Written Testimony Of
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To

United States Senate Committee on the Judiciary

On

"S. 1137, the 'PATENT ACT – Finding Effective Solutions to Address Abusive Patent Practices"

May 7, 2015

Chairman Grassley, Ranking Member Leahy and Distinguished Members of the Committee:

Thank you for the opportunity to appear on this panel and discuss "S. 1137, the 'PATENT ACT' – Finding Effective Solutions to Address Abusive Patent Practices." By way of introduction, I am Senior Vice President and Deputy General Counsel of Bristol-Myers Squibb Corporation (BMS), where I have served as the Chief Intellectual Property Counsel for the past 4 years. I am a registered patent attorney and have practiced intellectual property law and litigation since 1991, initially in private practice and then in-house for the past 16 years, first at Schering-Plough Corporation, where I also served as the Chief IP counsel, then at Johnson & Johnson, and now at BMS.

At BMS, I am responsible for all aspects of global intellectual property procurement, counseling, litigation, and policy. I am a member of the Boards of Directors of the Intellectual Property Owner's Association; the American Intellectual Property Law Association Education Foundation; and the Gibbons Institute of Law, Science and Technology at Seton Hall University School of Law. I am also a member of the steering committees of the Sedona Conference working group on patent litigation best practices, and the Coalition for 21st Century Patent Reform.

Although BMS and I are members of various other stakeholder groups, I am testifying today on behalf of BMS. The views that I share today reflect BMS and should not be taken as official views of any other organization or entity.

BMS is a global biopharmaceutical company firmly focused on our mission to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. Around the world, our medicines help millions of people in their fight against such diseases as cancer, cardiovascular disease, hepatitis B and hepatitis C, HIV/AIDS, rheumatoid arthritis and psychiatric disorders. Our 25,000 employees are committed to improving the lives of patients across the globe.

I am particularly proud that our research and development organization is considered among the most productive in the biopharmaceutical industry. Over the past 7 years, we have delivered 12 new medicines to patients. As this Committee understands, delivering new, innovative medicines to patients requires significant investment and commitment. In 2014 alone BMS spent over $4.5 billion in research and development. Ultimately, our success is measured by the difference we make in the lives of patients.

Today, BMS is at the forefront of innovation. We are proud to make available two approved immuno-oncology agents, and that we have what is considered the industry-leading immuno-oncology development program. Immuno-oncology is a new way to combat cancer by harnessing the body's own immune system to target and attack cancer cells. Our goal is to change survival expectations and the way patients live with cancer.

We have a significant pipeline of new therapies in development, and we are committed to investing the necessary resources to deliver these promising new therapies to patients. As you may know, the development time and cost for biopharmaceuticals is long and expensive. It takes at least 10 years, and in most cases longer, before a drug is approved, and at a cost on average exceeding $2.6 billion[1]. Despite this time and expense, biopharmaceutical research and development is exceptionally challenging, with less than 12% of investigational drugs that make it to Phase 1 clinical trials being approved by the FDA.[2]

To be successful, a biopharmaceutical company like BMS has to make very strategic choices in developing products in our pipeline. I am here today because an effective patent system is critical to our ability to discover, develop, and deliver new innovative medicines to patients. Strong intellectual property protections are essential to attracting and sustaining investment in the biopharmaceutical industry.

BMS applauds Chairman Grassley, Ranking Member Leahy, and Senators Cornyn, Schumer, Lee, Hatch, and Klobuchar for introducing S. 1137 (the "PATENT ACT"). BMS acknowledges the significant efforts by the bill's sponsors and their staffs to strike a balance between curbing abuses of the patent litigation process and promoting innovation by protecting the interests of patent holders. The bill reflects a number of meaningful compromises that would represent improvements to the litigation process, while also taking into account concerns of innovators. BMS's views on the specific provisions of S. 1137 are provided in section II below.

