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ONE JUDGE'S HISTORICAL VIEW OF A CHANGING PATENT WORLD

Alan D. Lourie†

Good morning. Thank you for inviting me to speak to you today at this conference on patent law.[1] Your invitation stated that I might speak on any relevant topics of my choosing, such as recent trends or developments in case law. But what I choose to speak on are not trends or developments in case law, but all the changes that have occurred in the patent world during my career as a patent attorney and judge. I will interpret the recent trends language loosely and translate "recent" to mean the entire period of time I have been in the patent profession, which has been fifty-four years. After all, the patent system began in this country in 1790, not counting state patent laws, so fifty-four years in the life of the patent system can be viewed as "recent." What is striking to me as I look back on that period of time is how much has changed.

In reviewing that recent period, I will focus on events as I have seen them as a practitioner and judge and comment on the changes that have led us to today's patent world. I don't intend this as biography but as a tour of the patent system through observations of a participant. I hope they will be of interest.

In 1964, I joined the patent profession by passing the Patent Office exam. In those days, chemists often failed on their first attempt at the exam because, until that time, applicants had to write mechanical claims, and chemists were not adept at mechanics. We knew benzene rings and steroids but not axles and pulleys. But I got lucky that year. We were given a choice of claims to write, and I obviously chose to write a chemical process claim. I accordingly aced the exam. Luck plays a role in all phases of life. I don't know what type of claim, if any, that applicants for membership in the patent bar have to write these days, but so much else has changed.

When I began patent work, the Court of Customs and Patent Appeals (CCPA) was the fount of wisdom interpreting the 1952 Patent Act. That statute was barely a decade old at the time. A few regional circuit opinions on patents appeared from time to time, but *Graham v. Deere* was the only decision from the Supreme Court that provided judicial guidance on a point of law that

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† Circuit Judge, U.S. Court of Appeals for the Federal Circuit.
1. Remarks presented at the Georgetown-Berkeley Tenth Annual Conference on Patent Law & Policy on November 16, 2018.

mattered to patent solicitors like me.[2] It was the CCPA that regularly handed down opinions from which I learned the patent law. Aside from my boss, who was himself a very smart patent attorney, Judge Rich was my patent teacher through his opinions. I was obviously very pleased to later be able to work with him on the court and even have him join my opinions. He only dissented from me once,[3] and I forgave him for that.

The fee to file a patent application then was $30, and a similar amount was required to issue the patent. There were no maintenance fees. Outside of corporations that had in-house patent departments, patent law was practiced by what have been called boutique firms. In Philadelphia, I believe only one general law firm had any patent lawyers, and it had only one, and then, later on, two. Patent law was generally not taught in the law schools; George Washington, John Marshall, and Franklin Pierce were the exceptions. When I began law school at night after I finished my Ph.D., there was no patent law class at Temple or at most law schools. I had one bar review course to choose from when I was preparing for the agents' exam, that at the Practicing Law Institute (PLI). It did its job well.

There was little patent litigation in those days compared with today. There were few pharmaceutical patent suits because generic companies had little opportunity to copy innovative products. Before Hatch-Waxman was enacted, it was too expensive for generic companies to generate their own safety and efficacy data to get approval from the Food and Drug Administration (FDA). Exceptions existed for antibiotics, which were covered by a biological statute,[4] and some old products, so generic companies didn't provide many challenges to innovators' patents.

Large companies did conflict with other large companies by inventing and filing patent applications on the same subject matter, but they tended to settle the ensuing interferences by the parties' exchanging notebook records showing dates of invention, with the winner often granting a license to the loser on suitable terms.

There were no software patents, and, of course, today's ubiquitous consumer electronic products with lots of patented components and patent suits were well into the future. The Supreme Court decided a case on patentable subject matter, the *Chakrabarty* case, by a slim 5–4 margin in 1980, permitting patents on living microorganisms.[5] When the Court granted

2. *See* Graham v. John Deere Co., 383 U.S. 1 (1966).
3. *See* Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1565 (Fed. Cir. 1991).
4. 21 U.S.C. § 357 (1996), repealed by Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997).
5. *See* Diamond v. Chakrabarty, 447 U.S. § 303 (1980).

certiorari in that case, it also did so in the *Bergy* case, which involved a purified natural product.[6] Some of us in the pharmaceutical industry were concerned that both cases were going up together for Supreme Court review, and *Chakrabarty* would be hurt by association with *Bergy*, so we persuaded the owner in the *Bergy* case to abandon its patent application, thereby removing it from possibly affecting the Court's review of *Chakrabarty*. One might imagine that if *Chakrabarty* had stayed paired with *Bergy*, the 5–4 result in *Chakrabarty* might have been different.

In the patent law associations in those years, all of industry supported the patent system as being important, if not essential, to innovation. The electronics and pharmaceutical people all backed the same changes that were proposed to strengthen and maintain the patent system. Obviously, that has since changed. In recent years, it has been very difficult to generate support for various pieces of proposed patent legislation because different industry groups have different views on them. That division of views may well have influenced the Supreme Court in deciding which cases of ours to review, a matter to which I shall return.

