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To the United States Senate Committee on the Judiciary Committee Hearing on

"The Impact of Abusive Patent Litigation Practices on the American Economy"

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Summary of Testimony:

As Congress considers legislation to curb misuse of the patent system by entities that seek to use the system for financial gain rather than to promote innovation, Congress must ensure that responsible patent owners remain able to protect and enforce their patents and protect their own businesses against patent infringement. And, in scrutinizing dubious practices of some patent holders, Congress should not overlook abuses by others who seek to undermine the patent system for similarly illegitimate reasons.

Unfortunately, misuse of the patent system against legitimate patent owners is a real and growing problem. In particular, the PTO's Inter Partes Review (IPR) system – a new administrative patent challenge system created by the America Invents Act of 2011 – is undermining the value and predictability of patent rights and wreaking havoc on the legitimate, investment-backed expectations of patent owners. This is happening because, contrary to the intentions of Congress, this new system unfairly stacks the deck against patent owners in many ways, leading to patent invalidation rates far exceeding those seen in district court patent litigation involving similar types of patents and similar grounds for challenges. Not surprisingly, the statistically disproportionate "kill rates" of IPR proceedings invite unintended abuses and predatory practices by those seeking to attack patents for illegitimate reasons, including for their own financial gain. For example, questionable entities have begun to approach biotech companies with threats of dragging their key patents into IPR proceedings unless substantial payments are made. And just recently, the New York Times reported on an investment scheme in which a hedge fund takes a "short" position in the stock of biopharmaceutical companies and then files IPR challenges against one or more patents protecting their key products in an effort to profit from driving down the companies' stock prices. The biotechnology industry is particularly vulnerable to such manipulation, because our companies tend to be small, derive most of their revenue from one or two products on the market, and have just a handful of very valuable patents protecting those products. The mere filing of an IPR demonstrably can have significant impact on the stock prices of such companies, as well as their ability to continue to raise the investment needed to develop future treatments for patients in need. Indeed, the first company to be targeted by this hedge fund strategy was a small biotech company whose main product is an innovative treatment that helps patients with Multiple Sclerosis walk better. In one day this company lost more than $150 million in market capitalization because a hedge fund, which may have shorted the stock, announced an IPR challenge. These market-manipulating, cynical efforts not only damage the value of companies working on cures, but also hurt patients and their families who are eagerly waiting for such cures.

Senators Coons, Durbin and Hirono have introduced the STRONG Patents Act, which BIO supports, which would prevent such abuse.

BIO encourages this Committee to develop a legislative package that will curb abusive patent practices, including the abuse of the IPR system, through a balanced and targeted approach that does not undermine the ability of legitimate patent owners to defend their inventions and businesses against infringement. We believe consensus can be achieved on a range of issues, including enhancing transparency of patent ownership and enforcement; curtailing unfair or deceptive practices in the indiscriminate sending of patent licensing or settlement demand letters; addressing how patents can be enforced against innocent end-users or consumers of infringing products manufactured and sold by others; and making the IPR system a more balanced and fair system for patent owners.

We remain concerned, however, that proposals for more general patent litigation changes presently lack this requisite balance. Concepts such as excessive pleading requirements, mandatory stays of merits discovery, and joinder of third parties as unwilling co-plaintiffs for the purpose of expanding liability for attorney fee awards, are found in no other area of civil litigation and go too far in restricting the ability of all patent owners to enforce their patents against infringers.

The re-introduction of the Innovation Act (H.R. 9) in the House of Representatives revives, on a dramatically shifted landscape, this debate over the right "balance" that was begun in the last Congress. A series of court decisions, Judicial Conference rule changes, PTO actions, and legislative and enforcement activities over the past two years have greatly changed the dynamic for systemic patent litigation reforms – by raising patentability standards and the requirements for filing patent lawsuits; increasing the shifting of litigation costs for baseless infringement suits; reducing the asymmetries in litigation that some plaintiffs have exploited to demand unfair settlements; and enhancing consumer protections against the bad faith assertion of patents against consumers and other end users. In short, both the bar and the stakes have been raised in the patent system, and the result has been a substantial decline in patent litigation since this Committee last considered the need for broad patent litigation reforms. These changes reinforce the need to ensure that any patent reform legislative package does not swing the pendulum too far in any one direction.

Achieving this balance is essential for biotechnology. Reliable patents are critical in ensuring the steady stream of investment necessary to develop innovative medicines, alternative sources of domestic renewable energy, and more productive and sustainable farming techniques that raise farm incomes and reduce environmental degradation. And they are essential to the technology transfer process that leads from inventions in the lab to products on the shelves. A recent independent study pegged the value of such technology transfer to the U.S. economy at up to $1.18 trillion since 1996 alone.

The majority of biotechnology companies are small businesses that have no products on the market, and thus their research and development activities are funded through massive amounts of private sector investment – on average, more than $2 billion per new biotech medicine – which must be sustained over many years, sometimes even decades. Without strong, predictable and enforceable patent protections, many investors will stop investing in

biotech innovation or limit such investment to only "low risk" products. This decline in investment will degrade our ability to provide solutions to the most pressing medical, agricultural, industrial and environmental challenges faced by our Nation today.

We look forward to working with this Committee towards developing a balanced legislative package that meets these requirements. We are optimistic that targeted solutions that address the practices of entities who unfairly enforce, or unfairly attack, patents can be achieved.

Introduction

Chairman Grassley, ranking member Mr. Leahy, members of the Judiciary Committee, thank you for inviting me today to testify on the subject of protecting small businesses and promoting innovation through further patent reform.

By way of personal introduction, I am Deputy General Counsel for Intellectual Property for the Biotechnology Industry Organization, a major trade association representing over 1,100 biotechnology companies, research institutions, technology incubators, and similar entities in the medical, agricultural, environmental and industrial biotechnology sectors. At BIO I advise the organization's board of directors and BIO's various policy departments on patent and other intellectual property-related matters. Prior to joining BIO in 2006, I was Chief Patent Counsel for MGI Pharma, Inc., in Bloomington, MN. I have 20 years of professional in-house experience in the biotechnology industry, having begun my career as a postdoctoral research fellow at Genentech, Inc. in South San Francisco in 1995, and subsequently worked as a research scientist at Guilford Pharmaceuticals Inc. in Baltimore. My research specialty was the biology of age-related degenerative brain disorders; in this role I participated in several drug development programs before becoming a patent lawyer in 2003. I hold an M.S. degree in biology from the University of Ulm in Germany; a Ph.D. in Neuroscience from the University of Lund, Sweden; and a J.D. degree from Georgetown University Law Center where I serve as adjunct professor of law.

Background

Very few sectors of the Nation's economy are as dependent on predictable, enforceable patent rights as is the biotechnology industry. Robust patents that cannot be easily circumvented, and that can be predictably enforced against infringers, enable biotechnology companies to secure the enormous financial resources needed to advance biotechnology products to the marketplace, and to engage in the partnering and technology transfer that is necessary to translate basic scientific discoveries into real-world solutions for disease, pollution, and hunger.

