast, Colon and Prostate Assays. These diagnostic technologies generate information that healthcare providers and patients can use in making treatment decisions.

Amici's past innovation and commercial success, as well as the patients whose lives have been im-

proved or saved by *Amici*'s products, have benefited greatly from a strong U.S. patent system. Banking on the prospect of continuing strong patent protection, *Amici* are making substantial investment in research and development and working diligently to prepare the next generation of personalized medicine products. *Amici* scientists analyze thousands of specimens, searching the human body's biochemicals (DNA, RNA, proteins, and metabolites) to identify biomarkers that can be applied in methods to diagnose disease characters and drug response. Applications of biomarkers are key to *Amici*'s development of new products, helping *Amici* deliver the promise of personalized medicine in preventing diseases, optimizing disease treatment, improving lives, and reducing healthcare costs.

Patent claims to diagnostic uses of such biomarkers and adequate enforcement of such patent claims are critical for the fledgling industry of personalized medicine. Very often, however, practical realities of molecular diagnostics and the current application of subject matter eligibility under 35 U.S.C. § 101 require that these patent claims be presented in the form of method claims that may often be easily divided between two or more parties.

Amici, like all other innovators and especially those in the molecular diagnostics industry, have an interest in ensuring that the patent system is not circumvented and investment in personalized medicine is not dis-incentivized by would-be infringers simply dividing the steps of such diagnostic method claims among multiple parties. Otherwise, there will not be adequate patent protection for future personalized medicine products, and the significant invest-

ment by *Amici* and others in research and development will be discouraged.

SUMMARY OF THE ARGUMENT

Personalized medicine depends on molecular diagnostic tests to obtain information on a patient's genetic and molecular markers and to use and manipulate this information to diagnose clinically useful disease characters. This new field holds enormous promise for improving people's lives and reducing healthcare cost at each stage of patient care, including helping prevent disease by identifying which patients are at increased risk and determining the best course of treatment (*e.g.*, deciding which drug to give, deciding which surgical or monitoring procedure is appropriate, etc.).

The significant investment and substantial risk involved in the discovery, development and implementation of personalized medicine products require strong patent protection. Much like the drug industry, personalized medicine relies on expensive and risky clinical trials to decipher and confirm which biomarkers may be used in what ways to diagnose specific disease characters.

Claims to biomarkers *per se, e.g.*, isolated genomic nucleic acids or proteins, are frequently unavailable because such patent claims are ineligible for patenting as products of nature. Thus, claims to specific *applications* of such biomarkers, including diagnostic uses (*e.g.*, applications of correlations between such biomarkers and disease characteristics), are very often the only patent claims available to protect adequately the large investment needed to bring a personalized medicine product to market.

In practice, such diagnostic use claims are presented in the form of method claims including two broad categories of steps: steps of measuring bi-

omarkers in a laboratory assay on one hand and, on the other, steps of applying the laboratory result (*e.g.*, diagnosing a disease character based on an application of the detected biomarker and/or treating the patient in view of the diagnosis).

These two categories of steps may often be easily divided between two or more parties, making divided infringement a serious issue. Without much-needed relief from the Federal Circuit's *en banc* decision in this case, patent applicants in personalized medicine are challenged to navigate between patent eligibility under § 101 (*e.g.*, *Bilski, Mayo, AMP*) on the one hand and divided infringement (*e.g.*, *BMC Resources, Muniauction*, etc.) on the other. *Amici* submit this brief primarily to draw the Court's attention to the interplay between these two areas of patent law.

Although divided infringement jurisprudence is driving forward almost exclusively in business method and software patents, its greatest impact will likely be felt in a very different area: personalized medicine. Reversing the Federal Circuit's *en banc* decision in this case could be devastating to personalized medicine.

Before the *en banc* decision in this case, the Federal Circuit's strict rule required that all steps of a method claim be performed by one party (or multiple parties strictly as agent of a single party) in order for any party to be held liable for infringement. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 629 F.3d 1311, 1318 (Fed. Cir. 2010) ("*Akamai I*"). This prior rule encourages collusion among collaborating parties to escape infringement liability. It further undermines a wide swath of method patent claims in the field of personalized medicine, as well as many

other fields, and significantly weakens the U.S. patent system.

