



AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

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STATEMENT OF

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BEFORE THE

SUBCOMMITTEE ON COURTS AND COMPETITION POLICY

COMMITTEE ON THE JUDICIARY

UNITED STATES HOUSE OF REPRESENTATIVES

HEARING ON

“BIOLOGICS AND BIOSIMILARS: BALANCING INCENTIVES FOR INNOVATION”

JULY 14, 2009

Mr. Chairman and Members of the Subcommittee,

I am pleased to have the opportunity to present the views of the American Intellectual Property Law Association (AIPLA) at this hearing on “Biologics and Biosimilars: Balancing Incentives for Innovation.” Let me first express our appreciation for your interest in this very important topic.

AIPLA is a national bar association of more than 16,000 members engaged in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property, and therefore have a keen interest in an efficient and smoothly functioning patent system.

As outlined in my biography, I have spent a good portion of my legal career working with patents related to biotechnology, pharmaceutical chemistry, medical devices, immunology, and specialty chemicals, as well as polymers and nanotechnology. I am also a registered pharmacist in the State of Michigan and worked for years as a hospital pharmacist. I believe that this experience provides me with a unique perspective to discuss the issues before the Subcommittee today.

AIPLA believes that, should Congress create an abbreviated regulatory approval process for a “follow-on” biological product, it is essential that such a process contain a patent enforcement mechanism that preserves the value of intellectual property. Such a regime should include:

1. a timely and confidential information exchange sufficient to allow the reference product holder and third-party patent holders to determine whether they have a good faith basis to assert a patent infringement claim;
2. a streamlined, efficient litigation scheme that encourages resolution of patent infringement claims by the reference product holder as well as by third-party patent holders before FDA approval of the follow-on product;
3. a corresponding opportunity for a follow-on product applicant to seek a declaratory judgment of non-infringement, invalidity or unenforceability as to patents that it believes in good faith may be asserted against the follow-on product, if the patent holder does not bring a timely infringement action before product launch;
4. procedures that apply the existing law of venue; and
5. all available remedies, including damages and injunctive relief, should patent infringement be found.

General Background

Patent rights play an important role in promoting and protecting biotechnology innovation, and the available enforcement mechanisms for these rights can significantly affect patent value and the ability to obtain investment for further research. In addition to creating an abbreviated regulatory approval pathway for biologics, the pending bills (H.R. 1548 and H.R. 1427) would create a mechanism for pre-launch patent dispute resolution. It is this mechanism that is the primary concern of AIPLA and the primary focus of this testimony. AIPLA submits that the patent dispute resolution mechanism should operate prior to FDA approval of the biosimilar product and should not unduly create additional rules that increase the cost and complexity of litigation or otherwise undermine the value of valid patent rights in biotechnology inventions.

The U.S. patent system stimulates technological innovation by providing legal protection to inventions and by disseminating useful technical information on which others can build. In essence, patents fuel research and development, which is particularly true in the biotechnology and pharmaceutical industries. The fact that the biotechnology and pharmaceutical industries rely

more heavily on patent protection than any other industry was recognized by the Federal Trade Commission in its 2003 Report entitled, “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy.”

The development of a new pharmaceutical or biological drug product is also very expensive and unpredictable. Pharmaceutical and biotech companies depend on patent protection to protect their innovations and to provide some expectation that they can recoup their investments in high-risk research and costly clinical trials. This reliance on patent protection arises long before a product is available to patients. Much of the early biotechnology research is conducted in academic institutions or in small technology firms that then seek to license to larger entities for the next, more costly, stage of research. Often, there are several transfers of rights for this purpose, and the availability of enforceable patent rights can determine the value of these transactions and the availability of any additional investments. In essence, the value of a patent is the right to exclude competitors from practicing the claimed invention for the life of the patent. Today, that generally means 20 years from the date when the patent application was filed. The value of a patent is undermined if there is no effective mechanism to enforce the patent and keep others from infringing that patent during its life.

Without question, an abbreviated regulatory approval pathway for biological drugs needs an effective pre-launch mechanism for resolving patent disputes to provide certainty as to the effect of patent rights to both biosimilar manufacturers and innovators. Without such a mechanism, patent disputes in this area would strain the federal judiciary by requiring -- in preliminary injunction proceedings -- resolution of the complex legal and scientific questions involved with each biosimilar product launch. Those circumstances would require quick decisions

on claims of patent infringement and invalidity in a pressurized context and without the benefit of a complete evidentiary record.

