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Seven Words You Can Never Say to the USPTO

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This paper is inspired by the famous stand-up comedy routine from George Carlin 1972 album "Class Clown." In the routine "Seven Words You Can Never Say on Television," Carlin pokes fun at the idea that words themselves could be so inherently bad that their mere utterance must be banned from public broadcasting regardless of context. Carlin points out that this particular brand of censorship is not aimed at ideas being expressed but rather in the manner in which these ideas are being expressed. A kind of codification of politeness rather than a true restriction on free thought. In a very real instance of life imitating art, a 1973 New York broadcast of the Carlin's routine over FM radio resulted in an FCC complaint that made it all the way to the US Supreme Court in the landmark decision of *Federal Communications Commission v. Pacifica Foundation*.[2] In its decision, the Supreme Court granted that the FCC had the authority to prohibit broadcasts like the Carlin routine during hours when children were likely to be among the audience, and also permitted the FCC to determine what was indecent in different contexts which may arise. [3]

In the Carlin tradition, this author has notice that in the past decade, there has emerged a group of words where their mere existence in a patent claim is sufficient to generate a rejection. If Carlin was a patent attorney one must wonder if the Courts decisions in these cases would feel eerily familiar. This paper will identify and explore each of these words, look at the "Carlin" and "FCC arguments" for each, and provide alternative strategies for claiming the ideas behind these banded words while evading the censors.

With the nature of topic that will be discussed herein, it is prudent to start with a reminder of the purpose of the patent system as articulated in the US Constitution which reads, "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and

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[2] Federal Communications Commission v. Pacifica Foundation, 438 U.S. 726 (1978).

[3] *Id.*

Discoveries."[4] The patent system is a kind of contract between the government and the technology community whereby in exchange for the disclosure of new and useful technological knowledge, the government grants to the discloser, a limited monopoly over the claimed technology, the purpose of which is to "promote the Progress of Science and useful Arts." That is, whenever one analyzes a particular rule or quirk of the patent system, it benefits the analysis to continually ask the question: Does this promote the Progress of Science and useful Arts?

35 USC § 112

Word #1: "Antibody"

In the 2017 Federal Circuit case *Amgen Inc., v. Sanofi*, the court held that one cannot describe a genus by what it does rather than what it is.[5] How this is consistent with the permissible practice of including function limitations in claims was not addressed in the decision.[6] The Court in *Amgen* specifically held that you cannot provide written description for an antibody by describing its antigen (target). The court cites the uncertainty in the art and that such claims could be very broad such that discerning all the species of the claim would require undue experimentation.

The USPTO has adopted and codified this decision in series of memos to its examiners, and also in MPEP 2163 stating,

> disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository does not, without more, provide an adequate written description of an antibody claimed by its binding affinity to that antigen, even when preparation of such an antibody is routine and conventional. *See Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1378, 124 USPQ2d 1354, 1361 (Fed. Cir. 2017).[7]

In a vacuum this position may appear perfectly reasonable (except its conflict with the permissibility of functional claim limitations). After all, if you are claiming to have invented something, shouldn't you have to disclose what the invention actually is? However, it is important to realize that this logic effectively bans claiming any genus without a definable common structural element. To be fair, this is not normally an issue. In most molecular art fields, the structure of a molecule greatly informs its function and there is almost always a common structure which defines a particular genus of molecules. It is also common for such geniuses to be quite large, including thousands or millions of species which share a common structure (common backbone) and function.

However, in the relevant biotech industry, the structure of an antibody generally doesn't relate all that much to its function, *i.e.*, what antigens it binds to.[8] In view of

[4] *See* U.S. Const. art I, § 8, cl 8.
[5] Amgen Inc., v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017).
[6] *See* MPEP § 2114.
[7] MPEP 2163(II)(3).
[8] Goel et al., *Plasticity within the Antigen Combining Site May Manifest as Molecular Mimicry in the Humoral*

this practical truth, it is standard practice to define antibodies by their target rather than their structure.[9] That is, the ties that bind the genus together are functional commonalities not structural commonalities. By banning an applicant's ability to define a genus by its functional commonality, the Federal Circuit has taken away the only practical method for this industry to define the relevant antibody genus.

