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Another Letter From Congress Complaining About Pharmaceutical Patents

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On April 26, 2023, Senator Elizabeth Warren and Congresswoman Pramila Jayapal sent a letter to USPTO Director Kathi Vidal complaining about the USPTO's failure "to address the pharmaceutical industry's abuse of the patent system." Frustrated by the USPTO's apparent willingness to grant "excessive patents because of the revenue it collects from patent issuance fees," the letter provides "specific recommendations, to urge the USPTO to take immediate action and do everything in its power to hold prescription drug companies accountable for their greedy business practices."

The Warren-Jayapal Recommendations

The letter outlines the following six proposals for the USPTO's consideration:

1. Revise the USPTO's practice of granting obvious patents.

This is referring to the grant of patents with claims that are obvious variations of each other on the condition of filing of a terminal disclaimer. The letter mischaracterizes the origin and effects of the doctrine of obviousness-type double patenting, referring to it as a "loophole." It's actually a judicially-created doctrine that poses *an additional hurdle* to obtaining a patent beyond the statutory requirements.

2. Patents tied together by terminal disclaimers should all stand or fall together when challenged.

This proposal stems from a theory that the sheer number of patents covering a drug—rather than their validity--discourages generics from even trying to enter the market. The drastic nature of this proposal is underscored by 35 USC § 282, which holds that *even within the same patent* "[e]ach claim … shall be presumed valid independently of the validity of other claims"

3. Raise filing fees and limit the number and time period for continuation applications to discourage "obviousness-type double patents."

The USPTO already has proposed to increase filing fees for certain continuation applications, but the USPTO's ability to impose extra-statutory restrictions on continuation applications was challenged in the *Tafas v. Dudas* dispute. *See* 511 F. Supp. 2d 652 (E.D. Va. 2007).

4. Require applicants to disclose at the time of filing whether the drug compound covered by the patent application is in clinical trials.

The aim of this proposal is to permit the USPTO to "rigorously examine" patents destined to be listed in the Orange Book and "assign more examiners and apply a more intensive examination." Would such a practice lead to a stronger presumption of validity?

5. Reverse policies that have led to an increase in discretionary denials of petitions filed through the inter partes review (IPR) process.

This proposal is aimed at the PTAB's *Fintiv* denials and the related Advance Notice of Proposed Rulemaking. That rulemaking aims to provide "clear, predictable rules … that would provide for discretionary denials of petitions in [specific] categories," such as petitions filed by certain non-market competitor for-profit entities; petitions challenging under-resourced patent owner patents; petitions challenging patent claims previously upheld against patentability challenges; serial petitions; parallel petitions; and petitions challenging patents involved to ongoing parallel district court litigation.

6. Establish an office dedicated to building public transparency, serving the public interest, and strengthening interagency communication.

Under this proposal, the letter notes:

"Accessing basic information about patents such as expiration dates, owners, licensing, and application statuses is difficult if not impossible for members of the public and even experts, limiting public knowledge and accountability of the U.S. patent system."

This is true. The USPTO does not even calculate expiration dates, let alone publish them, and determining a patent's expiration date requires digging deep into USPTO records and an understanding of various patent laws. The USPTO does not collect or publish licensing information, except when patent holders voluntarily record license agreements or voluntarily list their patents as available for licensing on the Patents 4 Partnerships Marketplace website, which currently is available for covid-19-related technologies.

The Warren-Jayapal Recommendations

The Warren-Jayapal letter follows the September 9, 2021 letter from Senators Leahy and Tillis to then-Acting Director Hirshfeld, but is decidedly less balanced. Where Senators Leahy and Tillis recognized that "strong intellectual property rights play an important role in the development of biopharmaceuticals, biosimilars, and treatments that save millions of lives every single year," Senator Warren and Congresswoman Jayapal barely acknowledge that "pharmaceutical companies have played essential roles in developing and producing lifesaving drugs" after accusing them of having "repeatedly abused the patent system to stifle competition and prolong their market power, showing no regard for the harm done to patients through sustained high prices."

Congress seems determined to "do something" about pharmaceutical patents, but it could be difficult to address the perceived problems without triggering unintended consequences with far-reaching effects across the U.S. economy. Unfortunately, Congress is not bound by the principle of the Hippocratic oath to *first do no harm*.

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