Responses of Professor David S. Olson, Boston College Law School*
to Questions for the Record Related to:

Hearing on Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition (May 7, 2019)

United States Senate Committee on the Judiciary

Questions for the Record from Senator Chuck Grassley of Iowa

USPTO Director Iancu says that the U.S. Patent Office does not grant patents for "tweaks" or minor improvements to inventions. Do you agree? Please explain. If you believe that this is an issue, what action would you recommend Congress take to ensure that follow on patents for drug improvements are only granted for true innovations?

Patents may not be granted for inventions that, at the time of filing, are lacking in novelty (35 U.S.C. §102), or are obvious to a person having ordinary skill in the art to which the invention pertains (35 U.S.C. §103). The law is very clear on this. Obvious improvements to current products or processes are not patentable. I assume that this is what Director Iancu meant when he said that patents cannot be granted for "tweaks" or minor improvements.

Having said that, there may be times when an improvement to a prior invention may be difficult to make, and therefore nonobvious, and thus patentable, but commercially may seem to be only a minor improvement. For example, if an inventor worked for years to invent a new way to increase the life of lithium ion batteries by 2%, and that invention was not obvious to others of ordinary skill in the field, this would qualify as a patentable invention. In the marketplace, however, 2% greater battery life might seem a minor improvement, and thus some might argue that the patent should not be granted.

Patent law does not primarily focus on significance in the market to determine patentability (although commercial success may sometimes be viewed as a sign the invention was nonobvious). Instead, patent law simply asks whether a person of ordinary skill in the art would find an improvement obvious. The test for this is to ask whether a person of ordinary skill acquainted with the relevant prior art and the problem to be solved, would have made the claimed invention without having to engage in undue experimentation. If the consideration of obviousness leads the PTO or a court to determine that the invention would have been nonobvious to a person with ordinary skill, then the invention is patentable (assuming all other requirements for patentability have been met).

This means that a large number of nonobvious advances can be made and patented even if each has small market significance. Thus, looked at from the perspective of market significance, one could argue that patents *can* be granted for minor improvements. Moreover, if a great number of patents are granted for improvements to a device like, say, a smart phone, each of which is of relatively low market value, one could call this a "patent thicket." One might argue that innovation will be retarded in smart phones because manufacturers will have to license thousands of patents and some patent owners may engage in hold-up behavior to obtain unreasonable royalties.

The scenario of numerous patents being granted for overlapping and complimentary technology (what some might call "patent thickets") is generally unproblematic, however, and in fact can be a benefit of patent law. There are a number of reasons for this. First, much of innovation is carried on by small, steady improvements, and patent law is designed to encourage such cumulative innovation by granting each small, nonobvious invention a patent. Second, if a patent owner seeks to charge an unreasonable rate for his/her invention, a manufacturer is free simply to use other

technology, or to produce the device by using older technology on which patents have expired (putting aside Standard Essential Patents as a special case for which FRAND licensing exists).

Third, the market has been innovative in decreasing transaction costs for licensing patents by use as such tools as patent pools from which a participant in an industry may obtain a single license to a large number of the patents that cover a particularly technology. The combination of competition from older and alternative technologies as well as the innovation of market tools to reduce licensing costs seems generally to have been sufficient to overcome significant risk to innovation from patent thickets and holdups. Indeed, in the area of smartphones, some estimate that thousands or tens of thousands of patents cover the complex hardware and software on modern smartphones. But notwithstanding the large number of patents in the field as well as a significant patent war between Samsung and Apple, smartphone innovation has continued at a rapid pace.