In 1979, President Carter appointed an Advisory Committee on Industry Innovation to consider why innovation in our country was flagging. My colleague, Judge Newman, before she was a judge, and other leading patent attorneys, including Don Dunner, were active contributors to the deliberations of its subcommittee on patent policy. Among its recommendations were that patents on regulated products should have their terms extended to recoup time lost in regulatory review, which led to the Hatch-Waxman Act; that a central court of appeals for patent cases be created, which of course led to the formation of the Federal Circuit; and that the patent office be upgraded, which led to higher fees and later a self-funding patent office.

The Federal Circuit began life in October 1982 as an amalgam of the Court of Claims and the CCPA.[7] The court has been in existence for thirty-six years and has had thirty-eight judges. I have been on the court for more than three-quarters of its existence. The judges of the court are quite collegial and do not think of themselves in political terms, as liberals or conservatives, Republicans or Democrats. Our job is to decide cases based on the standard of review, the law, and the facts; ideology or political views play no role in our work. We come from different backgrounds, but every judge has usefully brought his or her own experience to our joint task.

6. *See In re* Bergy, 596 F.2d 952 (C.C.P.A. 1979).
7. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 57 (1982).

Through the years, the court has encountered new types of appeals. Just before I joined the court, it began to hear veterans appeals as a result of legislation that created the Court of Appeals for Veterans Claims and gave us limited review authority over those decisions.[8] Along with government employee appeals from the Merit Systems Protection Board, they are our "people" cases, so our docket isn't only about money.

When I joined the court, it had just begun to review patent jury trials, which neither the Court of Claims nor the CCPA previously heard. The court thus had to learn to deal with issues peculiar to jury trials. Because we were hearing such appeals, the question arose concerning who should construe claims in the district courts, judges or juries. That led to our *Markman* case, which held that claim construction was a matter for the court, not a jury, and it was affirmed by the Supreme Court.[9] Following that resolution, we began to have a stream of appeals from summary judgments of non-infringement, more of those appeals than from jury trials. Obviously, when a claim construction has gone against the patent owner, it has seemed better in many cases to concede infringement, skip validity issues, and go right to appeal.

The court then began to see a regular flow of Hatch-Waxman cases, either appeals from generic companies found to have been intending to infringe a valid patent or from patent owners whose patents had been found invalid or not infringed by an Abbreviated New Drug Application (ANDA) applicant.

In the early 1980s, I had the opportunity to play a background role in the creation of the Hatch-Waxman Act, as I was chairman of the Patent Committee of the Pharmaceutical Manufacturers Association, which spearheaded the effort on the innovators' side. Aside from the unique experience of seeing how the sausage is made, I learned that when one initiates new legislation, one never knows how it will come out. Our goal was to restore patent life lost in development and regulatory review because studies had shown that effective patent life for pharmaceutical products had diminished to about eight or nine years, well short of the statutory seventeen. Our bill, sponsored by Senator Charles ("Mac") Mathias of Maryland, extended patent life for up to seven years, and it passed the Senate easily in 1982. Then, opposition appeared.

The generic companies, which predicted that their businesses would be adversely affected by the proposed legislation, saw an opportunity to fashion a deal. Their ally was Congressman Henry Waxman of California. They would support some patent term restoration, as it was termed, in return for being able

8. Veterans' Judicial Review Act, Pub. L. No. 100-687, 102 Stat. 4105, 4120–21 (1988).
9. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

to have generic products approved without having to prove safety and efficacy, as required by then-current law. The new statute would enable them to show, by blood levels, that their products were equivalent to the innovative product. Thus, over a four-year period ending in 1984, what resulted was the Drug Price Competition and Patent Term Restoration Act, which extended patent life on innovative products for up to five years and enabled easier approval of generic products.[10]

That Act created a new statutorily-defined act of patent infringement consisting of filing an abbreviated drug application with a so-called Paragraph IV certification that indicated that the applicant didn't believe it would infringe a patent covering the drug or its use, or that the patent was invalid.[11] These challenges, by virtue of the legislation, occurred before any product was marketed and have hastened the resolution of questions of validity and infringement. The Act transformed the litigation environment in the drug industry, as it seems like every major pharmaceutical product these days is subject to some litigation. I won't bother you with the details, but in the end, the innovative industry got part of what it wanted but had to abide by new competition. I am not in a position to comment on how it netted out for the two branches of the drug industry after thirty-five years, but I learned a lot about how the legislative process worked. Our court has since had many cases arising from that Act and no doubt will continue to do so.

Now we have another new statute, under which biological products are subject to similar litigation.[12] And the lines of interest are at times reversed as innovative companies are introducing generic biosimilars. The usual patent defenders are at times patent challengers.

Then the software cases started coming to our court. Everyone here knows that years ago the Supreme Court interpreted § 101 of the Patent Act to exclude patents claiming abstract ideas, natural laws, and products of nature.[13] But many patents have issued claiming methods and apparatus for performing various tasks using computers, and those patents have been asserted against large electronics companies. Questions of eligibility for patents under § 101 have arisen, and the Supreme Court has weighed in, attempting to provide

10. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); *see* Alan D. Lourie, *Patent Term Restoration*, 66 J. PAT. OFF. SOC'Y 526 (1984).

11. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2018).

12. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (codified in sections of 42 U.S.C. & 21 U.S.C.).

13. *See* Gottschalk v. Benson, 409 U.S. 63 (1972); Parker v. Flook, 437 U.S. 584 (1978); Diamond v. Diehr, 450 U.S. 175 (1981).

guidance concerning what methods of using computers are or are not patent-ineligible abstract ideas.[14] We and other tribunals have attempted to follow that guidance. It's not for me to say to what extent any of us are succeeding, but we are working hard at it.

The next wave of new cases to arrive at our court came as a result of the America Invents Act (AIA) that, among other things, provided for new inter partes review procedures in the Patent Office.[15] Challenges to patents can be brought before the Patent Trial and Appeal Board (PTAB), for the purpose of eliminating weak patents less expensively than in traditional district court proceedings. We, with guidance from the Supreme Court, have been reviewing those decisions, sorting out the meaning of the statute, and deciding specific cases of patentability.

Thus, what comes before us has varied through the years. The patent world, during the time I have been a part of it, has evolved from a quiet backwater of the law for specialists, with very little litigation, to one in which litigation is a major enterprise involving general practice firms bringing large numbers of district court and PTAB appeals to our court.

It is interesting to note that in 1964, only about 125 patent infringement appeals were decided by the various regional circuits. In contrast, in our fiscal year ending in 2017, over 500 patent appeals from the district courts were filed in our court.[16] And that was actually down from over 600 two years earlier.[17] In addition, we had almost 600 appeals from the PTAB in 2017.[18] Ten years earlier, there were less than one-tenth that number.[19] The patent world indeed has changed.

The question is often asked how well the court has carried out its role of deciding cases in all its fields of jurisdiction, especially in bringing more uniformity to the patent law than existed before. A prominent judge from

14. *See, e.g.*, Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208 (2014); Bilski v. Kappos, 561 U.S. 593 (2010).

15. 35 U.S.C. §§ 311–319 (2018).

16. *Year-to-Date Activity as of September 30, 2017*, U.S. CT. OF APPEALS FOR THE FED. CIR. (Sept. 30, 2017) http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/YTD_Activity_9.30.17.pdf [https://perma.cc/XUT3-KMS8] [hereinafter *2017 Year-to-Date Activity*].

17. *Year-to-Date Activity as of September 30, 2015*, U.S. CT. OF APPEALS FOR THE FED. CIR. (Sept. 30, 2015) http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/ytd_activity_9_30_15.pdf [https://perma.cc/U7V7-KHSX].

18. *2017 Year-to-Date Activity*, *supra* note 16.

19. *U.S. Court of Appeals for the Federal Circuit—Appeals Filed, Terminated, and Pending During the Twelve-Month Period Ended September 30, 2007*, U.S. CT. OF APPEALS FOR THE FED. CIR. (Sept. 30, 2007) http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/b08sep07.pdf [https://perma.cc/JF52-JPF8].

another circuit has suggested that we return to the past and permit other circuits to share the role of deciding patent cases.

In my view, the court has done quite well in performing its assigned tasks. I hear of little questioning about the court's performance in our non-patent appeals, so I will not dwell on them. But, regarding patents, I cannot believe that the law would be in a better or clearer state if patent appeals had remained in the regional circuits. Those courts would have had less experience with patent law than our court and less technical expertise, and the Supreme Court would have been taking even more patent cases in order to resolve circuit splits. And we have plenty of debate within our court, leading to dissents and sometimes grants of certiorari. I doubt that the law would have been better off under a different scenario.

As mentioned earlier, when I entered the patent world, patent law only was a niche in the law populated by specialist lawyers and law firms. There were a few academic papers about patents and an occasional governmental study but very little patent literature. Of course, there were no patent blogs and few reports of decisions. Reports of arguments did not widely appear in the press the day after they occurred, as we now see. From time to time, I have the informative experience of seeing in the press a report of an appeal in our court that had occurred the day before, about which I had no knowledge. The press thus sometimes tells us what is happening in our own court, as we are not necessarily aware of what cases other panels are hearing.

A major aspect of patent litigation these days is that many parties asserting patent infringement are not inventors or their immediate assignees. Patents are accumulated and aggregated by companies organized for just that purpose. Various names are used to describe these patent owners, implying value judgments concerning their motives for obtaining and suing under their patents. However, for us in the court, a party is a party, and we do not make value judgments concerning how or why they obtained their patents. We decide their cases as we do all cases, reviewing a decision of a lower tribunal on the law and facts, giving deference where appropriate.

An overriding factor in today's patent world is the interest of the Supreme Court in our cases. In the first decade of the court's existence, by my informal count, the Supreme Court only heard twenty cases from our court, only three of them were patent cases.[20] In the last decade, however, they have heard forty

20. The patent cases are: Christianson v. Colt Indus. Operating Corp., 486 U.S. 800 (1988); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990); Cardinal Chem. Co. v. Morton Int'l, 508 U.S. 83 (1993).

of our cases, twenty-eight of them, more than half, patent.

