Testimony of

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Reducing Barriers to Market Competition"

Chairwoman Eshoo and distinguished members of the Subcommittee:

Thank you for providing me with the opportunity of testifying before you today. I am testifying in my individual capacity based on my personal experiences with patent litigation in the life sciences sector. The opinions I offer in this testimony are my own and should not be attributed to any client of my firm.

I am a patent lawyer who has represented developers of new drugs and new biological products in patent litigation under both the Hatch-Waxman Act and under the Biologics Price Competition and Innovation Act (BPCIA). I also have defended life sciences and non-life sciences companies in litigation where patents have been asserted against them. And I have both challenged and defended patents in *inter partes* review proceedings before the Patent Trial and Appeal Board at the Patent Office.

Before entering private practice in 1998, I worked in the government for about ten years. I served in the Patent and Trademark Office as a biotechnology patent examiner, and later as an attorney on patent policy matters. I also served for two years in the Office of the United States Trade Representative in Geneva, where I gained an appreciation for the different ways our trading partners manage their patent systems and regulation drugs and biologics.

I believe my varied experiences have given me a good sense of the balance built into the patent system, and in the practical considerations that companies face in navigating patent disputes involving regulated products like drugs and biologics. From

these experiences, I can make the following observations that are relevant to many of the bills the subcommittee is now considering.

First, the unpredictable and burdensome nature of patent litigation encourages parties to find ways to resolve patent disputes through settlements. It is very difficult for both patent owners and those accused of infringement to predict with certainty whether a court will find a patent valid and infringed, and what the consequences of infringement will be. Litigation is also very disruptive for companies—the parties must make employees available for depositions and trial, and place demands on their time to help with discovery. And the outcomes of litigation, of course, can be very disruptive on the commercial activities of both parties—they can disrupt expectations, and force significant changes in the commercial operations of the company.

This is why, in my experience, regardless of the technology at issue, both sides of a patent dispute—the patent owner and the party accused of infringement—have a strong interest in finding a way to settle the patent litigation early in the dispute, even while they are aggressively litigating. Settlements often are the only practical way to secure the certainty companies need to plan and conduct their commercial operations and to avoid the disruptions that occur during litigation.

The parties to a patent dispute also are not the only entities with a strong interest in settling patent disputes. Courts have a very strong interest in seeing cases settle. Patent cases can be very demanding for a district court judge. They are technically complex, which makes resolving discovery disputes difficult. There are numerous hearings that take place during a typical patent case—on claim construction and dispositive motions. And trials take substantial time and effort for the Court to conduct and manage. Courts, thus, strongly encourage settlement of patent disputes.

Consequently, measures which effectively foreclose the possibility of settling patent litigation once it has started need to be considered very carefully. This is particularly true for litigation under the Hatch-Waxman Act and the BPCIA, where settlements can facilitate market entry of a generic or biosimilar product earlier than would be possible if the litigation continues to completion, and the relevant patents are

found both valid and infringed. In those situations, market entry by the biosimilar or generic product cannot occur until expiration of the valid and infringed patents.

Second, objectivity, clarity and certainty in the rules that govern patent enforcement and market entry for generic and biosimilar products are critical for both innovators and generic/biosmilar manufacturers. Innovators typically start development of a new drug or biologic a decade or more before the drug or biologic will be approved for use in patients. Companies must make substantial investments to clinically test these new drugs and biologics in the back third of this development period, and those business decisions are influenced by amount of certainty or uncertainty that exists about when a generic or biosimilar version of the new product they are developing will be marketed. Biosimilar and generic manufacturers also need certainty to plan their investments and activities. This is particularly true for biosimilar developers, who must make substantial investments in developing manufacturing facilities that are needed to produce biological products. Uncertainty over how the rules work, whether patents can be effectively enforced and whether the rules will change after investments have been made will have negative systemic effects on the environment for investments in clinical development of original and subsequent versions of drugs and biological products.

