Questions for the Record of Senator Patrick Leahy
Subcommittee on Competition Policy, Antitrust, and Consumer Rights
Hearing on: "A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets"
July 13, 2021

Questions for Dr. Rachel Moodie (Goode)

1. Patents should be a tool to reward innovation, and the patent process is abused when minor changes to a drug are patented and have the effect of extending patents beyond their intended 20-year term or creating an impenetrable thicket, as you so clearly explained in your testimony. I want to address steps the U.S. Patent and Trademark Office (PTO) can take the avoid issuing patents that unfairly extend drug patent terms.

    a. **Should the PTO limit continuation patent applications, either to a certain number per original specification, or to continuations filed within a certain period of time after the original specification is filed? How would you recommend the PTO limit continuations? What effect would that limit have on patent thickets and the ability for biosimilars to enter the market?**

Answer: It is true that preserving true innovation is vital to the American healthcare system, but a proper balance must be struck to foster affordability when those drugs are no longer considered innovative. One way that the USPTO could right this important balance would be to allow patent examiners to evaluate double patenting challenges by requiring that any terminal disclaimer filed by the patent holder to overcome an obviousness type double patenting challenge be recorded as a binding admission of double patenting. Alternatively, Congress could write this into legislation. The terminal disclaimer is just that, an admission that two or more patents are not patentably distinct from each other and should be enforced as such by the courts, i.e. if one patent is found to be invalid, then those patents that are tied to it through terminal disclaimers would become non-enforceable. However, by not making this distinction, those terminally disclaimed secondary patents are shielding entire patent families from scrutiny as a biosimilar manufacturer would be required to challenge each duplicate patent individually and cannot afford to do so, plus courts cannot effectively litigate scores of patents. This delays biosimilar launches. In some cases, terminally disclaimed patents make up a majority of the innovators' patent portfolio. This practice of circumventing double-patenting through terminal disclaimers is not allowed anywhere else in the world.

Example:

Case study: Drug X patent portfolio
Clusters of US patents

● = one patent

◯ = a cluster of patents linked through terminal disclaimers (non patentably-distinct claims)

▭ = a patent family (Inpadoc standard definition)

Product	Primary indications	Formulation single conc	Secondary indications	Purity level	Tertiary indications	Juvenile indications	Formulation double conc
10	4	21	15	8	2	3	4
1 invention	**4 inventions**	**1 invention**	**4 inventions**	**1 invention**	**1 invention**	**1 invention**	**1 invention**
10 patent cluster	4 patent cluster + 3 distinct patents	21 patent cluster	15 patent cluster + 3 distinct patents	8 patent cluster	2 patent cluster	3 patent cluster	4 patent cluster

Summary: 73 patents; 14 distinct inventions; 59 patents are non-patentably distinct

Such "obvious-type double patenting" is permissible under the US patent rules

Case study comparison to Europe, Drug X patent portfolio in Europe

● = one patent

◯ = a cluster of patents linked through terminal disclaimers (non patentably-distinct claims)

▭ = a patent family (Inpadoc standard definition)

Product	Primary indications	Formulation single conc	Secondary indications	Purity level	Tertiary indications	Juvenile indications	Formulation double conc
2	2	2	1	Patent not granted	1	Patent not granted	Patent not granted
2 inventions	**2 inventions**	**2 inventions**	**1 invention**	**-**	**1 invention**	**-**	**-**
2 distinct patents	2 distinct patents	2 distinct patents	1 distinct patent	-	1 distinct patent	-	-

Summary: 8 patents; 8 inventions; 0 patents are non-distinct; 0% of the portfolio is duplicative

Double patenting is not permitted by the European Patent Office

It is, however, important that originators are incentivized to continue to improve the drug after launch, which is why, each distinct invention should receive its own patent. Some of these patents are strong and should be respected as such. This policy would ensure that originators that innovate more, are rewarded for those inventions, but cannot game the patent system through double patenting. This would essentially allow these duplicates to stand and fall together based on the strength of the parent patent.

Another policy that would achieve the same goal of reducing duplicative patents within a thicket, would be to introduce legislation to cap the number of patents that can be litigated against a biosimilar. The cap could allow the patent owner to select one patent from each cluster of patents that are tied together with terminal disclaimers. In other words, the originator would litigate one patent per invention. This type of cap would incentivize originators to invest into innovation to increase the number of inventions, rather than increasing the number of obvious-type double patenting surrounding each invention.

b. As you indicated in your testimony at the hearing, continuation patents can sometimes be the lowest quality patents. Are continuation applications allowed by the PTO on a first office action more often than parent applications are allowed on a first office action? While it is currently the case that an examiner can allow an application without anyone else looking at the file, do you think it would help for the PTO to have a second person examine applications that the first examiner proposes to allow on a first office action?