So far, I have used non-pharmaceutical examples when discussing patent law, for the sake of simplicity and to show how patent law works uniformly across industries. Now let us consider the case of patents and pharmaceuticals. When it comes to pharmaceuticals, the likelihood of patent thickets is much lower. While tens of thousands of patents may cover a single smartphone, the most prominent example that some people point to for patent thickets is the allegation that AbbVie has over 100 patents related to Humira. I have not been able to carefully examine the patents related to Humira at the time of this writing, so I cannot speak to those patents specifically. But it is a requirement of patent law that each new patent be for a new, nonobvious improvement over the prior art. Thus, no patent can issue that covers a prior drug. A new patent may cover a nonobvious change to the prior drug, however, which may include a new formulation, extended release, etc., but only to the extent that these were nonobvious over the prior drug and other prior art. A drug manufacturer can also patent improvements to the methods of manufacturing a drug. While these new patents on changes to the drug or manufacturing methods may be commercially valuable, they cannot be used to prevent a generic from making the originally claimed drug once the original patent expires. 35 U.S.C. §112 requires that a patent must disclose the claimed invention and the method of making and using it in such clear and full language that a person having ordinary skill in the art can make and use it without having to engage in undue experimentation. Thus, every valid patent must teach competitors how to make and use the claimed invention.

In addition, when it comes to biologics, the methods of manufacture are more difficult and more expensive. It makes sense to offer the incentive of patent rights to encourage innovation in the best ways to manufacture specific biologics. These new method patents will give incentive for improvements, but cannot be used to stop generic competitors from using earlier methods of manufacture, once the earlier patents expire.

In sum, patent law is clear that only new, nonobvious inventions may be patented, and one may not extend the patent term of an earlier patent by filing a later patent. Having said that, there are certain ways that patent owners might seeks to abuse the patent system to deter competition.

First, patent owners may file later patents, and then argue that the later patent somehow covers the original invention. This is clearly wrong on the law, and should not be successful in court.[1] Moreover, a blatant assertion of patent coverage where there is none can qualify as an antitrust violation resulting in treble damages. Nevertheless, some drug companies may try to assert patents that do not cover earlier formulations of drugs. This may deter some competition, but it is so clearly wrong that it is likely an ineffective tool for drug companies.

Second, patent owners may file continuation patents and seek to assert them in overbroad or anticompetitive ways. Continuation patents cannot extend the term of the original patent, because continuation patents expire on the same day as the original patent to which they are related. But patent owners can use continuation patents to try to write claims that cover what their competitors are doing. For instance, if a drug company has a patent on a method of manufacturing its drug, it can prevent others from using that method of manufacture during the life of the patent. A competitor is free to "design around" the original patent, however, and come up with its own way of manufacturing the drug. At this point, an aggressive drug company might amend the claims in a pending continuation patent so that they cover the manufacturing method of the competitor. This new patent claim can only be valid if the originally filed patent truly disclosed the manufacturing method of the competitor. If it did not, the continuation claim to the competitor's method of manufacture is invalid.

Because language is inherently flexible, however, and because it can be difficult to tell exactly what a patent specification disclosed to one of skill in the art, a patent owner can argue that his/her original patent specification provides enough description and enablement to support a claim to a competitor's method of manufacture, and can thus threaten to sue for infringement. This threat may keep a competitor off the market, in certain circumstances if the competitor is litigation averse. The ability to use continuation patents in such an aggressive way is the reason a number of patent owners keep filing continuation patents throughout the life of their original patent, so that they have the option to write claims that cover their competitors' activities. Accordingly, it may make sense to look at limits to the number of continuation patents a patent owner can file.

Patent owners can also try to prevent competition by denying samples to generics, which is why passing the CREATES Act is important.

Likewise, patent owners may engage in product-hopping to try to prevent prescriptions being written for generic versions of drugs on which patents have expired. This is why product-hopping legislation is important.

Patent owners may also seek to engage in pay for delay with generics. This is why the proposed anti-pay for delay legislation is important.

[1] See, e.g., Schering (invalidating patent and rejecting argument that later-filed patent on the metabolite that inevitably results in the human body from taking Claritin prevented generic competitors from manufacturing generic Claritin once original Claritin patent expired).