Third, it is critically important for the ultimate beneficiary of innovation in the life sciences sector—the patient with unmet medical needs—that we maintain the strong incentives for innovation that the patent system provides. Innovation is not limited to the discovery of a new active ingredient or a new therapeutic use of a known drug. Innovation is pervasive, incremental and occurring within all participants in the life sciences industry. For example, biosimilar manufacturers are innovating—they are discovering—and patenting—new ways to manufacture biological products, new characterization technologies used to achieve consistent quality in production of their products, and new ways of formulating these products to make them safe and to exhibit improved characteristics. These patented innovations track the innovation experience of the original developers of the biological product—the process of starting with a protein and figuring out how to manufacture it at a large scale, and to then formulate it so that it can be safely distributed and prepared for safe use in patients forces companies to

innovate continuously through the development process. These innovations are important—they ensure consistent quality and safety of the product, and are essential to its effectiveness.

If enforceable patents are available for these types of innovations, the innovator is given an incentive to publicly disclose it, rather than hold it as a trade secret. That is a central purpose of the patent system—to provide an incentive to disclose innovations so others can learn from them and improve them further. It is plainly working—both original innovators and biosimilar manufacturers are innovating and securing patents on these types of innovations. The inherent design of the patent system also makes patent rights on these types of innovations narrow, which allows others to innovate around the original patented technology. That is how the patent system works to stimulate innovation—it pushes innovations into the public environment and forces others to innovate around the patented technology, which thereby advances the state of the art.

It is important to appreciate this inherent balance within the patent system when considering policies that would regulate patent enforcement and potentially cause forfeiture or impose limitations on patent rights. Patents on process and manufacturing innovations are important commercial assets, and often do not pose meaningful barriers to market entry.

Observations on the Proposed Legislation

I have not had sufficient time to study all of the legislation the Subcommittee is considering in this hearing. I can offer some preliminary observations on certain provisions that are found within the set of bills under consideration.

1. Purple Book Legislation

The legislation concerning the "Purple Book" for biological products raises certain practical concerns relating to obligations to list patents.

The Purple Book does not presently require patent listings analogous to the Orange Book for drugs, and there are good reasons for that policy. One is that the set of

patents that may be relevant to a first biosimilar product may not be relevant to the next biosimilar product (or any subsequent product). This is because the biosimilar products—including the precise nature of the active ingredient, the formulation of the product and the various manufacturing techniques used to produce it (including host cell choices, culturing and purification procedures, formulation choices, etc.)—will vary from one biosimilar product to the next. The BPCIA recognizes this with the way it calls for disclosure of manufacturing information from the biosimilar applicant to the reference product sponsor, which enables the reference product sponsor to identify patents that are relevant to that particular biosimilar product, including the particular technologies that biosimilar manufacturer is actually using.

Requiring patent listings for biological products thus raises a number of practical concerns. First, it is not possible for a reference product sponsor to know which patents are relevant to a biosimilar applicant's product until they see how that product is manufactured. Certainly, patents on the protein substance or on its use in particular therapeutic applications can be expected to be relevant, but many of the patents relating to how the product is manufactured and formulated may not. Moreover, it has not been my experience that it is difficult for a company to determine if patents or patent applications exist that might be relevant to a particular product. Patents and patent applications are published, and numerous tools exist for finding them and tracking their status. Listing patents in an FDA-hosted site that are already readily discoverable and are likely already known to a biosimilar manufacturer would not seem to add a lot of value while imposing administrative burdens on the FDA.

Second, legislation introduced in the Senate to require the listing of patents in the Purple Book would include a penalty of effective forfeiture of patents that are not properly listed. This type of severe penalty is unwarranted, given that relevant patents can be readily identified already from public sources, and that it is impossible for an innovator to know which patents might be relevant to any particular biosimilar manufacturer. It also will lead to a practice of over-listing of patents to avoid the potential forfeiture, which ultimately will eliminate the nominal benefit that might come from listing such patents.

