Senator David Perdue
Questions for the Record to Hans Sauer, Biotechnology Industry Organization
"The Impact of Abusive Patent Litigation Practices on the American Economy"
March 25, 2015

Washington, D.C., April 10, 2015

Dear Senator Perdue,

Thank you for your thoughtful questions and for the opportunity to elaborate further on certain aspects of my testimony before the Senate Judiciary Committee of March 18, 2015.

Question 1: A number of organizations representing the pharmaceutical industry and higher education have claimed that recent decisions by the Supreme Court and changes proposed by the Judicial Conference have fundamentally altered the playing field such that Congress should take a hard second look at provisions of the Innovation Act and the I-Squared Act to determine whether they are actually necessary before proceeding with legislation. Is it your view that decisions like Octane, Nautilus, and Alice have eliminated the need for any Congressional action? If not, what specific problems have those cases solved in your view, and what do we still need to address?

In my opinion, case law developments, judicial initiatives, and administrative actions have indeed greatly changed the patent litigation landscape in the two years since the House of Representatives first presented legislative proposals for reforming the way patents are enforced and litigated. The most recent numbers indicate that new patent case filings in 2014 dropped by 21% compared to 2013. Today, no more parties are being sued for infringement than was the case in 2009-20010. Meanwhile, the Supreme Court's *Alice* decision has resulted in an 8-10-fold increase in the numbers of patents that are invalidated for unpatentable subject matter under Section 101 of the Patent Act, often on motions to dismiss on the pleadings, or on summary judgment. It seems that this new theory of invalidity bites particularly hard in cases involving patents for software-implemented business methods and other processes for managing e-commerce transactions. The Supreme Court's decision in *Akamai* and the Federal Circuit's *Commil* decision have become powerful legal devices by which accused indirect infringers can insulate themselves from infringement liability while shifting their risk to blameless downstream users or consumers of their technology. And by every account, it has become significantly easier to obtain attorney fee awards in patent cases after the Supreme Court's fee shifting opinions, although awards of such fees in patent cases still continue to be uncommon, and are (rightly) not granted as a matter of course.

Overall, there is wide agreement in the biotech community that doctrinal developments in patent law over the past several years have clearly trended towards more and stronger protections for accused infringers. As a result, while jurisprudence in many areas of patent law is unsettled and in flux, the current picture does not support the notion of a deepening patent litigation crisis, or of a Judiciary that is helpless in the face of frivolous patent assertion.

This is not to say that biotechnology companies believe that recent caselaw developments have "fixed" all problems and eliminated the need for Congressional guidance. Congress is rightly concerned about abusive practices (such as patent enforcement against blameless end-users for purchasing and using an infringing product, or the indiscriminate sending of mass demand letters to small businesses, or the use of administrative patent challenge proceedings for stock manipulation). Rather, these caselaw developments reinforce the need to ensure that any patent reform legislative package does not swing the pendulum too far in any one direction.

<u>Question 2:</u> The fee-shifting provision of the Equal Access to Justice Act has been law since 1980 and has generated little controversy in the intervening three decades. The Innovation Act contains an identical prevailing-party standard for fee shifting. And, like the Equal Access to Justice Act, the standard in the Innovation Act only creates a presumption. It does not bind a district judge or restrict the judge's ability to exercise discretion on a case-by-case basis. Please explain your view of the Innovation Act's fee-shifting provisions and, more generally, whether any fee-shifting provision is a desirable component of a legislative reform package.

First, it is important to clarify that the cost award and recovery provisions of the Innovation Act 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 shouldn't have to pay. This default would distinguish patent litigation from other civil litigation in the American system, where ordinarily each party pays its own litigation expenses, and where the burden is on the prevailing party to explain why it should be reimbursed by the non-prevailing party.

Under the Innovation Act, the presumptively liable non-prevailing party can meet its burden by a showing of special circumstances making an award unjust, or by showing that its position was 'reasonably justified in law and 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, as you note in your question, 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, under which it has operated for decades.

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. In practice, the FEAJA standard is 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 concurring). In fairness, high numbers of fee awards in sympathetic cases such as successful veteran's, social security, or immigration appeals do not mean that patent cases, decided under the nominally same legal standard, would necessarily result in equally frequent fee awards to prevailing parties. But in the same vein, practical experience under FEAJA does not suggest that fee awards under H.R. 9's standard would be a rare occurrence.

