



September 10, 2021

Mr. Andrew Hirshfeld
Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual
Property and Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Mr. Hirshfeld,

I write pursuant to Executive Order 14036, and in the hope of further developing the Food and Drug Administration's (FDA) engagement with the United States Patent and Trademark Office (USPTO).

“To help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law,” section 5(p)(vi) of this Executive Order instructs the Secretary of Health and Human Services, through the Commissioner of Food and Drugs, to write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the USPTO “enumerating and describing any relevant concerns of the FDA.”

Bringing more drug competition to the market and addressing the high cost of medicines by improving access to affordable medicine is a top priority of the Administration, the Department of Health and Human Services, and FDA. FDA does not have a direct role in how drugs are priced; however, we play an indirect role in holding down prices by bringing efficiencies to the drug development and review process and by promoting robust competition for established drugs, both of which are of great importance to the Agency. Congress took care to promote innovation and access when it created the framework for generic drug development more than three decades ago in the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act), and when it established a pathway for biosimilar and interchangeable biological products 25 years later, in the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). We are committed to incentivizing innovation and fostering competition by approving high-quality, affordable, safe, and effective therapies including generic drugs and biosimilar and interchangeable biological products. We also are committed to identifying abuses of the system that can impede competition and will continue to take steps to address them consistent with our authorities.

The Agency recognizes that patents are critical to fostering innovation, including innovation in the pharmaceutical industry. Nonetheless, the impact of certain pharmaceutical company patenting practices on the pharmaceutical marketplace has attracted attention within the debate over drug pricing. As described below, FDA is actively evaluating the impact of pharmaceutical

patents in certain areas relevant to FDA regulation of drug products, with a focus on facilitating timely access to drug products approved under our abbreviated pathways. These abbreviated pathways, which enable the approval of generic drugs and biosimilars, play a foundational role in ensuring access to affordable medications for American patients. We invite USPTO to collaboratively engage with us in these efforts and in any complementary activities under your purview that can advance competition and access in the marketplace.

FDA's Role

As you know, the Hatch-Waxman Amendments created the modern pathway for generic and “505(b)(2)” follow-on drug products.¹ The Amendments strike an important balance between incentivizing brand-drug innovation and facilitating access to lower-cost options. FDA has an important but ministerial role with respect to patents under the Hatch-Waxman provisions. The FD&C Act requires brand-drug applicants to include in their applications information about certain patents for which a claim of patent infringement could reasonably be asserted. The statute specifies this requirement is applicable to each patent that claims the drug submitted in the application, or that claims a method of use for which approval is sought or has been granted in the application.² In turn, FDA must “list” those patents publicly, and generic and 505(b)(2) applicants must submit “certifications” with respect to listed patents, indicating, for example, whether they wish to challenge those patents prior to patent expiry. These certifications can impact the timing of FDA approval of generic and 505(b)(2) applications. We note that in addition, even when patents do not directly delay FDA’s approval of generic products, the launch of those products is routinely delayed by related patent litigation.

Mindful of our obligations under Hatch-Waxman, and the importance of carrying out our listing obligations in a way that does not improperly delay access to follow-on products, we have undertaken several efforts to ensure transparency with respect to patent listings. For example, we continue to enhance the patent information listed in FDA’s *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the Orange Book); we have issued guidance on Orange Book processes; and we have held related public educational events. We have also sought public comment on whether FDA should further evaluate or provide additional clarity regarding the types of patent information listed in the Orange Book. These efforts were endorsed in the Orange Book Transparency Act of 2020, which requires the Agency to solicit public comment regarding the types of patent information that should be included in, or removed from, the Orange Book, and to transmit to Congress a summary of such comments and actions the Agency is considering taking, if any, in response to such public comment by January 5, 2022. We are actively reviewing these comments and preparing the summary.

¹ In addition to the generic drug pathway in section 505(j) of the FD&C Act, section 505(b)(2) provides an abbreviated approval pathway for certain drugs. A 505(b)(2) application is a new drug application submitted under section 505(b)(1) and approved under section 505(c) of the FD&C Act that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (e.g., published literature or the Agency’s finding of safety and/or effectiveness for one or more listed drugs).

² See section 505(b)(1)(A)(viii) of the FD&C Act (21 U.S.C. 355(b)(1)(A)(viii)).

Similar to the Hatch-Waxman Amendments, the BPCI Act established an abbreviated approval pathway for biosimilar and interchangeable biological products that can offer additional treatment options and potentially lower health care costs. The BPCI Act also provided a process for patent disputes between reference product sponsors and proposed biosimilar and interchangeable applicants. Additionally, under the Biological Product Transparency section of the Consolidated Appropriations Act of 2021, FDA publishes patent lists provided by reference product sponsors for certain licensed biological products after those lists are provided to the Agency. FDA's role in publishing this patent information is ministerial. Patent litigation between a biosimilar or an interchangeable applicant and a reference product sponsor does not impact the timing of FDA approval of that biosimilar or interchangeable application, and FDA does not consider the applicability of patents to a biosimilar or interchangeable product (e.g., validity, enforceability, or potential infringement) in publishing this information or in FDA's review of the biosimilar or interchangeable application. As with generics, however, the launch of approved biosimilar or interchangeable biological products may be delayed by related patent litigation.