However, despite this significant progress, BMS strongly urges the Committee to strengthen the bill by addressing abusive litigation practices not only in the district courts

[1] Tufts Center for the Study of Drug Development & Tufts School of Medicine, *Briefing: Cost of Developing a New Drug* 5, 18 (Nov. 18, 2014) *available at* http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_Nov_18,_2014.pdf

[2] The likelihood of approval from phase 1 for lead indications is 15.3% and for all indications is 10.4%. Michael Hay, *Clinical Development Success Rates for Investigational Drugs*, Nature Biotechnology, Vol. 32 at 42 (January 2014).

but also in the context of adversarial proceedings before the United States Patent & Trademark Office (USPTO). The America Invents Act (AIA) created new post-grant proceedings before the Patent Trial and Appeal Board (PTAB), including inter partes review (IPR) and post grant review (PGR) proceedings. Congress intended IPR and PGR proceedings to be conducted in an efficient, fair and unbiased manner for both patent owners and challengers alike.

Unfortunately, these proceedings have been implemented in a manner that lacks basic due process protections and unfairly prejudices patent owners, as evidenced by recent statistics showing that the PTAB grants approximately 75% of petitions[3] and finds at least some challenged claims unpatentable in over 80% of final written decisions.[4] These one-sided results have led to increasing abuse of these proceedings, including IPR petition filings by hedge funds that are shorting stock to drive down share prices, by parties primarily seeking to extract a financial settlement from patent holders, and by litigants presenting the same or substantially the same arguments that were unsuccessful in federal court. Rather than provide a more efficient proceeding for determining patent validity, IPR and PGR proceedings unfortunately are being used to serially harass patent owners in multiple proceedings before the district courts and the USPTO.

The same issues that confront other members of this panel regarding patent assertion entities are mirrored in abuses of the IPR/PGR system. Litigants are subverting a well-intended but unfairly implemented system of adjudicating patents for their financial gain and to the detriment of innovation, investment and our economy. The stakes are high—if there is a reduced confidence in the patent system, there will be less incentive to invent. By analogy, would you buy a plot of land if you were told that there was a 75% chance that it would be taken from you in the future? Similarly, would you build a factory on that land if you could face duplicative, parallel and serial challenges to your title across multiple venues in a proceeding that is skewed to the benefit of the challenger? Would you employ the numerous workers needed to bring innovation to the public if this property right was so subject to removal?

Our Constitution recognizes the importance of intellectual property in fueling innovation, investment, and our economy. A patent is effectively a leap of faith—that if one performs the up-front work, one will be rewarded a limited period of exclusivity to recoup one's investment and hopefully receive revenue that can be used to fund further research in the future. Our government, and in particular the USPTO, is charged with

[3] http://www.uspto.gov/sites/default/files/documents/aia_statistics_04-30-2015.pdf;
[4] Patent Public Adv. Comm. Quarterly Meeting, Patent Trial and Appeal Board Update, at 13, 15, *available at* http://www.uspto.gov/sites/default/files/documents/20150219_PPAC_PTAB_Update.pdf.

ensuring that this leap of faith is justified, and that if one plays by the rules—that is, one pays their fees, files a patent application, participates in a rigorous examination process, and receives a granted patent years later—one can rely on the benefit that comes from meaningful investment in innovation.

While this leap of faith is particularly pronounced in the biopharmaceutical industry, it will be difficult to justify the investments of time and money that are needed to create new ground-breaking therapies if the current unfair and unbalanced IPR/PGR environment is not addressed through legislation. The newly implemented IPR/PGR procedures have caused innovators, and particularly the biopharmaceutical industry, to lose confidence in our IP system. While these proceedings are relatively new, the implications are clear: the biopharmaceutical industry will innovate less, invest less, and employ fewer, without a robust and predictable patent system. However, the new nature of IPR/PGR proceedings does provide a unique opportunity today to do a course correction in order to restore the system to the one that Congress intended when enacting the AIA.

