



Your Generics & Biosimilars Industry

Testimony of

Jeffrey K. Francer

Senior Vice President and General Counsel

Association for Accessible Medicines

Before the

Senate Judiciary Committee Subcommittee on Intellectual Property

“The State of Patent Eligibility in America: Part II”

June 5, 2019

Chairman Tillis, Ranking Member Coons, and Members of the Subcommittee:

Thank you for holding this important hearing, which could have great consequences on the Committee's work to lower drug prices and increase pharmaceutical price competition for America's patients. My name is Jeff Francer, and I am the general counsel of the Association for Accessible Medicines (AAM). AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Today, generic and biosimilar medicines comprise 90% of prescriptions in the United States at only 22% of total drug spending. AAM's members provide more than 36,000 jobs at nearly 150 facilities and manufacture more than 61 billion doses of generic medicines in the United States every year. Our core mission is to improve lives by advancing timely access to more affordable generic and biosimilar medications.

I. INTRODUCTION

AAM has worked with this Committee historically to ensure that the patent system strikes the appropriate balance between incentivizing innovation and ensuring access to affordable medicines. As the full Committee discussed in a hearing just last month, this balance is currently amiss. Some brand-name drug companies have abused the patent system to stave off generic and biosimilar competition—in some cases for decades—by applying for scores of patents on the same drug. In particular, members of this Committee identified pharmaceutical patent thickets as a key driver of prescription drug spending, and, on a bipartisan basis, senators agreed that something must be done to limit the ability of brand-name drug companies to weaponize these patent thickets to the detriment of patients and payers.

AAM and its member companies support a patent system that rewards true innovation *and* serves the public interest by allowing true inventions to be patented for a single, limited time. But the public interest, and public health, suffer when companies try to go beyond that principle and seek patents on subject matter they cannot patent. Invalidating those patents takes significant time and investment and, until they are invalid, these patents operate not just as a deterrent to competition, but as a complete block to it. Especially in the context of biologic drugs and other specialty medicines, invalid patents mean no competition, and no competition means higher prices—often astronomically higher. As Secretary Azar has observed on multiple occasions, “drug prices must come down.”¹ Patients and taxpayers are paying more for their medicines, for much longer than Congress ever intended.

II. OVERVIEW: HOW PROPOSED REVISIONS TO SECTION 101 WOULD LEAD TO HIGHER DRUG PRICES

AAM is deeply concerned about the proposed revisions to Section 101 of the Patent Act that we are discussing today. The proposed revisions—which include *expressly overruling* more

¹ Azar Says “All Options Are on the Table” to Bring Down Drug Prices, The Center for Biosimilars (Jan. 10, 2019), at <https://www.centerforbiosimilars.com/news/azar-says-all-options-are-on-the-table-to-bring-down-drug-prices>; see also Alison Kodjak, *How A Drugmaker Gamed The System To Keep Generic Competition Away*, NPR (May 17, 2018) (reporting that Secretary Azar used Revlimid “without naming it outright” as an example “of how some drug’s prices rise with impunity”), available at <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away>.

than 150 years of carefully crafted Supreme Court precedent—would incentivize monopolistic bad actors, deny patients access to lifesaving treatments and diagnostics, and reverse progress this Committee has made to lower drug prices for Americans. Making it *easier* to obtain less innovative patents fundamentally disrupts—and certainly does not promote—the “progress of science and useful arts.” Thus, the proposed legislation raises serious concerns for several reasons.

First, the proposed revisions to Section 101 of the Patent Act would allow brand-name drug companies to raise drug prices even more by adding basic mental processes, the facts of life, and laws of nature to their patent arsenals. Critically, the Supreme Court has held such patents to be ineligible for monopoly protection for 150 years. Now is not the time to arm brand-name drug companies with even more weapons to hold off pharmaceutical price competition.

Indeed, the proposed legislation would make pharmaceutical patent thickets even thicker and more difficult to navigate. Brand-name drug companies could seek to patent every conceivable implementation—from isolated genes to computerized methods of research and development—to lengthen their patent monopolies far beyond the periods contemplated by Congress. Based on current experience, we know that companies will take advantage of this expansion to the detriment of America’s patients and taxpayers who pay for prescription drugs. And incentives for generic and biosimilar competition will be dampened, if not destroyed. No generic or biosimilar company can litigate over 100 patents on a single product. Nor are Sections 102 and 103 an adequate remedy in these circumstances. Companies should not have to expend millions of dollars in litigation to costs to prove the self-evident—that patents covering universal scientific facts or basic mental processes are invalid. By dramatically expanding patentable subject matter in this manner, the Committee will embolden the very types of tactics that have caused the United States to have the highest drug prices in the world.