As explained below, AIPLA believes that H.R. 1548 achieves the objective of establishing an effective pre-launch mechanism for resolving patent disputes, and avoids many of the concerns raised by H.R. 1427.

Hatch-Waxman Model. Congress expressly recognized the critical role of patents in fostering innovation and the need to resolve patent disputes before FDA marketing approval in 1984 when it enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Act.”

As a first step, the Hatch-Waxman Act requires a reference product holder to list all patents which cover the reference product in the FDA’s Orange Book.¹ Unless the generics manufacturer agrees to defer launch until after the expiration of a listed patent, the reference product holder is given statutory authorization to file a patent infringement action to enforce any of the listed patents prior to the FDA’s approval of the generic manufacturer’s abbreviated new drug application. When such an infringement action is commenced, FDA approval of the generic product is stayed for 30 months to allow for resolution of patent disputes before market launch of the generic product.

¹ Consistent with the prevailing view of stakeholders that there should be no “Orange Book” equivalent in the follow-on context, neither bill would establish any sort of registry requiring the reference product holder to identify patents covering the reference product or its methods of manufacture. The “Orange Book” procedure was created by the Hatch-Waxman Act for small molecule compounds. Under 21 U.S.C. § 355(b)(1), the reference product sponsor must list all patents which claim the drug or method of using the drug with respect to which a claim of patent infringement could reasonably be asserted if an unlicensed person engaged in the manufacture, use or sale of the drug. Because there is no “Orange Book” equivalent, there is a need for information exchange sufficient to allow patent holders to determine whether the biosimilar product or its method of manufacture may be infringing their patents.

In other words, when it authorized a regulatory pathway for generics, Congress at the same time created a statutory mechanism permitting developers of innovative drugs to quickly resolve patent disputes, and developers of innovative biologic drugs should be able to do the same.

Need for Patent Dispute Mechanism. The specific procedures of the patent dispute mechanism which have been proposed deserve careful consideration. In addition to undermining the value of valid patent rights, inefficient or ineffective procedures will cause an unnecessary drain on the resources of the judiciary and will increase costs to the parties. Indeed, recent initiatives to reform the patent law have been driven in part by the spiraling cost and complexity associated with enforcing patent rights.

AIPLA conducts a nationwide survey of our members every two years on the cost of patent litigation. In 2007, we reported that the median cost of a patent infringement suit was \$1,600,000, if \$1 million to \$25 million was at risk. The cost rises significantly as the stakes increase. The median average cost of a patent infringement case involving more than \$25 million dollars was about \$5,500,000. Patent law is a complex, dynamic field of law, and the technologies at issue in these patent litigation suits have become increasingly sophisticated. Patent litigation places a significant burden on the federal judiciary, which by and large relies on generalist judges and lay juries.

For these reasons, care should be taken to ensure that the proposed patent dispute resolution procedures do not impose additional burdens on litigants or otherwise increase the complexity and uncertainty of enforcing these patents. Doing so would only exacerbate the problems that the ongoing patent law reform efforts aim to address.

With these thoughts in mind, I would like to share AIPLA's analysis of the patent dispute resolution procedures proposed in H.R. 1548 and H.R. 1427.

I. H.R. 1548's Patent Enforcement Provisions.

Information Exchange Provisions. H.R. 1548 would provide a reasonable, balanced procedure to exchange information. The reference product holder would be entitled to access to the follow-on product's abbreviated application as well as information about the product and its method of manufacture. Third-party patent holders would be entitled to notice of the abbreviated application filing, with the right to request information. The bill would require that all such information be treated as confidential by the recipients. Reference product holders and third-party patent holders could then conduct informed analysis about whether their patents cover the follow-on product and its method of manufacture. In order to begin enforcement proceedings before market launch, they must provide the basis for their infringement contentions to the follow-on applicant.

Scope of Pre-Market Launch Patent Litigation. Under H.R. 1548, the patents available for litigation would be limited to those patents that the reference product holder or third-party patent holder identifies as "covering" the follow-on product. This scope is much narrower than the categories of patents that may be challenged under H.R. 1427, and is consistent with declaratory judgment law and the requirements of Article III of the Constitution.