There are three procedural changes that, if enacted, would more fairly balance these proceedings, aid in their efficient adjudication to the benefit of both patent owners and challengers, and provide faith and predictability in a patent system that has served to stimulate innovation and support our economy since our country began. While each proposed change alone will not advance this goal sufficiently, these interconnected changes taken together are an important step in restoring faith in the patent system and ending these abusive litigation tactics.

1. Construe granted patent claims in PGR and IPR proceedings as they are construed in courts, and apply the same burdens and presumptions as are applied in courts, in a manner that will reduce inconsistent results and duplicative proceedings.

2. Provide the option for patent owners to amend patent claims in a USPTO reissue or reexamination proceeding prior to IPR/PGR institution.

3. Provide basic fairness in the consideration of IPR/PGR petitions.

In Section I, I will begin by addressing statistics evidencing imbalance in AIA post-grant proceedings. Then I will address each of these three proposed changes, and illustrate how they would work together to provide a system that is not prone to the abusive conduct that has become associated with IPR/PGR. In Section II, I will turn to the existing provisions of the PATENT Act.

I. Changes to Promote Fairness in IPR and PGR Proceedings

A. Statistics Evidencing Imbalance and Abuse

Although IPR and PGR proceedings have been touted as a faster and cheaper alternative to district court litigation, the PTAB has become a preferred forum for invalidating patents likely due to the inherent bias of the current procedures against patent owners. Indeed, as of April 30, 2015, 2,833 IPR petitions had been filed, a number that far exceeded the expectations of the USPTO.[5] Moreover, as of that same date, the PTAB had made a decision on institution for 1,759 IPR petitions and had instituted trials for 1,325 (75%) of those petitions.[6] As of February 5, 2015, the PTAB had issued final written decisions in 224 inter partes review proceedings.[7] The PTAB found that all of the instituted claims were unpatentable in 141, or 63%, of those decisions, and that some of the claims were unpatentable in another 47, or 21%, of those decisions.[8] The PTAB upheld all claims as patentable in only 36, or 16%, decisions issued to date.[9]

Because these results are heavily skewed against patent owners, petitioners have used IPRs to present arguments that were unsuccessful in federal court. For example, Ferrum Ferro Capital, a hedge fund, recently filed a petition for inter partes review of a claim of a patent owned by Allergan, which the Federal Circuit previously had upheld as valid.[10] Last year, Eli Lilly filed a lawsuit in the Southern District of Indiana against sixteen companies, claiming those companies had infringed Lilly's patents by filing an application with the FDA seeking to sell generic versions of Eli Lilly's Effient products.[11] In March of this year, nine of those companies filed IPR petitions challenging the validity of patents associated with Effient.[12] The parallel filing of these IPR petitions suggests that litigants will take advantage of these proceedings to disrupt the federal court litigation, providing a second opportunity to challenge patents in a more favorable setting for the defendants.

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[5] http://www.uspto.gov/sites/default/files/documents/aia_statistics_04-30-2015.pdf.
[6] http://www.uspto.gov/sites/default/files/documents/aia_statistics_04-30-2015.pdf. This number includes joinder.
[7] Patent Public Adv. Comm. Quarterly Meeting, Patent Trial and Appeal Board Update, at 13, 15, *available at* http://www.uspto.gov/sites/default/files/documents/20150219_PPAC_PTAB_Update.pdf.
[8] *Id*.
[9] *Id*.
[10] *Ferrum Ferro Capital, LLC v. Allergan Sales, LLC*, Petition for Inter Partes Review of U.S. Patent No. 7,030,149 (March 9, 015).
[11] *See, e.g., Eli Lilly and Co., et al. v. Accord Healthcare, Inc. et al*., No. 14cv00389.
[12] *See* Accord HealthCare, Inc. v. Eli Lilly and Co., IPR 2015-0064; Accord HealthCare, Inc. v. Eli Lilly and Co., IPR 2015-00865.