The Federal Circuit properly rejected its previous approach in favor of a better rule for analyzing potential infringement of method claims by multiple parties: A party can be held liable for inducing infringement if it can be shown that (1) it knew of a particular patent, (2) it induced the performance by a third party of one or more steps of the method claimed in the patent, and (3) those steps performed by the third party and combined with activities of the first party complete the claimed method. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1318 (Fed. Cir. 2012) ("*Akamai II*").

Akamai II's rule allowing liability for induced infringement is indeed better than *Akamai I*, under which there could be no infringement under any theory. Better still is a rule that permits liability for direct infringement by multiple parties acting in a coordinated way.

Either rule discourages would-be free-riders from unfairly gaming the patent system, while encouraging legitimate design-around and fair competition. If the rule endorsed by the *en banc* Federal Circuit on divided infringement is not upheld or even strengthened by this Court, such a decision will seriously harm the burgeoning field of personalized medicine.

ARGUMENT

I. Personalized Medicine Improves and Extends Life While Lowering Healthcare Costs By Correlating Molecular Biomarkers to Clinically Useful Disease Characters

Personalized medicine depends on diagnostic tests to obtain information on a patient's molecular biomarkers (gene sequence variations, gene or protein expression levels, metabolites, etc.) and using or applying this information to diagnose particular disease characters (*e.g.*, specific disease risk, presence or absence of disease, prognosis, response to particular drug therapies, etc.). Based on this information, preventive measures or treatment regimens can be applied to the right patient at the right time and in the right amount.

Already, a number of personalized medicine products are widely used, exemplifying the current value and future promise of personalized medicine in improving quality of life and reducing costs. A well-known example of a widely available molecular diagnostic is HER2 testing, which predicts a patient's response to the breast cancer drug Herceptin®. Patients whose tumors overexpress HER2 show dramatic response to treatment with Herceptin® while patients whose tumors do not overexpress HER2 show little or no benefit. While Herceptin is a powerful anti-cancer agent, there are drawbacks to the drug: Herceptin® costs over $50,000 a year and can cause severe side effects including cardiac complications and death in some patients. *See* Hillner & Smith, *Do the Large Benefits Justify the Large Costs of Adjuvant Breast Cancer Trastuzumab*? 25 J. CLINICAL ONCOLOGY 611, 612 (2007); Herceptin® Package Insert, *available at*

http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103792s5311lbl.pdf (last visited Mar. 30, 2014). Thus, a simple diagnostic test for HER2 overexpression can spare a woman both enormous cost and potential suffering if her tumor's biology indicates the drug will not work. *See generally* Dendukuri et al., *Testing for HER2-positive Breast Cancer: A Systematic Review and Cost-effectiveness Analysis*, 176 CAN. MED. ASS'N J. 1429 (2007).

More importantly, because treatment with an ineffective drug can erode part of a patient's window of opportunity for effective treatment, drug response tests such as the HER2 test can help physicians and patients make the right treatment decision at the right time. *See id*. Indeed, given the commonly low rate of drug efficacy in many medical fields,[1] there is a clear need for additional molecular diagnostic tests predicting a patient's response to many other drugs.

More recent examples of personalized medicine products developed by *Amici* that save and improve patient lives, but depend on strong patents, include:

- *Amicus* Myriad's Prolaris® testing, which can help a patient and his doctor decide whether his prostate cancer is aggressive enough to warrant surgery, and its significant side effects and costs, or is indolent enough to warrant active surveillance.[2]

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[1] Selected major drugs are effective in 50% of rheumatoid arthritis, 30% of Alzheimer's, and 25% of cancer patients. Spear *et al., Clinical Application of Pharmacogenetics*, 7 TRENDS MOLECULAR MED. 201, 202 (2001)

[2] *The effect of cell cycle progression (CCP) score on treatment decisions in prostate cancer: Results of an ongoing registry trial*, American Society of Clinical Oncologists, 2014 Genitourinary

- *Amicus* Genomic Health's Oncotype DX Breast Cancer Assay individualizes a patient's treatment planning by predicting the likelihood that patient with early stage invasive breast cancer will respond to chemotherapy as well as experience a cancer recurrence. This test has been incorporated into multiple clinical guidelines and has been demonstrated to identify the small percentage of women who will benefit from chemotherapy, allowing those who will not to avoid serious side effects, while at the same time decrease costs for our health care system.

