Responses to Questions From
Senator Tillis
by
The Honorable Paul R. Michel
June 26, 2019

I am confident that predictability will be greatly increased if the discussion draft is introduced and enacted. Even without further refinement, it represents an enormous improvement over the current state of the law of eligibility.

It will have many beneficial effects. Investment incentives, now lagging, will rise significantly. Research and development and follow-on commercialization will all increase proportionally. Likely, voluntary licensing will increase as will pre-suit and post-suit settlements. By reducing litigation, much time and money will be saved.

These and other beneficial effects can be further enhanced if still greater clarity were imported into the bill's language. But the text of section 101 (a) and (b) is perfectly crafted, and the subcommittee should reject any suggestions to alter it. It forms the heart of the needed reforms to restore predicability, consistent outcomes, reliable patents and increased investment incentives. It returns the application of section 101 to its stable state prior to the Supreme Court interventions in Bilski, Mayo, Myriad and Alice.

New section 100 (k) is also a critical part of the needed reforms. Among other benefits, it makes explicit what was only implied: that "invention" requires human activity, transforming the natural world. It also properly excludes innovations belonging to the fine arts as distinct from the "useful arts" of Article I, Section 8, Clause 8 of the Constitution. Section 101 likewise requires utility in the practical world, with the section's reference to "useful." Although "any field of technology" might be replaced with "any useful art," this provision greatly improves the clarity of the law.

Although the new text of 101 and 100 (k) are absolutely necessary and very helpful, they are not sufficient. Therefore, the three additional miscellaneous provisions must be included as well. First, unless the Supreme Court cases starting at least with Benson and Flook are abrogated, the high court can be expected to resume treating eligibility as if it were common law made by unelected judges rather than statutory law enacted by elected legislators. It will continue to create confusion and exclude important inventions. Despite the mandate of section 101(b), the Court will continue to differentiate among claim limitations, giving some no real effect and again assessing what the claim should be deemed as "directed to."

I would also expect the Court to resume conflating eligibility under 101 with what 101 itself properly calls the "conditions of patentability" as set forth in sections 102, 103, and 112. So, the provision prohibiting such mixing of separate issues is absolutely necessary to prevent a return to the present chaos, or what a former PTO Director testified is a "mess." Even the provision requiring that section 101 be construed "in favor of eligibility" is needed to end the practice of some courts of applying the opposite presumption.

Without all three miscellaneous provisions being enacted as well as sections 101 (a) and (b) and section 100 (k), the courts, including the Supreme Court, will continue to usurp the constitutionally-mandated prerogatives of the Congress to create and control the law of patents by statute.

I do, however, favor deleting or at least sharply confining the proposed expansion of section 112 (f). The new language would change the analysis from the claim as a whole to an element-by-element analysis. Second, it would automatically cover all claim elements containing any functional word, even though expressly drawn to specific structures. It thereby would apply to patents, past and future, in which the drafter deliberately elected not to invoke the protection and benefits, but thereby agree to the limiting effects, of subsection (f). Such a change in settled law works an unfairness as applied to previously issued patents. But it also harms future patents because in many cases it is not possible to entirely avoid terms with functional connotations. That is particular so in health sciences, but also is common in computer science patents.

Further, the alteration of (f) creates an impossible situation for many sciences in which there are hundreds or thousands of alternative structures. If all was required to be specifically disclosed, patent applications would have to run on for hundreds of pages, unfairly burdening independent inventors, start-ups, research universities, laboratories, hospitals, engineering firms, small business and others with staggering costs. Failure to do so would allow infringers to escape liability by making slight modifications in the structures disclosed.

Finally, the proposal to expand (f) interferes with the proper functioning of other subsections of section 112. And, the proposal did not have the benefit of discussion at the Roundtables and an opportunity to carefully assess its impacts. Nor was a need for such aggressive revision demonstrated. It is best removed from the bill to be introduced. At the very least, it needs substantial revision.

Responses to Questions From Senator Blumenthal
by
The Honorable Paul R. Michel
June 26, 2019

The primary impact of "broadening" (really, restoring) subject matter that is eligible for possible patenting (if it can meet the five additional tests of sections 102, 103, and 112) will be to increase incentives, now lagging, to invest, invent, disclose and patent. As a direct result industry will expand, accelerate and prosper, adding jobs and boosting economic growth. Indirect results include more, better and faster improvements in all "useful arts," including inventions in the field of human health for the prevention, diagnosis, control, and cure of disease.

The "broadening" of eligibility will likewise have many benefits for most consumers, including patients. As the history of many patented inventions shows, products continually improve and prices usually decline. Smart phones are a fitting example. For two decades, consumers got ever-better phones at ever-lower prices.

Although the Government funds much early research, most of the cost of developing and producing new products falls on private companies. Like the Government, the research universities it funds cannot finance commercialization, only private capital can. In the field of medicine, the cost of completing the research and development process, including FDA-mandated clinical trials, is enormous. On average, a new drug depends on investment of over $2.5 billion. That can only occur if the investment incentives are high enough. In the absence of fundamental reform of our entire health care system, only patent protection can provide the needed incentives.

The vast majority of human diseases as yet have no known cure. Recent breakthroughs in basic science show enormous promise in new areas such as genetic and personalized medicine, advanced diagnostics, and computer-assisted medicine. The promise can only be realized if the patent system is restored.