One would be hard pressed find a patent specification describing antibodies filed before the *Amgen* decision where the relevant antibodies were described by their structure rather than their target. Even after the Amgen decision such applications continue to be rare because it remains true that determining the specific structures for each and every antibody which will bind to the target is both impractical and technologically/scientifically insignificant.

The above series of unfortunate events has resulted in the effective ban of the word "Antibody" by the USPTO. This is because any mention of the word antibody in the claims prompts an inquiry under MPEP 2163 and *Amgen* where the Examiner looks to the specification for a structural definition of the antibodies which does not exist for the reasons above. In accordance with the guidance they have received, the Examiner then issues a written description rejection under 35 USC § 112 citing *Amgen* which is impossible to overcome as applicant's specification does not have a full structural definition of the applicable antibodies and no common structural feature to define such a group exists.

How then is one skilled in the biotech arts to address this issue? Product-by-process may offer a creative solution with the goal of finding a different way to express the scope of subject matter one wishes to protect. Product-by-process claims allow one to define the ultimate end product by its method of production rather than its structure while still making the ultimate determination of patentability is based on the product itself.[10] This is useful for addressing the above issues with antibodies as one could define the antibody as the product of binding to the antigen. Specifically, one can claim the product of a process for creating a binder or determining whether a molecule has bound to a target and simply include that product in its claim. This should avoid the *Amgen* case because it does not actually claim the antibody, it just claims the product of a process which will very likely yield the intended antibody. Given the nature of the art field, this is also unlikely to cause any prior art issues which were not already present as defining the antibody by its target is the standard in the field.

Viewed from the eyes of one of ordinary skill in the art, the holding in the *Amgen* does not appear to promote the progress of science and useful arts as intended by the US Constitution. The holding in *Amgen* practically prohibits the production of an adequate disclosure by the applicant. The applicant cannot practically fulfill their requirements to obtain the limited monopoly rights over the technology and therefore there is little if any incentive to publicly disclose the technology advancement and

Immune Response, 173 The Journal of Immunology 7358, 7358–67 (2004). *See also* Lloyd et al., *Modelling the human immune response: performance of a 1011 human antibody repertoire against a broad panel of therapeutically relevant antigens*, 22 Protein Engineering, Design &Selection 159–168 (2009).

[9] See, e.g., Dondelinger et al., *Understanding the Significance and Implications of Antibody Numbering and Antigen-Binding Surface/Residue Definition*, Front. Immunol. (16 October 2018), https://doi.org/10.3389/fimmu.2018.02278.

[10] *See In re* Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); *see also* MPEP § 2113(I).

thereby the progress of science and useful arts. Furthermore, allowing applicants to define their antibodies by their target would not deter progress of the science as it is the targets which are of value to the progression of the science, not the structures of the individual antibodies which bind thereto.

Nevertheless, until further notice applicants are advised to find a different way to say the word "Antibody" when communicating to the USPTO.

35 USC § 101 Natural Law

Word #2: "Diagnosing"
Word #3: "Determining"
Word #4: "Predisposition"

A series of decisions by the Supreme Court in the past decade have resulted in the expansion of what is considered to be a "natural law" or "product of nature,"[11] greatly increasing the difficulty for applicants to obtain meaningful patent rights in the field of diagnostic medicine. This is because the practices of diagnostic medicine have been determined to be what the Courts have termed "judicial exceptions." Judicial exceptions are generally considered to be abstract ideas, laws of nature and natural phenomena but what exactly falls in these categories can be a subjective issue which, unfortunately for the diagnostic medicine industry, has been expanding in their direction since the *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* in 2012.[12]

As a practical truth, most of diagnostic medicine is currently interpreted to fall into these judicial exceptions, and writing the words "diagnosing," "determining," or "predisposition" in a patent application claim in this art field appears to virtually guarantee a rejection under 35 USC § 101 as being directed to a natural law or product of nature.