Opportunity for At-Risk Launch of Follow-On Product. H.R. 1548 would provide a balanced approach for interested parties to initiate suit before FDA approval, although in some situations the bill may not sufficiently protect the interests of a follow-on applicant seeking resolution of patent issues before FDA approval and launch. In particular, the bill would give the reference product holder and/or patent holder the opportunity to bring an infringement action within 60 days of receiving the patent certification from the follow-on applicant. If no suit is

brought within this time frame, then the FDA's approval of the follow-on product may not be precluded on patent grounds. However, there is still the possibility that a "late" patent infringement proceeding could be brought and a preliminary injunction could be obtained to preclude market launch of the follow-on product, despite FDA approval.

H.R. 1548 would also provide the follow-on applicant the opportunity to bring a declaratory judgment action, in the event that the reference product holder or patent holder fails to bring suit within the 60-day period. However, the bill does not allow such an action to be brought until 3 years before expiration of the reference product's data exclusivity period. The assumption that a patent infringement litigation can be resolved in 3 years may not necessarily hold true. If patent reform legislation passes allowing interlocutory appeal of claim construction rulings, we can expect that a hard-fought patent litigation will not be completed within 3 years. We therefore recommend that this particular section of H.R. 1548 be revisited in the event that the patent law reform efforts succeed.

Venue of the Pre-Launch Litigation. Unlike H.R. 1427, H.R. 1548 does not attempt to alter the law of venue. As a result, the courts would have discretion to transfer and consolidate pre-launch lawsuits as appropriate. We believe this is a better approach than a blanket rule allowing a particular category of litigant to make the final determination of venue.

Multiplicity of Litigation and the Abuse of Litigation Process. Under H.R. 1548, there is the possibility for multiple litigations brought separately by the reference product holder and third-party patent holders.² For example, because the third-party patent holder has more time to provide its patent list to the follow-on applicant than the reference product holder has, it is

² There is also the possibility that a patent issues or the reference product holder in-licenses a patent after the initial certification process, whereupon the reference product holder or third-party patent owner could begin another lawsuit to enforce that "new" patent.

possible that the follow-on applicant could face separate lawsuits initiated at different times by each third-party patent holder. However, jurisdiction over the follow-on applicant would likely be limited because the follow-on applicant would not yet be marketing an approved product. Moreover, under the existing venue law, the follow-on applicant could move to transfer and consolidate patent infringement actions, if it chose to do so.

Effect on Third Party Patent Owners. H.R. 1548 has several provisions that recognize and attempt to balance the interests of third-party patent owners, including the requirement of notice that the follow-on application has been filed. The bill includes a procedure that would allow the third-party patent owner(s) to gain confidential access to information about the follow-on product, and a pre-launch litigation process that would allow a third-party patent owner to enforce its patent before FDA approval. The bill also includes a time-limit requirement if a third-party patent owner wishes to enforce the patent for the purpose of delaying FDA approval until after the expiration of the patent in suit. The bill would further create a mechanism by which a follow-on applicant may bring a declaratory judgment action.

II. H.R. 1427's Patent Enforcement Provisions

Information Request Provisions. H.R. 1427 would create an information request process that would allow any party to request that the reference product holder provide a list of “all those patents owned by, licensed to, or otherwise under the control of, the holder of the approved application that the holder believes in good faith relate to the reference product.”

Importantly, the bill does not define “relate to,” but expressly includes “patents that claim the approved biological product, any formulation of such product, any method of using such product, or any method or process that can be used to manufacture such product or component,

regardless of whether that method or process is used to manufacture the reference product.” This standard would require more than just an identification of patents owned or controlled by the reference product holder that cover the reference product. It would seem to require the reference product holder to review its entire patent portfolio, as well as all patents it has in-licensed for any purpose, to determine whether those patents “relate to” the reference product. In practice, this obligation would become most onerous with respect to methods that “can be used to manufacture” the reference product. This disclosure obligation would continue for 2 years after the date of the request, and may be extended by a subsequent request by the follow-on applicant.

The bill also includes forfeiture provisions directed against patent holders. If a “relevant patent” that “should have been disclosed” was not disclosed as required, then the owner of the patent or licensee of the patent may *never* sue for infringement of that patent. In effect, the patent would lose all value. This forfeiture provision would create uncertainty for all parties involved, harsh consequences for third-party patent owners who license their patents to others developing commercial products, and increased likelihood of complex, expensive litigation – all of which discourage continued investment in biomedical research and development.³