Second, enacting the proposal will stifle medical innovation. By allowing drug companies to monopolize laws of nature and abstract ideas, the legislation would give drug companies exclusive dominion over human DNA and research tools. As *Myriad*—a unanimous Supreme Court decision that this Committee seeks to overrule legislatively—amply demonstrates, such ownership would have disastrous downstream consequences for patients and doctors.² In *Myriad*, Myriad Genetics obtained a broad patent on an isolated DNA sequence for two genes associated with breast cancer, BRCA1 and BRCA2. Myriad obtained those exclusive rights from the Patent and Trademark Office (PTO) even though the only purported “invention” was snipping the naturally occurring genes from the surrounding DNA using standard techniques that Myriad did not invent.³

Myriad’s patent caused immediate and severe negative consequences. Patients paid extremely high prices—to the tune of \$3,000 per genetic test—and *numerous university researchers received cease-and-desist letters*.⁴ Researchers *actually stopped studying* the BRCA genes associated with breast cancer.⁵ Competition and innovation were thus both stifled

² *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 579 (2013).

³ *Id.*

⁴ Josh Dzieza, *Why the Supreme Court’s DNA Decision Is A Big Deal*, available at <https://www.thedailybeast.com/why-the-supreme-courts-dna-decision-is-a-big-deal?ref=scroll>.

⁵ *Id.*

by a patent that lacked actual innovation. As one researcher explained, “[y]ou could say people are dying of breast cancer because of this patent.”⁶

Cases such as *BRCA1* are equally concerning.⁷ There, the Federal Circuit invalidated, as unpatentable abstract ideas, claims relating to methods for screening patients for potential cancer-causing mutations by comparing a patient’s DNA sequence to the original DNA sequence.⁸ The Federal Circuit also found that DNA primers—research tools that are exact, single-stranded copies of the original gene—were unpatentable natural phenomena.⁹

As many stakeholders observed at the time, allowing patents on basic breast cancer diagnostic methods and tools would have far-reaching negative effects, including *preventing sick women from obtaining a second medical opinion*.¹⁰ Similarly, allowing patents on basic research tools such as DNA primers would “stop all others from analyzing people’s genetic information, the blueprint for our cells, organs, and bodies which contains significant medical clues about our susceptibility to diseases and responsiveness to treatments.”¹¹

And there is no tangible benefit or need for such patenting in this area—as a report from the Department of Health and Human Services Advisory Committee on Genetics, Health, and Society makes clear, “patents on genetic discoveries *do not appear to be necessary* for either basic genetic research or the development of available genetic tests.”¹² Allowing extensive patenting of isolated genes and medical tests would not help patients, payers, taxpayers, or doctors—they would only serve to increase the already-expanding bottom lines of branded pharmaceutical companies.

Third, the proposed revisions, as currently described, would give rise to serious constitutional concerns. As the Supreme Court has recognized, “Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.”¹³ Yet the proposed legislation—as presently drafted—substantially removes material from the public domain. If the proposed revisions were enacted, a pharmaceutical company could, under the guise of “human intervention,” obtain a patent on a DNA primer that is an exact copy of the gene as it exists in nature. The proposed legislation suffers from other constitutional defects. To the extent the legislation seeks to revive—

⁶ *Id.*

⁷ *In re BRCA1 and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2016).

⁸ *Id.* at 764.

⁹ *Id.* at 761.

¹⁰ Br. of ACLU, *In re BRCA1 and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 2014 WL 2813346, at *2 (Fed. Cir. 2014).

¹¹ *Id.* at *5.

¹² National Institutions of Health, *Gene Patents and Licensing Practices and the Impact on Patient Access to Genetic Tests: Report of the Secretary’s Advisory Committee on Genetics, Health, and Society* (Apr. 2010) (introductory letter from Secretary’s Advisory Committee on Genetics, Health, and Society).