Research and development within the biotechnology industry comes at a very high cost, and every idea that is funded comes with a much greater risk of failure than success. Investment thus is predicated on an expected return in the form of patent-protected

products or services that ultimately reach the market. The typical BIO member company does not have a product on the market yet, nor a steady source of revenue, and spends tens of millions of dollars on R&D annually. The biotechnology industry as a whole is responsible for well more than 20 billion dollars of annual research investment, and provides employment to millions of individuals nationwide. Virtually all of this investment is through private funding.[1] Developing a single therapy requires an average investment ranging from $1.2 billion to over $2 billion, and the clinical testing period alone consumes more than 8 years on average.[2]

Such investments are not only expensive; they are risky. For every successful biopharmaceutical product, thousands of candidates are designed, screened, and rejected after significant investments have been made. The chances that a biopharmaceutical medicine will advance from the laboratory bench to the hospital bedside are approximately one in 5,000.[3] Only a small minority of candidate drugs even advance to human clinical trials, and most of those will never ultimately reach the market. For example, at the time human clinical testing begins, the odds that a biopharmaceutical compound will eventually receive FDA approval are less than one-third.[4]

Because such risks and costs cannot usually be borne by any one entity alone, biotech drug development depends heavily on licensing, partnering, and access to capital. Patents allow biotech inventions of great societal value to be passed or shared among parties best suited to unlock their potential at any given stage of development and commercialization – each contributing their part, each sharing the risk of failure, each increasing the odds that a product eventually reaches patients.

If these patents can be invalidated under overly broad criteria, or if the ability to enforce them becomes limited due to an exceedingly high bar to filing a lawsuit or excessive delays in prosecuting a case through the courts, third parties would be less likely to invest in or license the technology, and major sources of R&D funding would move elsewhere. The result – patients waiting for the next new cure or treatment will have to wait longer, or may not ever get it at all.

For these reasons, currently-pending patent litigation reform legislation is highly relevant to the biotech business model. A small or mid-sized biotech company that today decides to begin development of, for example, an Alzheimer's treatment must look a decade or more

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[1] Moving Research from the Bench to the Bedside: Hearings Before the Subcomm. on Health of the House Comm. on Energy and Commerce, 108th Cong., 1st Sess. 47 (2003) (testimony of Phylliss Gardner, M.D) (http://archives.energycommerce.house.gov/reparchives/108/Hearings/07102003hearing990/Gardner1579.htm) ("The biotechnology industry is the most research and development-intensive and capital-focused industry in the world," noting that 98 percent of research and development investment comes from the private sector).

[2] Joseph A. Di Masi and Henry G. Grabowski, The Cost of Biopharmaceutical R & D: Is Biotech Different? Manage. Decis. Econ. 28: 469-479, 2007)(hereafter: "Di Masi and Grabowski").

[3] Secretary of Health and Human Services Tommy G. Thompson, Remarks at the Milken Institute's Global Conference (Apr. 26, 2004), available at www.hhs.gov/news/speech/2004/040426.html

[4] Di Masi and Grabowski, 472-3.

into the future. Long-term financial commitments will be required; several hundred million dollars will need to be raised; and development partnerships will need to be secured in a situation where the cost of capital is high and the odds of ultimate success are small. Because investment-intensive businesses can tolerate only so much risk, even moderate additional uncertainty can cause business decisions to tip against developing a high-risk, but potentially highly-beneficial, product. This is not an academic consideration. Every biotech executive has stories to tell about promising experimental compounds that had very favorable medicinal properties, but were never developed because their patent protection was too uncertain. And scholars have documented this unfortunate fact. [5] The injection of additional systemic uncertainty by, for example, making the enforceability of patents against infringers more uncertain can negatively affect which new cures and treatments may become available a decade from now.

The average American today can realistically hope to live into her or his 8th decade. At retirement, one out of five Americans can expect to develop Alzheimer's disease during her or his remaining years. The risk of developing cancer is even greater. While much has been said about inefficiencies in the patent system that drive up business costs and prices for consumers in some sectors today, we must keep in mind that that same patent system encourages risk-taking and long-term investment in potential solutions for the biggest problems facing our world and the generations to come: disease, hunger, and pollution. Great care must be taken to ensure that we do not focus too heavily on current complaints about abuses in the patent system without appreciating the system's longer-term benefits to society.

In this regard, it is important that, despite strident rhetoric, we do not overlook a 2013 nonpartisan Government Accountability Office (GAO) report[6] that found that patent assertion entities – the so-called "patent trolls" – bring less than 20 percent of patent litigation cases, while traditional businesses bring 68 percent of patent litigation. Any solutions proposed by this Congress must not impede the vast majority of patent owners from trying to enforce their legitimate patents in a legitimate way.

It also is important for Congress to recognize and consider that our patent system is undergoing a period of great change as a result of recent decisions of the courts and the Judicial Conference, the ongoing implementation of major patent legislation enacted only a few years ago, and new challenges posed by emerging technologies. In the barely 16 months since the U.S. House of Representatives voted on the 2013 Innovation Act (H.R. 3309, 113th Congress; passed December 5, 2013), the courts and the PTO have changed the patent litigation landscape in ways that should be carefully taken into account by this Committee. Form pleadings for patent infringement suits will be abolished, thereby heightening and conforming pleading requirements in patent cases to other civil litigation. Discovery in patent litigation will follow a proportionality standard that makes discovery more focused and affordable for both parties, and which will allow the costs of discovery to

[5] Benjamin Roin, Unpatentable Drugs and the Standards of Patentability. Texas Law Review, Vol. 87, pp. 503-570, 2009.

[6] Government Accountability Office report 13-465, August 2013, *Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality.*

be shifted to the party seeking it in certain instances. Supreme Court decisions on patent-eligible subject matter and claim definiteness have raised the standard for assessing the validity of patent claims, especially software and business method claims, and have made it easier to invalidate indefinite and/or overbroad patents. Attorney fee awards are allowed more frequently and flexibly in patent cases in the wake of Supreme Court and Federal Circuit decisions, raising the stakes for those who file frivolous or baseless patent suits. Deceptive practices in sending patent demand letters to small businesses are being targeted by the Federal Trade Commission (FTC), state Attorneys General (AGs), and dozens of recently-enacted state laws that clarify consumer protections against phony patent threats.

As a result of these and other developments, the number of patent cases filed has fallen significantly. For example, in comparing the number of new patent complaints filed in September 2013 versus September 2014, the number of new patent infringement complaints decreased by a remarkable 40 percent.[7] 2014 as a whole was down 18% from the previous year, and this decrease so far seems to hold steady.[8]

In parallel, it has become clear that the PTO's Inter Partes Review (IPR) system of administrative patent challenges is having a game-changing effect on the patent litigation system. Patents that are involved in district court litigation are now routinely subjected to "second rail" administrative litigation in the PTO, where they are being invalidated at rates so high that the basic procedural fairness of these proceedings is increasingly being questioned.

It is critical that the future path of our patent system is one that preserves and maintains the incentives for innovation that have made the United States the global leader in medical, agricultural, industrial and environmental biotechnology. With this in mind, I would like to provide the following views on legislation currently under consideration.

Discussion of Legislative Proposals Currently under Consideration

At the outset, BIO's member companies reiterate their support for targeted reforms that curtail abusive practices within the patent system, without undermining the ability of patent owners to fairly defend their businesses against patent infringement. We believe it is appropriate for Congress to explore how it can help improve aspects of the patent litigation system, and during the last Congress, BIO and its members invested an enormous amount of effort towards crafting good faith, constructive proposals in this regard, including with the Members and staff of this Committee.

