Evaluating § 101 Case Law After Alice, U.S. Global IP Positioning, Improvements to PTAB Practice, and Other Key Takeaways from a Recent Fireside Chat with USPTO Director Iancu

By George “Trey” Lyons, III

“We live in an age where IP is important, so we need to focus on how we use it to our greatest benefit.”

−Andrei Iancu, USPTO Director, February 19, 2019, Chicago, IL.

MBHB recently co-sponsored a fireside chat between USPTO Director Andrei Iancu and MBHB managing partner Grantland Drutchas [video here]. Director Iancu addressed the current state of § 101 case law, the new 2019 Revised Patent Subject Matter Eligibility Guidelines, the U.S.’s competitiveness in the global IP market, and the impact of the Supreme Court’s decision in SAS on PTAB practice. From the outset, however, one thing was immediately clear: Director Iancu has an immense passion for protecting intellectual property, wants to ensure that the U.S. remains hyper-competitive in a global economy, and is driving ahead with a proactive vision and plan for getting us there. One of the most important results of his efforts on this front: the USPTO’s January 7, 2019 Guidance to patent examiners applying 35 U.S.C. § 101, in the wake of Alice and its progeny, the 2019 Revised Patent Subject Matter Eligibility Guidance. A few key takeaways are unpacked below:

The Importance of § 101 and the Need to Address It (and Correctly Apply It)

At the forefront of Director Iancu’s focus, both in his time as Director and for this event specifically, are the difficulties of applying § 101 case law during prosecution and post-grant proceedings, alike. Director Iancu had the USPTO conduct a year-long synthesis of the most current § 101 jurisprudence. That endeavor resulted in the 2019 Revised Patent Subject Matter Eligibility Guidance.

As the “most important issue, substantive issue, in patent law,” right now, Director Iancu reiterated the importance of clarifying the current state of the law and ensuring its practical application across the hundreds of thousands of patent applications and post-grant challenges the USPTO and PTAB face every year.1

On the practical application front, Director Iancu articulated that the courts have found three types of subject matter under Alice step one to be abstract: (1) mathematical expressions (“Just math by itself, courts don’t like math apparently. So, no patents on math.”); (continued on page 2)
(continued from page 1)

(2) methods of organizing human activity ("like fundamental economic activity — principals, escrow accounts, hedging transactions and the like"); and (3) mental steps ("mental steps, things you do in your head, we are not going to have litigation over thinking"). Put simply, "those are the categories [of ineligible subject matter], and we said, 'If you're not in one of these categories there is no 101 problem.'"

Even if you do find yourself in one of these categories, however, "you don’t stop there," because there may be a practical application of the concept that renders the claim otherwise eligible under Alice step two. Specifically (and encouragingly), Director Iancu reiterated:

You go back a couple hundred years the courts have always said, "While we do not give patents on principles of nature, for example, we do give patents on the application of those principles." That was the whole point of the patent system — human beings harnessing nature, or harnessing mathematical concepts and the like, and applying them to useful ends. So if you’re applying those, you do get a patent on that. Many cases from going back to the 1800s to the present and our Guidance cites them, and quotes them, and finds the practical application is the way out, of these prohibited areas.

And for those of us who have spent so much time arguing against §101 rejections that are really only thinly-veiled §103 rejections, perhaps the most promising piece of Director Iancu’s commentary was the acknowledgement and stern criticism of this practice:

A lot of folks have been concerned about claims and want to reject claims, probably under 101, because it is the use of something old that has been done a lot in the past, but now it’s done on a general purpose computer or on a computer. So it’s the combination of something that has been done in the past with a general purpose computer, that combination, and that’s where people find a 101 problem. But that is really difficult to do under a 101. So if you take old technology and you automate it on a computer, how do you approach that 101 analysis? There are no guidelines. There is no test. But we really do have a good test that has been worked out for the past 50 some 60 some years, actually since 1952. Under 103, we have the four-part Graham factors and the like, the combination of old technology on an automated system, we know how to do that analysis. So do that. Now, reserve 101 issues like in Alice and Bilski for issues that are per se problematic. Like fundamental economic principles. Reserve 101 for that. Because for that alone, 103, 112, 102 may not suffice.

On the bio side, Director Iancu noted that although "the Guidance mentions that there is absolutely the fourth category [of patent ineligible subject matter], which is the life sciences issue — natural phenomenon and things like that," it does not provide substantive guidance for §101 bio analysis because "based on our experience at the PTO [] our examiners and our judges can recognize fairly consistently if [they] see a natural phenomenon in the claim." However, Director Iancu did note that there will be life sciences examples in the next iteration of §101 Guidance.

On its implementation and the USPTO’s ability to consistently apply the new Guidance, Director Iancu spoke candidly about the rollout and plan for consistent application and extensive, targeted training:

[W]e trained all 8,500 of the examiners, with very few exceptions — if an examiner was out sick or something. . . . Same on the PTAB side, all the judges are trained. And there are different levels of training. You can imagine there are some art units that don’t see 101 really all that often, some don’t see it at all whereas other art units, like crypto-currency, they see it in every other case. So there are different depths.