These are just a handful of products that illustrate personalized medicine's potential. Indeed, personalized medicine has been touted as one of the promising solutions to the current crisis in our healthcare system. *See* Personalized Medicine Coalition, *The Case for Personalized Medicine*, 4-6, *available at* http://www.personalizedmedicinecoalition.org/sites/default/files/files/Case_for_PM_3rd_edition.pdf (last visited Mar. 30, 2014).

II. Strong Patent Protection is Necessary to Incentivize and Reward the Massive Investment Required to Research and Develop Personalized Medicine Products

A basic understanding of the challenges faced by the personalized medicine industry shows that strong, enforceable patents claiming new diagnostic

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Cancers Symposium, Abstract #277 (*available at* http://meetinglibrary.asco.org/content/123761-142) (last visited March 31, 2014).

uses and applications of biomarkers are vital to its full emergence and continued viability.

Much like in the pharmaceutical industry, research and development in personalized medicine are extremely costly and offer a very low rate of success.[3] After generating data on biomarkers from hundreds or thousands of carefully selected patient samples, each having expertly collected clinical information, at a cost of hundreds or thousands of dollars per sample, scientists must sift through millions of data points in hopes of establishing a statistically significant connection between one or more of these markers and a particular clinical feature.[4]

Discovering a correlation is not the finish line, however; extensive additional clinical trials are required to validate the clinical utility of the new diagnostic method.[5] Even after such significant time and

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[3] *See generally*, Kling, *Diagnosis or Drug? Will Pharmaceutical Companies or Diagnostics Manufacturers Earn More from Personalized Medicine?*, 8 EMBO Rep. 903 (2007)

[4] The National Institutes of Health recently estimated the cost of a single genome-wide association (*i.e.*, correlation) study to be at least $6M, not counting the cost of patient samples. Press Release, NIH, Two NIH Initiatives Launch Intensive Efforts to Determine Genetic and Environmental Roots of Common Diseases (February 8, 2006), *available at* http://www.genome.gov/17516707 (last visited Mar. 30, 2014).

[5] For example, researchers at Genomic Health reportedly spent well over 100 million dollars and 7 years, including numerous clinical studies involving hundreds of patients, in bringing Onco*Type* DX® to market. *See also*, Department of Health and Human Services, *Personalized Health Care: Pioneers, Partnerships, Progress*, 84 (2008), *available at* http://medicalcenter.osu.edu/pdfs/cphc/USDHHS_White_Paper_PHC.pdf (last visited Mar. 30, 2014).

capital outlays, success is not guaranteed and failures far outnumber successes. Just like many drugs that were successful in a phase II clinical trial will fail in a larger phase III trial, similarly many molecular diagnostic products with promising results in a small discovery study will fail to show meaningful predictive value in a larger validation study.

Ironically, personalized medicine, where patents are under fire, is inherently riskier than pharmaceuticals, where the value of patents is not seriously questioned, for two reasons. First, molecular diagnostic testing is often a one-time event—*e.g.*, one germline genomic test determines whether a patient has a genetic predisposition to disease. Pharmaceutical products, on the other hand, typically have "repeat" customers taking a daily dose for months or years. Second, laboratory developed molecular diagnostic tests do not benefit from a pharmaceutical-like regulatory framework that makes relatively narrow patent protection sufficient. Copyists can make trivial modifications to an innovator's test and still potentially piggyback on the innovator's large and risky investment in clinical validation studies. This is not possible under the Hatch-Waxman framework for drugs, where a copyist must choose between exactly copying the innovator's drug (which means the copyist need not perform its own clinical trials but will also infringe a very narrow patent focused on the innovator's exact drug) and making even trivial changes to the innovator's chemical structure—which means the copyist might design around a narrow patent but might be required to perform its own expensive trials. Thus, whereas narrow patents will often be sufficient to protect a large investment in a drug, personalized medicine tests need broader patent protection.

Importantly, *Amici* are not asking for a special rule to benefit personalized medicine. *Amici* instead merely urge this Court to not establish an unfair rule driven by one industry—computer software—to enable ready infringement of patents in another.

III. Restricting Liability for Dividing Infringement Threatens the Patent-Fueled Foundation of Personalized Medicine

The Federal Circuit's *en banc* decision in this case correctly reversed several previous Federal Circuit decisions on so-called "divided infringement" that had created a wide loophole for would-be infringers. This Court should affirm or even strengthen the *Akamai II* decision because this will set up a fair, workable rule that balances concerns about over-breadth and worries about dis-incentivizing innovation better than the *Akamai I* decision and its predecessors.