It should also be noted that the FEAJA's fee recovery provisions were designed to compensate for the inequality of resources between small claimants on the one hand, and the federal government on the other, thereby serving primarily as a tool to promote access to justice – not to punish either party for their litigation conduct or as a special deterrent against certain claims (awards to punish or deter misconduct remain available through other means, such as Rule 11 sanctions). Seen this way, it is not an easy exercise to transpose FEAJA standards which are meant to *facilitate* litigation into the context of the Innovation Act, which is meant to deter litigation. For example, consistent with its goal to "level the playing field" between unequal litigants, FEAJA requires prevailing claimants to fall below certain "net worth" thresholds in order to be eligible for an award, and disqualifies wealthy, well-resourced litigants from fee recovery even if they prevail against unreasonable and unjustified government litigation. The Innovation Act, in distinction, would let all prevailing parties recover, even if the prevailing party had vastly more litigation resources than then non-prevailing party. Moreover, the FEAJA guards against the possibility of certain undesirable dynamics, such as runaway spending by claimants who seek to prevail 'at all cost' (and then be reimbursed), by capping recoverable attorney fees at a default of $125/hour, subject to certain adjustments which require special justification. The Innovation Act currently only provides that fee awards must be "reasonable," but otherwise lacks FEAJA's controls over unpredictable liability and runaway reimbursable costs.

At a minimum, the predicted operation of the Innovation Act is quite 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, such that it may be very unpredictable how fee awards would be assessed under such a system. Assume, for example, that 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 attorney fees? Does the prevailing 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?

To be clear, biotech companies are no strangers to fee shifting. Many have litigated in the patent courts of the major trading partners of the United States, which have sophisticated patent litigation systems where some form of "loser pays" is the norm. These systems, such as those in England, Germany or Canada, also provide a relatively high degree of predictability of a litigant's potential liability in the event of a loss, through various combinations of official attorney fee schedules, court-appointed assessors, the

availability of claim or litigation insurance in some instances, as well as special hearings or conferences before judges or specialized court officials that prospectively determine the kinds of litigation expenses that would be reasonable relative to the value and complexity of the case. Such mechanisms to provide more prospective business certainty would eventually need to be developed in the United States as well, if Congress chooses to implement a fee shifting regime for patent cases.

On a theoretical level at least, biotech businesses are well aware of arguments that fee shifting to non-prevailing parties is likely to encourage meritorious litigation over non-meritorious litigation, is likely to affect the settlement value of cases, and is likely to affect the litigation decisions of smaller litigants more than those of wealthier litigants. But whether or not any of the promises or pitfalls of fee-shifting in patent cases would ultimately materialize is impossible to predict from reviewing Section 3 of the Innovation Act alone. BIO's members hold diverse views on the inclusion of a fee-shifting provision in future patent legislation, and BIO therefore does not advocate for or against any particular fee shifting proposal that is currently pending or circulating. Notably, discussions about fee shifting in the Senate Judiciary Committee during the last Congress appeared to be trending away from the default "loser pays" concept that is embodied in Section 3 of the Innovation Act. I believe this was a helpful development insofar as it offered the prospect of an alternative option for Congress's consideration of this difficult issue.

Question 3: *In your written testimony, you state that "[t]he 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." Please describe the provisions of the Innovation Act and the I-Squared Act that would inhibit the ability of these fledgling businesses to attract investment or develop new technologies.*

