

United States Senate

WASHINGTON, DC 20510

September 9, 2021

Mr. Andrew Hirshfeld
Performing the Functions and Duties of Director
U.S. Patent and Trademark Office
600 Dulany St.
Alexandria, VA 22314

Dear Mr. Hirshfeld:

As Chairman and Ranking Member of the Senate Judiciary Intellectual Property Subcommittee, we strongly believe that improving patent quality will increase competition and drive economic growth. We also believe 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. However, in order to be entitled to strong intellectual property protections, a patent must meet all the requirements of patentability, including being non-obvious and not anticipated by any prior art.

Unfortunately, it has come to our attention that some patent applicants may, in certain circumstances, make significantly different statements in submissions to other federal agencies that conflict directly with those made at the U.S. Patent and Trademark Office (PTO). We seek to understand the circumstances around such statements, as such a practice could undermine both patent quality and competition. To improve the system, we write today to request that the PTO consider necessary measures requiring patent applicants to disclose additional information during the patent examination process.

We appreciate your recent effort to remind patent applicants about their disclosure obligations in the context of hypothetical experiments that they have not actually performed and that they are using to apply for a patent. Reminding applicants of their obligation to at least clarify when they have not performed experiments they purport to have performed is a good step toward preventing applicants from patenting imaginary or aspirational inventions, which, again, both dilute patent quality and stifle competition.

We are now requesting the PTO take steps to reduce patent applicants' making inappropriate conflicting statements in submissions to the PTO and other federal agencies. These conflicting statements too often are submitted confidentially or go unnoticed until after a patent issues, and only then do third parties have the incentive or ability to review the patent owner's statements before both agencies. There is a clear need for the PTO to take action to require applicants to disclose relevant statements they have made to other agencies relating to inventions discussed in their patent applications or about prior art that is being applied in the patent examination process.

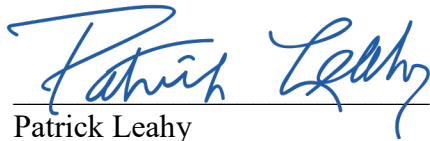
For example, inconsistent statements submitted to the Food and Drug Administration (FDA) to secure approval of a product—asserting that the product is the same as a prior product that is already on the market—can then be directly contradicted by statements made to the PTO to secure a patent on the product. When a certain piece of prior art is already being applied by the

examiner, and the patent applicant has made statements about that prior art to another federal agency that establish that the invention claimed is not novel, making conflicting statements to the PTO should be cause for rejecting the application and, when made knowingly and with bad intent, potentially other sanctions.

Of course, we understand that requiring patent examiners, who are already time constrained, to consider even more prior art information will impose some costs. But we believe that such costs can be reduced and constrained by the creation of a smooth, predictable, and regular channel of information from other federal agencies to the Patent Office. This, in turn, could create savings that accrue from the earlier entry of truly new and innovative competitors.

We ask that you take steps as soon as is feasible to enforce patent applicants' obligations to disclose statements made to other government agencies. Thank you for your prompt attention to this matter. We look forward to continuing to work with you to improve the quality of patents issued by the PTO and promote competition in our economy.

Sincerely,



Patrick Leahy
United States Senator



Thom Tillis
United States Senator