Based on that experience, we believe consensus can be achieved on a range of proposals that were and are being advanced in Congress, including enhancing transparency of patent ownership and enforcement; curtailing unfair or deceptive practices in the indiscriminate sending of patent licensing or settlement demand letters; and addressing the enforcement of patents against blameless end-users or consumers of infringing products manufactured and sold by others. Such provisions would seem to address the most stridently-voiced

[7] https://lexmachina.com/2014/10/september-2014-new-patent-case-filings-40-september-2013/

[8] https://lexmachina.com/2015/02/patent-case-trends-business-litigation/

concerns in the current debate, and would be appropriately focused on the need to protect small businesses, end-users, and others who do not have the resources or the means to defend themselves from unfair or misdirected patent enforcement efforts by dubious patent assertion entities.

To this end, BIO believes that a number of productive proposals have been circulated that deserve this Committee's consideration. For example, the STRONG Patents Act, as recently introduced by Senators Coons, Durbin, and Hirono, contains patent demand letter provisions that should prove effective at protecting small businesses from abusive patent enforcement practices, while at the same time sustaining the ability of innovators to continue to send legitimate licensing and enforcement-related communications to those using their technologies. The "Targeting Rogue and Opaque Letters Act" (TROL Act), a consensus bill that was crafted by the House Energy and Commerce Committee during the last Congress with diverse stakeholder input, contained similar provisions that were likewise aimed at curbing abusive patent demand practices. As did S. 1720, which as introduced by Senators Leahy and Lee in the past Congress similarly would have brought the indiscriminate, widespread sending of bad-faith demand letters within the ambit of the FTC's enforcement authority. This bill also would have advanced transparency of patent enforcement in litigation by leveraging familiar "interested party" disclosure obligations that already are in use under certain local court rules, and would have provided for "customer stays" that would make it easier for willing manufacturers of allegedly infringing products to join infringement suits against resellers or end-users of their products,[9] thereby providing their customers with relief from litigation pressure.

In contrast to such targeted proposals, other proposals under consideration in the recent and current Congress include far-reaching patent litigation changes, such as:

- New requirements under which initial complaints in patent lawsuits would be required to set forth vastly increased amounts of detailed information or be deemed insufficient and subject to motions to dismiss;
- Mandatory stays of discovery pending patent claim construction, forcing delays of 12 or more months in the typical patent litigation;
- Mandatory stays of actions against a broadly defined class of "customers" that could allow product manufacturers to deflect patent lawsuits towards their suppliers; and
- New impleader authority under which additional parties with a financial interest in the plaintiff or patent at issue – such as investors, licensors, or commercial partners – could be joined to the litigation as unwilling co-plaintiffs to pay the other side's costs under a new "losers pay" approach.

These provisions represent stark departures from the normal civil litigation rules that apply to other commercial litigation under the U.S. system. Congress should consider carefully the

[9] Section 5 of H.R. 9, as recently introduced in the House of Representatives, likewise contains such a "customer suit" provision. Going forward, Congress should consider modifications to this provision to guard against opportunities for misuse and unintended consequences. As written, the provision could unexpectedly benefit accused infringers at every level of the manufacturing and distribution chain, contrary to its declared goal of protecting ends-users and retailers of infringing products. For example, in current form the provision would allow even manufacturers of infringing products to deflect infringement suits towards their parts suppliers, thereby inviting piecemeal adjudication and systematic litigation delays in conventional infringement cases having nothing to do with end users, retailers, or "patent trolls." Additional amendments should provide more clarity around the class of intended beneficiaries, the scope of the stay, and the circumstances under which a litigation stay would be inappropriate.

wisdom of singling out patent litigation for such an astonishing array of special rules found in no other area of civil litigation. Furthermore, in their current form these litigation reform provisions are one-sided (that is, similar requirements are not imposed on those accused of patent infringement), and will almost uniformly work against patentees of all stripes. In an effort to erect barriers against patent-asserting entities, or so-called "patent trolls," these provisions would systematically raise the cost and risk of patent enforcement for all patentees, with disproportionately greater negative impact on smaller, poorly-funded patent holders.

In this regard, it is important to emphasize that litigation reform, by its very nature, most benefits those who have the means and the will to litigate. In our opinion, large businesses with well-funded litigation budgets are most likely to leverage these litigation changes to their advantage. At the same time, it is questionable whether small businesses that need protection from unfair patent enforcement would be able to leverage sophisticated new litigation maneuvers – such as impleader practice and extensive preliminary motion practice – that would be enabled by the various pending litigation change proposals. Patent litigation is already known as a "game of kings" and surely the pending litigation reform proposals would make it even more so.

The risk of unintended negative consequences on small-business innovation can be illustrated by consideration of several specific pending legislative proposals:

Enhanced pleading requirements: H.R. 9 (the Innovation Act) would require that complaints, and counter- or cross-claims, for patent infringement include a number of new information items in order to qualify as legally sufficient. The level of required detail is high and would require plaintiffs to fill out a potentially very large matrix of information: each asserted patent; each claim for each patent; each accused product for each claim; for each accused product an explanation of how each element of each claim meets each feature of each accused product, and the like.

Nobody would disagree that the pleading requirements in patent cases should be enhanced to conform to the standards generally applicable in civil litigation, and BIO supports the proposed repeal of Form 18 in the Federal Rules. However, the proposed exhaustive pleading standard requires an amount of information and degree of specificity that go beyond what would be necessary to support a civil claimant's request for relief and to provide the defendant fair and reasonable notice of the infringement allegation. To legislate pleading requirements at such a high level of specificity invites litigation over the sufficiency of the patentee's efforts even in instances where all parties and the court would agree that there is "enough" for a lawsuit, and where the parties fully understand the factual basis for the infringement allegations. Instead of streamlining the litigation process, the proposed pleadings provision of the Innovation Act would enable accused infringers to litigate whether otherwise sufficient pleading-stage information was nevertheless incomplete; would fuel disputes over whether information was or was not readily accessible and whether the patentee tried hard enough to obtain it; and would empower well-funded defendants to engage in extensive motion practice and "churn" to prevent the litigation from advancing to even its preliminary stages.

The provisions also lack balance and reciprocity: responsive pleadings by alleged infringers often contain counterclaims and affirmative defenses (such as patent invalidity or unenforceability) that frequently fail to provide sufficient notice to the other party (the patentee) of the underlying factual bases for such assertions. But this practice by alleged infringers would not be addressed under the provisions of H.R. 9; only patentees are singled out for additional, burdensome requirements.

We trust that this Committee will understand that patentees do not always have access to the information needed to plead at the outset of a lawsuit, with the required specificity, how the accused infringer's conduct precisely infringes which element of which patent claim. This consideration is particularly relevant to biotechnology, where, for example, a competitor's sophisticated biomanufacturing process, or the use of precursor molecules or proprietary production cell lines, are simply not accessible to a patent owner without some discovery, even if there is good reason to believe that a patent is being infringed.