With all of these thoughtful and proactive measures taken to improve §101 analysis and application by the USPTO, it is hard not to be both impressed and encouraged by Director Iancu’s vision for the U.S. patent system — particularly when considered in view of its impact on the global IP market.

The Importance of the U.S. Fostering Innovation in the Global IP Market

Another key takeaway from the conversation (and potentially the impetus for his proactivity on improving §101 affairs) was Director Iancu’s clear directive to ensure that the U.S. fosters innovation and is as competitive in a global economy as possible. At the outset, Director Iancu acknowledged that in 2016 and 2017, the U.S. had “slipped” from number one to number twelve in the Global Intellectual Property Center’s annual global economic IP survey based largely on two issues: IPRs and §101 subject matter. But, he noted, the U.S. has now risen back to number two in the world, after the City-Nation Singapore.

On the first issue, Director Iancu credited the “number of changes” propagated throughout the post-grant system this year (discussed in more detail below) for the U.S.’s recent ascent in the survey. On the second point, he recognized “that the 101 issues are not solved yet and that’s why we’re still tied for number two, we still have work to do.”

On this point, specifically, Director Iancu again stressed the importance of clarifying §101 subject matter and its impact at a global level: Folks seem to have lost sight of Justice Thomas’s careful statement in the Alice case itself that you have to tread carefully here because otherwise these exceptions can swallow the whole patent system. And unfortunately I am afraid we have marched down that path.

I cannot overemphasize how important this issue is. This issue of patentable subject matter in section 101 goes to the heart of the patent system because it tells you, up front, “What are the areas of (continued on page 3)
technology that the United States values for investment of time and money and for the future, so that we award and protect with a patent." And we are in a huge globally competitive war. The competition for the technologies of the future is unlike what we have seen ever in the past. Everybody is innovating, from the smallest countries to the largest countries. Some of those countries have gotten past this issue. And while we are twisting ourselves into a pretzel here, on almost every case, and we don’t have clarity on to what is and what is not patent eligible here, the other countries are marching forward full steam ahead, to develop things like 5G, artificial intelligence, biotechnology, some of the diagnostic techniques that have somehow found to be ineligible would certainly be eligible in Europe, China, and Japan for example. And I think that as a nation we need to put this issue to bed ASAP so that we can compete on a global level.

To say the least, again, Director Iancu’s comments remain encouraging for the future of the U.S. patent system and the U.S.’s ability to remain a global IP thought leader and bulwark moving forward.

**Improvements to PTAB Practice**

The final group of topics Director Iancu addressed concerned improvements the USPTO has made to PTAB practice under his tenure. Aware of the longstanding criticism that the PTAB may be a “death squad” for patents, Director Iancu identified three important changes to the PTAB that he believes will help assuage these concerns.

First, Director Iancu addressed the change of claim standards in PTAB proceedings (previously broadest reasonable interpretation) to the same one used in district courts and ITC proceedings currently, as articulated in *Phillips v. AWH Corp.*, and its progeny. Director Iancu believes this change “will go a long way to where it increases predictability and increasing the efficiency, holistically, for the patent system,” as “more than 85% of the patents we have at the PTO for IPR proceedings have parallel litigation.”

Second, in an effort to avoid any concerns of impropriety, Director Iancu addressed the issuance of new standard operating procedures for empaneling PTAB judges. Although circumspect about any real instance of “panel stacking,” “for full transparency, we changed the process” and now have “a standard operating procedure that tells the public precisely how we panel the judges and how under what circumstances we would change a judge . . . basically eliminat[ing] the enlargement of panels.” Restating that under the new procedure “we’re always going to have three judges,” Director Iancu also addressed the formation of the new Precedential Opinion Panel, which “includes the Director, the Chief Patent Judge, and the Commissioner of Patents,” and allows dissatisfied parties to seek review of a panel opinion.

Third, in the wake of *SAS*, Director Iancu addressed the new PTAB practice of instituting on all challenged claims, as well as on all asserted bases. Recognizing that some might believe this view is broader than the actual holding of *SAS*, Director Iancu noted “[d]epending on how you read the *SAS* decision . . . it should include all challenged bases . . . [f]or example the majority said that the petitioner is the master of the case. Period.”

On a more practical (and policy-based) note, Director Iancu stressed the burden of piecemeal challenges on the PTAB: “[M]ore importantly, from a policy point of view, really if you look at the system holistically, and again, more than 85% of our IPRs are involved in parallel litigation, you know, a petitioner, when they file an IPR, chooses the IPR forum at that point. And the statutes say . . . post grant proceedings should be an alternative to district court litigation. So if the petitioner chooses to have the dispute as they frame it, litigate it in this forum at the PTAB, let’s do it there as opposed to the piecemeal approach. And I think that is what the Supreme Court had in mind as well. And, probably holistically for the system, it is more efficient.