Answer: As exists in many patent offices around the world, the U.S. could consider establishing a pilot program for a quality control committee in the pharmaceutical and biotechnology art units. A team of experienced examiners that approve any notice of allowance before it is sent to the patent filer could help evaluate the validity of multiple patents being filed by the same patent holder. This coupled with rebalancing the count system, which is the system used to evaluate patent examiner performance. Currently, patent examiners receive more points for granting a patent than for rejecting a patent. Under a revised count system, patent examiners would receive the same count for patent grants as for a final office action. Furthermore, by limiting requests for continued examination (RCEs) from the innovator would go along way towards ensuring that only high-quality patents are granted.

c. You mentioned at the hearing that ending the option for applicants to file repetitive claims would help solve some anticompetitive harms. What are some steps the PTO could take to end repetitive claiming?

Answer: Tightening written description rules regarding claim amendments and the filing of claims in continuation & divisional patent applications would help to correct this anticompetitive behavior. Policies should be adopted that prevent the “cherry picking” of elements from different disclosures or “laundry lists” within the specification and combine them into claims to create artificial embodiments. The USPTO could also update MPEP to include impermissible examples of broad claim language in the pharmaceutical secondary patent space. In particular, the practice of granting broad claims on pharmaceutical formulations should be restricted because such broad claims impede biosimilar companies from designing non-infringing formulations. This reduces the investment into innovation of alternative, new formulations of old drugs. Furthermore, secondary

patents having broad claims to the formulation can result in an inappropriate extension of the monopoly on the drug itself by blocking the development of non-infringing alternatives.

2. You testified that one way to improve generics' ability to compete is having better third-party tools during patent examination.

    a. **Would it help to have more incentives, and fewer disincentives, for the public to submit relevant prior art during examination? What do you recommend as ways to improve the current incentives?**

Answer: Currently the public is disincentivized from submitting prior art to the USPTO during patent prosecution because, in case the examiner has the discretion of whether or not to use it against the patent. Even if an examiner does not review the prior art, the document is on the record, meaning that its value in an inter partes review or post grant review is diminished. Therefore, the public would be incentivized to submit relevant prior art if the patent examiners are mandated to comment on the document. Furthermore, the deadline for submitting prior art to the USPTO should be extended.

    b. **Would it help to have a way for the public to alert the PTO of non-prior-art issues, such as knowledge that the application is based on retracted scientific information or that the application is claiming a competitor's existing product?**

Answer: Yes.

3. At the hearing, you mentioned that inter partes reviews have been weakened recently as a tool to limit drug prices.

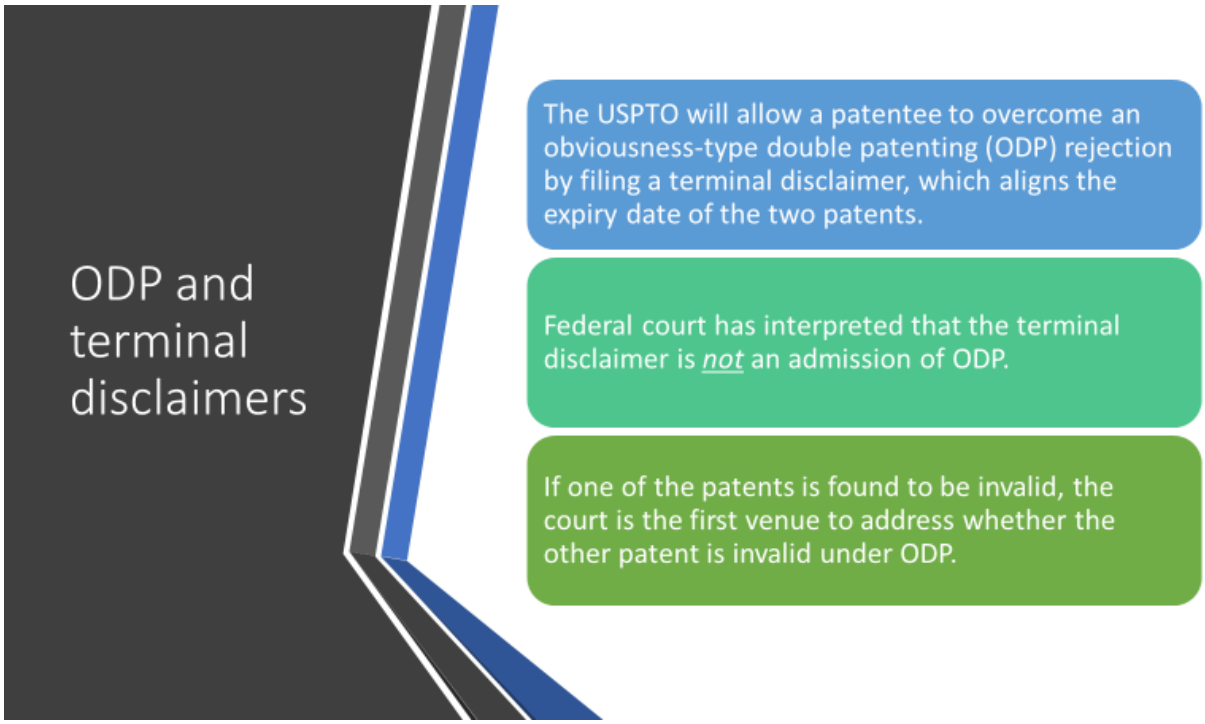
    a. **Please explain what steps were taken to weaken inter partes reviews recently and how that weakening affects drug prices.**