³ Given the high stakes involved in the potential forfeiture of the right to enforce a patent, the ambiguity of the phrase “relate to” would likely create an entirely new unenforceability defense that would parallel the inequitable conduct defense in terms of the amount of discovery required. Accused infringers would be encouraged to seek discovery from every entity that controlled the patent over time, including third parties, in an attempt to make an argument that the patent should have been disclosed in response to a patent notice request provision. In addition to extensive fact discovery, including inquiries into the subjective intent of reference product holder employees, each party would hire one or more experts to address the question of whether the patented process “relates to” the reference product. Would the inquiry be whether one of ordinary skill in the art believed that the patent process “related” to the reference product at any time during the 2-year obligation to list period? What if the process was “obvious to try” but no one had done so? To complicate matters, the use of the phrase “in good faith” suggests that the inquiry is the state of mind of the patent owner during the 2-year time period. In this context, which employees’ state of mind is/are relevant? Does the belief of a single scientist employed by the reference product holder that the patented process could have been used to make the reference product at a lab bench constitute such “good faith”? This subjective standard would create a new unenforceability defense, similar to the often maligned inequitable conduct defense, but with even less certainty about how the inquiry should be performed.

Moreover, because the forfeiture provision apparently attaches to the patent itself, rather than limiting the enforcement right of the particular reference product holder or licensor with respect to the particular proposed follow-on product, it could have profound implications in *all* litigation involving biotechnology patents, not just the pre-launch provided by H.R. 1427, as well as in all transactions involving the sale or license of biotechnology patents. Any party against whom a biotechnology-related patent was asserted could request discovery of all communications with follow-on applicants by any owner or licensee of the patent at issue as well as discovery directed to the “good faith belief” of the owner or licensee during the obligation-to-list period, regardless of whether the owner or licensee is a party to this litigation. In addition, potential purchasers or licensees in transactions involving biotech patents would be forced to engage in time-consuming and expensive diligence to determine whether the patent(s) involved in the transaction may be rendered valueless by this new form of unenforceability defense.

At the same time, H.R. 1427 does not provide the reference product holder with *any* access to information to determine whether the follow-on product likely infringes any of the reference product holder’s patents. The reference product holder who receives a patent statement from a follow-on applicant, which may represent that the applicant does not infringe, must sue for infringement of its patents within a specified and very limited time period or else forfeit its opportunity to obtain injunctive relief. Yet, the reference product holder has no ability under the terms of the bill to obtain information sufficient to provide a good faith basis to make infringement allegations under Rule 11 of the Federal Rules of Civil Procedure. The reference product holder may ultimately determine, after expensive discovery and the intervention of the courts, that there is no infringement. This would be a waste of court and party resources.

Scope of Pre-Market Launch Patent Litigation. Under H.R. 1427's patent enforcement procedures, the follow-on applicant would have the ability to determine which and how many patents owned or licensed by the reference product holder would be litigated before follow-on product launch. The follow-on applicant's patent notice must provide a detailed statement of the factual and legal bases for the applicant's belief that the *cited* patents are invalid, are unenforceable, *or* will not be infringed by sale of the follow-on product. However, the bill does not require the follow-on applicant to include such notice for all the patents identified by the reference product holder, nor does it require the follow-on applicant to request patent information at all. Only the patents included in the follow-on applicant's patent notification are subject to litigation before the follow-on product launch.

Indeed, H.R. 1427 would amend 35 U.S.C. § 271(e) to define the follow-on applicant's patent notice as an act of infringement only as to a patent identified in that notice. The reference product holder must then bring suit within 45 days of receiving this patent notification. Failure to do so would limit the patent holder's available remedies to a "reasonable royalty." This is neither an equitable nor efficient method of identifying patents for resolution before launch. The patent owner would lack any certainty concerning whether relevant patents can be enforced before the launch of the follow-on product.

Significantly, the follow-on applicant may identify patent(s) that it would like to challenge *for any reason*, regardless of whether there is a colorable argument that the follow-on product would infringe the patent. For example, the follow-on applicant could send a notice challenging the validity of any patent listed by the reference product holder as "relating to" the reference product, even if the patent does not cover the proposed follow-on product. The follow-on applicant's notice could state that the patent will not be infringed and is invalid. If the reference

product holder agrees that the patent is not infringed on the basis of the information provided, it would lack any basis to sue. However, the follow-on applicant could still seek a declaratory judgment that the patent is invalid, in the hope of obtaining freedom to practice the patent with respect to other products or operations. This provision is counter to declaratory judgment standards, which require an actual case or controversy, may violate Article III of the U.S. Constitution, and could burden the federal judiciary with needless patent cases.