For example, imagine you were to discover that having above a certain threshold level of protein X in the blood indicated a 95% chance of having a heart attack in the next 30–90 days, and you developed a test using existing testing methods to measure for that specific threshold level of protein X. If you tried to file a patent on that test, you would likely find yourself facing the allegation that your claim was directed to a judicial exception. The allegation being that the threshold level of protein X being associated with heart attacks is a natural law and your application of a test to determine it does not add significantly more.

Furthermore, the mere use of any of the words above in a patent claim are sufficient in the art field to trigger an analysis under USPTO guidelines for judicial exceptions which inevitably result in a rejection under 35 USC § 101. For example, diagnosing a predisposition towards a heart attack in the next 30–90 days by determining the level of protein X in a patient's blood. The example uses all three words, however, any one of which would be sufficient to provoke the rejection.

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[11] *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 573 U.S. 208, 216, 110 USPQ2d 1976, 1980 (2014); *see also Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. 576, 589, 106 USPQ2d 1972, 1979 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 566 U.S. 66, 71, 101 USPQ2d 1961, 1965 (2012); MPEP § 2106.

[12] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71, 101 USPQ2d 1961, 1965 (2012).

Even worse for applicants, once they enter the judicial exception analysis, they are destined to fail. This is because, once the claim has been interpreted as being directed to a judicial exception, the applicant must show that the claims are also directed to some additional element that amounts to significantly more than the judicial exception.[13] Unless the applicant has also simultaneously invented a completely new way to, for example, measure the level of protein X in a patient's blood, there is almost certainly nothing in their specification that will qualify as "significantly more."[14] Notably, such a new measuring method would likely qualify as its own separate invention meaning adding the additional requirement that it be applied to a specific diagnostic method is of no benefit for the applicant and they would be better off just pursuing the measuring method by itself.

As of the writing of this paper there is only one reliable method for adding "something significantly more" to a claim in this art field to overcome the rejection under 35 USC § 101 and that is to add a method of treatment step.[15]

While this is a solution in theory, it presents a new and different problem for those seeking to enforce such a patent. Such a patent to a diagnostic method and a treatment step will rarely if ever have a useful direct infringer. This is because a different entity will likely perform the diagnostic method (laboratory) vs. the treatment (doctor). Even just claiming the treatment step based on the resulting diagnostic method at best forces the applicant to pursue a theory of induced infringement by the lab giving the results to doctor as doctors are the direct infringers but immune to enforcement.

Applicants in diagnostic medicine are therefore left with no viable path to obtain a reliably enforceable patent. The only way for an applicant to win this game is not to play.

Kobayashi Maru

Kobayashi Maru is a test in the fictional Star Trek universe which is intended to be impossible to pass.[16] A person is presented with a choice of either rescuing or abandoning a disabled ship where either choice results in failure. The purpose of the test is actually to see how one will react in a no-win situation. Captain Kirk famously defeats the test by hacking it and programing a path to victory before the test begins.

Kirk recognized the only way to win the game was to avoid playing by the rules which were presented. Like Kirk patent applicants must find an alternative path around the Kobayshi Maru that is § 101 practice.

One such path, is to avoid any mention of the words which may trigger the § 101 analysis. Applicants should not diagnosis, determine, or claim a patient predisposition to anything. Instead, applicants should target a mandatory intermediate product of the diagnostic method.

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[13] MPEP § 2106(II).

[14] *See* Rapid Litigation Management v. CellzDirect, 827 F.3d 1042 (Fed. Cir. 2016).

[15] *See* Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals, 887 F.3d 1117, 1135–36, 126 USPQ2d 1266, 1281 (Fed. Cir. 2018).

[16] Star Trek II: The Wrath of Khan (Paramount 1982).

