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To the United States Senate Committee on the Judiciary

Committee Hearing on "Protecting Small Businesses and Promoting Innovation by Limiting Patent Troll Abuse"

December 17, 2013, 10:00 AM, Dirksen Senate Office Building, Room 226

Summary of Testimony

My long experience in biotechnology research and patenting, coupled with Alnylam's remarkable journey as a pioneer in this field, has taught me three essential truths relevant to today's hearing. First, the life sciences ecosystem of university research, technology transfer to the private sector, venture capital funding, and industry collaborations is a lengthy, expensive, and high-risk enterprise. Second, changes that create uncertainty regarding the strength and enforceability of patents undermine both the ecosystem and the job creation generated by thousands of companies such as ours. And, third, harming this sensitive ecosystem has real health care consequences – millions of patients suffering from life-threatening and debilitating diseases are counting on these partnerships to produce the next wave of cures and therapies for so many currently unmet medical needs.

So I am not here to defend or attack the abusive patent enforcement practices of so-called "patent trolls." Indeed, certain targeted reforms – such as those embodied in Chairman Leahy's recently introduced Patent Transparency and Improvement Act – likely will help small businesses such as Alnylam by protecting us against bad faith patent enforcement by others. But I am here today primarily because, in their well-intentioned efforts to curb such abuses, many other proponents of patent litigation reform are rushing ahead with sweeping ideas to remake the patent litigation system in fundamental and untested ways, without sufficient consideration of the impact of those changes on the vast majority of patent owners and licensees who engage in legitimate and good faith patent licensing and enforcement activities. This concern is especially acute for critically-important fields such as biotechnology, which is largely made up of small, investment-intensive businesses that are at the cutting-edge of innovation in America. Thus, our experience is highly relevant to the subject of today's hearing.

Proposals that would routinely and indiscriminately complicate, delay, and make more risky and expensive the efforts of all patent owners or licensees to protect and enforce their patents would do serious harm to the life sciences ecosystem in particular. In this regard, I commend to the Committee's consideration the excellent summary of views on patent litigation reform submitted by our partners in academia, who conduct the basic research and discovery that fuel the biotechnology enterprise, as well as the views of our partners in the venture capital community, without whom those inventions would never be developed into beneficial and often life-saving products for millions of our families, friends, and neighbors. We are united in our desire to support targeted reforms that will protect all of us

from unscrupulous patent assertion activities that serve only to raise the cost of doing business, and thus the cost of our products to consumers. But we also are united in the firm belief that, if we do not go about such reforms in the right way that protects patent holders, the long-term costs to the entire innovation ecosystem and overall American job creation will be far greater than any short-term benefits that might be derived by one or two sectors of our economy.

I commend Chairman Leahy for beginning this process with this hearing to give Senators a variety of stakeholder perspectives. I urge the Committee and the full Senate to proceed thoughtfully and deliberately in this complex area, and to focus on those reforms that would clearly target abusive behavior without undermining the ability of small, investment-intensive businesses to be able to protect and enforce their key assets – their patents – in a timely and efficient manner. The Chairman's America Invents Act of 2011 is a model for a balanced approach that ultimately benefitted the vast majority of patent stakeholders and enhanced the most innovative economy in the world.

Introduction

Chairman Leahy, Ranking Member Grassley, 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 vice president for intellectual property for Alnylam Pharmaceuticals in Boston MA. I am a registered patent attorney and have over 18 years of experience in the biotechnology field, beginning my career as a bench scientist at Millennium Pharmaceuticals. For the past 14 years, I have been part of the intellectual property department of companies ranging from a small privately held start-up company to a large multinational biotechnology company with sales in excess of $5 billion annually, starting as a technology specialist up through my current position. While I speak today on behalf of Alnylam, my views are informed by the shared corporate experience of many colleagues in the biotechnology industry from companies both large and small. Alnylam is not unique in its views on the importance of intellectual property to the biotech business model, but my company has been recognized as a compelling example of how intellectual property can be used to fund R&D efforts and accelerate drug development.[1]

Alnylam is an innovator company developing, protecting, and actively practicing its intellectual property. So I speak today not on behalf of patent monetization entities or on behalf of those who have been the target of their patent enforcement efforts, but to discuss the collateral impact of pending legislation on *investment-intensive* innovation, especially in the life sciences sector. It is critical that legislation addressing patent litigation balance the need to preserve the strength and enforceability of patents to foster innovation with protection from unfair patent enforcement practices.