¹³ *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5–6 (1966).

through retroactive application—finally adjudicated, invalid patents, it would almost certainly be unconstitutional. Indeed, such a retroactive reopening of a final judgment “effects a clear violation of the separation-of-powers.”¹⁴ Retroactivity, in the case of prescription drugs, could also mean that patients currently enjoying the benefits of more affordable generic and biosimilar medicines could be forced to pay much higher brand-name drug prices, if the previously-invalidated patents and concomitant monopoly pricing are reinstated.

Fourth, this proposal would undermine several other bipartisan legislative projects that members of this Committee are championing to lower drug prices and increase competition. For example, Senators Cornyn and Blumenthal’s recent bipartisan bill, S. 1416, the “Affordable Prescriptions for Patients Act of 2019,” would be neutralized. Rather than stopping patent thickening, the proposed legislation would give patent owners many more tools to build larger and larger thickets—thickets that could eventually overshadow the 136-patent estate that now covers the world’s highest-revenue drug, Humira®.

For all of these reasons, the proposed legislation raises serious concerns and would detrimentally impact numerous other pieces of legislation that the Committee is considering to lower drug prices for Americans. Given these issues, AAM respectfully opposes the proposed legislation in its current form.

Below, I summarize the importance of Section 101 in bringing generic and biosimilar price competition to the prescription drug market and the specific, technical concerns that AAM has with the various proposed provisions. I also summarize the impact that the legislation would have on several categories of patents. Finally, AAM would like to address two additional areas—patent settlements and *inter partes* review—that are relevant to the discussion today.

III. THE IMPORTANCE OF SECTION 101 IN FACILITATING PHARMACEUTICAL COMPETITION

A. Section 101 Is Critical in the Life-Sciences Context

Section 101 is especially important to streamline pharmaceutical litigation that enables healthy competition. Eliminating invalid patents on Section 101 grounds avoids the expense of thousands of hours in time-consuming, burdensome discovery. That aspect of Section 101 sets it apart from other provisions of the Patent Act.

As explained above, a company seeking to bring a more affordable generic or biosimilar alternative to market often faces a thicket of dozens or even hundreds of patents shielding a brand-name drug from competition. Section 101 can be a useful tool to prune parts of the thicket early in the process. Pharmaceutical patent cases usually go to trial—sometimes multiple trials, costing millions of dollars to litigate—and it is relatively rare for validity issues to be resolved early in the process, by motions to dismiss or for summary judgment. Section 101 is a useful and important exception: It can be addressed at the outset of the case, streamlining the issues and allowing the case as a whole to be litigated more efficiently.

¹⁴ *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 219, 225 (1995); see also *id.* at 240 (“We know of no previous instance in which Congress has enacted retroactive legislation requiring an Article III court to set aside a final judgment, and for good reason.”).

This is particularly critical because there has been widespread agreement in recent years that patent litigation is too expensive and takes too long; that is why, for example, there has been broad support in this Committee for more streamlined procedures like *inter partes* review. And early resolution of Section 101 is not just a matter of efficiency: Patents that are not even directed to a patent-eligible invention should be eliminated as a block on competition as soon as possible.

Section 101 has been an important bulwark against attempts to patent aspects of the natural world that no human being invented. I will address some aspects of that later in my testimony. But Section 101 affects our efforts to lower drug prices in many other ways as well.

You might think that the pharmaceutical sector would not see the kind of patent-ineligible business-method claims that have plagued the technology and financial sectors for some time. But with the kind of financial stakes that are at issue in the pharmaceutical sector, more and more pharmaceutical companies are patenting precisely those types of business methods.

The framework that the sponsors have released indicates that ineligibility under Section 101 does not turn on whether a patent is invalid under Sections 102, 103, or 112. We agree with that principle so far as it goes: Section 101 does and should continue to require its own analysis. But as I will highlight shortly, we are concerned with the draft legislation's blanket statement dismissing the relevance of whether particular limitations are routine, conventional, or well known.

B. The Supreme Court Has Imposed Sensible Limitations on Patentability

U.S. patents have always been reserved for inventions—that is, applications of *human* ingenuity. Finding a new plant on an expedition to the rain forest does not qualify because the explorer, however intrepid, did not invent the plant. What the Supreme Court called long ago “the ancient secrets of nature” are not patentable.¹⁵

That principle has been extremely important in recent years. Let me emphasize some of the ways that ought to concern patients, doctors, and everyone who pays for health care. As explained above, Myriad Genetics actually obtained a patent on a human gene.¹⁶ But Myriad ultimately claimed the genetic sequence itself. Those claims were not invalidated under the “novelty” provisions of the Patent Act. They were invalidated under Section 101.