In addition, Wall Street hedge funds have begun to exploit the IPR process as an investment strategy. One firm has filed thirteen IPR petitions challenging pharmaceutical patents to date, while betting against the shares of the targeted patent's owner.[13] The success of such a strategy depends on the perceived anti-patent bias of IPR proceedings being so strong that the mere filing of a petition can cause share price to drop.

B. Suggested Proposals to Ensure Fairness in AIA Trial Proceedings

Congress should implement at least three changes to ensure that AIA trial proceedings are fair to both patent owners and challengers.

First, in IPR and PGR proceedings, the PTAB should apply the same "correct" claim construction standard as district courts, rather than the "broadest reasonable" interpretation (BRI). In addition, the PTAB should respect the presumption of validity for granted patents, and apply the same "clear and convincing" evidentiary standard as applied in district courts for establishing invalidity of a patent, rather than the more lenient "preponderance of the evidence" standard. By applying the appropriate standards to granted patents, the likelihood of inconsistent results and duplicative proceedings should drop.

Over 80% of patents challenged in IPR are also asserted in district court.[14] Using different claim construction and evidentiary standards promotes inconsistency, and unnecessarily burdens patent owners with defending against challenges that would not

[13] *Coalition for Affordable Drugs (ADROCA), LLC. v. ACORDA Therapeutics, INC*., Petition for Inter Partes Review of U.S. Patent No. 8,663,685 (February 11, 2015); *Coalition for Affordable Drugs (ADROCA), LLC. v. ACORDA Therapeutics, INC*., Petition for Inter Partes Review of U.S. Patent No. 8,007,826 (February 27, 2015); *Coalition for Affordable Drug (ADROCA), LLC. v. Shire, INC*., Petition for Inter Partes Review of U.S. Patent No. 6,773,720 (April 1, 2015); *Coalition for Affordable Drugs II, LLC. v. NPS Pharmaceuticals, INC*., Inter Partes Review of U.S. Patent No. 7,056,886 (April 1, 2015); *Coalition for Affordable Drugs III, LLC. v. Jazz Pharmaceuticals, INC*., Petition for Inter Partes Review of U.S. Patent No. 7,895,059 (April 6, 2015); *Coalition for Affordable Drugs IV, LLC. v. Pharmacyclics, INC*., Petition for Inter Partes Review of U.S. Patent No. 8,754,090 (April 20, 2015); *Coalition for Affordable Drugs V, LLC. v. Biogen IDEC International GmbH*, Petition for Inter Partes Review of U.S. Patent No. 8,759,393 (April 22, 2015); *Coalition for Affordable Drugs IV, LLC. v. Celgene* Corporation, Petition for Inter Partes Review of U.S. Patent No. 6,045,501 (April 22, 2015); *Coalition for Affordable Drugs II, LLC. v. NPS Pharmaceuticals*, Petition for Inter Partes Review of U.S. Patent No. 7,056,886 (April 23, 2015); *Coalition for Affordable Drugs VI, LLC. v. Celgene*, Petition for Inter Partes Review of U.S. Patent No. 6,315,720 (April 23, 2015); *Coalition for Affordable Drugs VI, LLC. v. Celgene Corporation*, Petition for Inter Partes Review of U.S. Patent No. 6,315,720 (April 23, 2015); *Coalition for Affordable Drugs VI, LLC. v. Celgene Corporation*, Petition for Inter Partes Review of U.S. Patent No. 6,315,720 (April 23, 2015); *Coalition for Affordable Drugs V, LLC v. Biogen MA*, Inc., Petition for Inter Partes Review of U.S. Patent No.8,399,514 (May 1, 2015).

[14] El-Gammal, Yasser, The New Battlefield: *One year of Inter-Partes Review Under the America Invents Act*, 42 AIPLA Q. J. 39 (2014); *see also* Venable LLP, Patent Trial and Appeal Board Statistics, April 23, 2014, https://www.venable.com/patent-trial-and-appeal-board-statistics-04-23-2014/ (noting that the PTO indicated during a roundtable discussion that 80-90% of IPR petitions are in district court litigation).

survive in district court. Further, it leads to the strange result that patents are construed narrowly when assessing whether a product infringes, but broadly for invalidity purposes. Applying the "correct" standards for issued patent claims will properly define the intellectual property right granted by the USPTO, in a consistent and fair manner.