Background

[1] Shih, Willy C., and Sen Chai. "Alnylam Pharmaceuticals: Building Value from the IP Estate". Harvard Business School Case 611-009, September 2010. (Revised July 2013)

Alnylam was founded in 2002 to develop human therapeutics based on the Nobel Prize-winning discovery termed RNA interference or RNAi, first published in 1998 by Andrew Fire and Craig Mello based on their work in the nematode worm. RNAi is a biological process in which double stranded RNA (dsRNA) inhibits gene expression. The implications of this discovery, if it existed in the human, had the potential to transform drug development as it meant that one could design a dsRNA to inhibit in a specific manner any gene. The founding scientists of Alnylam extended the original work of Fire and Mello and showed that RNAi did indeed exist in mammals. They then designed synthetic dsRNA molecules and showed how these had drug-like properties and the potential to be used as human therapeutics. One benefit of this technology over traditional small molecule drugs or other biologics is the ability to target any gene in the body, and thus design therapeutics for diseases that are not treatable by previously existing technology. To protect the invention of this entirely new class of potential drugs, the Alnylam scientists filed patent applications and founded the company with the goal to further develop this remarkable invention into commercial products to benefit patients. Very early on, Alnylam's management sought to identify and license any available intellectual property, as well as to continue filing patents on inventions made at Alnylam to establish a leadership position on RNAi therapeutics and intellectual property. This strategy proved successful in that Alnylam was able to leverage this leadership position in forming major alliances with leading companies including Merck, Medtronic, Novartis, Biogen Idec, Roche, Takeda, Kyowa Hakko Kirin, Cubist, Ascletis, Monsanto, Genzyme, and The Medicines Company. The revenue obtained from licensing the intellectual property and know-how developed at Alnylam was used to fund the company's research and development efforts and accelerate our efforts to bring RNAi therapeutics to patients in need. A mere four years after its founding and only six years after RNAi was discovered in the worm, Alnylam conducted its first clinical trial in healthy volunteers. Its second clinical trial began in 2009 with a dsRNA designed to target two key genes in the pathway of liver cancer, and was conducted in volunteers with advanced liver cancer. Multiple individuals achieved stable disease and one had a complete response.

Currently, a little more than a decade after the company's founding, Alnylam has conducted nine clinical trials with 11 programs in clinical development, with the most advanced, an investigational candidate called patisiran for the treatment of associated fatal neurologic amyloidosis, in a pivotal Phase III clinical trial. The Phase I results for patisiran have been published in the New England Journal of Medicine.[2] In addition, Alnylam has active research programs in, among other areas, hemophilia, cardiac disease, complement-mediated diseases, and liver cancers. To enable development and protect this clinical pipeline, the patent department manages a portfolio of over 1800 active patent applications, with over 700 granted patents world-wide.

This remarkable achievement by Alnylam was enabled by our ability to raise large amounts of private capital to carry on research and conduct clinical trials. 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

[2] Coelho *et al., N Engl J Med* 2013;369:819-29

reach the market. Alnylam does not have a product on the market yet, nor a steady source of revenue, and continues to spend 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.[3] Developing a single therapy requires an average investment of $1.2 billion, and the clinical testing period alone consumes more than 8 years on average.[4]

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.[5] Only a small minority of 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.[6]

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.

Alnylam is an example of a company that has benefitted from having valid and enforceable patents and has used these patents in a responsible, ethical, and strategic manner to accelerate the development of RNAi therapeutics for patients in need. If these patents can be invalidated under overly broad criteria, or if the ability to enforce them becomes limited due to an incredibly 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 a major source of Alnylam's R&D funding would dry up. 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 cure must look a decade or more into

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[3] 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).

[4] 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").

[5] 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

[6] Di Masi and Grabowski, 472-3

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. In this way, 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 we do not overlook a recent nonpartisan Government Accountability Office (GAO) report[7] that found that patent assertion entities bring less than 20 percent of patent litigation cases while operating companies 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. With this in mind, I would like to provide the following views on specific legislation currently under consideration.