This has been a bedrock principle for many years: Just as a patent cannot claim the Pythagorean theorem or $e=mc^2$, a patent cannot claim a naturally existing compound, cell, or life form. That line has existed in the caselaw for many decades. That is why naturally occurring bacteria could not be patented, but bacteria genetically modified through human ingenuity could.

That principle is deeply rooted in the Constitution, and in the reasons why we protect intellectual property at all. The Intellectual Property Clause of the Constitution, after all, allows Congress to grant exclusive rights to “*Inventors*” for limited times. Someone who identifies a naturally occurring substance, gene, life form, or relationship is not properly considered an “Inventor.”

¹⁵ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948).

¹⁶ *Myriad*, 569 U.S. at 580.

C. Section 101 Serves an Important, Independent Function Apart from Sections 102 and 103

Some have suggested that Sections 102 and 103 can do the work that Section 101 is currently doing. But as the Supreme Court has recognized, “shift[ing] the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.”¹⁷ For at least four reasons, the Committee should follow the Supreme Court’s guidance and decline to substitute Sections 102 and 103 for Section 101.

First, while there may be disagreement about *where* to draw the Section 101 line, that disagreement is not sufficient to discard Section 101 entirely. Otherwise, the Committee seriously risks returning to the pre-*Alice* days, where non-innovative patents abounded and hundreds of companies “faced expensive litigation when they got sued over patents on basic ideas like updating video games online, on tracking the location of a vehicle, and on storing and labeling information.”¹⁸ Those lawsuits frequently involved “settlement shakedowns”—a practice previously described to Congress as “a legal form of extortion” that serves as a “tax on innocent operating companies” who cannot afford to defend themselves.¹⁹ Section 103—which typically cannot be resolved pre-trial and requires millions of dollars of expensive fact and expert discovery—certainly is not a meaningful substitute in those circumstances.

Second, the inventive concept test is critical to avoid a divide-and-conquer strategy. Without that test, a patent that merely recites a conventional application of a law of nature could readily survive scrutiny under each of the requirements for patentability. Indeed, it could survive Section 101 on the ground that it is not a claim on the law of nature itself, but then also survive the novelty and non-obviousness requirements of Sections 102 and 103 on the ground that the law of nature *itself* is inventive, even though nothing else is. These types of claims would seemingly be insulated from attack under the proposed legislation.

Third, contrary to some stakeholders’ assertions, the inventive concept test does not require a detailed novelty or obviousness inquiry. The partial “overlap”²⁰ between the different requirements merely ensures that each patentability requirement appropriately performs its own

¹⁷ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012).

¹⁸ EFF, *Save Alice: Tell the Patent Office to Apply Supreme Court Law*, available at <https://act.eff.org/action/save-alice-tell-the-patent-office-to-apply-supreme-court-law>; see also Steven J. Vaughan-Nichols, *Patent Troll Innovatio IP Goes After Small Businesses*, ZDNet (Oct. 5, 2011), available at <http://www.zdnet.com/article/patent-troll-innovatio-ip-goes-after-small-businesses/>; Joe Mullin, *Patent Trolls Want \$1,000—for Using Scanners*, Ars Technica (Jan. 2, 2013), available at <http://arstechnica.com/tech-policy/2013/01/patent-trolls-want-1000-for-using-scanners/>; Jim Beesen, *Op-ed, How Patent Trolls Doomed Themselves by Targeting Main Street*, ARS TECHNICA (Sept. 12, 2013), available at <http://arstechnica.com/tech-policy/2013/09/op-ed-how-patent-trolls-doomed-themselves-by-targeting-main-street/>.

¹⁹ Jeff John Roberts, *CEOs Tell Congress: Patent Trolls are Giving Us the Shakedown*, Fortune (Mar. 26, 2015), available at <http://fortune.com/2015/03/26/corporate-patent-shakedowns-reform/>; see also Ranganath Sudarshan, *Nuisance-Value Patent Suits: An Economic Model and Proposal*, 25 Santa Clara High Tech. L.J. 159 (2008).

²⁰ *Mayo*, 132 S. Ct. at 1304.

function. In particular, Section 101 only considers inventiveness to the extent necessary to ensure that artful drafting does not defeat the substantive requirement of Section 101. By contrast, the novelty and non-obviousness requirements are squarely focused on inventiveness and may require extensive fact development beyond the analysis contemplated by *Alice/Mayo*.