For example, in the example above, at some point a laboratory technician will likely have to prepare a sample having some of the patients' blood and some binder to protein X to enable the measurement of protein X to determine whether or not it is above the relevant threshold. Applicants can therefore direct their claim to a sample comprising the patients' blood, binder, and protein X above the threshold amount. The presence of the binder in the sample ensures that that the sample is not a product of nature, and the requirement of the protein X above the threshold amount should eliminate prior art issues. Any lab who performs the diagnostic method will necessarily produce the sample to be tested which will infringe the patent. Notably such a claim strategy excludes negative tests, but any infringer of note would certainly be performing at least the occasional positive test.

Again, it is worth asking the question whether forbidding the diagnostic medicine industry from obtaining patents on their diagnostic methods actually promotes the progress of science and useful arts. Diagnostic methods tend to be somewhat like pharmaceuticals in that they are very expensive to develop but relatively inexpensive to administer once the final product has been determined. Should the industry not be able to adequately recoup the costs of development, its viability as a business model comes into serious question.

One alternative to patenting is turn instead to trade secrets. However, considering the regulatory hurdles in the medical field it seems unlikely that one would be able to gain approval for performing a diagnostic method without some public disclosure as to what the method is.

Some analysts estimate the diagnostic laboratory services market to be a 125-billion-dollar industry which is growing at a rate of over 8% a year.[17] That is, clearly this industry has substantial value, the foundation of which is jeopardized if it is not granted the use of the US patent system.

One of Carlin's points in his *Class Clown* comedy special[18] was that words are not inherently profane. Words are merely a specifically arranged series of letters. Their ultimate meaning depends on both the context and manner in which they are used and the circumstances of those experiencing their use. Shakespeare makes this same point both more broadly and more succinctly in Hamlet saying, "there is nothing either good or bad, but thinking makes it so."[19]

In regards to biotech, the courts and the USPTO's application of their rulings appear to have forgotten this wisdom. Instead, the terms above are treated as patent f-words. So profane, their mere utterance provokes rejection regardless of context.

The current system borders on the absurd and deserves our disobedience. On this, Captain Kirk and George Carlin can agree.

[17] *See* Medical and Diagnostic Laboratory Services Global Market Report 2021: COVID-19 Impact and Recovery to 2030 (2021), https://www.researchandmarkets.com/reports/5292757.

[18] George Carlin, Class Clown (Little David 1972).

[19] William Shakespeare, Hamlet act 2, sc. 2.

35 USC § 101 Abstract Idea

Word 5: "Calculating"
Word 6: "Processing"
Word 7: "Comparing"

Computer science has its own set of banned words. This art field has it a little better than biotech however, as some account is given to context and the manner in which the words are used. In computer science, abstract ideas are the flavor of the month for § 101 rejections and indiscriminate usage of any the above words in a patent claim is a great way to trigger such a rejection.

The word "calculating" becomes a problem if the subsequent terms in the clause describe a mathematical relationship or formula, and particularly if this mathematical relationship is the crux of the inventive concept. The word "calculating" puts Examiners on high alert that they are likely dealing with a § 101-banned "Mathematical Concept" and will very likely provoke a rejection under this section.[20]

The word "processing" (or "managing") can be problematic if it is not clear from the elements recited in the clause that it is a machine performing these steps in a way that a human being could not possibly do. Processing, without the recitation of specific machine implementation details, is very likely to be treated as "certain methods of organizing human activity" or "mental steps."[21] The idea being that a human could perform these tasks, unless the claim specifies otherwise, they are patent ineligible.