The BRI standard applied by the PTAB, which is used during the initial examination of a patent application, will be broader than the "correct" interpretation adopted by a district court. Using the BRI interpretation, the PTAB is more likely to find claims unpatentable in view of the prior art. The BRI standard has been justified by the ability to amend patent claims. But despite the AIA's express authorization of patent claim amendments, the PTAB has granted only three motions to amend by adding substitute claims in IPR proceedings to date. [15] IPR and PGR are more akin to district court litigation than examination by the PTO, where applicants have a liberal right to amend. Accordingly, the district court standard is more appropriate than the BRI standard for post-grant proceedings. For similar reasons, using a more lenient "preponderance of the evidence" standard for establishing invalidity in IPR and PGR proceedings, and not applying the presumption of validity for issued patents, also promotes inconsistent outcomes between the PTAB and district court.

The use of BRI and weaker evidentiary standards raises two additional concerns. First, it ignores the often substantial prosecution record, which is the dialogue between the USTPO and the patent applicant on the patentability of the presented claims, and the meaning of key claim terms. While the district court and the public takes this record into account in construing the meaning of patent claims, the USPTO-the very agency that examined the patent-ignores this record. This diminishes the importance of initial examination. Second, and most importantly, the application of different standards has been used to justify duplicative, parallel and serial proceedings in district courts and at the USPTO.

Having the USPTO apply the same standards as the courts will achieve increased fairness, predictability and uniformity among the different proceedings involving granted patents. Moreover, duplicative proceedings could be avoided by confirming that the Director or her proper delegate shall (rather than may) deny petitions presenting the same or substantially the same arguments presented in an earlier PTO or district court proceeding, and by applying consistent standards.

[15] *International Flavors & Fragrances Inc., v. U.S. Department of Agriculture*, IPR2013- 00124 (PTAB May 20, 2014); *Riverbed Technology v. Silver Peak Systems, Inc.*, IPRs 2013-00402 (PTAB December 30, 2014) and 2013-00403 (PTAB December 30, 2014).

Second, patent owners should be able to amend claims to address issues raised in an IPR or PGR petition. Under this proposal, all claims in IPR and PGR proceedings, including original patent claims and any substitutes for them, will be construed using the district court standards described above. Substitute claims would be permitted only if they narrow an originally granted patent claim by adding one or more limitations that have been taken verbatim from another issued claim of the challenged patent. If a patent owner wants to have an opportunity to make more substantial amendments, following receipt of an IPR or PGR petition but prior to its institution, the patent owner may remove any of the challenged claims from the IPR or PGR process by filing a request for reissue or reexamination. The USPTO would then examine the claims in view of issues raised in the petition, using the lower BRI and evidentiary standards applicable in those proceedings, with the possibility that the claims may never emerge from this proceeding. In addition, any claims that were amended in these proceedings would be subject to intervening rights under 35 USC 252, and no estoppels would attach to a challenger, who would remain free to dispute the validity of the amended claims in subsequent patent office or district court proceedings. These changes would promote administrative efficiency by streamlining IPR and PGR proceedings, reduce overall costs, reduce the need for the PTAB, an adjudicative body, to handle claim amendments beyond those allowed for substitutes, and avoid potentially duplicative or inconsistent proceedings within the USPTO.