It is difficult to point at any single provision of the Innovation Act as the one that would most impact smaller biotech businesses, because the effect of its litigation reform provisions is cumulative and "stacked." On balance, we believe that the combined effect of the Innovation Act's litigation provisions would systematically raise the cost and risk of patent enforcement for biotech businesses, with a disproportionately larger effect on smaller companies. Pleading standards that go beyond those applicable in other civil litigation would not only make it harder to file a patent lawsuit (compared to e.g. a contract lawsuit) but are also likely to lead to more motion practice that prevents patent cases from getting underway on the merits, involving churn and delay. Stays of discovery pending claim construction are likely to lead to threshold litigation over the kinds of information that is or is not necessary for claim construction, could lead to claim constructions that are done on an insufficient record, and to unnecessary disputes over claim terms that wouldn't need to be construed if the parties had developed their case more fully. Meanwhile, merits discovery would be delayed in many patent cases even when there is ongoing competitive harm. Similarly, the Innovation Act's impleader provisions for interested parties would significantly impact the business relationships between the plaintiff and its

licensors, venture capital backers, and business partners, who would all face the risk of being joined to a lawsuit as unwilling co-plaintiffs under the threat of liability for attorney fee awards. The net effect of such provisions, from an investment perspective, is a perception that the patents that back up a fledgling company will be harder to enforce by its owners, and easier to infringe by its competitors. Yet, investors in such companies expect that their investment will be secured by patents, and will rationally reduce their investment if patent rights are weakened.

Question 4: Your written testimony states that "any legislation on discovery in patent cases should explicitly permit the development of a reasonable amount of evidence on both sides" and proposes the creation of a "nationally uniform pathway for developing evidence and contentions during the early stages of patent litigation in cases requiring claim construction." Please briefly describe what you envision as the optimal "uniform pathway" for early-stage discovery in patent litigation and what constitutes a "reasonable amount of evidence" within the context of the pathway you propose.

Biotech companies agree that there shouldn't be unfocused discovery during the early phases of patent litigation. One of the ideas that we have continued to come back to, in conversations with our member companies, is the concept that Congress could explore a nationally uniform model process for the focused, rational development of relevant information during the early phases of patent litigation. This process would involve a step-wise, comprehensive – but focused - exchange of information between the parties; it would be designed to give the case clear contours as early as possible, so as to allow the parties to identify and prioritize the issues that should be resolved next, whether it's claim construction or something else. Our members consistently tell us that a good, high-quality judicial claim interpretation is always informed by certain facts and legal positions that must have been developed in the case by that time. In other words, it is not possible to prospectively limit discovery only to what is necessary for claim construction - because neither party knows at the outset the full range of facts and contentions that will turn out to be important for construing the claims. It also helps tremendously if the judge 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 factual basis thereof, in order to agree which claim terms need to be construed, and to put forward a proposed claim construction.

In such a model process, both parties would be required to disclose to each other their legal contentions relating to infringement, invalidity, or absence of liability for infringement, together with supporting documentation. These party contentions and supporting documentation, and limited discovery relating thereto, would form a "default" body of information that would need to be developed initially, unless the judge decides otherwise or the parties agree otherwise.

In most cases, we believe such a process could be concluded within 6 months from the time the defendant first appears; the parties would then have enough information to negotiate a joint proposed claim construction, and identify claim terms that must be construed. This process would also often be helpful in getting cases in a posture for summary judgment soon after a claim construction order is issued.

We've also given some thought to discovery that may fall outside these default categories. Ordinarily, we would expect that most cases should initially be focused on the fundamental threshold issues (how is there infringement; what are the defendant's affirmative defenses). For this purpose, the judge or magistrate is going to take a close look at whether all discoverable information is equally necessary. For example, a plaintiff doesn't necessarily, in every case, need evidence of willfulness before he even knows whether he can prove infringement. The same may be true for damages discovery (unless, maybe, if it helps the plaintiff to decide whether to drop the case), or discovery relating to customers, licensees, or business partners of the defendant (unless it is relevant to establish liability for inducement or contributory infringement). Similarly, a defendant that defends on grounds of invalidity or non-infringement may not need discovery on inequitable conduct to do so. In any event there should be sufficient flexibility to account for instances where parties need additional discovery, for example if there is ongoing competitive harm or another reason for urgency that would make it fair and efficient to take additional discovery.

There may also be instances where a party seeking additional discovery would offer to pay the costs of production, or be ordered to do so. BIO would be open to conversations about how to keep the parties' appetite for discovery focused on the threshold issues (and how to give judges the tools to limit excess discovery requests to what is proportional to the needs of the case).

I want to thank you again for the opportunity to further elaborate on my testimony, and I hope these answers are helpful to you. If you or your staff have any additional questions, please do not hesitate to contact me.

Respectfully submitted,

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