Accordingly, BIO's members do not believe that such high levels of additional pleading specificity offer a targeted solution that would protect small businesses from abusive patent assertion on the one hand, while at the same time enabling them to protect their own businesses against patent infringement on the other hand. To be sure, some additional information beyond what is currently required under Form 18 of the Federal Rules of Civil Procedure may be beneficial for inclusion in model complaints for patent infringement, so as to convey reasonably detailed information on which the infringement allegation is based. The level of detail should be adequate to allow parties and judges to decide whether there is a sufficient basis for a lawsuit. Indeed, if the complaint sets forth sufficiently detailed grounds explaining why and how at least one patent claim is believed to be infringed, then good grounds for a lawsuit exist. There is no need to additionally require the inclusion within the initial complaint itself of dozens of alternative grounds, or to litigate the sufficiency of such alternative grounds, when it is already clear that there is "enough" for a lawsuit to proceed. To require otherwise would impose an undue burden on the patent owner to plead all details of its case before any discovery has commenced. And doing so would significantly raise the cost and complexity of preparing a patent suit, particularly harming the ability of small businesses to enforce their patent rights, as well as those that need to protect their inventions against competitive threats in an immediate manner.

Instead of legislating this extreme heightened pleading proposal, it would be preferable to amend the law in ways that ensure that the judiciary would play a greater role, and assume more responsibility, for developing the applicable pleading standards in a balanced manner, as part of its traditional rulemaking function. Any final approach also would need to ensure that existing statutory schemes governing certain biopharmaceutical patent litigation are not covered by these new pleading rules, in order to avoid conflicts with the highly detailed nature of the statutory rules already in place for such litigation.

Fee Awards and "Interested Parties": Within the context of the currently-pending H.R. 9, and the Patent Abuse Reduction Act (S. 1013) from the last Congress, the concepts of "real party in interest," "loser pays," and "impleader" are all connected, and should be evaluated together. The cost award and recovery provisions of both bills constitute a true "loser pays" system: as a default, the non-prevailing party must pay the winner's

reasonable costs and expenses, and the burden will be on the loser to explain why it should not have to pay. Under H.R. 9, the non-prevailing party can meet this burden by a showing of special circumstances making an award unjust, or by showing that its position was "reasonably justified in law and in fact." Among its proponents there is an assumption that this standard will be easy to meet, and that fee and cost awards will therefore occur only in truly frivolous cases. In the same vein, it has been said that this standard is not unprecedented – it is the same standard that has been in place since 1980 in the Federal Equal Access to Justice Act (FEAJA).

Despite such assurances, there is reason to wonder whether cost and fee awards would not occur more often than expected if this standard were transposed to patent litigation.[10] At a minimum, its predicted operation is unclear: unlike many other tort cases, patent cases often do not have clear winners and losers; each party may prevail on some issues and lose on others,[11] such that little can be predicted at this time about how fee awards would be assessed under such a system.

To be clear, BIO's members hold a diversity of views on the advisability of including fee-shifting provisions, such as those of H.R. 9, in any further patent legislation, and therefore BIO does not support or oppose any particular fee-shifting proposal at this time.

Our members have pointed out, however, that proposed "loser pays" provisions currently use overly broad language in defining the classes of civil actions to which they would apply, and are in no way limited to patent infringement actions under title 35 or section 337 investigations in the International Trade Commission under title 19. For example, by their plain terms the provisions include claimants who neither enforce, attack, nor defend against patents – such as a disappointed patent applicant who appeals to a court from an adverse decision of the PTO, or an academic inventor who seeks an accounting of royalties from a non-profit university under the Bayh-Dole Act. Much litigation over the applicability of the provision could, and should, be avoided by narrower legislative language.

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[10] In practice, the FEAJA standard may be more often met than one might assume. The Veteran's Administration, for example, estimates that around 45% of all cases before the Court of Veteran's Appeals result in a FEAJA attorney fee and cost award against the Government. Social Security cases in which the claimant prevails result in awards over 40% of the time. The Supreme Court has noted that these are "hardly vanishing odds of success for an attorney deciding whether to take a client's case" (*Astrue v. Ratliff*, 130 S. Ct. 2521 (2010), at n. 2, Sotomayor, J., concurring). It also should be noted that the FEAJA's fee recovery provisions are only available to small entity, nonprofit, or non-wealthy individual claimants, whereas H.R. 9 and S.1013 would let all prevailing parties recover regardless of their wealth. Moreover, the FEAJA caps recoverable attorney fees at a default of $125/hour, whereas neither H.R. 9 nor S.1013 provide such caps – or any other protections – against runaway costs.

[11] To give a simple example: assume a patentee sues a competitor for patent infringement. The competitor alleges that the patent is (i) invalid, (ii) unenforceable, and (iii) not infringed. The court rules *against* the competitor on the question of patent validity and enforceability, but agrees that the patent is not infringed. In this scenario, the competitor ultimately "prevailed" because it escaped liability, but did not "prevail" in its attempt at striking down the patent. Who reimburses whose litigation costs? Does the competitor reimburse the patentee for defending the patent? Or does the patentee pay the competitor for unsuccessfully attacking the patent? Or do both parties reimburse each other for portions of each other's cases?

In addition, under H.R. 9's fee-shifting provision, patentees (but not defendant-counterclaimants) would be penalized for extending a covenant not to sue after an answer has been filed in the lawsuit, by deeming such a patentee to be a non-prevailing party for purposes of recovering the defendant's attorney fees and costs. Doing so would create disincentives for the private resolution of patent litigation. There also are many legitimate reasons why either party to a patent infringement case may extend a covenant not to sue at some point in the litigation. It remains unclear why covenants not to sue should be disfavored in such a blanket fashion.

We also trust that this Committee is conscious of significant judicial developments in the fee-shifting area, which have taken place over the past year. Federal courts have long had the power to award attorney fees to prevailing parties in exceptional cases, although traditionally the showing required to make a case exceptional has been high, and fee shifting has been uncommon. The 2014 Supreme Court decisions in *Octane Fitness v. Icon* and *Highmark v. Allcare* now permit courts to grant such awards more readily, and provide that a court's fee-shifting decision is reviewed more deferentially on appeal. Preliminary indications are that these decisions may be having a real impact. A recently-published analysis[12] reports 43 published decisions on fee awards in the eight months following the Supreme Court decisions, of which 21 of them, or nearly half, granted a fee award. In contrast, in the eight months *before* the Supreme Court decisions, there were 31 such decisions and only six of them granted fee awards, or less than 20 percent.

The fee-shifting provisions of H.R. 9 also are relevant to the provisions regarding disclosure and joinder of "interested parties." Under the bill, an interested party would be defined as anyone who has an ownership interest in the patent, or is an exclusive licensee, has enforcement rights, or who has a direct financial interest in the outcome of the litigation, including a right to receive royalties based on the patent or part of a damages award. Under H.R. 9, such "interested parties" must be disclosed in patent litigation, and can be impleaded into the lawsuit and held liable for the winning party's costs, expenses and attorney fees if a fee award is granted.