FDA's Concerns

We believe that rewarding innovation should not improperly forestall access to lower cost medicines. We fully acknowledge that the regulatory structure surrounding drugs is complex, and not all of the gaming of the system is related to patents or their issuance. Certain uses of the patent system, however, have been criticized as allowing companies to inappropriately impede competition from generic, biosimilar and interchangeable biological products. Here are several areas of concern:

Some companies have adopted the practice of filing "continuation" patent applications, which may allow the filer to obtain follow-on patents directed to inventions disclosed in earlier patents. This practice can allow companies to create "patent thickets" by obtaining multiple patents on different aspects of the same product within a patent application. Although the term of a continuation patent typically expires at the same time as the original patent expires, so that continuation patents do not extend the term of the original patent, the existence of multiple patents increases litigation burdens and potentially delays the approval of generics and the launch of generics and biosimilar and interchangeable biological products.

Concerns also have been raised about patent "evergreening," or the practice of patenting "post-approval" or "secondary" changes to previously approved drug products such as new formulations of the same drug, new delivery systems, or patents claiming various additional methods of use. Brand sponsors often seek approval for these changes just as earlier patents on the drug product are expiring, effectively extending protection against competition. One study of which we are aware found that 78 percent of the drug products for which new patents were listed in the Orange Book from 2005-2015 were existing drug products, not new drugs entering the market.³ Stakeholders have asked whether these patents should be listed in the Orange Book for

³ See, generally, Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & Biosci. 590 (2018).

products approved under the FD&C Act, and more generally have questioned whether some of these patenting practices encourage innovation that is meaningful for patients.⁴

Similarly, brand sponsors will sometimes submit a new application for a modified drug product (e.g., changing the dosing regimen from twice a day to once a day), obtain a patent for the related modification that can forestall competition, and effectively switch the market to the new product right before generic or biosimilar competition on the previously approved product is set to commence. Referred to as “product-hopping,” this practice has the practical effect of forestalling competition notwithstanding the fact that the prior product (for which generic, biosimilar, or interchangeable competition has become available) remains safe and effective.

Suggestions and Questions

Pursuant to the Executive Order cited above, and with the goal of increasing competition and access to affordable drugs while respecting the need to preserve patent rights and incentives for innovation generally, FDA offers the below ideas for the USPTO’s consideration. The Agency is interested in engaging in further dialogue on these and other potential topics and activities that fall within the responsibilities and authorities of our respective organizations to improve competition.

1. *Engagement between FDA and USPTO.* While there is currently some engagement between FDA and USPTO, we are seeking to facilitate greater awareness of our complementary work and introduce efficiency in our respective workstreams. For example, we recognize that there are certain constraints on the time and resources available to the USPTO for the examination of patent applications, and also recognize the importance of being able to fully examine the complex scientific and technological information found in pharmaceutical patent applications. We would like to explore opportunities to facilitate examiners’ work by offering training on FDA’s public information and databases that may help USPTO locate pertinent references and determine whether particular documents constitute prior art to a claimed invention. We would be interested in understanding USPTO’s assessment of other resources that would support examiners in their review of pharmaceutical patent applications, consistent with applicable laws governing disclosure. Other topics for joint training could include FDA and USPTO roles in determining a product’s eligibility for patent term extension. FDA can provide information on the scope and nature of FDA approvals to support USPTO’s ability to accurately and fairly grant patent term extensions, and to grant them only in those instances where such extensions are appropriate. If useful to the USPTO, FDA would be happy to engage in discussions about the format and content of these types of exchanges.
2. *Possible Misuse of the Patent System.* We recognize that to obtain a patent, the invention claimed must be new and non-obvious. Some of the challenges that the public and the Administration face with respect to drug pricing, however, seem to stem from the

⁴ See, e.g., Congressional Research Service, Drug Pricing and Pharmaceutical Patent Practices (CRS Report No. R46221) (Feb. 11, 2020), available at <https://fas.org/sgp/crs/misc/R46221.pdf> (accessed on August 24, 2021).

concerning practices described above (such as brand use of the patent continuation process to create patent thickets, product hopping, and evergreening) being used in ways that unduly extend market monopolies and keep drug prices high without any meaningful benefits for patients. We would be interested in learning USPTO's perspective on these practices and whether it is considering means of limiting such practices.

3. *Adequate Time and Resources for PTO Examiners*: Related to the above points, we appreciate the inherent complexity of this field and the challenges in assessing patentability. We would be interested in USPTO's views on whether additional resources or increasing the time given examiners for patents relating to sensitive and complex subject matter, such as pharmaceutical patents, would help ensure the right balance of rewarding innovation and facilitating competition.
4. *The Patent Trial and Appeal Board (PTAB)*: The PTAB is a relatively new body that offers a mechanism for reviewing the patentability of claims. We would be interested in continuing to receive any data and analyses USPTO may have regarding the Post Grant Review (PGR) and Inter Partes Review (IPR) processes. In particular, we would be interested in data regarding the impact of PGR and IPR proceedings, if any, on Orange Book-listed patents and/or patents covering biological products. FDA would also be open to further discussing with USPTO how the PTAB framework might be optimized to support timely availability of generic drugs.

In addition to the foregoing, we are interested in USPTO's ideas for other areas in which FDA and USPTO can exchange information and experience to enhance our respective efforts to address the need for an appropriate balance between innovation and patient access to needed medicines. FDA looks forward to leveraging this engagement with USPTO to support a competitive marketplace.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Woodcock', written in a cursive style.

Janet Woodcock, M.D.

Acting Commissioner of Food and Drugs