Questions for the Record from Senator Thom Tillis of North Carolina

1. Is it true that every patent is for a separate invention?

The simple answer to this question is no, not every issued patent is for a separate invention. But it is also true that applicants *cannot* extend the term of patent protection for the same invention by filing multiple patents. So, in effect, it is true that every new patent that expires later in time must be for a new invention. Put differently, a patent owner can never extend the length of patent coverage for the same invention by filing additional patents.[2]

To understand how this works, it is necessary to understand the basics of patent prosecution and of continuation patents. In a nutshell, when a patent applicant applies to the Patent and Trademark Office ("PTO") for a patent on an invention, the applicant is required to submit a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the [invention]."[3] This written description includes drawings and any comparison of the invention with prior art to show how the invention is new and nonobvious. This written description, including all of the drawings and the abstract, is generally referred to as the patent "specification." Basically, the "specification" is everything except the claims, which are at the very end of the patent document. When the patent applicant files a patent, s/he discloses the invention in the specification, and then negotiates with the Patent Office over which (if any) of the claims to the invention will be allowed to issue as part of the patent.

To receive a patent, the inventor must file claims "particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."[4] Thus, in patent law, people often say "the claim is the game," because it is the claim that sets forth the boundaries of the claimed invention, and thus it is only claims that may be infringed, not patents as a whole. Patent law teachers often make a comparison between claims in patents and deeds for real property, because both describe the limits of the owners' property rights to exclude others.

Because there is likely to be some uncertainty and disagreement as to the full extent of what can be claimed as an inventor's exclusive right, in light of the patent specification and the relevant prior art, it is unsurprising that there is typically discussion back and forth between the patent applicant and the patent examiner as to which claims the examiner will allow to issue. During this process, the patent applicant can amend, cancel, or write new claims that seek to set forth the boundaries of the invention, or perhaps different embodiments of the invention. In addition, each patent may have multiple claims. This allows the patent applicant to claim his/her invention both broadly and narrowly, and to claim different ways of making or using his/her invention.

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[2] 35 U.S.C. § 112. 35 U.S.C. § 120. *Mendenhall v. Cedarapids Inc.*, 5 F.3d 1557, 1566, 28 USPQ2d 1081, 1088-89 (Fed. Cir. 1993) ("A patentee cannot obtain the benefit of the filing date of an earlier application where the claims in issue could not have been made in the earlier application.");*In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995).
[3] 35 U.S.C. §112(a).
[4] 35 U.S.C. §112(b).

An example will help illustrate this. Imagine going back in time to when the humble stool was first invented. The inventor could file a patent describing the stool as a generally horizontal seating surface roughly parallel to the ground, with at least three elongate members [legs] supporting the seating surface. The inventor must also explain how to build a stool. S/he can then file a number of claims, including the following:

1. A seating apparatus comprising a seating surface and three elongate members [legs].
2. A seating apparatus comprising a seating surface and four elongate members [legs].

In this hypothetical example, the inventor described and enabled building a stool with at least three legs. Thus, if the inventor likes, s/he may write separate patent claims for stools with three legs, four legs, five legs, etc. This is allowed because the inventor has taught in the specification how to make all of these things, and thus can claim all of these variations of his/her invention. It is true that the inventor could merely claim a stool with three or more legs, but s/he is smarter to draft multiple claims because s/he knows that there could be prior art out there that might invalidate one of her claims, but not another. For instance, if s/he claimed a stool with six legs, a prior art picnic bench may qualify as a seating surface with six legs, and thus invalidate a claim to a stool with six legs, but not invalidate a claim to a stool with three legs (although it is true that the bench might make the three legged stool invalid for lack of obviousness given how simple the technology is in this example, but that is not always the case).

It is important to note that during all of the drafting and amending of claims, the patent specification, which describes and enables the invention, may never be changed. Claim drafting and negotiation is about setting the official limits to the exclusive rights that come with a patent, not about adding any new description or invention to the patent.

Once the patent examiner says that a particular patent claim is ready for allowance, that claim will issue as part of the patent upon issuance. Thus, a patent may issue with multiple claims, and each claim is evaluated separately for infringement and validity purposes when asserting the patent. If the hypothetical patent owner sues someone else for making stools, that other person may violate the claim to four-legged stools, but not three-legged stools. But infringement of a single claim is enough. If a single claim is both valid and infringed, the patent owner may receive a judgment against the infringer, and may be allowed an injunction and/or money damages.