Many commentators have speculated as to why this is so. Guesses have included the importance of patent law to today's commercial world; the fact that leading Supreme Court advocates, some of whom have actually argued the appeals in our court, are filing certiorari petitions; academic participation in amicus briefs; the sharp division in views among different parts of industry concerning issues of patent law; and, perhaps, a feeling on the part of the Justices that, as the Supreme Court, they should have their imprint on important issues of patent law. After all, contrary to some outside references to our court as the supreme court of patents, they are the Supreme Court on all aspects of law.

There are no circuit splits in patent law these days, so the Court has to rule on patent issues by hearing our cases. While the principal reason for the formation of our court was to establish uniformity on issues of patent law, presumably by laying down rules, the Court has disagreed with some of our attempts and emphasized flexibility. They also have worked to put or keep patent law in line with other areas of the law.

The Supreme Court has come in for some criticism concerning its decisions reversing some of our decisions. I will not here add to that criticism. We do not seek certiorari. But I will say what I have said elsewhere, that courts, which review specific cases, are not the best venue for establishing general principles of law in complex issues such as categories of patentable subject matter. Congress has its imperfections, but, in Congress, various points of view can be presented and balanced out. As I mentioned earlier, I saw that process play out in the consideration of the Hatch-Waxman Act, and, while the result was not perfect from any standpoint, the various factions and industry components each had their say and input. And something was accomplished. Courts are limited to the cases that come before them. We are subject to a standard of review of a particular decision, giving some deference to prior tribunals, and we are limited to the issues decided there and argued before us. The presence of other issues and the variability in performance among lawyers are also factors tied to specific cases. It's an old saying that hard facts make bad law.

The patent system is under criticism these days, but that has always been so. In 1958, a distinguished economist, Fritz Machlup, opined that "[i]f we did not have a patent system, it would be irresponsible, on the basis of our present knowledge . . . to recommend instituting one. But since we have had a patent system . . . it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it."[21] Of course, we do have a patent system, and, in my early days in the profession, as mentioned, all of industry that was involved in science or technology supported the patent system. As indicated above, that is certainly not the case today.

And academic writing and press coverage of patent decisions, from all tribunals, not just our court, have much to say about the patent system and play an important role in today's patent world. I have already mentioned the overwhelming factor in today's patent world, the role of reexamination created by the AIA.[22] Patents, which by statute are endowed with a presumption of validity and can be challenged in district court only by parties with an interest that creates a genuine case or controversy, are now reexamined at the PTO at the behest of anyone and subject to cancellation based on a preponderance of evidence.[23] These are major changes in the patent world. We, at the court, now have more patent appeals coming from the PTAB than from district courts. There are obvious beneficial aspects of the new procedures, namely, less expense and reexamination by a panel of administrative judges who know patent law and have technical knowledge. But whether the net of these pros and cons is positive or negative is not for me to say. I just note that, in my timeline review of factors affecting the patent world, the role of the PTAB is certainly a new and powerful one.

That brings me to the end of my review of the last fifty-four years of the patent world that I have seen. But, before I conclude, a few words about innovation. A reliable patent system is important to incentivize invention and investment, no doubt in some fields more than in others. My experience in the pharmaceutical field bore that out, where large investments were not made without expectation of effective patent protection.

Other innovators need patent protection as well. One can cite the well-known historic experiences of Polaroid and Xerox, both of which owed their corporate existence and success to individual inventors who relied heavily on

21. SUBCOMM. ON PATENTS, TRADEMARKS & COPYRIGHTS OF THE COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 80 (Comm. Print 1958) (a study prepared by Fritz Machlup, Dep't of Political Econ., Johns Hopkins Univ.).

22. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

23. *See* 35 U.S.C. §§ 311(a), 316(e) (2012).

the exclusive rights provided by patents to sustain their work.[24] As Edwin Land, the Polaroid inventor and founder, stated when Polaroid sued Kodak, "The only thing that keeps us alive is our brilliance . . . . The only thing protecting our brilliance is our patents."[25] That statement so struck me when I read it that I had it imprinted on the wall of our company's patent department. It reflected the necessary role of patents in our company's work.

Xerox had a similar history where its inventor, Chester Carlson, a patent attorney, had to hunt around for someone to take on his invention, and his patents eventually enabled that to happen. No doubt, other more recent stories can be told, but a reliable patent system is essential to sustain individual inventors as well as support investment by larger entities.

I hope my chronological remarks, albeit having a personal focus, have been of interest. Thank you for listening.

24. *See generally* RONALD K. FIERSTEIN, A TRIUMPH OF GENIUS: EDWIN LAND, POLAROID, AND THE KODAK PATENT WAR (2015).

25. NEWSWEEK, May 10, 1976, at 86.

THE ROLE OF THE COURTS IN SHAPING PATENT LAW & POLICY

Andrei Iancu†

It's a pleasure to be with all of you this afternoon as we discuss "The Role of the Courts in Shaping Patent Law & Policy." And what better to address on this issue than the judicial exceptions to § 101?[1] So, you will forgive me if we get a bit into the weeds today, as this is obviously a complex topic.