Discussion of Legislative Provisions Currently under Consideration

As the title of this hearing indicates, the most stridently-voiced concerns in the current round of patent reform involve 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 patent assertion entities, or "trolls." Alnylam believes that the Patent Transparency and Improvement Act (S. 1720), introduced by Chairman Leahy, contains multiple, targeted provisions that would effectively advance the goal of protecting small businesses from abusive patent enforcement practices, while at the same time sustaining the ability of innovators to rely on their patents for long-term business and investment decisions. Specifically, S. 1720 would

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

- bring the indiscriminate, widespread sending of bad-faith demand letters within the ambit of the Federal Trade Commission's enforcement authority if it qualifies as an unfair or deceptive trade practice;
- advance transparency of patent enforcement in litigation by leveraging familiar "interested party" disclosure obligations that are already in use under certain local court rules;
- provide 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, thereby providing their customers with relief from litigation pressure.

While modifications to these provisions will be needed to guard against opportunities for misuse and unintended consequences,[8] S. 1720 represents a targeted patent enforcement reform package that, in comparison with other bills, is most likely to offer specific relief to small businesses that have been unfairly targeted by patent assertion entities, and that presents much less risk for systemic negative impact on innovative businesses in capital-intensive R&D areas such as biotechnology.

In contrast to the targeted proposals of S. 1720, other pending bills propose a wide range of more far-reaching general litigation reforms, such as

- mandatory stays of discovery pending patent claim construction;
- new impleader authority under which additional parties could be joined to the litigation as unwilling co-plaintiffs;
- cost and fee award provisions under which "loser pays" awards could be recovered against third parties;
- new requirements under which complaints in patent cases would have to set forth vastly increased amounts of detailed information;
- "requester pays" proposals providing for upfront payment of the costs of electronic discovery to the producing party;
- provisions for singling out patents on software-implemented technologies for particularly unfavorable treatment by subjecting them to harsh administrative invalidation proceedings in the PTO; and
- authority to require plaintiffs to post litigation bonds at the inception of district court litigation.

Many of these provisions represent stark departures from the normal civil litigation rules that apply to other commercial litigation under the U.S. system. While this Committee would do well to consider carefully the wisdom of singling out patent litigation for such an astonishing array of special rules found in no other area of civil litigation, it would be even

[8] For example, the "customer stay" provision of S. 1720 currently appears drafted to 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. As written, it 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. S. 1720's "demand letter" provisions likewise need minor amendments to ensure that legitimate licensing communications remain protected, and to guard against non-uniformity and interference with the statutory scheme due to state enforcement efforts.

more important to consider their impact on the intended beneficiaries of these reform proposals. Litigation reform, by its very nature, most benefits those who have the means and the will to litigate. In my opinion, large businesses with well-funded litigation budgets are most likely to leverage these litigation reform provisions to their advantage. At the same time, it is questionable whether small businesses that need protection from patent troll abuse would benefit from sophisticated new litigation maneuvers – such as impleader practice and extensive early motion practice – that would be enabled by the various pending litigation reform proposals. Patent litigation is already known as a "game of kings" and surely the pending litigation reform proposals would make it even more so. Further, in their current form these litigation reform provisions will almost uniformly work against patentees of all stripes. In an effort to erect barriers against patent-asserting entities, 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 who must defend their businesses against patent infringement.

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

Enhanced pleading requirements: H.R. 3309, and to an even greater extent S. 1013, would require that complaints, and counter- or cross-claims, for patent infringement include a number of new information items to be considered 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 claim element of each claim meets each feature of each accused product, and the like. For each allegation of indirect infringement, a description of the direct infringement, the identity of known direct infringers, and a description of the acts constituting indirect infringement would need to be provided. In addition, a number of other information items such as licensing rights, licensing obligations, the identity of co-owners, assignees, and exclusive licensees, and other parties with a financial interest in the matter, would need to be disclosed. Both bills would direct the Supreme Court to amend Form 18, used for filing infringement complaints, accordingly.

Few stakeholders would disagree that the pleading requirements in patent cases should be enhanced to conform with the standards generally applicable in civil litigation. However, the now-proposed amount of information and the specificity with which it would need to be pleaded go far beyond what is necessary to support a patentee's claim 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 the parties fully understand the factual basis for the infringement allegations. Instead of streamlining the litigation process, the proposed provisions of S. 1013 and H.R. 3309 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 that likewise can fail to provide sufficient notice to the other party (the patentee) of any underlying factual allegations. But this practice by alleged infringers would not be addressed under the provisions of H.R. 3309 or S. 1013; only patentees are singled out for additional, burdensome requirements.