All of the above is important for an understanding of how modern patent prosecution works, and especially how patent continuations work. When a patent is filed, the patent examiner will go back and forth with the patent applicant up to three times evaluating the patent claims. Each of these responses from the patent examiner is called an “office action.” A patentee is only allowed three office actions per patent, and then s/he may abandon claims that have not been allowed, or may appeal to the Patent Trial and Appeal Board (“PTAB”). In actuality, however, a patent applicant has a third option. If the patentee pays an additional fee, s/he may have three more office actions with the patent examiner in which to fight for the allowance of his/her claims, or continue to amend claims. This is achieved by filing a “continuation patent.” A continuation patent must have the same specification as the first (“parent”) application, but may have new claims. Basically, a continuation patent is a way to allow the initial claims, and then pay to have remaining or new

claims examined. Any claims that issue when the continuation patent issues will have exactly the same term as the patent claims that issued with the original, parent application, because term runs from the date of filing of the earliest patent in a patent chain. Thus, even though the patent continuation claims may issue five years later, they will still expire twenty years after the patent application was first filed.

There is one slight exception to this, the continuation-in-part ("CIP") patent. This is a hybrid. In a CIP, an applicant may continue to press for claims disclosed in the specification of the parent application, but may also add new material to the specification, and then write new claims that are enabled and described by that new material in the specification. In effect, a CIP is a combination of a continuation patent and a new patent.

An example will again be helpful. If the inventor of the stool later determines that adding a back support to the stool will improve it by giving the person something to lean against, the inventor can file a new patent application for a chair. Alternatively, the inventor could file a CIP and add to his/her specification a description of the back support that s/he has added to the stool to transform it into a chair. S/he must add enough description to meet the requirements of §112 that the description enable a person of ordinary skill in the art to make and use the new invention. Once s/he does this, s/he can add new claims to the CIP that claim the chair and common variants. These new claims will not have the same priority date as the original, parent application. Instead, because these new claims are only fully disclosed in the new matter that the inventor has added to the specification, the claims to the chair will have as their priority date the filing date of the CIP. This is only fair, as the invention was not disclosed in the original application. For purposes of determining novelty and nonobviousness of the claims that are disclosed in the new matter in the CIP, any prior art that was public before the date the CIP was filed will invalidate the new claims.

Thus, for CIPs some claims may be fully disclosed in the original parent application, and others may need to rely on the new matter added to the description in the CIP. The priority date for each claim will depend on whether the claim was fully disclosed in the parent or in the new matter in the CIP. Most importantly for concerns of patent extension, however, continuation patents, including CIPs, expire twenty years from the date of the earliest application in the chain (parent, grandparent, great-grandparent, etc.). Thus, CIPs can be used as a way to file a hybrid patent, but they are often disfavored because they cannot be used to extend the term of a patent, and therefore provide a shorter term than would a new patent filing for the new matter added. In the example above, if the inventor simply filed a separate new patent for the chair, the chair would get a patent term of twenty years from the date of filing. This would be better for the inventor than getting the shorter term that would come with a CIP.

Some might call getting a patent on both a stool and a chair "evergreening" or "thicketing." But a closer look shows that a chair is an improvement over a stool, and thus it is appropriate to grant a new patent to encourage invention of the chair, even if the new patent adds just one new element—in this example, the chair back. Thus, while two patents now cover the chair (the stool and the chair patent), this is not a harmful thicket because providing incentive to turn the stool into a chair is a good thing.

Finally, the chair patent cannot be used to extend the monopoly over the stool. The patent on the chair can never be used to prevent others from making stools once the stool patent expires. It is undisputed patent law that a later patent can never cover the invention disclosed in an earlier patent. If it does, the later patent is invalid because it is not novel.