The Federal Circuit's previous jurisprudence on divided infringement developed largely in the realm business methods and computer software and systems. *See, e.g.*, *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007; *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008); *Leader Techs., Inc. v. Facebook, Inc.*, 770 F. Supp. 2d 686 (D. Del. 2011); *Inv. Tech. Group, Inc. v. Liquidnet Holdings, Inc.*, 759 F. Supp. 2d 387 (S.D.N.Y. 2010). The present case, involving content delivery for the Internet, is in line with this trend. But while severely limited liability for divided infringement set forth in these cases is problematic and unfair in these fields, *McKesson Techs. Inc. v. Epic Sys. Corp.*, No. 2010-1291, 2011 U.S. App. LEXIS 7531, at *17-*18 (Fed. Cir. Apr. 12, 2011) (Newman, J., dissenting), it will be devastating in personalized medicine. This is

because important patent claims in personalized medicine, especially following this Court's recent decisions on patent eligibility under 35 U.S.C. § 101 and the PTO's very broad reading of those decisions, typically take the form of method claims including steps that can be performed by multiple parties among whom no agency relationship or contractual obligation is needed.

A. The Interplay of Patent Eligibility and Severely Limited Liability for Divided Infringement Is Particularly Problematic for Personalized Medicine

Personalized medicine depends on molecular diagnostic tests, which typically are diagnostic applications of correlations between specific molecular markers and specific disease characters. After this Court's recent decision in *AMP v. Myriad*, claims to the biomarkers themselves in isolated form may be unavailable. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013). Under the Patent Office's current overly broad interpretation of the *AMP* decision, even specific, novel laboratory tools designed by scientists to test for those biomarkers may be ineligible for patenting.[6] Depending on this Court's decision in the co-pending case of *Alice Corp. Pty. Ltd., v. CLS Bank International*, Docket No. 13-298, claims to laboratory systems for measuring and interpreting these biomarkers may be subject to further restriction.

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[6] *Available at* http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf (last visited Mar. 28, 2014). Until these examination guidelines are ruled on by the courts, which may well take years, patent examiners will apply them with the force of law to exclude large swaths of patentable subject.

Thus, in personalized medicine products, a primary patent that gets over the § 101 hurdle is a method of applying new knowledge about a biomarker or group of biomarkers to produce a new diagnostic conclusion. Yet under this Court's recent decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), and the Patent Office's current, expansive interpretation of that decision, patentees must include additional steps in diagnostic methods in order to make those method claims eligible for patenting. For example, in *Mayo*, the Court held invalid a claim that recited administering a drug and testing for metabolites of that drug, and then informed doctors of the clinical significance of the results of that test. *Mayo*, 132 S. Ct. at 1297-98. The Court noted that the claims did not require a step of acting on the clinical significance of the test (*e.g.*, adjusting the drug dose if the metabolite levels are too high in the patient's blood), *id.* at 1296, suggesting that such an additional step may have made the claim eligible for patenting. In *Amici*'s practical experience, patent examiners often apply this precise thinking, requiring just such a step to finalize a diagnostic method claim under § 101.

Setting up this claim structure as required for threshold eligibility for patenting, when paired with a restrictive rule of liability for divided infringement, puts personalized medicine patent applicants in a challenging position. The new rules of patent eligibility require diagnostic method claims to include two general categories of steps: (1) detecting or measuring one or more biomarkers in a biological sample (*e.g.*, testing a patient sample to see if HER2 levels are higher than expected) and (2) acting on the information gained by the measurement (*e.g.*, administering Herceptin if HER2 levels are high). But the-

se two activities may easily be, and in the normal practice of medicine often are, divided between separate parties with at most an arms-length contractual relationship (*e.g.*, a doctor ordering a test from an independent laboratory and then acting on the result). Warren & Fang, *Biotechnology Patent Validity in Jeopardy*, GENETIC ENGINEERING NEWS: LEGAL AFFAIRS (Oct 1, 2010, Vol. 30, No. 17) (*available at* http://www.genengnews.com/gen-articles/biotechnology-patent-validity-in-jeopardy/3421/). In fact, the first category is often further split in patent claims into two sub-categories: (a) physically measuring biomarkers in a laboratory assay and (b) using informatics to combine these measurements into a score that can be used to statistically predict some particular clinical characteristic like drug response.