Answer: There are two main issues at the PTAB level that weaken IPR as a tool, and as a result, delay biosimilar launch, and keep patients paying high prices for branded drugs. The first is that, currently, biosimilar companies do not have standing to appeal a negative IPR/PGR decision if they have not already submitted a dossier to the FDA. This rule treats legitimate biosimilar manufacturers as patent trolls, as opposed to legitimate competitors acting in good faith. This rule precludes biosimilar companies for pre-emptively clearing the path of invalid patents prior to FDA approval. This allows the patent owner to use the uncertainty of the patent situation to chill timely launches of biosimilars because the launch at risk calculation includes the threat of owing lost profit damages to the originator, which is untenable for a biosimilar manufacturer.

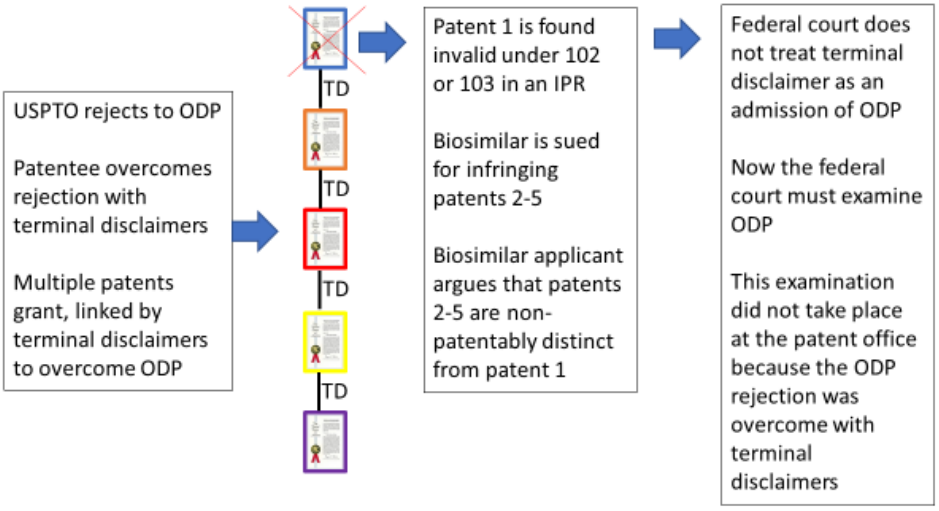
Secondly, in the last several years, the Patent Trial and Appeal Board (PTAB) has increased the number of "discretionary" denials for institution of IPRs, PGRs and ex parte reexamination. The overuse of denying institution of IPRs impacts all areas of technology and is not consistent with the expectations of Congress when they created the Leahy-Smith America Invents Act (AIA). Institution decisions are not appealable.

    b. **Based on your testimony about repetitive patent claims, would it be useful for double patenting to be a basis for inter partes reviews at the PTO?**

Answer: As stated above, we believe that double patenting should be addressed at the patent examiner level. For example:

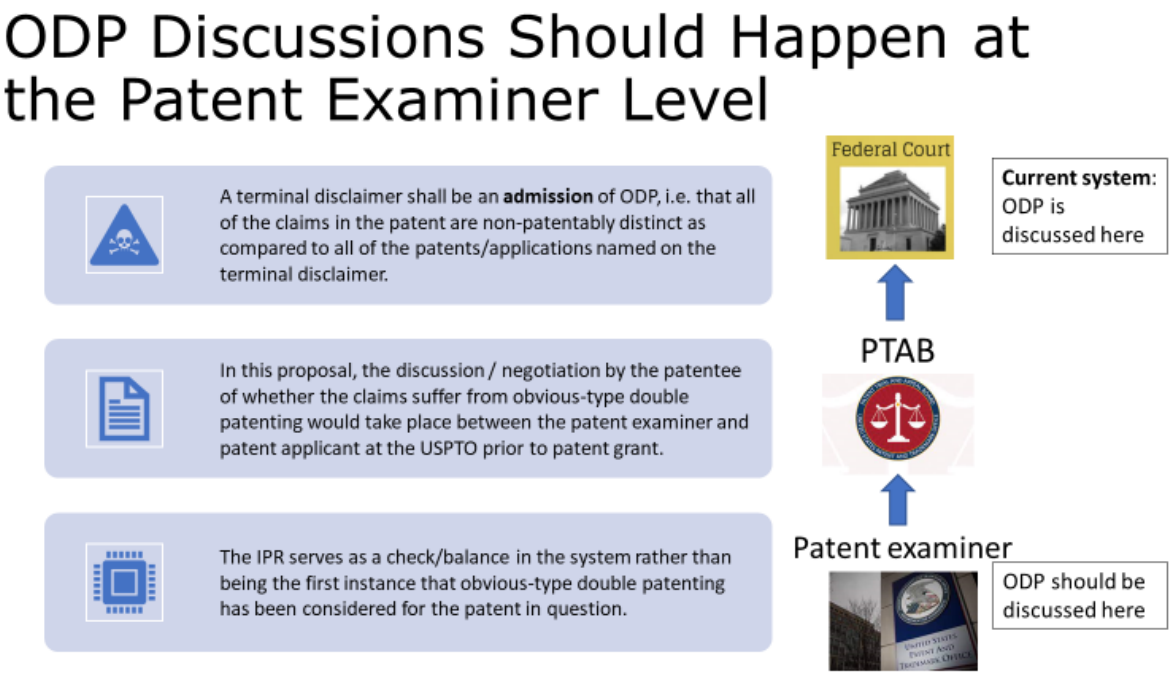


Example



Why should ODP be added as an IPR ground

- Instead of the Federal Court being the first venue to examine ODP, the USPTO would be required to consider ODP
- The USPTO would have an opportunity to weigh in on ODP before the question reaches the court
- The USPTO is the expert on ODP



4. Certain products, including drugs, are cleared by the Food and Drug Administration (FDA) after the maker establishes that the products are sufficiently similar to products already on the market. At the same time, these companies are often applying for patents for the same products. In some cases, drug makers may make significantly different statements in submissions to the FDA that conflict with those made at the PTO.

    a. **In your view, would statements made by a patent applicant to another federal agency such as the FDA be relevant to the PTO's patent examination effort?**

Answer: We support FDA/USPTO coordination for this very reason. If a patent holder disclosed an invention in an FDA filing several years prior to when the patent on the same invention was filed, that patent should not be granted by the PTO examiner because it was obvious as of the number of years that patent was not filed, but was disclosed to the FDA. This is a harmful brand behavior that ensures that they will have strong patents standing at the end of their patent portfolio life which could serve to shield their weaker patents and force settlement dates beyond what is appropriate. It is not dissimilar to the "submarine patent" behavior that was corrected with legislation several years ago.

Should there be improved coordination between the PTO and agencies such as the FDA to ensure that the PTO is aware of relevant statements the applicant has made in other contexts?

Answer: Yes, we believe that this is important to eliminating barrier to biosimilar entry. For example:

Policy ideas: FDA / USPTO Coordination

FDA / USPTO Coordination	
3a	The PTO Director shall require the inventor and patent applicant to disclose the existence of any FDA submissions related to the subject matter of the invention and confirm that the inventor or patent applicant is not aware of any inconsistent information submitted to the FDA.
3b	The FDA is available to (1) answer questions from the PTO regarding the technical details of the subject matter of the pharmaceutical invention, (2) provide relevant extracts from the drug dossier (NDS, BLA) and (3) to conduct research on special problems.

Example of how this might work in practice:

1997: Product patent publishes ⟷ Same drug ⟷ **2006:** Purity level patent filed

- FDA informs PTO that this level of purity is necessary for FDA approval of this drug.
- PTO decides that patent claims are obvious compared to the 1997 patent.