This Committee should be mindful that patentees do not always have access to the information needed to plead at the outset, with the required specificity, how the accused infringer's conduct precisely infringes 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, I 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 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 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 undue burden on the patent owner to plead all details of its case before any discovery has commenced.

It would be preferable to amend the pending "enhanced pleading" provisions 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 rules, in order to avoid conflicts with the highly detailed nature of the statutory rules already in place for such litigation.

"Interested parties": S. 1013 and H.R. 3309 contain similar definitions for "interested parties" that cover 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 or part of a damages award. Such "interested parties" can be impleaded into the lawsuit and held liable for the winning party's costs, expenses and attorney fees.

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 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.

Within the context of both H.R. 3309 and S. 1013, the concepts of "real party in interest," "loser pays," and "impleader" are all connected, and should be appraised together. The cost award and recovery provisions of both bills constitute a true "loser pays" system: as a default, the nonprevailing 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. The nonprevailing party can meet this burden by a showing of special circumstances making an award unjust, or by showing that its position was "objectively reasonable and substantially justified."[9] 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.

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 very 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 it may be very unpredictable how fee awards would be assessed under such a system.

The proposed "loser pays" provisions also use strikingly 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 describe claimants who neither enforce, attack, nor defend against patents – such as a disappointed patent applicant who obtains judicial relief against the U.S. Patent and Trademark Office

[9] The applicable, similar standard in H.R. 3309 is: "reasonably justified in law and fact."

[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 EAJA's fee recovery provisions are only available to small entity, nonprofit, or non-wealthy individual claimants, whereas H.R. 3309 and S.1013 would let all prevailing parties recover regardless of their wealth. Moreover, the EAJA caps recoverable attorney fees at a default of $125/hour, whereas neither H.R. 3309 nor S.1013 provide such caps - or other protection - 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?

(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.

In addition, under H.R. 3309's 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.

Impleader of interested parties: As currently drafted, both H.R. 3309 and S. 1013 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 bills' 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. Both bills seem to be targeted at ensuring that only winning defendants will be reimbursed, as there are no comparable provisions under which winning patentees can join potential payors on the defendant's side.

The procedures for joining third parties as plaintiffs to the litigation differ between the two bills. S. 1013 provides that the defending party can 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 is intended to capture only "patent troll" lawsuits, it could easily apply to conventional litigation between brick-and-mortar businesses:

- For example, if a complaint asserts 20 claims in three patents, and the defendant makes the requisite showing with respect to one of these claims, the litigation would become subject to the impleader provision. 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. 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.

The business and litigation ramifications of joining unwilling "interested" third parties as co-plaintiffs on the patentee's side of the lawsuit are significant. As described above, S. 1013 defines 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 have 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 is especially problematic when the university-licensor, as is common, does not actually have control over the litigation.

Because they would now 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 will 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 net result would be that, on the plaintiff's side, S. 1013's joinder provision would create many additional encumbrances for legitimate small innovators that would make partnering and collaborations, as well as the enforcement of patents, more expensive and more complicated. Defendants, on the other hand, would have opportunities for ancillary joinder litigation before the case can proceed to the merits. Such delays would be compounded if S. 1013's impleader provision for interested parties were stacked with the "covered manufacturer" stay provision in S. 1720, thus providing defendants multiple opportunities to engage in front-end litigation about who should be in the lawsuit before the lawsuit can even get underway.