Thus, the typical personalized medicine paradigm is as follows: A diagnostic testing laboratory markets a test to a physician, encouraging the doctor to order the test (the step(s) of measuring biomarkers). The lab then conducts these measuring steps (*e.g.*, testing a patient sample for high levels of HER2) and, optionally, guides the physician on how to interpret the results to reach some useful diagnostic conclusion (*e.g.*, "Based on HER2 levels detected in the sample, the patient will/will not respond to Herceptin®") or even to take appropriate further actions according to the test result (*e.g.*, "Based on HER2 levels detected in the sample, administering Herceptin® is recommended"). The physician then acts, independent of the lab, to select and administer a treatment regimen to the patient based on the test result. A rule requiring one party to independently complete all steps of a patented method would in

practice exempt such activities from patent protection.

B. The Former Rule Exalted Form Over Substance, Forced Innovators into an Impossible Dilemma and Provided a Ready Loophole for Would-Be Infringers

The problem in the present case is that previous Federal Circuit case law in the *Akamai I* line held that "when two entities collaborate to infringe a patent, such that one performs some steps of the claim and the other performs the other steps, there cannot be any infringement, on any theory, unless one entity 'controls or directs' the activity of the other." *Golden Hour Data Sys. v. emsCharts, Inc.*, 614 F.3d 1367, 1382 (Fed. Cir. 2010) (Newman, J., dissenting). In the core paradigm of personalized medicine outlined above, however, a single party rarely performs all steps that are likely required by recent developments in the law of patent eligibility. Nor is there an agency or "mastermind" relationship between the parties—the doctor orders the test and the lab returns the result in an arm's length transaction.

Under the *Akamai I* rule, which this Court should reject, seemingly the only way to prove liability is for the infringing parties to enter a relationship that is unlikely to exist in practice and which, for savvy parties, is easy to avoid. The overturned Federal Circuit decisions refused to find divided infringement liability in the face of close relationships that fall short of a principal's control over an agent. *McKesson*, 2011 U.S. App. LEXIS 7531, at *17 (Newman, J., dissenting) ("Some recent [decisions hold] that neither collaboration nor joint action nor facilitation nor authorization nor invitation can overcome the immutable barrier to infringement when all

of the participating entities are not under the 'control or direction' of a mastermind infringer."). In *Golden Hour*, for example, the Court found no joint infringement despite the fact the accused infringers "formed a strategic partnership, enabled their two programs to work together, and collaborated to sell the two programs as a unit." *Golden Hour*, 614 F.3d at 1382 (Newman, J., dissenting); *see also Cross Med. Prods. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311-2 (Fed. Cir. 2005) (accused infringer's employees attended surgery to show surgeons how to assemble infringing device).

Courts have responded to complaints about unfair outcomes and potentially disastrous impact under the restrictive divided infringement rule with a simple refrain: "Draft better claims." *See, e.g., BMC Res.*, 498 F.3d at 1381 ("The concerns over a party avoiding infringement by arms-length cooperation can usually be offset by proper claim drafting. A patentee can usually structure a claim to capture infringement by a single party. […] The steps of the claim might have featured references to a single party's supplying or receiving each element of the claimed process."); *McKesson*, 2011 U.S. App. LEXIS 7531, at *14. As discussed above, however, in the field of personalized medicine this advice rings particularly hollow as pressures from other areas of the law make such "better claims" practically impossible.[7]

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[7] Even if there were no problematic interplay of § 101 eligibility and divided infringement liability, the former limits on divided infringement liability would still encourage parties to simply divide the steps of any process in an arm's length transaction in order to escape infringement liability. Virtually any method with more than one step can be split up between multiple actors

The result is a dilemma for those seeking to protect their risky, expensive and valuable inventions: Either languish at the patent office wrestling with the current law of patent eligibility, or comply with the Patent Office's interpretation of patent eligibility and receive a patent claim that can be readily practiced without fear of liability under an unreasonably restrictive rule for divided infringement. If this Court does not affirm the Federal Circuit's en banc decision in Akamai II, it will in effect result in the "removal of interactive methods [such as personalized medicine methods] from the purview of the patent system." *McKesson*, 2011 U.S. App. LEXIS 7531, at *20 (Newman, J., dissenting).