"It will be of little avail to the people . . . if the laws be so incoherent that they cannot be understood," James Madison said in 1788.[2] Known as the "Father of the Constitution," Madison also recognized the importance of intellectual property (IP). In Federalist 43, for example, he addressed the constitutional power to create an IP system, stating that "the utility of this power will scarcely be questioned" because "the public good fully coincides . . . with the claims of individuals."[3]

Madison was right. Based on this careful balance between the rights of the individuals and those of the public, IP has been the engine behind America's economic and cultural development from the very start of the republic. But, for the IP system to work as intended, we must ensure that our laws are clear and that the IP rights we issue are predictable, reliable, and of high quality.

Today, however, the law surrounding what subject matter is eligible for patenting under 35 U.S.C. § 101 is anything but clear. There is a general consensus that something needs to be done. Several Federal Circuit judges, for example, have recently filed concurrences or dissents highlighting the uncertain nature of the law and calling for change.[4]

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† Director of the U.S. Patent and Trademark Office. Remarks presented at the Georgetown-Berkeley Tenth Annual Conference on Patent Law & Policy on November 16, 2018.

1. 35 U.S.C. § 101 (2018).
2. THE FEDERALIST NO. 62 (James Madison) (Clinton Rossiter ed., 1961).
3. THE FEDERALIST NO. 43 (James Madison) (Clinton Rossiter ed., 1961).
4. *See, e.g.*, Berkheimer v. HP Inc., 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., concurring); Interval Licensing LLC v. AOL, Inc., 896 F.3d 1335, 1348 (Fed. Cir. 2018)

In order to "work its way out of what so many in the innovation field consider § 101 problems," Judge Lourie—in an opinion joined by Judge Newman—appealed to a higher authority.[5] "Resolution of patent-eligibility issues requires higher intervention, hopefully with ideas reflective of the best thinking that can be brought to bear on the subject."[6]

Judge Plager noted that "the state of the law is such as to give little confidence that the outcome is necessarily correct."[7] Given current § 101 jurisprudence, he explained it is "near impossible to know with any certainty whether the invention is or is not patent eligible."[8] And he concluded that we currently have an "incoherent body of doctrine."[9] And Judge Linn said that the abstract idea test is "indeterminate and often leads to arbitrary results."[10]

Others in the IP community have expressed similar sentiments.[11]

In order to increase the certainty of whether particular subject matter is eligible or not, and to simplify our analysis, the United States Patent and Trademark Office (USPTO) plans to issue guidance to help our examiners and applicants who struggle with these issues every single day.

(Plager, J., concurring in part and dissenting in part); Smart Sys. Innovations, LLC v. Chi. Transit Auth., 873 F.3d 1364, 1376 (Fed. Cir. 2017) (Linn, J., dissenting in part and concurring in part).

5. *Berkheimer*, 890 F.3d at 1374.

6. *Id.* at 1376.

7. *Interval Licensing*, 896 F.3d at 1348.

8. *Id.*

9. *Id.*

10. Smart Sys. Innovations, LLC v. Chi. Transit Auth., 873 F.3d 1364, 1377 (Fed. Cir. 2017) (Linn, J., dissenting in part and concurring in part).

11. *See, e.g.*, Email from Mark K. Dickson, Chair, Am. Bar Ass'n Section of Intellectual Prop. Law, to Hon. Andrei Iancu, Under Sec'y, Commerce for Intellectual Prop. & Dir., U.S. Patent & Trademark Office (Mar. 7, 2019), https://www.uspto.gov/sites/default/files/documents/eligibility2019comments_a_abaipl_2019mar07.pdf [https://perma.cc/C5S4-R2KV]; Email from Sheldon H. Klein, Am. Intellectual Prop. Law Ass'n (AIPLA), to Hon. Andrei Iancu, Under Sec'y, Commerce for Intellectual Prop. & Dir., U.S. Patent & Trademark Office (Mar. 8, 2019), https://www.uspto.gov/sites/default/files/documents/eligibility2019comments_a_aipla_2019mar08.pdf [https://perma.cc/65AE-8BCT]; Email from Henry Hadad, President, Intellectual Prop. Owners Ass'n (IPO), to Hon. Andrei Iancu, Under Sec'y, Commerce for Intellectual Prop. & Dir., U.S. Patent & Trademark Office (Mar. 8, 2019), https://www.uspto.gov/sites/default/files/documents/eligibility2019comments_a_ipo_2019mar08.pdf [https://perma.cc/BR9N-RDBS]; *see also, e.g.*, Judge Paul Michel, *Is 2019 the Year Clarity Returns to Section 101? Judge Paul Michel Is Hopeful*, IPWATCHDOG (Jan. 24, 2019), https://www.ipwatchdog.com/2019/01/24/2019-year-clarity-returns-section-101-judge-paul-michel-hopeful/id=105566/ [https://perma.cc/33DX-L9E3] ("[T]he current Section 101 is inherently unclear and therefore could not be consistently administered by patent examiners and judges, much less juries.").

As a matter of fact, many of you know that we have already issued two new guidance memos to our examiners on § 101: the first dealing with the "conventionality" analysis in the second step of the *Mayo/Alice* framework and the second regarding "method of treatment" claims.[12]

Our data shows that these two memos have already had a positive impact on § 101 analysis during examination. But much more work needs to be done, especially with respect to step one of *Alice/Mayo*. And this is what our forthcoming guidance aims to do.