Given their potential negative impact on the businesses of legitimate patent-owning innovators, the justifications for creating such new impleader provisions for "interested parties" deserves to be questioned. If these provisions are being proposed to ensure that someone will be responsible for reimbursing the winner's litigation costs, this Committee should keep in mind that S. 1013 would allow unwilling "interested parties" to be impleaded before it is 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. Not all patentees lose, not all act unreasonably, and not all are penniless. S. 1013 would create a great deal of litigation 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.[12]

[12] 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

Impleader and cost recovery from "interested parties" under H.R. 3309: The process by which "loser pays" awards can be recovered from third parties under H.R. 3309 differs from that described above for S. 1013. First, under section 4 of H.R. 3309, 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. 3309 is both byzantine and problematic. 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. 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 the 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 unintelligible and, like the parallel definition in S. 1013, 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. Like the provision in S. 1013, the impleader provision of H.R. 3309 could make arm's-length business partners of the patentee, such as university licensors, venture capital investors, and other entities liable for fee awards *even if they have no control over the litigation*, thereby injecting uncertainty and complication into the legitimate licensing and partnering activities of research and development-intensive companies that must defend their businesses against patent infringement. In this regard, I would direct the Committee to the excellent summary of concerns raised by various university associations about several of these related provisions.[13]

In short, the fee-shifting and joinder provisions of H.R. 3309 and S. 1013 present a great departure from normal civil litigation under the American system, with the potential for

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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.

[13] Statement from the Higher Education Community on S. 1720, the "Patent Transparency and Improvements Act of 2013", on behalf of the Association of American Universities, Association of Public and Land-grant Universities, American Council on Education, Association of University Technology Managers, Association of American Medical Colleges, and the Council on Governmental Relations; dated 12/11/2013; available at: http://www.acenet.edu/news-room/Documents/Statement-Senate-Judiciary-S1720.pdf

significant negative business impact on investment-intensive innovation especially for smaller companies and non-profit and academic innovators. If Congress wishes to go forward with a "loser pays" system for patent litigation, such a system must incorporate safeguards against runaway awards and provisions that offer at least some predictability of a litigant's potential liability. Courts also should have clear authority to offset "loser pays" awards under circumstances where the prevailing party engaged in dilatory litigation conduct or otherwise unreasonably "ran up the bills." The joinder/impleader provisions should likewise, 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 benefit from and have the right to control the patentee's litigation conduct. 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 undercapitalized paper entities, rather than creating broad and vague new categories of potentially impleaded parties.

Bonding: Another pending bill, S. 1612, would offer an alternative to the above-described impleader provisions that is problematic in its own way: S. 1612 would establish a "loser pays" system similar to those discussed above, but would add a bonding provision under which a court would be authorized, on motion by a defendant, to order the patentee to post a bond sufficient to ensure payment of the accused infringer's reasonable litigation costs.

From a small-business perspective, financial inequality between litigants is a significant concern under such a system. Bonds are costly and accrue interest during the time they are kept on a company's books over potentially several years of litigation. Bonds are easily available to well-funded litigants, but for a small company to borrow or set aside potentially several million dollars to cover an accused infringer's prospective litigation expenses could be so burdensome that unfavorable settlements or non-enforcement of its patent rights could become the only practical option.

Perplexingly, S. 1612's factors for ordering the posting of a bond do not require any consideration of the likelihood that a litigation fee award will actually be imposed against the plaintiff.[14] Thus, motions for posting burdensome litigation bonds are likely to be brought at

[14] The factors to be considered are:

(1) whether the bond will burden the ability of the party alleging infringement to pursue activities unrelated to the assertion, acquisition, litigation, or licensing of any patent;

(2) whether the party alleging infringement is--

(A) an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a))); or

(B) a non-profit technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more institutions of higher education;

(3) whether a licensee, who has an exclusive right under a patent held by an institution of higher education or a non-profit organization described in paragraph (2), conducts further research on or development of the subject matter to make the subject matter more licensable;

(4) whether the party alleging infringement is a named inventor of or an original assignee to an asserted patent;

the inception of a litigation, before there is a factual record in the case or any indication that the plaintiff's allegations are unjustified. Because only patentees would be subject to bonding under S. 1612, defendants would be free to make counterclaims regardless of their merit.

While a bonding approach could be preferable to the alternative impleader provisions discussed above, this Committee should give substantial thought as to whether existing mechanisms for piercing corporate veils and other "sham" corporate structures are sufficient to achieve this same purpose without engendering the types of inequalities and negative impacts on small-business innovation that such new approaches could bring. At a minimum, any further consideration of bonding proposals must consider any potential interference of such a requirement with the plaintiff's business operations. Small, innovative businesses should not be put to the choice of suspending their ongoing R&D efforts or enforcing their patent rights against ongoing infringement. An obligation to post a litigation bond in the amount of several million dollars can easily mean deferring the advancement of a promising drug candidate through preclinical development or disbanding a team of scientists.