The word "comparing" (or "executing" or "applying") can result in rejection if the clause does not also recite elements that make clear how the machine is performing the step. These actions can again trigger the allegation that the claim step is drawn to a "mental process" unless the claim elements further specify and limit the action to a machine implementation.[22]

tThe law concerning 35 USC § 101 in the computer science space is changing at a rapid pace. This unfortunately results in a situation for applicants where it is likely that the state of the law that one drafts an application under will not be the same as the state of the law that one prosecutes that application under. One must also anticipate the rules may change again by the time one looks to enforce the patent. Drafting applications to withstand future unknown patentability standards is extremely difficult and fundamentally unfair to applicants, which is particularly unfair given that they are forbidden from adding new matter to their specification after filing. That is, they are unable to change the description of their invention even when the rules related to this description are changed without warning. Additionally, the changes in the law of the past decade frequently create situations where following the best practices of the day when drafting an

[20] Based on the author's professional experience. *See*, *generally*, MPEP 2106.04(a)(2)(I) which cites cases illustrating examples of this issue.

[21] Based on the author's professional experience. *See*, *generally*, MPEP 2106.04(a)(2).

[22] *See* MPEP 2106.04(a)(2)(III).

application results a virtual guarantee of invalidity a few years later when that patent is being enforced.

Keep in mind that the inventions themselves are not changing, only the way in which they are described and claimed in patent applications. It would appear difficult to argue that these developments in the law over the past decade are promoting the progress of science and useful arts. It instead appears to be arbitrarily suppressing the development of this industry by devaluing, if not eliminating, the value of patents in this field though repeated rule changes which disfavor applicants.

Yu v. Apple

An example of the above can be seen in the recent decision of *Yu v. Apple*.[23] In this case, the court expanded the Mayo/Alice eligibility test holding that a claim which included *e.g.*, image sensors, lenses mounted to the image sensors, a digital image processor, and analog-to-digital converting circuits to be directed to an abstract idea, because all these tangible real-world elements were "routine and conventional."[24]

Applicants in *Yu v. Apple*, following the best practices of the day, claimed a hardware configuration in combination with a software process on that specific hardware configuration and included in the specification an explanation of how the software worked with the hardware and how the invention was unique compared to the prior art which included the same individual "routine and conventional" elements in a different configuration.[25] The court in *Yu v. Apple* held "the claimed hardware configuration itself is not in advance and does not itself produce the asserted advance of enhancement of one image by another, which, as explained, is an abstract idea."[26]

The court dismissed the fact that applicant's specification explained how the invention was unique compared to the prior art, holding that the claims did not exactly match the scope taught in the specification and were thus overboard.[27] The court's analysis looked suspiciously like a 35 USC § 112 analysis being applied inside a 35 USC § 101 rejection. To make matters worse, this entire analysis occurred in the context of a motion to dismiss by the defendants, which is supposed to afford the patent holder with all possible advantages regarding facts and inferences. The Federal Circuit reviewed all of the above and gave it their stamp of approval.[28]

It appears more and more that the courts are trying to squeeze every single basis for rejection under the umbrella of 35 USC § 101. "Routine and conventional" is merely obviousness in trendy clothes. Now *Yu v. Apple* introduces the idea that if the claim scope does not match the specification's scope of description for that claim element exactly, a kind of § 112 (enablement/written description) / § 101 rejection can be made.

This practice by the courts offers substantial value to those seeking to invalidate a patent. For example, the finding that a claim component is "routine and conventional" allows one to simply eliminate that claim element for the purpose

[23] Yu v. Apple, 1 F.4th 1040 (Fed. Cir. 2021).
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*

of determining whether the claim as a whole is directed to an abstract idea. This is exactly what happened in *Yu v. Apple* to all the tangible, real world, components in applicants claim.[29]

The total effect of these practices points to a future where all claims are invalid unless the physically existing real-world elements of the claim, taken alone, clear all hurdles to patentability. Such a practice would eliminate software from being patentably relevant.

Unusual Proposal for Computer Science Applicants

In the section of this paper regarding biotech above, it was argued that the best way to handle § 101 was to avoid it. Assuming this is good advice, it makes sense to ask if it can be applied to computer science inventions as well.

In short, this papers proposal is to define all the method steps that trigger "abstract idea" allegations purely in terms of physical science. Perhaps the best explanation of this proposal is through an example.