Third, the procedural rules governing IPR and PGR should be revised to ensure fairness and due process for patent owners. Currently, the institution process for post-grant proceedings is biased against the patent owner. For example, while the challenger may submit expert declarations to support its petition to institute an IPR or PGR, the patent owner may not do so in opposing institution. Allowing the patent holder to introduce the same evidence as the petitioner will ensure that the petition institution decision will be made a more balanced evidentiary record. Furthermore, the same PTAB panel currently makes both the decision on institution and the final decision on the merits. The PTAB panel thus becomes predisposed to the outcome of the proceeding at a very early stage, effectively placing the burden on the patent holder to effectively overcome a presumption of invalidity during the merits phase. Ensuring that the Director, or her proper delegate, and not the PTAB, will decide whether to grant the petition will reduce any perception of bias by the merits panel. Last, ensuring that testimony related to material disputes of fact and witness credibility will be heard live by the PTAB at the final hearing, will address additional due process concerns.

Recognizing the need for Congress to consider additional reforms to USPTO proceedings, I will turn now to discussing the PATENT Act introduced last week.

II. The PATENT Act

Over the last two years, Congress has considered a number of significant legislative proposals to address perceived litigation abuses caused by patent assertion entities. As Congress debates patent reform legislation, it also must recognize that major judicial developments in patent law over the last several years have successfully reduced abusive patent litigation. Indeed, the number of new patent cases fell by 21 percent from 2013 to 2014,[16] which suggests that recent case law changes may already have a significant impact on the ability to enforce patents.

While these developments tended to focus on perceived abuses by patent assertion entities, biopharmaceutical companies, like other innovators, continue to be forced to expend significant resources defending against non-meritorious claims. For example, litigation abuses are present in Hatch-Waxman litigation under 271(e), where multiple generic companies challenge innovator patents on questionable grounds, where the need to finish the district court proceeding within 30 months can lead to gamesmanship, and where the risk between the litigants in terms of overall investment are asymmetric. This problem is compounded by the fact that discovery in Hatch-Waxman cases disproportionately impacts the innovator who, unlike the generic challenger, has invested years and even decades in the development of a successful product. Moreover, innovative biopharmaceutical companies are also plaintiffs and defendants in non-Hatch-Waxman litigation, so any general litigation reform will have a significant impact on this industry.

BMS supports legislation that targets abusive patent enforcement practices while maintaining the strong patent protection needed to justify biopharmaceutical companies' investment in life-saving medicines. BMS believes that the PATENT Act's provisions regarding district court litigation represent a welcome compromise of various stakeholder interests on issues such as pleadings, early disclosures, fee-shifting and recovery, and discovery stays, with the understanding that this legislation is incomplete without provisions aimed at preventing abuse of IPR and PGR proceedings.

A. Pleadings

As the Supreme Court stated in its *Iqbal* and *Twombly* decisions, pleadings should contain enough factual content to allow the court to draw the reasonable inference that

[16] http://www.corpcounsel.com/top-stories/id=1202721760927/Data-Shows-2014-a-Historic-Year-for-Patent-Litigation?mcode=1202615620321&curindex=0&slreturn=20150227140117

the defendant is liable for the misconduct alleged. The issue is one of balance. Requiring too much specificity in a complaint for patent infringement would result in unmanageably long complaints and endless motions practice regarding the adequacy of the pleading. While this provision does require a detailed claim-by-claim description of the alleged infringement that could increase the likelihood of these unintended consequences, BMS recognizes that these concerns are counterbalanced by a number of compromises in the pleading provisions, including removing certain information from the complaint to early disclosures, permitting plaintiffs to plead generally where the information is not accessible upon reasonable inquiry, and providing an exemption for 271(e) cases due to their unique procedural requirements.

B. Transparency of Patent Ownership

The PATENT Act strikes an appropriate balance by requiring transparency disclosures early in litigation but not in the complaint. Specifically, Section 3 requires the plaintiff to disclose entities with rights in the patent in suit or financial interests in the case, previous complaints filed alleging infringement of the patent in suit and whether the patent is subject to certain licensing obligations within 14 days of filing the complaint. While this information should be disclosed in litigation, the disclosures are unnecessary to state a claim for relief and requiring them to be pled in the complaint would discourage patent owners from pursuing legitimate claims in court and lead to abusive motion practice. By requiring that such information be presented in initial disclosures rather than the pleadings, this reduces the likelihood of unnecessary motion practice.