Deferral of discovery: Both S. 1013 and H.R. 3309 contain 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 9-12 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 my opinion, 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 could end up achieving the opposite result.

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(5) whether the party alleging infringement makes or sells a product related to the subject matter described in an asserted patent;
(6) whether the party alleging infringement can demonstrate that it has and will have the ability to pay the accused infringer's fees and other expenses if ordered to do so; and
(7) whether any party will agree to pay the accused infringer's shifted fees and other expenses, provided that the person or entity can demonstrate that it has and will have the ability to pay the accused infringer's shifted fees and other expenses.

To be sure, both H.R. 3309 and S. 1013 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 provisions do not detract from the overall result: 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. In other words: there are no true exceptions – all patent cases would be subject to deferred discovery, no litigant seeking additional discovery would be exempt from having to make a burdensome showing, and any additional discovery would be granted only to the extent it was shown to be necessary for a small number of permissible purposes.

If the goal is to rein in a subset of cases – abusive litigation 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." For example, as passed by the House, H.R. 3309 was amended to provide that the 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 a step in the right direction. 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 (PAE) 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 broad 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 broad competitive harm exception between actively marketing competitors, a clear exemption for patent litigation under the HWA and BPCIA should also be included.

Going beyond the question of statutory exemptions from the pending discovery stay provisions, it must be understood that not all patent litigation in biotechnology will fall into the above categories. The vast majority of American 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.

In my opinion, innovative small businesses would be best served by dedicating the question of discovery stays to the judiciary, which is in the best position to further develop its case-management practices to prevent discovery abuses in cases where they occur. At a minimum, judges should be given much more discretion as to when additional discovery should be permitted. For example, the Judicial Conference could be asked to develop discovery management standards for cases falling outside the above described statutory exemptions, under which additional discovery should be granted for good cause shown. Such recommended standards, to be developed 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.

Changes to the America Invents Act:

Covered Business Method Patent Review Expansion: The 2011 Leahy-Smith America Invents Act (AIA) provides that certain business method patents can be challenged administratively in an enhanced post-grant review proceeding in the PTO. This "CBM" proceeding was designed as a transitional program, with an eight-year sunset. This was done with the expectation that non-technological patents on financial services could be subjected to enhanced review during a sufficiently-long eight-year window, after which they could be challenged only in the normal inter partes review (IPR) or post-grant review (PGR) proceedings that apply to all patents. S. 866 would significantly expand the scope of this two-year old proceeding by broadening the class of reviewable patents to a wide range of methods used in the management of an enterprise and to the software that implements them, and would make this expanded review proceeding permanent by eliminating the sunset.

I am troubled by the proposed expansion of the scope and length of this special type of proceeding barely two years after it was first created by Congress. The class of patents that

could be subjected to this harsh administrative review proceeding appears broad and could be construed to encompass many, if not most, software-implemented processes. Many biotechnology companies in the medical, pharmaceutical, and agricultural spaces do have proprietary software for a wide range of processes, including drug design, inventory tracking, and product distribution, or for providing value-added services that help their customers use their products more effectively. Some such software may be patented, so it is possible that biotechnology companies could be affected by the proposed provision.

More importantly, I believe that singling out patents on certain classes of technology for particularly unfavorable treatment undermines the basic principle in U.S. and international law that patent rules must be technologically neutral and non-discriminatory. Internationally, the United States has always advocated for robust and technology-neutral patent rules, and the proposed provision undermines U.S. credibility in international fora and in negotiations with our trading partners. The biotechnology industry – a field the United States has created and led – is acutely aware that policymakers in a number of countries would like nothing more than to subject patents on medical and agricultural biotechnological products to selective, unfavorable rules under their own patent laws. In my opinion, the provisions of S. 866 that would greatly expand and make permanent this system for review of business method patents would set an alarming precedent of technology-discrimination that will sooner or later come back to haunt other industries, including biotechnology.

PTO Claim Construction Standard in Administrative Patent Review Proceedings: Both S. 1720 and H.R. 3309 include an important provision that would specify, in statute, that patent claims in PGR and IPR 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). I believe this provision is necessary to ensure that patent claims are not unjustifiably invalidated under a misguidedly broad administrative standard that is currently being used by the PTO. This statutory fix should be part of any final patent reform bill.