Let's take the forbidden word "calculating" discussed above. Instead of having a step of calculating in the claims, use

> receiving at least one stream of elections or photons in a specific sequence from at least one source, changing the charge or magnetic state of a physical medium, producing at least one stream of elections or photons in a specific sequence in accordance with the new charge or magnetic state of the physical medium, wherein the stream of elections or photons is different from the at least one stream of elections or photons received, returning the physical medium to the original charge or magnetic state.[30]

At its core, "calculating" is not abstract. It is instead a shorthand way of articulating the verbose and inelegant description above. This is well understood by one skilled in the art and should be available to applicants under their right to be their own lexicographer.[31] However, whether through misunderstanding, ignorance, or disdain for IP protection in this art, courts have failed to understand this shorthand terminology.

This strategy seeks to remove all elements of abstractness from the claim and force either an examiner or court to address the claim on its merits by defining every step of a computer process only in terms of how it physically affects the world. The strategy should prevent a reasonable allegation that any portion of the claim or the claim as a whole is drawn to an abstract idea, without actually changing the scope to the claims. That is, if every claim element is directed to the physical movement of matter in space rather than the useful short hand end result of that movement (*i.e.*, processing date, calculating a result, etc) it would seem difficult to take the position that this claim is directed to an abstract idea.

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[29] *Id.*

[30] Wherein clauses can be used to customize the exiting stream of elections or photons.

[31] *See* MPEP § 2111.01(IV).

To implement this strategy, it would be best to insert physical science definitions for each "abstract idea" in the specification during the application drafting phase. However, it might be possible to implement in existing cases with the justification that alternative definition is well known to one skilled in the art and thus supported under 35 USC § 112.[32] However, given the recent history of the courts, the latter is not preferred.

In addition to possibly solving the § 101 problem, drafting claims in this manner could strengthen the patent holders' portfolios by providing additional independent claims (or even separate patents) with similar claim scopes which infringers would have to separately address during litigation. This advantage which would also be shared by the biotech strategies above.

The Profane and the Sacred

This paper would seem incomplete without at least some attempt to address the reason why the biotech and computer science industries are being treated so differently, and why courts are twisting § 101 into a pretzel to accommodate rejections to claims in these industries.

Perhaps the most salient commonality between these industries which could explain this concerted effort to block acquisition of patent rights, is that they both are perceived to touch on fundamental pieces of humanity.

Biotech, particularly diagnostic methods, look at a human's most basic building blocks. The inventions in this field reduce us to flesh robots run by allele macros coded in nucleotides. For those who believe that there is something more or something metaphysical in a human being, this technology is existentially troubling.

Whereas biotech assaults the body, computer science attacks the mind. Where, at best, the brain and CPU are vastly different machines running different operating systems and using completely different hardware, there appears to be a fear that, unless the claims are carefully crafted, we might accidently give an applicant ownership of thought.

There can be no reasonable debate that the invention of *Yu v. Apple* was a real (non-abstract) thing. The claims are directed to components which one can literally hold in one's hand. Nevertheless, applicants sinned in the way in which they worded their patent claim and as punishment for this sin, their patent was destroyed.

The current complicated § 101 analysis constructed by the USPTO, with its multiple steps and prongs, attempts to make sense of the absurd and bring order to the chaos that is the judicial decisions in biotech and computer science over the last decade.[33] Instead of addressing the patentability of these inventions under § 112 and in view of the prior art, courts have given the concepts behind these standard rejections new names and attempted to graft them into 35 USC § 101.

Of course, Occam's Razor instructs us to look for the simplest answer which in this case might be that the Courts simply lack the technical background to adequately

[32] *See* MPEP § 2164.01, citing *In re* Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) ("A patent need not teach, and preferably omits, what is well known in the art.").

[33] *See* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (January 7, 2019).

understand these technologies and this ignorance alone is sufficient to explain the current state of 101 law.