Fourth, whatever disagreement there might be about whether a particular technology is routine, there should be no dispute that some technologies are routine beyond any reasonable dispute, like the “general-purpose computer” often seen in Section 101 cases. Similarly, there have been numerous cases where the patentee conceded in the specification that certain technology is routine or conventional.²¹ In all those cases, courts should not be required to treat the recitation of generic technology as if it were inventive.

IV. SPECIFIC CONCERNS WITH THE PROPOSED LEGISLATION

AAM believes that the proposed legislation is based on an incorrect premise. According to some stakeholders, the *Alice/Mayo* framework for assessing Section 101 has become unwieldy and unpredictable. Yet the proposed revisions introduce new terms of art that are vague and unpredictable. For example, amorphous, undefined concepts such as “field of technology” and “human intervention” have been substituted in place of “inventive concept” and “abstract idea.” These undefined concepts will lead to substantial satellite litigation—as the Federal Circuit recognized in *Bilski*, “the contours of such . . . [tests] . . . would be unclear because the meanings of the terms ‘technological arts’ and ‘technology’ are *both ambiguous and ever-changing*.”²² The proposed revisions serve only to amplify—and certainly not solve—the alleged clarity and unpredictability concerns articulated by stakeholders and the Committee. In this section, we discuss some of the practical limitations of the proposed revisions to Section 101.

A. Congress Should Not Overrule 150+ Years of Supreme Court Precedent and Development of the Patent System

The summary of the draft legislation states that all cases interpreting the previous version of Section 101 will be “abrogated.” We recognize that a revised statute must be interpreted in accordance with the changes Congress makes to it, but we urge the Committee to consider what a drastic step it would be to “abrogate” the entire 150+ year-old body of law on patent-eligible subject matter. The Supreme Court has examined this issue since well before the current Patent Act was written. There is and should be a degree of continuity in any revision.

Fundamentally, AAM believes the Committee should adhere to the principle that humans cannot patent what already exists in nature. Whether the test should use the current form of the

²¹ See, e.g., *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App’x 1013, 1019 (Fed. Cir. 2019) (non-precedential) (“There is no reason to task the district court with finding an inventive concept that the specification and prosecution history concede does not exist”); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015) (“The specification of the ‘540 patent confirms that the preparation and amplification of DNA sequences in plasma or serum were well-understood, routine, conventional activities performed by doctors in 1997”).

²² *In re Bilski*, 545 F.3d 943, 960 (Fed. Cir. 2008), *aff’d but criticized sub nom. Bilski v. Kappos*, 561 U.S. 593 (2010) (emphasis added).

words “law of nature” is one thing; whether the door should be opened for the first time to patenting naturally occurring organisms, genes, or relationships is quite another.

Consider the wide body of caselaw that would be “abrogated” by such a broad statement: cases holding that a naturally occurring life form is not patent-eligible, cases holding that a human gene is not patentable, and cases holding that a pure mathematical formula is not patent-eligible. Congress should move with deliberate caution when considering whether to overturn such fundamental aspects of American jurisprudence.

B. “Human Intervention” Is Not an Appropriate Filter for Patentability

AAM recognizes that the current draft proposal acknowledges the need to preserve the important principle precluding patents on subject matter that occurs in the natural world. The phrase the draft legislation uses to accomplish that goal, however, is too permissive. The draft requires only that the invention provide utility “through human intervention.” But that appears to be a weaker protection against patenting natural phenomena than no human invented. So for example, in the *Myriad* gene-patent case, one of the theories advanced was that Myriad was entitled to patent the gene because Myriad had snipped it out of the middle of a DNA molecule.²³ The snipping was not innovative, and it certainly wasn’t innovative on the part of Myriad. Yet it was clearly “human intervention.”

The same is true of cloning. The scientists who produced Dolly the cloned sheep sought and obtained patent protection not just on their method of cloning, which seems appropriate, but on Dolly herself, and on any sheep, goat, cow, or pig that might be produced by cloning in the future.²⁴ Remember that Dolly is an exact replica of a naturally born organism. There’s certainly an argument that the copy was produced through human intervention—but humans didn’t do anything to create the “composition of matter” that was the sheep herself, because it is simply a duplicate of what Dolly’s sheep parents produced.