There is nothing remarkable about the proposition that litigants should identify to the court those who have a financial interest in the litigation or the litigated assets. Under many local court rules, judges require such information today, as they need to know when to recuse themselves from a case, or to take other action to avoid conflicts of interest. But there is a real question whether the pending "real party in interest" provisions go too far in requiring disclosure of any financial interest, including for example, extensive disclosures of patent ownership transfers between subsidiaries having the same corporate parent, and extensive disclosures of third parties having "financial interests" (including passive financial interests) and *their* corporate parents. This level of disclosure would significantly increase the burden of compliance and create traps for unwary legitimate patent holders without providing substantially more useful information in many cases. And, such requirements become

[12] Synopsis is available at: http://www.insidecounsel.com/2015/02/25/fee-shifting-before-and-after-the-supreme-court-de

particularly problematic when they are being leveraged to join third parties into the lawsuit as unwilling plaintiffs, or to subject them to liability for litigation conduct that is beyond their control.

To this end, H.R. 9 would provide new impleader authority under which the court "shall" grant a defendant's motion to join "interested" third parties as plaintiffs. These impleader provisions are closely linked to the bill's litigation cost-shifting provisions, and are intended to ensure that somebody will be responsible for paying the winning party's litigation expenses if the losing party cannot or will not pay. Only winning defendants would have an opportunity for 3rd party reimbursement, as there are no comparable provisions under which winning patentees can join potential payors on the defendant's side.

Section 3(c) of H.R. 9 is not the first time impleader practice in patent cases that is being discussed. During the last Congress, H.R. 3309 and S. 1013 contained similar provisions for joining third parties as plaintiffs to ongoing infringement litigation. To inform the Committee's deliberations on the matter, it is useful to highlight some differences between the impleader provisions of these bills: S. 1013 would have provided that the defending party could at any time join an interested party by showing that the plaintiff's interest in "any patent identified in the complaint, including a claim asserted in the complaint, is limited primarily to asserting any such patent claim in litigation." While this definition was intended to capture only "patent troll" lawsuits, BIO was concerned that it could easily apply also to conventional litigation between brick-and-mortar businesses.[13]

The business ramifications of joining unwilling "interested" third parties as co-plaintiffs on the patentee's side of a lawsuit would be significant. As described above, S. 1013 would have defined an interested party as anyone who has an ownership interest in the asserted patent, is an assignee, or an exclusive licensee, or who has a direct financial interest in the outcome of the litigation, including the right to receive proceeds from the litigation. Under this definition, university licensors or business partners who sublicensed the patent to the plaintiff could be impleaded into the litigation at the infringer's option, and face potential liability for the defendant's litigation costs. While university-licensors today often appear as co-plaintiffs in patent cases *pro forma*, the prospect of potentially having to pay part or all of the infringer's defense costs is an entirely new proposition for academic institutions. This

[13] For example, if a complaint were to assert 20 claims in three patents, and the defendant makes the requisite showing with respect to only one of these claims, the whole litigation would become subject to the impleader provision. In other words: defendants would have as many opportunities to invoke the impleader provision as there are asserted claims. This would be the case even if the remaining claims in the litigation involve patent-infringing products that compete with the patentee's own products. We note that the heightened pleading requirements of S. 1013 (as do those of currently-pending H.R. 9) would require patentees to assert greater numbers of patent claims than is required under current law, thereby increasing a defendant's chances to implead additional parties. Moreover, it is not uncommon, especially among start-up businesses, to hold patents on "unfunded" technology. For example, a company may start out with two in-licensed portfolios of patents, and proceed with R&D work on one of them while seeking funding to begin development of the other. If a patent on such unfunded technology is infringed, even a brick-and-mortar research company that sees its chances for future funding evaporate if it does not defend itself against ongoing infringement could be deemed indistinguishable from a patent-assertion-entity under the definition in S. 1013.

is especially problematic when the university-licensor, as is common, does not actually have control over the litigation.

Because they would face potential liability for the patentee's litigation decisions, impleaded university-patent owners or corporate licensors likely would have to hire their own legal teams to participate in the litigation, complicating and raising the costs of patent litigation for all parties. Existing and future licensing agreements would need to be restructured to insulate licensors or business partners from potential liability in these circumstances, or to provide for indemnification. The more risk-averse parties to patent licensing agreements would want to retain enforcement rights or the right to veto patent enforcement decisions and litigation strategies – or worse, may decide against entering into these transactions at all.

The process by which "loser pays" awards can be recovered from third parties under H.R. 9 differs from that described above for S. 1013. First, under section 4 of H.R. 9, the plaintiff must disclose the identity of "interested parties" at the inception of the litigation. Then, the defendant can provide these interested parties notice that they could be impleaded and that the defendant's litigation expenses could be recovered from them if the court confirms that they are an interested party. The third-party recipient of such a notice then has the option to renounce, within 30 days, any and all ownership, right, or direct financial interest in the patent – or otherwise face the risk of being joined to the action at the end to pay the winner's bills. Later, if the plaintiff loses and is subjected to a "loser pays" award that it cannot satisfy, the prevailing defendant can make a showing that the plaintiff had "no substantial interest in the subject matter at issue other than asserting such patent claim in litigation." If this showing is met, the court "shall" grant a motion to implead the third party that was earlier notified. The award can then be made recoverable against the impleaded interested party.

The impleader provision of H.R. 9 is byzantine, and problematic for several reasons. A third party would be identified at the beginning of a lawsuit with no input from that party, and would receive a notice of potential liability with an invitation to renounce all interest in the patent at that time or else face such potential liability. Later, after the plaintiff loses the case, the third party could be impleaded "after the fact" and made responsible for meeting unsatisfied "loser pays" awards that are premised on litigation conduct over which that third party may have had no control. The required showing of "no substantial interest in the subject matter at issue other than asserting such patent claim in litigation" is not readily intelligible and (just like the parallel definition in S. 1013 in the last Congress) does not clearly limit the provision to litigation that was brought by patent assertion entities, but could capture R&D businesses that have to enforce patents they were not yet able to develop or commercialize.

On the patentee's side, the net result of such joinder provisions would be to create many additional encumbrances especially for smaller R&D businesses, that would make partnering and collaborations, as well as the enforcement of patents, needlessly more expensive and more complicated. Given their potential negative impact on the businesses of legitimate

patent-owning innovators, the rationale for creating such new impleader provisions for "interested parties" deserves further debate.

Proponents have described these provisions as safeguards that would only very rarely come into play, under truly egregious circumstances when deliberately under-capitalized paper entities bring frivolous litigation in the knowledge that they would be "judgment proof" against a litigation cost award. And yet, under H.R. 9 for example, a broad class of business partners, licensors, or other affiliates of *any* patent plaintiff would be exposed to preemptive threats of liability in the form of menacing legal notices informing them that they could be joined to a lawsuit over which they may have no control, be subjected to fee awards over which they have no control either, and inviting them to renounce all interest in the patent (and effectively dissolve their business relationship with the plaintiff). And under the process that was proposed in S. 1013, such unwilling "interested parties" would be impleaded *before* it is even known that the patentee lost the case, before it is known that the patentee acted unreasonably and without justification, and before it is known that the patentee cannot or will not reimburse the defendant's litigation costs. But not all patentees lose, not all act unreasonably, and not all are penniless. In such ways, the proposed impleader provisions would not just systematically interfere with the business relationships of patentees of all stripes, but also lead to a great deal of legal conflict over who should be in a patent case at its inception when, after all is said and done, it likely will not have been necessary to do so.[14]