Opportunity for At-Risk Launch of Follow-On Product. Under H.R. 1427, pre-launch litigation of any patent is entirely within the control of the follow-on applicant, despite patents held by the reference product owner that cover the follow-on product or its method of manufacture. For example, under paragraph (18)(B), a follow-on applicant *may*, at any time after submitting its application, provide “patent notification,” which serves as the trigger for pre-launch litigation.⁴ However, nothing in H.R. 1427 would require the follow-on applicant to trigger the pre-litigation process before launch of its follow-on product. The bill expressly recognizes the “discretion of applicants” and provides that an applicant is not required by this bill, nor can it be required by court order or otherwise, to initiate the patent notification or litigation procedures under paragraph (18).

In effect, H.R. 1427 would enable the follow-on applicant to pursue an “at risk” launch, *i.e.*, launch without resolution of infringement of *any* patents owned or licensed by the reference product holder. Unlike under the Hatch-Waxman Act, which provides for an automatic 30-month stay of approval when an infringement suit is brought, the reference product holder would be

⁴ The first step in the litigation process is the “Patent Notification” step, under which the follow-on applicant provides notice to the reference product holder and, in certain circumstances, the third-party patent owner (if that patent owner was previously identified in an optional information exchange between the reference product holder and the follow-on applicant). Within 45 days of receiving notice, the reference product holder or third-party patent owner may bring an infringement action. As noted above, failure to bring suit in 45 days results in a forfeiture of the right to injunctive relief and limits damages to a “reasonable royalty.”

limited to seeking preliminary injunctive relief through the courts. This likely will impose a significant burden on the federal court system to consider and quickly make preliminary injunctive relief determinations. Such determinations will require an analysis of the likelihood of success on the merits of the patent infringement claim as well as the invalidity and unenforceability defenses asserted in connection with each patent in suit. In addition, whatever the district court decides, the decision would be immediately appealable to the Federal Circuit.

If the reference product holder does not obtain a preliminary injunction preventing launch, once the product is available and being administered to patients, the follow-on applicant likely would argue, even if the patent is found to be valid and infringed, that the Supreme Court's decision of *eBay Inc. v. MercExchange, L.L.C.* requires trial courts to consider the effect on the public health of removing a drug from the marketplace. Unless the newly approved follow-on product is determined to be "interchangeable" with the previously reference product by the FDA, which is unlikely in the near term, the follow-on applicant likely would argue that the public would be harmed by the removal of the follow-on product from the market because, due to lack of substitutability, the patients taking the follow-on product cannot simply switch to the licensed product if the follow-on product is removed from the market. This mechanism, with no stay of approval during litigation and no ability of the patent holder to resolve a patent dispute in advance of product launch, would undermine the value of patents covering the reference product.

Venue of Pre-Launch Litigation. H.R. 1427's venue provisions appear to give follow-on applicants an unfettered ability to transfer infringement cases away from the forum chosen by the reference product holder (and third-party patent owner) into whatever district the follow-on applicant prefers, allowing for forum shopping and strategic separation of related cases that could otherwise be consolidated to maximize efficient use of judicial resources. The venue provision

would amend 28 U.S.C. § 1404 to allow the follow-on applicant who has been sued for infringement to move to transfer the action to any other jurisdiction in which venue is proper. The proposed amendment further provides that, in ruling on any motion to transfer, “the greatest weight shall be given to . . . the interest in identifying a district court in which the case will be adjudicated expeditiously . . . [and] the strong public interest in obtaining prompt judicial resolution” This provision would constrain the district court’s discretion to consider other traditional factors such as the convenience of the witnesses and parties, and the interests of justice, which would otherwise be relevant to such transfer motions under 28 U.S.C. § 1404.

Multiplicity of Litigation. H.R. 1427 appears to neither limit nor streamline the pre-launch litigation process. Because there is no streamlined process requiring a review and certification of all relevant patents at one time, one possible consequence is that there would be multiple litigations pending at the same time. For example, the follow-on applicant could make a strategic decision to “divide and conquer,” sending patent notices to the reference product holder and third-party patent holders in a seriatim manner. Because of the requirement that a patent holder or reference product holder must bring suit within 45 days of receiving that notice, there could be separate, serial proceedings over a lengthy period of time. It is unclear whether, even if the cases were all brought over time against the follow-on applicant in the same district, those cases could be consolidated as related cases. Indeed, under the bill’s venue provision, the follow-on applicant could decide to move to transfer to another jurisdiction and the district courts appear to have no discretion to override the follow-on applicant’s decision, even if the patents in suit were related. In sum, these provisions would create opportunities for strategic use of multiple, separate lawsuits that would result in an inefficient use of judicial resources and cause undue diversion of the resources of the reference product holders and third-party patent holders.