The “human intervention” test should be made more robust. The patent-eligible subject matter should be created through human *invention*, not just *intervention*.

C. As The Federal Circuit Has Recognized, “Field of Technology” Is Not an Appropriate Test

AAM is also concerned with the language in the new definition of the term “useful,” which defines subject-matter as useful, if it provides utility “in any field of technology.” One generally accepted and easy-to-apply principle under current Section 101 is that if a claim is not directed to patent-eligible subject matter, it cannot be made eligible simply by restricting its use to a single field.²⁵ So, for example, if a method of playing bingo is not patent-eligible, neither is a method of playing bingo *on a computer*. (That’s no exaggeration—that’s an actual patent that was issued by the PTO and had to be invalidated in court.)²⁶

²³ *Myriad*, 569 U.S. at 579.

²⁴ *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333, 1337 (Fed. Cir. 2014).

²⁵ *Bilski v. Kappos*, 561 U.S. 593, 612 (2010) (“*Flook* established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable”).

²⁶ *Planet Bingo, LLC v. VKGS LLC*, 576 F. App’x 1005, 1006 (Fed. Cir. 2014) (non-precedential).

Providing utility “in any field of technology,” the test currently in the draft legislation, could be read to make patents eligible if they do no more than bring something found in nature into a new field of technology. For example, penicillin is a naturally occurring substance produced by a mold. That is why it is not patentable—as Alexander Fleming conceded, he “did not invent penicillin. Nature did that.”²⁷ The fact that penicillin is not patentable should not change, even if it were restricted to the medical field.

A related problem arises from the provision admonishing courts not to look at the routine nature of any claim limitation. That creates an important gap between the limits of Section 101, on the one hand, and obviousness and anticipation on the other. For example, if you are the first person to create bingo on a general-purpose computer, or a smartphone, or any kind of new technology that you didn’t invent but are capitalizing on, you would argue that the computer or smartphone element renders the claim patent-eligible. And you would argue that because nobody has done bingo in that format before, it’s not anticipated or obvious. Under current law, Section 101 is robust enough to ensure that strategy does not work. The Committee should not change that basic principle.

Patents on the inventive *application* of natural laws are entirely appropriate. But the application has to be inventive because the natural law itself is not an invention. And declaring a field of use, such as “on a computer,” isn’t inventive either. Whatever the Committee adopts should ensure that patent-eligible subject matter isn’t determined by the inventor’s declaration of a limited field of use.

D. “Specific and Practical Utility” Is Not A Meaningful Filter

The proposal’s use of the terms “specific and practical utility” suffers from at least two defects. *First*, it is vague, ambiguous, and difficult to apply. As the Supreme Court has recognized, “a simple, everyday word [“useful,” as found in section 101] can be pregnant with ambiguity when applied to the facts of life.”²⁸ That concern will be particularly amplified if “utility” becomes the primary test for Section 101.

Second, the Federal Circuit has repeatedly held that the “threshold of utility is *not high*”— “[a]n invention is ‘useful’ under section 101 if it is capable of *providing some identifiable benefit*.”²⁹ To violate Section 101, “the claimed device must be totally incapable of achieving a useful result.”³⁰ The Federal Circuit’s doctrine confirms that utility is not a filter at all—much less a meaningful filter. Every conceivable invention could arguably provide some sort of theoretical benefit. “Specific and practical utility” simply cannot substitute for a meaningful analysis.

²⁷ Siang Yong Tan & Yvonne Tatsumura, Alexander Fleming (1881–1955): Discoverer of Penicillin, 56 Singapore J. of Medicine 366 (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4520913/>.

²⁸ *Brenner v. Manson*, 383 U.S. 519, 529 (1966).

²⁹ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).

³⁰ *Id.*

E. There Should Not Be A “Double Presumption” of Validity for Section 101

The proposal also states that “[t]he provisions of section 101 should be construed in favor of eligibility.” But there is already a presumption of validity in patent law: Section 282 states that “[e]ach claim of a patent . . . shall be presumed valid.”³¹ The proposal thus gives patent owners an unwarranted and unnecessary “double presumption” with respect to Section 101. This “double presumption” will potentially create significant confusion about the precise showing required to invalidate a patent under Section 101. It also places Section 101 on different footing than every other statutory requirement for patentability. And it will likely lead to significant litigation disputes on how it should apply. For all these reasons, a “double presumption” should not be imposed.