2. And PTO determines, in each case, whether to grant a patent?

The PTO is the entity that determines whether each patent is granted. More precisely, each patent application is assigned to a patent examiner, according to the field of the invention and the examiner's area of expertise. The examiner then examines the patent application and decides whether each claim listed in the application is valid. The examiner makes this determination by assessing, for each claim, whether the claim is:

1. patentable subject matter
2. for a useful invention
3. novel
4. nonobvious
5. enabled by the written description in the specification
6. adequately described in the patent specification so that the boundaries of the invention are clear to one of ordinary skill in the art.

The patent examiner makes this determination by comparing each patent claim to the prior art, including published and issued patents, printed publications, and products and processes that the examiners finds were in public use at the time of filing. For each claim in an application, the patent examiner notes in his/her office action whether the claim is valid or not, and why. For any claims the examiner rejects as being invalid, the applicant can respond to the office action by attempting to convince the patent examiner that the claim is actually valid compared to the prior art, or by amending the claim to try to address the examiner's rejection. If at the end of three office actions, the examiner still rejects some claims, the patent applicant may appeal the decision to the Patent Trial and Appeal Board ("PTAB"), and from there to the Court of Appeals for the Federal Circuit, and, finally, the Supreme Court. Any of these entities may overturn the patent examiner's decision to reject a claim(s). The applicant may, as an alternative, file a continuation patent and continue to attempt to convince the patent examiner to grant his/her rejected claims, or may amend or write new claims (although these claims must always be adequately described in the written specification).

3. And a new patent doesn't ever extend protection of an existing patent?

It is axiomatic patent law that a new patent may never extend the term for an existing patent, nor may a new patent ever cover the invention that was disclosed in a prior patent. Continuation patents may seem like an exception to this, but continuations are actually just a way to get more claims for an earlier filed patent. Continuations are, in effect, a way to let an earlier patent issue with the claims the examiner agrees are valid, while being able to continue to discuss or shape other claims that are also valid and allowable based on the specification. So, one can think of a continuation

patent as simply the same original patent with additional claims that a patent applicant had a right to as of his/her initial patent application filing. And indeed, this is the way patent law treats continuation patents—they always expire on exactly the date of the first patent in a chain of patents (parent, grandparent, etc.).

4. If I, or a company, want to challenge a patent because I think it shouldn't have been granted are there ways to do that?

There are a number of ways to challenge a patent's validity. The America Invents Act of 2011 added some powerful administrative procedures for challenging patent validity in the PTO. First, during the nine months after a patent issues, one may file a Post-Grant Review (PGR) challenge in the PTO based on a claim of invalidity based on any grounds. The Patent Trial and Appeal Board ("PTAB") then examines any new prior art that has been submitted for consideration, and determines whether some or all of the challenged patent claims should be invalidated. Second, after the period for PGR has closed, at any time during the life of a patent, one can file a challenge to a patent's validity via Inter Partes Review ("IPR") at the PTO. The prior art evidence allowed to be considered during an IPR is limited to patents and printed publications. But unlike during patent examination, IPR is an adversarial process in which a challenger can make arguments of invalidity to the PTAB, and thus more zealously argue for invalidity. The PTAB has already invalidated many patents via these administrative procedures.

One can also challenge the validity of a patent's claims in court either via defenses to an infringement suit, or by filing a declaratory judgment action (so long as one has standing). If, after all appeals have run, a court finds any of a patent's claims invalid, those claims are invalid against all others as well. In effect, one can "kill" patent claims either in courts or in PTO administrative proceedings. The administrative proceedings are generally faster and less expensive than determining patent validity in court. In addition, one can move to stay a patent infringement litigation while an administrative review of patent validity is pending, and many stays are granted.

5. What if there was fraud on the PTO? Like if an applicant lied. Are there existing remedies for that?

Committing fraud on the PTO is a serious matter, and there are a number of tools to punish those who do so. A patent owner may have his/her patent invalidated under the doctrine of patent misuse, including fraud on the patent office. This could also qualify as an antitrust violation. In addition, a patent attorney who commits fraud on the patent office may be subject to discipline as a member of the patent bar, as well as to discipline in the states in which that lawyer is admitted to the bar.