Prepared remarks of David Korn, PhRMA, for the January 19, 2023
USPTO-FDA Public Listening Session

Thank you for holding this meeting and inviting views of the public. I am David Korn, Vice President, IP and Law, at the Pharmaceutical Research and Manufacturers of America.

PhRMA represents leading innovative biopharmaceutical companies, whose mission is to research and develop new and improved medicines for patients.

Intellectual property provides critical incentives for biopharmaceutical innovation, given the unique nature of the biopharmaceutical research and development, or R&D, process, which is lengthy, costly and uncertain. It takes 10 to 15 years and costs on average 2.6 billion dollars to develop a new medicine. In 2021, PhRMA members alone invested more than 100 billion dollars in researching and developing medicines. IP protections support such continued future innovation in the long term.

PhRMA supports the important role of generic and biosimilar products for patients. The natural evolution of medicines is that, after an innovator undertakes the time-consuming and expensive development process and obtains FDA approval, it enjoys an appropriate period of IP protections, following which a generic or biosimilar version may become available for patients. This is the cycle that Hatch-Waxman and the BPCIA contemplated for generics and biosimilars.

Hatch-Waxman has fostered competition through the timely entry of generics. Today 90% of all prescriptions for drugs are filled with generic products. And the biosimilar market continues to grow. Both have led to cost savings.

Post-approval innovation, such as new dosage forms and routes of administration, is a critical part of pharmaceutical development, producing important treatment benefits for patients. R&D does not stop and should not stop with initial FDA approval of a medicine. A medicine's safety and effectiveness are not determined solely by its active ingredient, and its therapeutic usefulness is not limited to its first approved disease; post-approval changes can improve a medicine's tolerability, effectiveness, adherence, or convenience, and support its approval for new diseases and patients with unmet medical needs. Such post-approval advances benefit patients and the public health and should be incentivized by the patent system, rather than discouraged.

U.S. continuation practice helps provide the incentives for innovators to develop the many types of patentable inventions at different stages of a product's life. The availability of continuation applications helps foster the patent system's goal of promoting innovation and earlier disclosure in the original application of the underlying research that resulted in that innovation. The original application provides the public and competitors with notice of the applicant's inventions and thus what can be claimed in continuation applications. This framework is fair and strikes the right balance

between protecting inventors and providing societal benefits. Such a system differentiates the patent system from other means of IP protection, such as trade secret protection, by rewarding innovators who disclose their inventions.

Limiting continuation practice would not promote innovation and progress in science. Inventors would be disincentivized from robustly disclosing their inventions if there were uncertainty around whether they could receive the benefit of patent protection for the full scope of the disclosed innovation.

Indeed, the negative rhetoric regarding patents on post-approval advances more broadly, including on manufacturing process patents, is concerning. Providing IP protection for such innovation does not negatively affect access to generics or biosimilars. Once IP protections on an original drug product have ended, and provided there are no safety issues, copies of that product may be approved. Health care providers and payors can then decide whether clinical benefits offered by improved branded products are more important than the cost savings available through use of less expensive generics or biosimilars. And generic or biosimilar applicants can often design around certain patents and carve protected conditions of use out of their labeling, allowing generic or biosimilar products to enter the market prior to the expiry of all patents or exclusivities covering a product.

We have seen letters that suggest more collaboration between FDA and USPTO is warranted due to concerns about potential inconsistent statements made to the agencies by pharmaceutical innovators. We also have heard theoretical concerns about manufacturing process patents.

Proponents of the inconsistent statement narrative cite a single drug case – *Belcher v. Hospira*. One case is hardly indicative of a systemic problem. And in that case, the court imposed a severe penalty – the patent was held unenforceable. Indeed, there have been 4,696 Hatch-Waxman cases filed in US district courts between 2008 and 2022, and we have seen no evidence of a widespread problem of inconsistent statements to FDA and USPTO.

Moreover, increased information-sharing across agencies raises confidentiality concerns. The agencies have different practices for handling confidential information. USPTO's general position is that information material to patentability must be disclosed to the public, whereas FDA is subject to specific statutory restrictions on sharing proprietary information. Accordingly, PhRMA is concerned that materials that are confidential at FDA will not be treated as confidential by USPTO.

Any policy changes to the U.S. patent system, including increased collaboration between these two agencies, should be based on evidence of a need for the change. This is especially the case when the collaboration could put trade secrets and confidential commercial information at risk.

Similarly, PhRMA is aware that there are alleged concerns about the number of patents per product. Reports on this topic are inaccurate, and the validity of the numbers of patents and protections reported have been called into question. Further, this is not a useful measure for policymaking. Many of society's most innovative products embody numerous inventions protected by multiple patents. The U.S. patent system should celebrate and encourage such complex innovation.

The United States has historically been a science and technology innovation leader in the world. To maintain this standing in the 21st Century, policy leaders must ensure that our laws continue to support innovation.

PhRMA plans to submit written comments and looks forward to working with the agencies on policy issues to improve the biopharmaceutical ecosystem. We need a policy and regulatory framework that fosters the continued innovation necessary to address the world's most challenging diseases.