F. Any Legislative Changes Should Be Prospective Only

Separate from its consideration of whether to revise Section 101, the Committee must also consider when to put any changes into effect. The presumption has always been that legislation will operate on a going-forward basis, and that certainly has been how this Committee handled patent reform legislation in the past, including the America Invents Act (AIA).³²

Some have asked that the Committee take the truly unprecedented step of applying this new legislation retroactively. Not only would that raise serious constitutional problems, reviving existing patents that are invalid under the current statute would be a fundamentally unfair changing of the rules in the middle of the game.

Many patents have already had their validity fully litigated and decided by the courts, whether in a trial court or on judicial review of the Patent Trial and Appeal Board. As the Supreme Court has recognized, overturning a final judgment of the federal courts would violate the separation of powers.³³

Even if the Committee worked to avoid that kind of explicitly unconstitutional application, changing the rules in mid-game for individual patents would be profoundly unfair to the entire system. Patents that were examined and issued under one set of rules should have their validity litigated in court, or in post-grant reviews, under the same set of rules. And patents that are issued for a term of years should have the same rules apply to them throughout their term. This should be something that everyone should be able to agree on, whether they like the old rules or the new rules better, or some parts of each. Under no circumstances should the new rules apply to a patent issued before a new statute is adopted, and we submit that the simplest effective date for any changes would be to apply the new statute only to patents with an “earliest effective filing date” that is after the date of enactment.³⁴

³¹ 35 U.S.C. § 282(a).

³² *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994).

³³ *Plaut*, 514 U.S. at 219.

³⁴ See *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1357 n.2 (Fed. Cir. 2018) (citing the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(c), 125 Stat. 284, 287 (2011), which amended 35 U.S.C. § 103 and specified that the revised statute applied only to patent claims having an effective filing date after the date specified in the AIA, *i.e.*, March 16, 2013).

V. THE PROPOSED REVISIONS HIGHLIGHT THE IMPORTANCE OF BEING ABLE TO SETTLE PATENT DISPUTES

Given that the proposed legislation—if enacted—will serve to enlarge pharmaceutical patent thickets, we think the Committee should reevaluate a critical, related issue: proposals to severely limit the ability to settle pharmaceutical patent litigation. Frequently, the only economical, procompetitive way to address patent thickets is through settlement. Recent legislative proposals substantially threaten pro-consumer litigation settlements that bring generic and biosimilar competition to patients before the expiry of the brand-name drug’s patents.³⁵

As we explained in our May 7, 2019 statement to the Committee, settlement of Hatch-Waxman and Biologics Price Competition and Innovation Act (BPCIA) litigation enables competition and benefits the public in a very tangible way: It can allow the public access to more affordable generic alternatives considerably sooner than the patents would otherwise allow. At least one analysis has found that patent settlements lead to generic entry, on average, *81 months* before patent expiry.³⁶ This option is becoming all the more important as branded companies amass larger and larger thickets: if every patent had to be litigated all the way to final judgment—with no possibility of settlement—that would create a barrier to entry and deter generic manufacturers from even trying to launch a competing product before the patent expires.

Despite these tangible benefits, the proposed legislation deems many of these pro-consumer settlements presumptively anticompetitive. Those proposals—if enacted—would severely chill the ability of generic and biosimilar manufacturers to obtain a settlement and disincentivize their ability to challenge patents in the first place. And, fundamentally, there is no reasoned basis for them—as the FTC has itself conceded, “the number of settlements potentially involving “pay for delay” decreased significantly in the wake of the *Actavis* decision.” FTC’s own data confirm as much: Potential “pay-for-delay” deals dropped from 33 immediately prior to *Actavis* to five in 2015 to just one in 2016.³⁷ Given the FTC’s data, the Committee should reevaluate the need for legislation on patent settlements.

VI. THE PROPOSED REVISIONS HIGHLIGHT THE IMPORTANCE OF INTER PARTES REVIEW (IPR)

Finally, the proposed legislation highlights the critical importance of *inter partes* review. As a strong majority of the Supreme Court explained in upholding the Committee’s work on the

³⁵ S. 64; H.R. 1499; H.R. 2375.

³⁶ Kevin E. Noonan, *IMS Study Shows Pro-Competitive Effects of Reverse Payment Settlement Agreements in ANDA Litigation*, Patent Docs (July 18, 2013), available at <https://www.patentdocs.org/2013/07/ims-study-shows-pro-competitive-effects-of-reverse-payment-settlement-agreements-in-anda-litigation.html>.