We start with a principle articulated by Judge Giles Rich in 1979. He said that problems can arise due to the "unfortunate . . . though clear commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the categories of invention in § 101 which may be patentable, and to the conditions for patentability demanded by the statute."[13]

In other words, and pursuant to the Patent Act of 1952, we should keep invalidity rejections in their own lanes. If something is not novel or is obvious, we should invalidate it under § 102 or § 103. If something is indefinite, or too broad to be fully enabled or described, we should invalidate it under § 112. We have decades of case law from the courts and decades of experience at the USPTO examining millions of patent applications which guide us in our §§ 102, 103, and 112 analyses. People know these standards and know how to apply these well-defined statutory requirements.

The genius of the 1952 Patent Act[14] was that it clearly categorized the conditions for patentability in addition to, and separate from, the categories of invention. But some recent § 101 findings seem to mix them all up again. As Judge Rich cautioned, this "may lead to distorted legal conclusions."[15] So, I propose that we stop commingling patent eligibility, on one hand, with the conditions for patentability, on the other.

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12. *See* Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination Policy to the Patent Examining Corps on Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*) (Apr. 19, 2018), https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF [https://perma.cc/ZB4N-GE2M]; Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination Policy to the Patent Examining Corps on Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* (June 7, 2018), https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF [https://perma.cc/8PQ4-54PL].

13. *In re* Bergy, 596 F.2d 952, 959 (C.C.P.A. 1979).

14. Act of July 19, 1952, Pub. L. 593, 66 Stat. 792 [hereinafter 1952 Patent Act].

15. *Bergy*, 596 F.2d at 959.

Section 101 is about the eligibility of subject matter. To that end, the judicial exceptions should address categories of subject matter that are not eligible per se, or on their own, no matter how inventive or well-claimed they are.

We don't need § 101 to address other problems with the claims. We have §§ 102, 103, and 112 for that purpose.

The exceptions to § 101 are judicially created. In the spirit of judicial restraint, let's apply them only where we have to.

For example, a pure discovery of nature, like gravity or electromagnetism, is per se not eligible, no matter how perfectly drafted the claims might be. This is an example of a subject matter issue. The category itself is problematic, and that cannot be addressed by §§ 102, 103, and 112. In other words, even if the applicants are the very first to have discovered gravity or electromagnetism, and there is zero published prior art, and even if they describe the principle in great detail and claim it well enough to satisfy all § 112 requirements perfectly, even then, the Supreme Court has told us that we should still not issue a patent on the principle itself.[16]

This is an example where a judicial exception to § 101 is arguably necessary under current law. The question then becomes, what are all such categories where a judicial exception to § 101 is necessary?

The Supreme Court has told us that, other than natural phenomena and laws of nature, the only other exception is "abstract ideas."[17] But what exactly are these prohibited "abstract ideas"?

After detailed studies of all relevant cases, and based on our extensive experience at the USPTO, it appears to us that "abstract ideas" can be synthesized to fall into the following three categories:

Mathematical concepts like mathematical relationships, formulas, and calculations.[18]

Certain methods of organizing human interactions, such as fundamental economic practices; commercial and legal interactions; managing

16. *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (citing Le Roy v. Tatham, 55 U.S. 156, 175 (1852)); *see also* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 4 (Jan. 7, 2019), https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf [https://perma.cc/584S-98HX] [hereinafter 2019 Guidelines].

17. *See* Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217–19 (2014) (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 67 (2012)).

18. *See, e.g.*, Bilski v. Kappos, 561 U.S. 593, 611 (2010) ("The concept of hedging . . . reduced to a mathematical formula . . . is an unpatentable abstract idea."); Diamond v. Diehr, 450 U.S. 175, 191 (1981); Parker v. Flook, 437 U.S. 584, 594 (1978).

relationships or interactions between people; and advertising, marketing, and sales activities.[19]

Mental processes, which are concepts performed in the human mind, such as forming an observation, evaluation, judgment, or opinion.[20]

Specifying the prohibited categories is important, at least for the sake of predictability, so that the public can invent, invest, and transact business with increased confidence.

And again, these are categories of subject matter that are not eligible per se, or on their own, irrespective of how inventive or well-claimed they are. That is, regardless of how novel and well-described Newton's calculus may have been, it is still not patentable by itself. Same with hedging or escrow transactions, as in *Alice*[21] and *Bilski*.[22] On their own, this subject matter can be thought of as abstract. Perhaps "inherently" abstract, some might say.

It is important to contrast these categories that the Supreme Court has told us are inherently prohibited on one hand, with examples where subject matter could be eligible on the other.

We are all currently grappling with the eligibility of all sorts of technology, from things like toys that communicate with one another to computer virus screening, from computer databases to methods of treating various diseases. Now I am not expressing any view as to the ultimate validity of any particular claims drawn to these technologies. Such claims, if they are actually "directed to" math or laws of nature or some other matter that the Supreme Court said is per se ineligible, might perhaps fail under § 101.[23]

But without more, why would such technology be deemed as ineligible by itself? The Supreme Court has never held such technology, by itself, to be prohibited. And why should it be?