In our view, the joinder provisions under consideration present a great departure from normal civil litigation under the American system, and have the potential for significant negative business impact on investment-intensive innovation, especially for smaller companies and non-profit and academic innovators. The joinder/impleader provisions should, at a minimum, be changed to limit the class of "interested parties" that could be brought into the lawsuit as unwilling co-plaintiffs. Business partners, patent owners, financing companies, and others who engage only in arm's length business with the patentee should not be subjected to potential liability or forced to renounce all of their rights in a patent just to avoid being dragged into litigation between two other parties. On the other hand, with proper safeguards it may be fair to permit impleader of entities that directly benefit from and have the right to control the patentee's litigation conduct. In particular, courts should be encouraged to look to well-established bodies of law that permit vicarious liability or corporate veil-piercing to identify patent enforcers who operate through

[14] If, on the other hand, the reason for impleading "interested parties" is to address "privateering" – a practice whereby large companies reportedly license or assign their patents to other entities that then assert these patents as a proxy for the large company – it is unclear what the impleader provision would accomplish in such instances. For example, it has been said that large companies assert patents through proxies in this way to insulate themselves from counterclaims – but if good grounds for a meritorious counterclaim exist, it should almost certainly be possible to sue such a company separately. At any rate, under U.S. corporate law, it is perfectly common and permissible to establish corporate affiliates for the purpose of isolating assets or liabilities, and that holds true for IP assets as well. There also is a well-developed body of law that allows veil-piercing, not just to establish liability but also to collect debts and unpaid awards, and U.S. courts have not shied away from allowing recovery against corporate parents or affiliates that sought to hide behind paper entities. We are not convinced that opening the doors to new, relatively unselective impleader authority would accomplish anything that cannot already, under existing law, be done more selectively and with less collateral damage.

undercapitalized paper entities, rather than creating broad and vague new categories of potentially impleaded parties.

Deferral of discovery: H.R. 9, as did bills in the past Congress, contains provisions that would require courts to defer discovery in patent cases except as necessary to judicially construe the meaning and scope of the asserted patent claims. In effect, these provisions would routinely defer merits discovery in virtually all patent cases until after the court issues a claim construction order. While there undoubtedly are cases in which such discovery deferrals are appropriate, doing so as a general rule would effectively bifurcate discovery on the merits in most cases and tend to prolong patent litigation by 12 months, if not longer, across the board. Such delays would accrue even in routine patent litigation that does not involve meritless claims, small businesses defendants, or "patent trolls."

In BIO's view, these proposals are too rigid and interfere unduly with the responsibility and authority of district courts to manage patent litigation in a case-specific manner. In instances where there is ongoing infringement, these provisions would perpetuate uncertainty for patentees whose market share continues to erode, as well as for accused infringers whose potential damages continue to accrue. Settlement negotiations would be hampered by delays in developing a sufficient factual record. The development of other potentially case-dispositive issues would be put on hold, and opportunities for early resolution of the litigation on other grounds would be lost. Interlocutory appeals from claim construction orders would become more common, which would contribute to further piecemeal adjudication and delay. In such ways, legislation that is intended to make patent litigation more streamlined and less costly likely would end up achieving the exact opposite result.

To be sure, the discovery stay provision of H.R. 9 does permit limited flexibilities – for additional discovery "as necessary" to ensure timely resolution of certain litigation that is required by existing federal laws to proceed under defined statutory timelines, or as necessary "to resolve a motion properly raised" prior to claim construction, or to prevent "manifest injustice." But these exceptions do not alter the fact that patent litigation in the overwhelming majority of patent cases would incur significant across-the-board delays and increased expense for all parties. Even in cases where these very limited flexibilities can be invoked, it is clear that litigants would *not* be entitled to discovery as under current practice. Instead, the burden would be on the requesting party to show why its discovery request is necessary and how its rights would be affected if the discovery request were not granted, all of which would be subject to dispute and counterarguments by the opposing party.

If the goal is to address a subset of cases – litigation brought by patent-assertion entities – it is unclear why Congress would insist on such across-the-board rigidity. The majority of patent litigation manifestly does not involve "patent trolls," and while it may be difficult to define "troll" cases *affirmatively* in statutory language, it is not too difficult to identify whole classes of cases that have nothing to do with "patent trolling." H.R. 9 takes one half-step in this direction: as introduced, H.R. 9 provides that its limitation on discovery would not apply to "an action seeking a preliminary injunction to redress harm arising from any allegedly infringing instrumentality that competes with a product sold or offered for sale, or a process used by a party alleging infringement." Providing such a categorical exemption for cases

between manufacturing marketplace competitors is entirely reasonable. It is perplexing, however, that this exemption should be limited only to preliminary injunction cases. Preliminary injunctions are uncommon in cases between manufacturing competitors, and it is not understood how the goal of limiting discovery in patent-assertion-entity cases would in any way be advanced by interfering with patent litigation between marketplace competitors. If there is a reasonable basis for objecting to a general competitive harm exception for cases between practicing patent owners, it has not been articulated.

In the same vein – and of particular relevance to biotechnology companies – patent litigation under the Hatch-Waxman (HWA) or the Biologics Price Competition and Innovation Acts (BPCIA) likewise manifestly does not involve patent-assertion entities. These statutes spell out in detail the identity of the parties, the products that are the subject of the litigation, and the timelines under which the litigation must commence and proceed. Not only is there no question that the parties to this special kind of patent litigation are each involved in the real-life commercialization of valuable therapeutic products, but there is also a real risk that the currently-pending general patent litigation reforms could interfere with the detailed litigation schemes previously established by Congress under the HWA and BPCIA. Patentees under the HWA and BPCIA have very little leeway as to who they can sue, when they can sue, and the timelines under which the litigation must go forward. It would be simply inconsistent with these statutory litigation schemes to now inject systematic discovery stays into these cases, to require the parties to such litigation to make burdensome showings why any given discovery request is necessary under the circumstances of their case, and to narrowly tailor permissible discovery accordingly. Notably, parties to such litigation may not be able to take advantage of a broad competitive harm exemption such as the one discussed above, because under the unique provisions of the HWA and the BPCIA, patent litigation is intended to begin before the allegedly infringing product enters the marketplace. Accordingly, for reasons that are at least as strong as those supporting a general competitive harm exception between actively marketing competitors, a clear exemption for patent litigation under the HWA and BPCIA should also be included in any discovery stay provision.

It also must be understood that not all patent litigation in biotechnology will fall into the above categories. The vast majority of U.S. biotechnology businesses are far from having a product on the market, yet depend critically on the enforceability of their patents to attract funding, to enter into development partnerships, and to advance their technology. A solution must be found for such businesses as well, businesses that are actively trying to develop, and seeking investment to further develop, patent-protected inventions. Any bill that would equate such quintessentially American entrepreneurial companies with patent trolls would be highly objectionable.

To be clear, BIO's members agree that there should not be unfocused discovery during the early phases of patent litigation. Focusing on the *Markman* hearing as the point on which early evidence development should hinge is a reasonable approach, but it is not the only way to address the matter. For example, claim interpretation is not an issue in every

patent case,[15] yet every patent case should have focused, rational early development of evidence and legal positions.