In the case of either cause, the result has been that the fundamental reasoning behind 101 rejections in these art fields has become largely an issue of claim semantics. As such, the Carlin routine turns out to be particularly salient. In an interview with NPR about this famous routine Carlin said:

> On these other things, we get into the field of hypocrisy. Where you really cannot pin down what these rules they want to enforce are. It's just impossible to say "this is a blanket rule." You'll see some newspapers print "f *blank blank* k." Some print "f *asterisk asterisk* k." Some put "f *blank blank blank*." Some put the word "bleep." Some put "expletive deleted." So there's no real consistent standard. It's not a science. It's a notion that they have and it's superstitious. These words have no power. We give them this power by refusing to be free and easy with them. We give them great power over us. They really, in themselves, have no power. It's the thrust of the sentence that makes them either good or bad.[34]

This is why the unusual proposals above make such satisfying solutions to the problems of § 101. These proposals attack the underlying semantics issue rather than just addressing the manifested symptoms. They seek to strip the power from the claim terms themselves and force examiners and courts to consider the actual thrust of claimed invention. These strategies thereby avoid the fickle § 101 analysis of the USPTO by avoiding it completely.. . . . . .

Whether or not they will ultimately be successful and widely adopted is certainly in question. However, one can hope that should courts decide to strike them down, that the reasoning required to justify these decisions will be so absurd that even legislatures will take notice and perhaps decide to solve the issues with new law. As either solution is favorable, it is sensible to advocate the extreme in an attempt to provoke change.

The Beast is Growing

More and more inventions are being offered to the Moloch that is 35 USC § 101. For those in industries other than biotech and computer science, you may think—that's too bad for those guys, but I don't have to worry about § 101—be careful.[35] *Stare decisis* can generate some dangerous momentum when left unchecked, and the reasoning used to in the court decisions used to invalidate the biotech and computer science patents is not written to be strictly limited to these art fields. The momentum built in the decisions in biotech and computer science cases is now plowing through to the mechanical field. To borrow a quote from Mark Lawrence, "There's a slope down toward evil, a gentle gradient that can be ignored at each step, unfelt. It's

[34] *Comedian and Actor George Carlin* (National Public Radio broadcast Nov. 1, 2004).

[35] Judge Chen's Concurrence in Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 966 F.3d 1347 (Fed. Cir. 2020) explicitly stated that he rejected the notion that mechanical or industrial inventions should be categorically excluded from § 101 concerns.

not until you look back, see the distant heights where you once lived, that you understand your journey."[36]

In the recent *American Axle* decision, the Federal Circuit struck down patent claims based on section 101 in a mechanical case.[37] That's right, a mechanical case. The patent dealt with a method of making driveline propeller shafts with liners that reduced vibrations. The inventors had devised an ingenious application of Hooke's Law which defines the relationship between an objects' mass, its stiffness, and the frequency at which it vibrates.[38] The Federal Circuit held that the claims which required tuning the mass and stiffness of a liner to address vibration issues was broad enough to cover any method of applying Hooke's Law and therefore the claim amounted to merely the application of Hooke's law, *i.e.*, patent ineligible under section 101 based on the natural law judicial exception.[39]

To be clear, the claims of *American Axle* required the actual manufacture of a real life tangible[40] thing, a "shaft assembly of a driveline system," and required things like, "inserting the at least one liner into the shaft member." When performing the claimed method, one can literally hold this thing in one's hands.[41] It is difficult to imagine a situation in nature where this would naturally occur. Perhaps the court is simply a firm believer in the totalitarian principle.[42] In any case, the Federal Circuit invalidated the patent as being patent ineligible under the natural law judicial exception.