I do not expect the proposed reforms to increase drug prices. The reforms will simply restore the scope of eligibility under Section 101 to what it was before the Supreme Court's restrictions imposed by the Mayo/Alice line of recent cases made section 101 law -- and the entire patent system -- so uncertain, unreliable and unpredictable.

History is a useful guide as to how robust a nation's patent system must be to advance human welfare and human health. In the last 100 years and until the last decade, nearly every advance in health science occurred in the United States. European and Asian countries lagged behind, owing largely to their lack of strong patent systems. But now, after our foreign competitors have clarified and broadened eligibility and otherwise strengthened their patent systems while we have narrowed and weakened ours, US capital investments are increasingly going abroad. This trend must be reversed. If it is not, talent and jobs will likely follow these investment outflows.

Responses to Senator Mazie K. Hirono's Questions for the Record

by the Honorable Paul R. Michel

June 26, 2019

Section 101 chaos surely needs a Congressional fix. The only court capable of fixing it, the Supreme Court, has refused every one of dozens of petitions for review during the five years since Alice, the six years since Myriad, seven years since Mayo, and nine years since Bilski. The Federal Circuit has failed over the same time-frame to increase certainty in any meaningful way. Clearly, comments from judges like Lourie and Newman (and there are others) suggest they feel unable to help, given the very emphatic and broad rationales stated by the high court in these cases. The last chance for the Federal Circuit to lead came and went with its decision not to adopt or defer to the USPTO's January 2019 Guidance on Section 101 case law as it could have done.

My recommendation is that Congress not "let the courts continue to work things out" because actually they are not doing so at all. In fact, they have made matters worse. I cannot reconcile the manyFederal Circuit decisions with one another and the court keeps declining to sit *en banc* to overrule the incorrect decisions and eliminate the inconsistencies.

I do not consider "field of technology" to have an agreed upon and clear meaning. I expect that, unless defined in the new bill, it will result in many years of litigation, with all the costs and delays associate therewith, and enable the tech giants in Silicon Valley to argue that every patent asserted against them falls outside that category. From recent experience, we know many district judges will dismiss suits at the outset based on such assertions even when unsupported by prior art or other evidence and even without defining claim scope. Such dismissals are unwise and unfair.

Europe does have law that uses the word "technical" but has never been able to define it so as to create an objective and useable test. In the US, the PTO regulations for Covered Business Method (CBM) reviews under the AIA could not define it either. Efforts to try failed, so the PTO at last provided a completely circular definition. The courts have also been unable to give it clear meaning in the seven years of CBM appeals.

The Bilski claims, at least when requiring computer implementation, are eligible in my view of the correct law, but clearly not patentable, because implementing hedging, etc., on a computer is blatantly obvious and fails under Section 103.

I suggest that the subcommittee replace "any field of technology" with "any useful art", the constitutional phrase, repeated in Section 101. Settled Federal Circuit case law requires "practical application" with "specific, substantial and immediate benefits to the public." In addition, new Section 100 (k) makes express the requirement for an "invention" to result from "human intervention." These filters are amply adequate to exclude from eligibility what should be excluded. If Congress identifies any further specific subject matter that as a matter of national policy should be excluded, it can do so in other sections, as it did with "human organisms" and "tax strategies." I myself do not recommend any other express exclusions. Already, Sections 102, 103, and 112 render unpatentable 99% of what should not be patented. The utility requirement of Section 101 case law does the rest.

Enforcement of Section 112 by the Federal Circuit has been vigorous and continually expanding for many years, especially the requirement of "written description" commensurate with the full scope of the broadest claims to show mental possession by the inventor of all that the claims cover. That a few district judges may have been slow to enforce such evolving limits does not justify Congressional intervention to alter Section 112.

The proposed changes to Section 112 are not needed and will cause widespread harm to owners of past and future patents. The written description requirement already limits claim scope and invalidates claims that cannot be construed so as to cover only what was actually invented. The proposed changes, however, would cover nearly all patents, particularly in the health and computer sciences, as some functional-sounding works are unavoidable in many such patents, even those defining specific structures. Moreover, the change would force inventors who elected not to invoke Section 112 (f) by expressing an element in "means plus function" terms to have their patents later assessed as if they had. That seems unfair, as they had no notice.

The complaints regarding Section 112 not being applied to "inventions in the hi tech space" are highly exaggerated, unsupported, unreliable and self-serving. They should simply be dismissed.

Design arounds will evade patents assessed under the proposed changes in vast numbers of cases, especially in health science, but also in computer science.

Otherwise, I do not see any problem under the Due Process or the Takings Clauses of enacting the proposed bill because it restores eligibility and therefore does not eliminate or diminish any property or other rights of patentees, much less does so without fair warning and an opportunity to respond.

As to the obviousness-type double patenting doctrine, it is really based on Section 103. Section 101 was only referenced because it, redundantly, required that inventions be "new." This judge-made law is entirely unaffected by the proposed legislation, so I see no need to codify it. Moreover, it has been sharply enlarged of late by the Federal Circuit, perhaps even too much. Codifying current, shifting case law would in any event be premature. It would prevent further rebalancing.

It is true that in a few cases this doctrine blocks attempts to extend protection "through additional patents on minor changes," but that is only so when a single application is divided by the PTO into two, with different patents issuing at different times. The overwhelming number of such attempts are defeated by routine application of Section 103 by the PTO and the courts. By definition, if a change is "minor," it is almost always "obvious."