³⁷ FTC, *Overview of Agreements Filed in FY2016*, available at https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf

America Invents Act, IPR “protects ‘the public’s paramount interest in seeing that patent monopolies are kept within their legitimate scope.’”³⁸

The examination process is not by itself sufficient to serve that “paramount” public interest. The process is one-sided and limited, and provides no meaningful opportunity for interested third parties to participate. Significantly, the examiner must accomplish a number of distinct tasks during the examination process—all of which must be completed in a mere *19 hours*.³⁹ And the examiner’s ability to search for prior art—much less to apply its teachings to the application—is highly constrained. That dearth of information is magnified by the Patent Office’s “count” system—a system set up to reward productivity, not care.⁴⁰

That is why Congress adopted legislation allowing the Patent Office to fix its own mistakes with the benefit of more time and more information. IPR allows interested parties to supply the Patent Office with important pieces of prior art that the examiner may have missed during examination. It allows invalidity issues to go before experts from within the Patent Office, rather than lay jurors or generalist federal trial judges. It also allows certain grounds of invalidity to be tested in a speedy, time-limited, and streamlined proceeding without the distraction of other issues such as infringement.

Unfortunately, the careful and comprehensive IPR system that this Committee created has been substantially diluted since its establishment. For the generic industry, studies report a lower success rate for generics at the PTAB compared to district courts—a particularly jarring statistic given that the PTAB is applying a lower standard of proof than district courts.⁴¹ According to Bloomberg, Orange Book patents are upheld about 77% of the time at the PTAB.⁴²

Rather than addressing this downward trend, the Patent Office has been actively revising the IPR system in a way that compounds the problem. Most notably, Director Iancu recently abolished the longstanding practice of interpreting a patent the same way in IPR as in examination.⁴³ The recent change instead interprets a patent more narrowly, as a court would in litigation. In other words, some patents that should not have survived examination *will* now survive

³⁸ *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018) (citation omitted).

³⁹ Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, Nat’l Bureau of Econ. Research Working Paper 20337, at 7 (July 2014), <http://www.nber.org/papers/w20337.pdf>.

⁴⁰ Eric Blatt & Lian Huang, *USPTO Incentive Policies Influence Patentability Decisions*, Law360 (July 23, 2018), *available at* <https://www.law360.com/articles/1052622/uspto-incentive-policies-influence-patentability-decisions>.

⁴¹ Scott McKeown, Filko Prugo & Jon Tanaka, *Insight: Orange, Purple Book Patentees Hone PTAB Survival Skills*, Bloomberg Law, 2 (June 13, 2018), *available at* <https://news.bloomberglaw.com/ip-law/insight-orange-purple-book-patentees-hone-ptab-survival-skills-1>.

⁴² *Id.*

⁴³ Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,341 (Oct. 11, 2018).

IPR. The PTAB has also created an amendment “pilot program” that gives patent owners multiple opportunities to amend and morph their claims during the IPR proceeding.⁴⁴

The Committee should preserve and strengthen IPR and resist changes that would weaken it — especially as this Committee has reviewed evidence that some brand-name pharmaceutical companies have abused the patent system, facilitating annual price increases for far longer than Congress could have imagined. *First*, it should make clear in the statute that a patent should be interpreted in IPR the same way that it would be interpreted in examination. *Second*, it should make clear—consistent with the AIA provisions stating that “the patent owner may file one motion to amend the patent”—that patent owners do not get multiple bites at the amendment apple.⁴⁵ *Third*, it should make clear that the statutory provisions restricting the Patent Office from instituting duplicative IPRs are sufficient—the Patent Office should not exercise its discretion to create *new* limitations on instituting an IPR. *Fourth*, the Committee should allow appeals of legally and factually erroneous decisions not to institute IPR consistent with the strong presumption in favor of judicial review.

* * * * *

Thank you again for the opportunity to appear before you on this important issue. As part of my testimony, I am also including a letter from the Coalition Against Patent Abuse, of which AAM and other stakeholders are members.

I look forward to answering your questions.

⁴⁴ Notice Regarding a New Pilot Program Concerning Motion To Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 Fed. Reg. 9497, 9497–98 (Mar. 15, 2019).

⁴⁵ 35 U.S.C. §§ 316(d)(1), 326(d)(1).