United States Senate

WASHINGTON, DC 20510

June 8, 2022

The Honorable Kathi Vidal
Director
U.S. Patent and Trademark Office
600 Dulany St.
Alexandria, VA 22314

Dear Director Vidal:

The patent system is an engine of our economy. But when misused, it can stifle innovation and harm ordinary Americans and small businesses. Some of us wrote to you last year about two patent-quality-related concerns: the U.S. Patent and Trademark Office (USPTO) declining to address poor quality patents on their merits through discretionary denials of inter partes review proceedings, and drug companies making conflicting statements about the novelty of their drug formulations to two different government agencies, with no repercussions for that behavior. We look forward to receiving answers to those letters as soon as possible.

Today we write about a third problem that negatively impacts millions of Americans: large numbers of patents that cover a single product or minor variations on a single product, commonly known as patent thickets. These are primarily made up of continuation patents and can stifle competition. President Biden recently recognized that, in the context of prescription drug prices, these patent thickets "have been misused to inhibit or delay—for years and even decades—competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs."

Patent thickets harm competition through sheer numbers. In the drug industry, with the most minor, even cosmetic, tweaks to delivery mechanisms, dosages, and formulations, companies are able to obtain dozens or hundreds of patents for a single drug. This practice impedes generic drugs' production, hurts competition, and can even extend exclusivity beyond the congressionally mandated patent term. In other industries, there is a similar problem where companies use continuations to get patents covering existing standard technology that is already widely adopted. And continuation applications, rather than being closely scrutinized because of these harmful incentives, are granted at *higher* rates than original applications.

We are concerned about the prevalence of continuation and other highly similar patents. The Patent Act envisions a single patent per invention, not a large portfolio based on one creation.[1] But continuations now account for almost a quarter of all patent filings. We are concerned this could mean the USPTO is granting multiple patents for one invention, in contravention of the statutory text.

[1] "Whoever invents or discovers any new and useful process … may obtain *a* patent therefor." 35 U.S.C. § 101. And patents must "particularly point[] out and *distinctly* claim[] the subject matter" of the invention. 35 U.S.C. § 112(b).

We ask that you consider changes to your regulations and practices to address these problems where they start, during examination. While we still need consistent avenues to address poor-quality patents after issuance, this is an opportunity to take prompt action at the preissuance stage. We are interested in your views and those of the public. We therefore ask that your office issue a notice of proposed rulemaking or a public request for comments by September 1, 2022 based on the following questions, with responses due within sixty days. We ask that your office then consider the responses, send us your reactions, and take regulatory steps to improve patent quality and eliminate large collections of patents on a single invention.

1. Terminal disclaimers, allowed under 37 C.F.R. 1.321(d), allow applicants to receive patents that are obvious variations of each other as long as the expiration dates match. How would eliminating terminal disclaimers, thus prohibiting patents that are obvious variations of each other, affect patent prosecution strategies and patent quality overall?

2. Currently, patents tied together with a terminal disclaimer after an obviousness-type double patent rejection must be separately challenged on validity grounds. However, if these patents are obvious variations of each other, should the filing of a terminal disclaimer be an admission of obviousness? And if so, would these patents, when their validity is challenged after issuance, stand and fall together?

3. Should the USPTO require a second look, by a team of patent quality specialists, before issuing a continuation patent on a first office action, with special emphasis on whether the claims satisfy the written description, enablement, and definiteness requirements of 35 U.S.C. § 112, and whether the claims do not cover the same invention as a related application?

4. Should there be heightened examination requirements for continuation patents,[2] to ensure that minor modifications do not receive second or subsequent patents?

5. The Patent Act requires the USPTO Director to set a "time during the pendency of the [original] application" in which continuation status may be filed. Currently there is no time limit relative to the original application. Can the USPTO implement a rule change that requires any continuation application to be filed within a set time frame of the ultimate parent application? What is the appropriate timeframe after the applicant files an application before the applicant should know what types of inventions the patent will actually cover? Would a benchmark (e.g., within six months of the first office action on the earliest application in a family) be preferable to a specific deadline (e.g., one year after the earliest application in a family)?

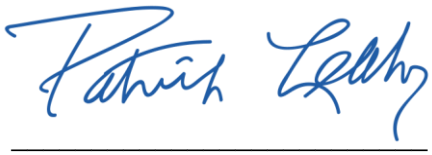
6. The USPTO has fee-setting authority and has set fees for filing, search, and examination of applications below the actual costs of carrying out these activities,

[2] See U.S. House Committee on Oversight and Reform, "Drug Pricing Investigation Majority Staff Report," at 107 (Dec. 10, 2021).

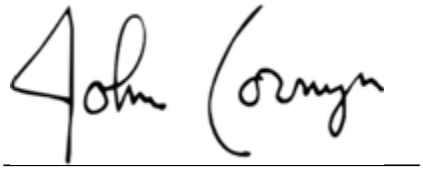
while maintenance fees for issued patents are above the actual cost. If the up-front fees reflected the actual cost of obtaining a patent, would this increase patent quality by discouraging filing of patents unlikely to succeed? Similarly, if fees for continuation applications were increased above the initial filing fees, would examination be more thorough and would applicants be less likely to use continuations to cover, for example, inventions that are obvious variations of each other?

We look forward to hearing the public's comments on these questions, as well as any other solutions you might propose to end the abuse from repetitive patents.

Sincerely,



Patrick Leahy
United States Senator



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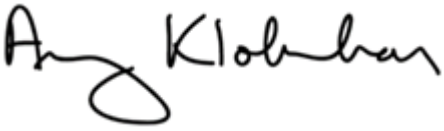

Amy Klobuchar
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