Further, our members consistently tell us that a reliable, high-quality judicial claim interpretation is always informed by a range of legal and factual contentions, and backed up by evidence that must have been developed in the case at the time of the claim construction hearing. But it is all but impossible to *prospectively* limit discovery only to what is necessary for claim construction – as H.R. 9 would require – because neither party can predict at the outset the full range of facts and contentions that will turn out to be important for construing the claims. Further, in our experience, it is critically important that a judge construing disputed claims understands how the technology at issue actually works and how it compares to the prior art. And both parties need to understand the other party's legal positions, and the evidence that backs them up, in order to agree which claim terms need to be construed and to put forward a proposed claim construction.[16]

Accordingly, BIO believes that any legislation on discovery in patent cases should explicitly permit the development of a reasonable amount of evidence on both sides, to give the case the contours needed to identify and prioritize the questions that need to be resolved first, be it claim construction or other issues. To this end, it would be beneficial to survey the local patent rules that have been adopted in many United States District Courts, and to explore whether the principles of these rules could be applied to craft a nationally uniform pathway for developing evidence and contentions during the early stages of patent litigation in cases requiring claim construction. Under such a nationally uniform framework, the parties' contentions and supporting documentation, and discovery relating thereto, would form a "default" body of information that would need to be developed initially in patent cases. In this context, we also support the Judicial Conference's recent discovery-related initiative, which would require judges to generally grant discovery only in proportion to the needs of any particular case; and this general proposition would apply in all stages of patent cases as it should in other civil litigation. Such recommended standards, to be developed in conjunction with and implemented by the courts, would go a long way to addressing Congress's concern about discovery abuses by the few, without causing systemic harm to the large majority of legitimate participants in the patent litigation system.

[15] For example if the defendant claims that he actually co-owns the patent, or that he is licensed, or that his infringing product is protected by prior user rights, or that the patent is unenforceable due to laches -- for such defenses it ordinarily won't matter very much how the patent claim is interpreted. On the other hand, if anticipation or obviousness is an issue, or infringement is disputed, claim interpretation often matters very much.

[16] For example, if the defendant contends that the patent is invalid in light of prior art, and for lack of enablement – this is something the patentee needs to know with specificity prior to claim construction. Which prior art, and how does it supposedly fall into the claim? And what within the supposed scope of the claim is not enabled? Likewise, if the patent holder alleges, for example, that the accused product infringes the patent under the doctrine of equivalents, then the defendant needs to know which elements of its product are supposed to be covered literally by the claim and which ones are substantial equivalents and why. If such information isn't sufficiently developed and backed up by evidence, neither party could put forward a proposed claim construction.

Reform of the PTO Patent Challenge System:

The PTO's Post Grant Review (PGR) and Inter Partes Review (IPR) processes, as established by the America Invents Act (AIA), were designed to provide a quicker, cost-effective alternative to litigation. More than 2,500 petitions for such AIA proceedings have been received by the PTO since these proceedings became available in September 2012. The overwhelming majority (up to 80% by some accounts) involve patents that are in concurrent district court litigation, showing that these proceedings are being used in conjunction with, rather than as an alternative to, litigation. This creates a great risk of duplicative proceedings and inconsistent outcomes, as alleged infringers seek to gain advantages or leverage over patent owners that would not exist under district court litigation alone. For example, the way claims are interpreted, the burden of proof, and other procedural protections are less favorable to patent owners in the PTO administrative setting.

In addition, third parties with no commercial interest in the patent or field to which the patent pertains have figured out that they can extort settlements or otherwise gain financially from bringing, or even threatening to bring, patent challenges against critical patents owned or licensed by biotech companies. Biotech companies can be particularly vulnerable to such extortion because – in contrast to most high-tech companies – biotech companies often rely on just a handful of highly valuable patents to protect their products and massive investment therein. This already is being seen by several biotech companies, who have been approached by third parties threatening to file IPRs unless the company makes a substantial payment to them. And a hedge fund manager recently made news by announcing his plans to "short" the stocks of more than a dozen biotech companies and then file IPRs against their most valuable product patents in an attempt to drive down their stock prices. The first such IPR petition, filed by this hedge fund in February against Acorda Therapeutics (a mid-size biotech company which brought to market an innovative treatment for multiple sclerosis) caused the value of the company to drop by over $150 million in one afternoon. A second IPR has now been filed against this same company, and other hedge funds are starting to get into the IPR business as well.

Such abuses of the PTO administrative review system are attractive and growing because, as is quite clear to anyone following the evidence to date, the rules governing these proceedings are unfairly stacked against patent owners in many ways. To address one of the problems with this system, H.R. 9 includes an important provision that would specify that patent claims in AIA proceedings are to be construed as they were or would be in district court, according to their ordinary and customary meaning as understood by one skilled in the art (under a *Phillips v. AWH standard*) – rather than the PTO's current "broadest reasonable construction" standard, which is more likely to result in invalidation of patent claims. This statutory change would harmonize the claim construction standards in PTO litigation with those in district court litigation, thereby increasing predictability and avoiding inconsistencies and wasteful litigation.

An IPR petition filed against BIO member company Allergan on March 9 illustrates that the difference in claim construction standards is not just an academic consideration. In this

petition, a recently-formed self-described privately-held investment venture is challenging a patent claim that had previously been litigated and upheld by both the U.S. District Court and the U.S. Court of Appeals for the Federal Circuit. The challenger candidly repeats the legal arguments that had been unsuccessfully made by prior litigants in the Article III courts, but argues that the broader claim construction standard in IPR proceedings should lead to a different outcome. In effect, the petition seeks to leverage the difference in claim construction standards to reverse the results of over four years of litigation in two Article III courts.

In light of such developments, BIO's members have firmly concluded that the harmonization of legal claim interpretation standards between district courts and the PTO is a necessary and common-sense reform that should be part of any final patent reform bill. However, any patent reform bill must go further and provide patent owners with greater procedural protections in IPR as well. First, the PTO has made it effectively impossible for patent owners to amend their claims in AIA proceedings, even though the AIA expressly grants the patent owner this right (as of November 2014, with over 2,300 such proceedings requested and close to 200 completed, the PTO had virtually never approved a claim amendment). Such a rigid approach to the granting of claim amendments undermines the purpose of the proceeding, which is to help improve patent quality and provide freedom to innovate by ensuring that patent claims are not overly broad. Instead, AIA proceedings have become a forum in which patent claims that could be sustained if properly amended are equally thrown out with the unsustainable ones, which contributes to the high "kill" rates that are driving the abusive behaviors described above. Congress should clarify its intent regarding narrowing claim amendments in AIA proceedings, so that they are more liberally allowed by the PTO, within reason.

Second, Congress should include other procedural protections to ensure that patent owners receive adequate due process, including –

- Developing rules for dealing with AIA proceedings that are brought for illegitimate reasons. Most patent challengers who file petitions for AIA proceedings seem to do so to obtain freedom-to-operate, or because they are already involved in an ongoing legal or business dispute involving the challenged patent. But as discussed above there is emerging evidence that AIA proceedings also are being brought or threatened by entities that have no interest in the challenged patent other than to extract a settlement payment or unrelated concessions from the patent owner – or to profit from the declining stock value of companies subject to these challenges. Such "reverse trolling" practices were clearly not intended by the AIA, and they deserve Congress's remedial action.