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19. *See, e.g.*, *Alice*, 573 U.S. at 219–20 (concluding that use of a third party to mediate settlement risk is a "fundamental economic practice" and thus an abstract idea); *Bilski*, 561 U.S. at 611–12.

20. *See, e.g.*, Intellectual Ventures I LLC v. Symantec Corp., 838 F.3d 1307, 1318 (Fed. Cir. 2016) ("[W]ith the exception of generic computer-implemented steps, there is nothing in the claims themselves that foreclose them from being performed by a human, mentally or with pen and paper."); Mortg. Grader, Inc. v. First Choice Loan Servs. Inc., 811 F.3d. 1314, 1324 (Fed. Cir. 2016) (holding that computer-implemented method for "anonymous loan shopping" was an abstract idea because it could be "performed by humans without a computer").

21. *Alice*, 573 U.S. at 219–20.

22. *Bilski*, 561 U.S. at 611.

23. *Alice*, 573 U.S. at 217 (citing *Mayo*, 566 U.S. at 77); *see also* 2019 Guidelines, *supra* note 16, at 1.

If claims drawn to such matter are novel and nonobvious, and if they are enabled, well-described and definite, I suspect most would agree that they could be patentable. For example, wouldn't we tend to think that toys that communicate with each other might be patentable—if new, nonobvious, definite, well-described, and the like?

This is in stark contrast to the categories the Supreme Court has identified as per se ineligible, such as math, fundamental economic principles, or mental processes. Those categories, by themselves, are ineligible for patenting regardless of how novel, nonobvious, well-described, or well-claimed they might be.

Of course, as I mentioned, claims drawn to other technologies could actually turn out to be ineligible—if they are ultimately "directed to" matter that is per se ineligible. For example, they might contain math and not much more. But if that is the case, we should so specify in our rejections and identify exactly what matter prohibited by the Supreme Court makes the claim ineligible—math, mental processes, economic practices, etc.

Or, perhaps the real problem with the claim is that it really is vague, unsupported, or impermissibly result-oriented. If so, we should probably reject it under § 112 as appropriate. Or, perhaps the claim is too broad and recites only well-known matter. If so, we should probably reject it under § 102 or § 103.

But by themselves (per se), the Supreme Court has not found these other technologies to be prohibited.

Some believe that recent Supreme Court decisions have left us no choice but to consider the applicability of judicial exceptions to a vast array of technology.[24] Perhaps. But before reaching a final conclusion on this, let us all consider it again with fresh eyes.

And as we do so, we should heed Justice Thomas's warning to "tread carefully in construing this exclusionary principle lest it swallow all of patent law."[25] Because, as the Court correctly recognized, "at some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.' "[26]

And the fact is, after more than 200 years of Supreme Court precedent regarding § 101 and its predecessors, the Court so far has arguably only identified the few categories I described above as per se ineligible. Why go

24. *See, e.g.*, Athena Diagnostics v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 753 n.4 (2019).

25. *Alice*, 573 U.S. at 217 (citing *Mayo*, 566 U.S. at 77).

26. *Id.* (quoting *Mayo*, 566 U.S. at 71).

beyond these, especially where we don't have to, given the availability of §§ 102, 103, and 112?

Section 101 itself lists four broad categories for patentable subject matter: process, machine, manufacture, and composition of matter. [27] These categories have not substantively changed since our founders wrote them into the Patent Act of 1793.[28]

The Supreme Court has often noted just how broad the statutory language is with regard to the scope of subject matter eligible for patent protection: "In choosing such expansive terms . . . Congress plainly contemplated that the patent laws would be given wide scope."[29] This is because, the Court stated, "ingenuity should receive a liberal encouragement."[30]

In contrast, the Court's judicial exceptions are specific, and the Court itself cautioned us to "tread carefully"—in other words, not to apply the exceptions liberally—"lest we swallow all of patent law."[31]

Indeed, the Supreme Court has made it clear that the judicial exceptions are only meant to cover the "basic tools of scientific and technological work."[32] And the only such basic tools the Court has identified over time appear to be the ones I mentioned above.

In other words, the Supreme Court has never stated that talking toys or a myriad of other applied technologies—by themselves—are "basic tools of scientific and technological work." Indeed, there is no reason to think they might be because—as with most technologies—by themselves, they are merely applications of such "basic tools."

In fact, the Court's jurisprudence taken as a whole makes it clear that a practical application of otherwise excluded subject matter is eligible. The Supreme Court has drawn a clear line that separates mere principles (or "basic tools") on one hand, from practical applications of such principles on the other.[33]

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27. 35 U.S.C. § 101 (2018).

28. Act of Feb. 21, 1793, ch. 11, 1 Stat. 318 (1793).

29. Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).

30. *Id.* (quoting THOMAS JEFFERSON, 5 WRITINGS OF THOMAS JEFFERSON 75–76 (Washington ed., 1871)).

31. *See Alice*, 573 U.S. at 217.