A generation ago, this legal analysis would have seemed a bad joke or maybe a dystopian farce. However, upon review of the logic and reasoning in the last decade of holdings from the biotech and computer science industries, the *American Axle* holding feels like the only possible outcome. The majority in *American Axle* held, "the patent claims do not describe a specific method for applying Hooke's law in this context. They simply state that the liner should be tuned to dampen certain vibrations," which they equate to the mere application of a natural law which is patent ineligible under *Alice/Mayo*, *i.e.*, the application of Hook's Law to the manufacture of a shaft assembly of a driveline system.[43]

One is left wonder how this case might have turned out if Mr. Hook had not made his scientific discovery those many years ago. That is, what if the inventors had stumbled into their method of manufacturing without any knowledge of the "natural laws" which enabled its advantages? If the reasoning for the arrangement of their components was arbitrary and yet offered the same reduced vibration advantage would their invention have been patentable? Perhaps the reduced vibration would have even been seen as an unexpected result rather than a mere application of a natural law.

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[36] Mark Lawrence, Emperor of Thorns (2013).

[37] *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 966 F.3d 1347 (Fed. Cir. 2020).

[38] *See id*. Hooke's Law: the force (F) needed to extend or compress a spring by some distance (x) scales linearly with respect to that distance. Expressed Fs = kx, where k is a constant factor characteristic of the spring (stiffness).

[39] *See Am. Axle*, 966 F.3d at 1362.

[40] See claims 1 and 22 of U.S. Patent No. 7,774,911 (filed Feb. 27, 2006).

[41] Warning, it's a bit heavy.

[42] The totalitarian principle states that "everything not forbidden is compulsory," which essentially means, given infinite time, anything not forbidden by the laws of physics must occur.

[43] *See Am. Axle*, 966 F.3d at 1362; *see also* Alice Corp. v. CLS Bank International, 573 U.S. 208 (2014); Mayo v. Prometheus, 566 U.S. 66 (2012).

This begs an even broader question of whether all "unexpected results" are merely applications of unknown natural laws. Imagine a situation where the patents claim where otherwise obvious, but the inventor was able to demonstrate sufficient unexpected results to ultimately obtain a patent. Later, a new natural law is discovered which explains the unexpected result. Does that patent become invalid under § 101?

The above analysis by the Federal Circuit also begs the question, what technology is not based on the "mere" application of a natural law? Where exactly is the line between enablement and mere application of a natural law? Isn't the application of a natural law what separates science from technology in the first place? That is, science discovers the laws of nature and then technology applies them to useful pursuits like, for example, making a shaft assembly of a driveline system that doesn't vibrate as much. Taken to its extreme, it might seem as if one must break the laws of physics to obtain patent eligible subject matter.

The majority in *American Axle* sought to defend against the above hyperbole by arguing that it was the failure of the claims to describe any specific method for applying Hooke's law which led to their undoing, *i.e.*, semantics. However, how specific one must be remains unclear. The claims in *American Axle* required "tuning of a mass and stiffness of at least one liner" where the liner is tuned to "for attenuating shell mode vibrations . . . and . . . attenuating bending mode vibrations." Did the court want the patent holder to be limited to only one specific method of tuning? That seems rather arbitrary. Is the patent holder also required to invent a new method of tuning?[44]

As of this writing, *American Axle* has been petitioned to the Supreme Court, and there is some optimism that facts of this case might allow the Supreme Court to look back and see the distant heights where patent law once lived, and maybe even turn around and start walking back up the hill.

American Axle is important at least because it shows that the leviathan of § 101 might not be done growing. If not brought under control, § 101 will likely become a major barrier to patentability for all technology arts, the consequences of which would be detrimental to the future of innovation and the American economy.

At the beginning of the paper we said that whenever one analyzes a particular rule or quirk of the patent system, it benefits the analysis to continually ask the question, does this promote the Progress of Science and Useful Arts? It is therefore fitting to end with the same question. Does the current analysis under § 101 (and written description in biotech) promote the Progress of Science and Useful Arts? This author suspects a growing majority would answer that it does not.

[44] *Compare* Rapid Litigation Management v. CellzDirect, 827 F.3d 1042 (Fed. Cir. 2016) *with* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 966 F.3d 1347 (Fed. Cir. 2020).