- Allowing patent owners to submit declarations of scientific experts in order to inform the PTO's decision whether or not to institute an AIA proceeding. Currently, only the patent challenger has this right, making it more likely that review proceedings will be initiated.

- Assigning different administrative panels to (i) the "institution phase" and (ii) the "merits phase" of the AIA proceeding. Currently, before instituting the proceeding, the administrative panel first decides whether there is a "reasonable likelihood" that the challenger will prevail in its challenge (or, in the case of a PGR, whether the patent is "more likely than not" invalid). The administrative panel thus becomes, at a very early point, invested in its finding that there is something seriously wrong with the challenged patent. This affects all subsequent stages of the proceeding, stacks the decks against the patent owner, and is contrary to basic notions of procedural fairness. It also appears quite clearly contrary to what Congress had intended in the AIA's language.

- Imposing a duty of candor not just on the patent owner, but also on the patent challenger. Currently, patent challengers are under no obligation to disclose information that is favorable to patentability of the challenged claims, but patent owners are under an obligation to disclose all information that is unfavorable to patentability.

- Permitting appeals from IPR and PGR decisions to not only the Court of Appeals for the Federal Circuit (as currently allowed), but also to U.S. District Courts where appropriate. Appeals to district courts have long been an important right in administrative trials in the PTO. This form of appeal helps to ensure proper due process and fairness for patentees in situations in which there is a need for the introduction of evidence that is not available or realistically obtainable during IPR or PGR.

Clarification of Liability for "Divided Infringement" of Process or Method Patents :

Incredibly, under current patent law principles, an infringer who arranges for the steps of a patented method to be practiced by different actors escapes all liability because no "single entity" practiced the entire patented method. This legal loophole has existed since 2007, when the U.S. Court of Appeals for the Federal Circuit established a strict rule according to which a process patent cannot be infringed by multiple parties together unless these parties are vicariously liable for each other's actions (e.g., they must be in a master-servant, employer-employee, agent-principal, or legally equivalent contractual relationship). Patent infringers were quick to take advantage of this strict rule, for example by agreeing to infringe the patent through their concerted actions while structuring their legal relationship with each other as an "arms-length" transaction in which neither party has the formal right to direct or control the other, thereby avoiding all liability for patent infringement.

In its July 7, 2014 decision in *Limelight Networks, Inc. v. Akamai Technologies, Inc.,* the Supreme Court (i) rejected the Federal Circuit's subsequent attempt to close this loophole, and (ii) declined to craft an alternative rule that would bring greater clarity to this area of the law. As a result, there is now great uncertainty about the enforceability of process and method patents. Every industrial process that has more than one step is capable of being divided up between multiple actors, and the current state of the law essentially provides a

roadmap for patent circumvention whereby there would be no liability at all for, by way of example, a patent infringer who himself practices all but the final step of a patented process and then induces another actor to practice the final step.[17]

In its brief to the Supreme Court in the *Limelight* case, the U.S. Government identified these and other concerns with the law on divided infringement and explained the need for a Congressional (not judicial) solution. This serious anomaly in patent law urgently needs to be addressed, and Congress now has the opportunity to do so.

Proper Codification of "Double Patenting":

H.R. 9 would codify the judicially-created doctrine of "double patenting" for patents that are prosecuted under the AIA's new first-inventor-to-file standard for patentability. While we support these provisions, they do not go far enough. Legislative clarification of the "double patenting" doctrine also is needed for patents that were issued prior to the AIA's effective date.

Patent-eligible Subject Matter under Section 101:

Among BIO's members, no area of substantive patent has received more attention over the past several years than the topic of patent-eligible subject matter under section 101 of the Patent Act. The Supreme Court has weighed in on this subject four times in as many years, and patent practitioners are losing count of the numbers of patents that have been rejected by the PTO or struck down in the lower courts on this ground over the past year alone. While in terms of sheer numbers the impact on software-implemented inventions has been particularly harsh, the patentability of biotechnology inventions relating to products and processes derived from natural sources or materials also has been affected significantly by this ongoing judicial and administrative expansion of non-statutory patent law in the United States. BIO's members are greatly concerned by the significant departure from internationally-accepted norms of patentability that is increasingly manifesting itself in the courts and the PTO, particularly with regard to industrial, agricultural, and pharmaceutical preparations of naturally-derived substances, compositions, and processes.

Inventive preparations based on naturally-occurring substances have historically been of great importance in biotechnology, and innovation in this area has been spurred, at least in part, by the availability of patent protection. This is true for every sector of biotechnology. Examples include vaccine preparations, crop protection products, plant biotechnology and

[17] Those who benefit from this rigid rule have expressed great concern that Sec. 109 of the STRONG Patents Act, which would close this loophole, would create unfair patent infringement liability even in instances where "no one" practices the patent claim. Statements of this kind misrepresent both current law and the STRONG Act's legislative proposal. Patent law has always required that the patent claim, with all its elements and steps, must of course have been practiced, without authority, before there can be infringement liability, and this bedrock requirement would in no way be altered by the STRONG Patents Act. The STRONG Patents Act merely clarifies, in a narrowly targeted manner, that those who orchestrate the infringement of process claims by others do not escape any potential liability. The proposal does not change the demanding showing a plaintiff would otherwise have to make in order to establish indirect infringement, and it has BIO's full support.

breeding processes, industrial enzymes, immunosuppressive drugs, anticancer compounds, and antibiotic medicines. Such historically uncontroversial inventions are now increasingly being rejected in the PTO as unpatentable subject matter under an expanded extra-statutory exception for "natural phenomena," even if they are otherwise novel, unobvious, and useful inventions that, but for the intervention of man, would not have ever been known and put into useful forms to benefit humankind. By subjecting such inventions to an unstable patent-eligibility analysis that focuses on the "gist" of the invention instead of the specific scope of the patent claim itself, courts and the PTO are in the process of creating a deep disparity in substantive patent law whereby whole categories of socially beneficial inventions would face obstacles to patent protection in the United States but remain patentable among its major trading partners, with attendant harmful effects on the flow of investment, trade, and cross-border transfer of innovation.

BIO believes that the Congress should undertake a comprehensive review of Section 101 jurisprudence and PTO implementation to determine what needs to be done to ensure that the patentability of naturally-derived substances, compositions, and processes remains consistent with our nation's best interests.

Diversion of PTO User Fees: On the issue of PTO user fees, BIO's members are incredulous that, after more than a decade of sustained Congressional interest in improving the nation's patent system, resulting in landmark legislation in 2011 and now progressing towards another major bill, the PTO still has neither full funding nor access to all user fees it collects. We would urge Congress to fix this problem once and for all, and applaud Senators Coons, Durbin, and Hirono for including provisions to that effect in the STRONG Patents Act of 2015.

Conclusion:

I want to thank the Committee for the opportunity to testify today and explain a view of patent litigation reform from the perspective of small, innovative, investment-intensive biotech businesses. I urge the Members of this Committee and the full Senate to ensure that adopted reforms are truly targeted at abusive practices – both by patent owners and against patent owners – and do not have negative, unintended consequences for the vast majority of legitimate patent owners or licensees who simply are seeking to protect and enforce their patents in good faith. The long-term benefit to society of a strong and predictable patent system may hang in the balance.