C. Customer Stay

Some patent owners have filed abusive infringement actions against a number of participants in a manufacturing/supply/retail/distribution chain, including ultimate customers, to extract settlements from multiple defendants. BMS supports protecting customers who are targeted for infringement based on a product they merely purchased from a manufacturer or off the shelf. In this regard, the PATENT Act appropriately focuses the patent litigation on the suppliers of the infringing product while permitting a stay of litigation against the customers under certain circumstances.

D. Discovery Limits

The PATENT Act provides for a stay of discovery pending resolution of preliminary motions. BMS appreciates that courts will have the discretion to allow discovery necessary to resolve these motions, motions for preliminary relief, or to prevent prejudice to a party. BMS further believes that the discovery limits imposed under the PATENT Act improve upon prior proposals that would limit discovery until after claim

construction, which could delay ultimate resolution of patent litigation and increase costs. Moreover, the PATENT Act's exemption for 271(e) cases reduces the risk that litigants will abuse this stay to prolong the case beyond thirty months.

E. Procedures to Implement Judicial Conference Recommendations

BMS supports the provisions in the bill that direct the Judicial Conference to examine and consider developing rules or procedures to address additional issues involving discovery in patent cases, including the extent to which each party is entitled to "core documentary evidence" and other evidence. The Judicial Conference, drawing upon its vast experience and knowledge of patent disputes, is well positioned to implement case management procedures for patent cases based on best practices.

F. Fee Shifting & Recovery

It is no coincidence that there has been a substantial decrease in the number of infringement actions filed in federal district court following the Supreme Court's decisions in *Octane Fitness* and *Highmark*. More frequent fee-shifting can encourage positive litigation behavior and discourage potential abuse. BMS supports the approach that reasonable attorney fees will be awarded to a prevailing party if a court determines that the position or conduct of the non-prevailing party was not objectively reasonable. BMS further believes that judges should have discretion to rule on fee shifting and to consider special circumstances that may make an award unjust. Fee shifting should be premised on unreasonable positions or conduct of the losing party, which will target abusive behavior while not unduly undermining litigation to assert well-founded claims of patent infringement nor the rights of small entities or academic institutions. Notably, for the biopharmaceutical industry, the PATENT Act fee shifting provisions exempt 271(e) litigation. While the relevant provision makes clear that the exceptional case standard does applies to 271(e) litigation, it is unclear how the Supreme Court standard, and a new statutory standard under the PATENT Act, will be comparatively applied. BMS further appreciates the Fee Recovery provisions of the bill, and in particular the contingent liability certification process where a patent litigant cannot satisfy an attorney fee award, as it reflects a balanced and improved approach over prior proposals.

G. Demand Letters

Finally, BMS supports targeted reforms that curb abusive, bad-faith demand letter behavior, not legitimate business behaviors. The relevant PATENT Act provisions focuses on widespread demand letter abuse, and assertions that lack a reasonable, objective basis in fact. In our view, it is preferable that the FTC have authority to enforce violations of Section 9 under the Federal Trade Commission Act under a nationwide

standard rather than allowing a patchwork of different state laws govern this area of patent law.

III. Conclusion.

Chairman Grassley, Ranking Member Leahy and Distinguished Members of the Judiciary Committee, I thank you for the opportunity to appear here today and to offer BMS's views on the subject of "S. 1137, the 'PATENT Act' – Finding Effective Solutions to Address Abusive Patent Practices."

I appreciate the efforts of the Members and staff of this Committee to develop meaningful patent litigation reforms that will curb abusive practices and minimize unintended consequences for legitimate patent owners. The PATENT Act, with the suggested modifications to USPTO post grant proceedings, is a productive step in that direction, and we look forward to working with Members and Staff on modifications to existing provisions and additional provisions that are necessary to ensure fairness in AIA trial proceedings.

I will be pleased to answer any questions or to supply additional information.