Effect on Third Party Patent Holders. The complexity of the proposed process increases when patents owned by third parties are involved. This is often the case with patents covering biotechnology products, which may have originated in academic research and been licensed to the reference product holder. Correspondingly, the burdens on these third parties, who may have limited resources to engage in litigation, are greatly increased. For example, there is no absolute requirement that the follow-on applicant send its patent statement to third-party patent owners. If the follow-on applicant has not requested information from the reference product holder in advance of sending a “patent notification” to the reference product holder, then the follow-on applicant can list a patent that the reference product holder has non-exclusively licensed from a third-party, yet the follow-on applicant has no obligation to send a notice to the patent owner/licensor. Because the patent owner would not have received notice from the follow-on applicant, it would not have the right to sue under the patent enforcement litigation provisions of this bill. However, under the Federal Circuit’s standing law requirements, the patent owner may be a necessary party without whom the reference product holder could not bring an infringement action. As a result, both the reference product holder and the patent owner could be deprived of any remedy for infringement other than a reasonable royalty, *i.e.*, no injunctive relief and no recovery of lost profits.

H.R. 1427’s patent enforcement procedures could create significant problems for third party patent holders, many of whom are universities, research organizations or small biotechnology companies with little or no resources available for litigation. The follow-on applicant could use a combination of seriatim proceedings and venue changes to put pressure on third-party patent owners with limited budgets. The follow-on applicant could, through the “patent statement” procedure, bring separate lawsuits at different times on different patents. This

would multiply the burden of discovery: university inventors, who are research scientists and medical doctors, could be forced to engage in time-consuming and duplicative document production and depositions in each case. These cases may be pending in different jurisdictions, far from the university, adding to the expense and burden on the researchers' time.

In addition, the forfeiture provision's potential effect on third-party patent owners is troubling. Many biotechnology products are covered by patents originally developed and licensed by universities and research institutions. Under H.R. 1427, a reference product holder that is a non-exclusive licensee of a university patent covering platform biotechnology could forfeit the university's right to enforce the patent against any party, even if the university never received the follow-on applicant's patent notification statement, and even if the reference product holder is not using the licensed method in its reference product or for any purpose. In short, as a result of actions or omissions of its non-exclusive licensee, the university could in effect forfeit all of its patent rights and lose its entire royalty stream. The university's other non-exclusive licensees could then stop paying royalties to the university on the ground that the patent has been rendered unenforceable. Moreover, there is a strong argument that, since the request for information is directed only to the reference product holder (and not third-party patent owners), forfeiture of the owner's right to enforce the patent based upon the reference product holder's failure to list the patent would violate the patent owner's constitutional right of due process.

Conclusion

In our view, the patent enforcement provisions of the H.R. 1427 would likely weaken the value of biotechnology patents by severely limiting the ability of the reference product holder to assert its patents prior to market launch of a follow-on product. The bill lacks sufficient

mechanism for reference product holders or third-party patent owners to obtain access to product and manufacturing information necessary to determine whether they have a good-faith basis for asserting an infringement claim. At the same time, the bill would expand declaratory judgment jurisdiction to create opportunities for interested parties to challenge patents which may not cover either the reference product or the planned follow-on biologic product. The patent notification procedure includes ambiguous standards with severe penalties that would encourage additional patent challenges and create uncertainty in subsequent intellectual property litigation and transactions. Moreover, the ambiguous standards and expanded declaratory judgment jurisdiction in the bill would create opportunity for abuse of the patent litigation system that would waste judicial resources and unduly burden third-party patent owners.

By contrast, H.R. 1548 would encourage efficient, streamlined pre-launch patent litigation involving patents that may cover the follow-on product, employing procedures that would be less subject to gamesmanship and abuse. The bill addresses the need for an exchange of information about the follow-on product to conduct a preliminary infringement assessment by the reference product holders and third-party patent owners. The bill's notice/certification provisions would limit the patents that may be challenged to those which the patent holder believes are infringed by the follow-on product. The bill would allow the follow-on applicant to bring a declaratory judgment action on any of the patents identified by the reference product holder or a third-party patent holder if an infringement suit is not filed on a timely basis.

I wish to thank the Subcommittee for the opportunity to present these views and I look forward to any questions that you may have concerning the observations and comments that have been presented.