32. *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 67 (1972); *Mayo*, 566 U.S. at 71 (citing *Benson*, 409 U.S. at 67); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 576 (2013) (citing *Mayo*, 566 U.S. at 71); *Alice*, 573 U.S. at 216 (citing *Myriad*, 569 U.S. at 576).

33. *See Alice*, 573 U.S. at 216; *Mayo*, 566 U.S. at 71.

So, for example, for the purpose of § 101, we should be able to differentiate between electromagnetism itself on one hand, and toys that communicate with each other using electromagnetic signals on the other.

Over time, the Supreme Court has reiterated this concept. For example, in 1852 in *Le Roy v. Tatham*, the Court said that "a new property discovered in matter, when practically applied in the construction of a useful article of commerce or manufacture, is patentable."[34]

One hundred and twenty-nine years later, in *Diamond v. Diehr*, the Court repeated that "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."[35] And most recently, in *Alice*, the Court explained that "applications of such concepts to a new and useful end . . . remain eligible for patent protection."[36]

In other words, if the claim integrates the excluded subject matter into a practical application of that matter, then the claim should be eligible. Such a claim is not on the excluded matter itself. Or, in the words of the *Alice/Mayo* line of cases, it should not be interpreted as being "directed to" the prohibited subject matter.

Furthermore, a practical application of otherwise excluded matter is not "directed to" that matter because, among other things, it does not substantially preempt the excluded subject matter itself. Such patents arguably only cover the particular applications claimed. And in any event, any defect in claiming with respect to such practical applications can be addressed with the patentability statutes: §§ 102, 103, and 112.

In short, I think that we can overcome the current § 101 morass if we carefully follow Supreme Court precedent, if we don't allow the judicial exceptions to swallow the entire statute, and if we allow the rest of the statutes (§§ 102, 103, 112) to do the work they were meant to do.

So, we at the USPTO are preparing revised guidance along these lines. In particular, our guidance will categorize the judicial exceptions and clearly instruct examiners on how to apply them.

Under the first step of the proposed guidance, examiners would first look to see if the claims fall within the four statutory categories: process, machine, manufacture, or composition of matter. This is not new—we always do this.

If so, examiners then determine if the claims recite subject matter within one of the judicial exceptions, categorized as I just described. (This is the

34. 55 U.S. 156, 176 (1852).
35. Diamond v. Diehr, 450 U.S. 175, 187 (1981) (emphasis omitted).
36. *Alice*, 573 U.S. at 217 (citing *Benson*, 409 U.S. at 67) (internal quotations omitted).

new approach.) If the claims at issue do not recite subject matter falling into one of these categories, then the § 101 analysis is essentially concluded, and the claim is deemed patent eligible. If an examiner does not find subject matter within the disallowed categories, then he or she can move on to considering the other conditions for patentability.

However, if the claims do recite subject matter in one of the excluded categories, the Supreme Court demands more analysis. Specifically, the Court instructed us that in such cases, we need to decide whether the claims are "directed to" the excluded categories.[37] To that end, examiners would assess whether the claims integrate the exception into a practical application of the otherwise excluded material.[38] If so, the claim passes the § 101 test, and the eligibility analysis is concluded.

It is important to note what is not a "practical application." For example, mere performance of excluded subject matter, like math or fundamental economics, on a general-purpose computer is not a practical application, as we learned at least in the *Benson*,[39] *Bilski*,[40] and *Alice*[41] cases. Likewise, insignificant post-solution activity by itself does not create a practical application. Our guidance and training materials will specify these and other such examples.

Furthermore, as stated previously, the examination does not conclude merely because we overcome § 101; we must still examine for patentability under §§ 102, 103, and 112. Indeed, we also plan to issue shortly enhanced guidance for the treatment of § 112 in certain circumstances. So, for claims that do pass § 101 because they don't recite subject matter in a defined excluded category or integrate the exception subject matter into a practical application, we can rest assured that other sections of the code should still prevent a patent from issuing if the claim is obvious, not novel, not enabled, or indefinite.

In sum, our proposed guidance is meant to simplify the § 101 analysis by synthesizing controlling case law and providing greater clarity for the majority of cases that come before us. And we are in dire need of clarity and simplification. I hope other authorities will join in helping us achieve this goal. For when it comes to the role of the courts in shaping patent law and policy (the theme for this conference), there can hardly be a more significant

37. *Id.* (citing *Mayo*, 566 U.S. at 77).
38. *Id.*; *see also* 2019 Guidelines, *supra* note 16, at 50–51.
39. *Benson*, 409 U.S. 63.
40. Bilski v. Kappos, 561 U.S. 593 (2010).
41. *Alice*, 573 U.S. 218.

issue today than clarifying our analysis for the judicial exceptions to § 101.

With a clear, predictable, and reliable patent system, I firmly believe that American inventors will continue to—as was said of Thomas Edison in 1877—"push[] the whole world ahead in its march to the highest civilization."[42]

Thank you again for the opportunity to be with you here today.

42. EDISON AND HIS INVENTIONS: INCLUDING THE MANY INCIDENTS, ANECDOTES AND INTERESTING PARTICULARS CONNECTED WITH THE EARLY AND LATE LIFE OF THE GREAT INVENTOR 20 (J.B. McClure ed., 1889).