The AIA's IPR and PGR provisions were designed to provide a quicker, cost-effective alternative to litigation. More than 500 IPR proceedings have been received by the PTO since September 2012. However, the overwhelming majority (up to 80% by some accounts) involve patents that are in concurrent district court litigation. This creates a great risk of duplicative litigation and inconsistent outcomes. Accordingly, it is important that challenged patent claims are interpreted the same way in both litigation fora. Like other legal instruments (such as contracts or wills or statutes), the language of patents must often be construed to establish their precise scope and applicability in a legal dispute. Depending on how patent claims are interpreted, a patent case can be won or lost.

In administrative IPR and PGR litigation, the PTO now uses the "broadest reasonable claim construction." District courts, on the other hand, use the "most" reasonable claim construction, i.e., unlike the PTO, courts take into account the examination record of the patent, and earlier statements of the patentee and the patent examiner about the scope of the claims, as well as evidence about how scientists or engineers in the field would have

understood the language of the patent claims and other evidence. As a result, district courts often give patent claims a narrower, more particularized meaning than the PTO.

These dual standards in concurrent litigation work against the patentee in two ways: by giving patent claims their broadest reasonable meaning, the PTO makes it harder for patentees to defend the validity of their claims in IPR or PGR because, as interpreted, the claims are more likely to impermissibly capture preexisting technology (i.e., the broader they are interpreted, the more likely they would be deemed obvious or anticipated). And by giving the same patent claims a narrower meaning, district courts make it harder for the patentee to show that its patent claims actually cover the infringing product.

By harmonizing the claim construction standards in PTO litigation with those in district court litigation, both parties will gain predictability, and avoid inconsistencies and wasteful litigation. Challengers who would no longer be able to take advantage of two different standards would be encouraged to choose one or the other forum (instead of litigating in both), while patentees would be required to prove infringement in district court under the same standard that would apply to the potential invalidation of their patent claim in the PTO. This is a common sense reform that Congress should adopt.

Repeal of 35 U.S.C. 145: As reported by the House Judiciary Committee, H.R. 3309 included a provision that would have repealed Section 145 of the Patent Act. This provision was struck from the bill by amendment on the House floor – so, as passed, the Innovation Act no longer provides for repeal of 35 USC 145. In my opinion, the provision was rightly eliminated from the bill and should not be resurrected by the Senate, at least not in the same form.

Currently, final adverse decisions of the PTO in patent examination can be appealed either to the U.S. Court of Appeals for the Federal Circuit (under 35 USC 146), or to U.S. district court under section 145. This right has existed in U.S. patent law for a long time. Today, patent applicants rarely use section 145 appeals. I myself have never used it on behalf of my employers, and I am aware of only a few colleagues in my industry who have. I believe that there are relatively few situations where such appeals would be necessary, such as, for example, in instances where certain testimonial evidence must be elicited in order to establish an applicant's entitlement to a patent. Accordingly, Section 145 should not be repealed outright: when such appeals are needed they are important because appeals to the Federal Circuit are not a viable alternative.

On the other hand, I understand that such appeals are a significant burden on the PTO's small litigation team. Also, it is not clear that all section 145 appeals are brought truly because the patent applicant has no other alternative and needs to pursue an appeal in district court to establish his entitlement to a patent. Given the disproportionate burden on the PTO to try such cases compared to the perhaps rare instances when such appeals are really necessary, I wonder if middle ground could be found whereby such appeals would continue to be available to those applicants who truly need them, while some constraints might be introduced for applicants who merely use them as one of several options.

Miscellaneous provisions: H.R. 3309 and S. 1720 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. I believe this provision to be both beneficial and uncontroversial, and would support its inclusion in any final bill.

On the other hand, H.R. 3309 contains a provision that would change the way patent term adjustment for prosecution delays in the USPTO would be calculated. This particular issue is currently under judicial review, such that legislation on the matter would seem premature.

Finally, I would like to express my disappointment that after nearly eight years 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. I would urge Congress to fix this problem once and for all.

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 a small, innovative, investment-intensive company like Alnylam. I urge the Members of this Committee and the full Senate to tread more carefully than your counterparts in the House of Representatives, to ensure that adopted reforms are truly targeted at abusive practices 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.