GEORGETOWN LAW

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Listening Session on Joint USPTO-FDA Collaboration Initiatives
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The Biden Administration's Whole of Government approach affords the USPTO and FDA a long-delayed opportunity to revisit neglected opportunities to fulfill the goals of the Hatch-Waxman Act—encouraging pharmaceutical innovation, while also promoting access to medicines for the American people. With these brief remarks, I focus upon the FDA publication known as the Orange Book. I have also provided more extensive Written Remarks with additional views.

Orange Book patent listings hold extraordinary consequences for public health. They allow brand-name drug companies to sue generic firms for patent infringement, even though they have done nothing more than file an entirely accurate petition asking the government for marketing approval. In such cases, FDA ordinarily may not approve the ANDA for 30 months. The 30-month stay effectively acts as a preliminary injunction against the generic firm, without requiring the patent proprietor to address the usual equitable factors or post a bond. These incentives strongly encourage brand-name drug companies to identify as many patents to the FDA as possible. Numerous patents that fail to meet the statutory criteria have made their way to the Orange Book.

Despite their impact, Orange Book patent listings receive no FDA oversight. FDA simply lists in the Orange Book all identified patents without review. If a private party disputes the listing of a patent in the Orange Book, FDA merely informs the brand-name drug company. Unless the brand-name drug company withdraws or amends its patent information in response, FDA will not change the information in the Orange Book.

The significance of Orange Book patent listings for public health cannot be gainsaid. As a result, the FDA should assess submitted patents to determine whether they meet the statutory requirements for listing. USPTO employees, such as APJs detailed from the PTAB, could contribute to this task.

The agencies should also provide for more robust Orange Book listing challenges. FDA plays no substantive role in current Orange Book listing challenges. Rather, the agency merely allows any interested person to provide it with a statement of dispute. Unless the brand-name drug

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company withdraws or amends its patent information in response to the patent listing dispute, FDA will not change the information in the Orange Book.

USPTO stands in a position to fill this gap. FDA and USPTO should support legislation creating Orange Book Listing Review (OBLR) proceedings to be conducted by the PTAB. Such OBLR proceedings would involve a review of patent claims alongside the specification of an approved New Drug Application—a paper-to-paper comparison well within the capabilities of the corps of APJs. OBLR proceedings would comport with increased emphasis on administrative dispute resolution within the patent system, harness the considerable expertise of APJs in adjudicating adversarial proceedings and, in view of the declining number of *ex parte* appeals to the PTAB, make use of available USPTO capacity.

To further facilitate Orange Book administration, USPTO restriction and FDA patent certification practices should be aligned. The Hatch-Waxman Act does not treat all patents alike. Only patents on active ingredients, formulations, or methods of medical treatment should be identified for listing in the Orange Book. In contrast, brand-name drug companies should not identify patents claiming a process for chemical manufacture to FDA for listing. And only patents on methods of medical treatment may be subject to section viii statements.

USPTO does not maintain these statutory categories when it issues patents. Because the USPTO routinely issues patents across multiple inventive categories, the FDA has developed a complex "split certification" process. USPTO should instead alter its restriction practice to account for the Hatch-Waxman Act's different treatment of distinct categories of invention. In particular, USPTO pharmaceutical patent practice should distinguish between (1) an active ingredient or formulation; (2) a method of medical treatment; and (3) a method of manufacture. No granted pharmaceutical patent should be directed towards more than one of these categories.

Finally, FDA's anomalous, nonstatutory use code practice should be discarded immediately. FDA does not assess the right to exclude afforded by a method-of-use patent in terms of the claims that the USPTO grants. Rather, FDA relies upon patent proprietors to paraphrase the scope of their patents using 250 characters or less. FDA apparently did not establish the 250-character limit following consultation with USPTO. Rather, FDA decided that this highly condensed summary of complex legal texts granted by USPTO was appropriate due to the size of a database field in FDA's antiquated computer system.

FDA has elevated use codes to the status of proprietary rights to which generic drug companies are accountable. If the use code indicates that the patent claims a method of use for which approval is sought, then the generic applicant must submit an ANDA with either a paragraph III or paragraph IV certification. Otherwise, the generic applicant may submit a section viii statement.

At the outset, FDA does not verify any of the submitted use code information provided by a brand-name drug company. It merely lists the use code and its accompanying narrative in the Orange Book. FDA's dispute resolution process with respect to use codes is also constrained. The relevant FDA regulation limits statements of dispute regarding use codes to 250 words directed

towards the "person's interpretation of the scope of the patent." FDA then forwards the information to the brand-name drug company. Unless the brand-name drug company withdraws or amends its patent information in response to the patent listing dispute, FDA will not change the information in the Orange Book.

This anomalous, nonstatutory use code practice for paraphrasing patents is so reductionist as to be absurd. It results in broader intellectual property protection for brand-name drug companies than Congress has allowed. It should be terminated immediately.

FDA should read the claims of issued patents as the USPTO granted them, not in a summary and potentially self-serving form that may inaccurately portray the scope of exclusivity they provide. If FDA remains unwilling to acquire sufficient expertise to construe the legal texts to which all members of the public are accountable, and which were granted by a peer agency, then FDA ought to avail itself of USPTO resources as soon as possible.

Thank you for the opportunity to provide these remarks.