C. The Federal Circuit's *En Banc* Rule Should at Least Be Affirmed, or in the Alternative Improved, by the Court

Instead of requiring patentees to choose between these undesirable extremes, the *Akamai II* rule strikes a reasonable compromise and is carefully balanced to assign liability only to those parties for whom it is proper while not allowing easy circumvention of patents. For instance, a party with no knowledge of another party's actions in completing a method claim should not be subject to liability. *BMC Res.*, 498 F.3d at 1381. However, if a first party asks, orders, or otherwise *knowingly causes* a second party to perform certain actions or has reason to believe his request will result in the second party performing these actions, and the second party's actions complete a claimed method when combined with those of the first party, liability should attach.

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in a way that avoids liability under the former rule's requirement of strict agency or control.

The Court should at least affirm *Akamai II*'s induced infringement rule under § 271(b) or, preferably, the Court should further allow for direct infringement liability under § 271(a). *Akamai II* found liability under § 271(b) for induced infringement only and declined to find liability under § 271(a) for direct infringement. *Akamai II*, 692 F.3d at 1307. This is better than the former state of things, under which "there cannot be any infringement, on any theory…" for divided infringement. *Golden Hour*, 614 F.3d at 1382 (Newman, J., dissenting). An even better rule, however, is that urged by Respondent and numerous *amici*: Whenever a first party performing one or more steps of a method claim knowingly causes one or more other parties to perform the rest of the steps of the same method claim, or when two or more parties act in a concerted manner to perform all steps of a method claim, equity requires that the first party or the parties acting in concert be found liable for patent infringement. Limiting divided infringement liability to induced infringement is unduly narrow under the increasingly difficult burden of proving inducement under § 271(b). *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011) ("[W]e now hold that induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement").

Some have expressed concerns over potentially turning innocent end consumers into infringers. First, end-consumers are not sued in practice; the commercial actor is invariably the target of suit. *See, e.g., McKesson*, 2011 U.S. App. LEXIS 7531 (software provider); Akamai II, 692 F.3d 1311 (competing data service provider); *Golden Hour*, 614 F.3d 1367 (software providers); *BMC Res.*, 498 F.3d 1373 (debit transaction network provider); *Muniauction*, 532

F.3d 1318 (internet auction provider); and *Cross Med. Prods.*, 424 F.3d 1293 (medical device company employees). This fact of companies not suing their end-users is even clearer in personalized medicine, where there is little incentive to sue doctors or patients (*e.g.*, no damages) and strong incentives toward "rational forbearance" (*e.g.*, greater dissemination of technology, not suing one's customers, etc.). Brief of *Amici Curiae* Roche Molecular Systems, Inc. et al., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012). Parties raising this red-herring are asking the Court to fashion a rule that exalts form-over-substance and significantly weakens the patent system, all in the name of protecting consumers who were never threatened.

Second, liability for divided infringement, whether direct or induced, will require a level of knowledge and sophistication that few if any consumers will possess. Direct infringement liability should only attach when the accused infringer knows or has reason to know that the actions of the second party will complete the claimed method. It is difficult to imagine unwary consumers being dragged into court under this rule.

If the Court affirms the *Akamai II* decision only on the ground of induced infringement, liability for divided infringement for consumers will be even less likely. A patentee will need to pass the ever rising bar of induced infringement under 35 U.S.C. § 271(b), which the Federal Circuit appears to interpret as requiring knowledge of the patent in a divided infringement context. *Akamai II*, 692 F.3d at 1308 (citing *Global-Tech Appliances*, 131 S. Ct. at 2068). No unwitting end consumer should fall into this category.

The rule applied in *Akamai II* should be affirmed or even strengthened by this Court to discourage collusion, prevent unfair results, and stimulate investment and innovation in personalized medicine and beyond.

CONCLUSION

For the reasons stated above, the decision of the appeals court should be affirmed.

Respectfully submitted,

BENJAMIN G. JACKSON
MYRIAD GENETICS, INC.
320 Wakara Way
Salt Lake City, UT 84108
(801) 584-3600

Counsel for Myriad Genetics, Inc.
**Counsel of Record*

KATHLEEN DETERMANN
GENOMIC HEALTH, INC.
301 Penobscot Drive
Redwood City, CA 94063
(650) 569-2051

Counsel for Genomic Health, Inc.

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