Third, the legislation pending in this Subcommittee raises some practical concerns. For example, it calls for the reference product sponsor to identify patents relevant to the confidential manufacturing process of the biosimilar sponsor before and regardless of whether those patents are ever asserted. The BPCIA, however, mandates that the manufacturing information provided by the biosimilar sponsor during the patent identification process be maintained in strict confidence. A requirement to publicly disclose patents found to be relevant to the biosimilar sponsor's manufacturing process could compromise the confidentiality of the biosimilar's manufacturing processes and thus creates a tension within the BPCIA. I also note that the Supreme Court has held that the patent identification process is optional, which means the patent listings presumably would not be made if the biosimilar manufacturer opts out of the patent identification process. How the patent listing obligation would apply in such a scenario is hard to predict, and may not yield any benefits.

2. Legislation Implicating Patent Settlements

Certain of the bills pending before this Subcommittee would impose new reviews and restrictions on patent settlement agreements entered into between innovators and generic or biosimilar manufacturers. I believe these types of measures must be carefully considered to ensure they do not discourage pro-competitive conduct that can deliver biosimilar and generic versions of innovative products to the market sooner than might otherwise be possible through litigation where applicable patents have been successfully asserted. Patent settlements which allow a generic or biosimilar manufacturer to commence marketing of their products before expiration of valid patents advances the goal of accelerating market entry of the biosimilar or generic product and should not be discouraged when they are commercially feasible.

One bill would prohibit settlements where the biosimilar or generic manufacturer would receive anything of value from the reference product sponsor or NDA holder. What might be covered by this very broad language is hard to determine. That creates practical concerns for the entities considering a patent settlement, as every settlement invariably provides practical benefits to each side. For example, there may be provisions

in a settlement that involve technical cooperation between the companies outside the area of the particular product, which could serve pro-competitive and pro-patient goals. It would also be very difficult for the FTC to apply this standard, as it would require investigations into the potential value of provisions in the agreement, which are invariably subjective and linked to the particular parties involved.

The bill also would impose penalties in connection with patent settlements and would apply these standards retroactively to settlements that already have been entered into by the parties. This raises some serious concerns. For example, it would make conduct that the relevant antitrust authorities have already found proper to now be improper, and would potentially expose companies to liability long after they have taken actions based on good faith compliance with existing standards. It also appears to call for voiding of patent settlement agreements that have led to dismissal of the underlying patent litigation. It is not clear whether the reference product sponsor or NDA holder would be able to restart the dismissed patent litigation if the settlement that prompted termination of it were voided, which could thus indirectly lead to a forfeiture of the underlying patent rights.

3. Changes to Orange Book Patent Listings

Some of the bills under consideration by the Subcommittee propose to alter the parameters governing patents listed in the Orange Book. I raise two concerns regarding these proposals.

First, one provision would prohibit listing of patents that involve medical devices that incorporate a new drug product. It is unclear what the scope of this provision will actually be, but it does raise concerns that patents integral to a new drug product could be omitted from the Orange Book. For example, many examples exist of active ingredients that have been viable drug products because of the mechanisms used to deliver the drug to the patient. Often, those mechanisms fall under the definition of a medical device, and are integral to the therapeutic effectiveness and safety of the drug product. These patents should be able to be enforced like other patents that are integral to the drug product.

Second, the bill would allow the FDA to grant final approval to an abbreviated new drug application if the Patent Trial and Appeal Board (PTAB) issues a decision holding that a patent listed in the Orange Book is invalid. This raises several concerns. For example, decisions by the PTAB are almost always appealed to the Federal Circuit and are often reversed. If that occurs, and the generic manufacturer commences marketing of its product, the legitimate economic interests of the NDA holder derived from their valid patent will be impaired, and there can be market disruptions if marketing of the generic terminates. In addition, PTAB challenges occur outside the scheme of the Hatch-Waxman Act—they can be commenced before an ANDA applicant may file the application and before the NDA holder can assert the patent. Allowing this type of indirect challenge would undermine the carefully regulated scheme of the Hatch-Waxman Act that governs when patent challenges can be commenced.

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In conclusion, legislation that has the potential to foreclose commercially reasonable settlements, impair valid patent rights, or retroactively penalize entities that acted in good faith under current laws and policies needs to be very carefully considered. In addition, measures intended to accelerate market entry of biosimilar and generic products need to ensure that they do not disincentivize not only development of new drugs and biologics, but the innovations needed to manufacture them and deliver these products safely to the patients that need them.

Thank you for considering my views.