Director Iancu also discussed the impact this goal for improved efficiency may have on other PTAB practices moving forward, particularly when a PTAB board is determining: (1) whether to allow follow-on petitions under the General Plastics factors (“At some point you have to ask, how many petitions suffice on the same patent at the same time. . . . I mean, you know, why is it in the interest of the United States to devote so much resources to address every single ground for invalidity?”); and (2) how much weight to give events in parallel district court proceedings (e.g., claim construction, “So I think our judges are instructed to look at [district court claim construction orders], to consider very carefully, nobody wants to duplicate work, and if the issues are fairly presented in a parallel case we should obviously look at it very carefully and consider it.”). Put simply, “the overall goal for the U.S. Patent system, would be to be as efficient holistically, as possible.”

**Conclusion**

It is difficult to know how much impact Director Iancu’s time as Director of the USPTO will have on the U.S. patent system in the future; but it is easy to appreciate the impact it is having now. His ability to thoughtfully unpack complex issues under § 101 (and elsewhere) and proactively forge effective solutions is undeniable. Here’s to hoping there’s even more positive change to the U.S. patent system on the horizon.

**Endnotes**

1. The quotes herein, unless indicated otherwise, are all taken from comments Director Iancu made during the February 19, 2019 fireside chat in Chicago, IL.
2. 415 F.3d 1303 (Fed. Cir. 2005) (en banc).
4. The opening exchange of the conversation was telling in this regard:

Granetland Drutchas:

You know, a couple of years ago, you were a successful litigator and the managing partner of a leading law firm of the United States. You were well respected and yet you made the decision to accept the position as the Director of the PTODuring a time when the PTODuring a time when the PT0 was riding high for funding from Congress, and, frankly, patents seemed under attack from Congress, the Supreme Court, sometimes even the executive on the pharma side, and in some ways the public itself. What were you thinking?

Andre Iancu:

For a lot of the reasons you mentioned, I wanted to get in and try to make a bit of a difference, if possible. The IP system, which we all love quite a bit, especially on the patent side, has been pushed and pulled, and as you indicated, significant issues have developed, at least over the past decade or maybe even more. So instead of talking about it, I thought I could throw my hat in the ring and try to do something about it.

George “Trey” Lyons, III, an MBHB associate, helps clients protect their intellectual property by providing advice and crafting solutions related to the validity, enforcement, and infringement of patent, copyright, and trademark rights. lyons@mbhb.com
Expedited Trademark Cancellation Proceedings at the USPTO

By Eric R. Moran

The U.S. Patent and Trademark Office (“USPTO”) currently offers a pilot program that provides parties the opportunity to engage in expedited non-use cancellation proceedings. Broadly speaking, cancellation proceedings allow third-parties to challenge a trademark registration and to seek its cancellation on a number of different grounds, such as, for example, that the mark is merely descriptive, the mark was obtained fraudulently, there is a likelihood of confusion between the registered mark and petitioner’s mark, or the mark has been abandoned. As a subset of abandonment cancellation proceedings, non-use cancellation proceedings allege that a trademark registration should be cancelled due to lack of use of the mark by the registrant.

Background on Cancellation Proceedings:

Under the U.S. Trademark Act, “a mark registered on the principal register . . . shall be prima facie evidence of the validity of the registered mark.” Despite registration of a mark, however, the U.S. Trademark Act provides that:

A mark shall be deemed to be “abandoned” if . . . the following occurs:

1. When its use has been discontinued with intent not to resume such use. Intent not to resume may be inferred from circumstances. Nonuse for 3 consecutive years shall be prima facie evidence of abandonment. “Use” of a mark means the bona fide use of such mark made in the ordinary course of trade, and not made merely to reserve a right in a mark.

As a result, the trademark register contains a large number of registered but abandoned trademarks that properly should no longer be registered. Such marks are periodically cleared of a mark, however, the U.S. Trademark Act registered. Such marks are periodically cleared. As a result, the trademark register contains a number of registered but abandoned trademarks that properly should no longer be registered.

In many cases, however, such cancellations happen too slowly. Often, “abandoned” registered marks either (i) appear in clearance searching for potential new marks or (ii) are cited by the USPTO to refuse registration of newly applied-for marks. Because such registrations involve marks that have been abandoned, they should not properly present a conflict for a mark under consideration or a basis for a refusal to register by the USPTO.

Cancellation provides a means to clear such abandoned marks from the register.

Cancellation proceedings are mini-litigations, involving a petition for cancellation (similar to a complaint in district court) with a $400 USPTO fee, an answer (and potential counterclaims), and, many times, discovery (including document production and depositions), expert witnesses, and an oral hearing. When fully litigated, cancellations can last for several years before a decision by the Trademark Trial and Appeal Board (“TTAB”) at the USPTO.

Often, however, cancellations — especially non-use cancellations — end in default. For example, a registrant who is no longer using a mark may simply not respond to a cancellation petition (or may never receive service of the petition). In either case, the cancellation may quickly end with the TTAB entering a notice of default, followed by entry of judgment by default and cancellation of the challenged registration — all occurring within about 5 or 6 months of the cancellation petition being filed.

The current pilot program seeks to provide a means to expedite non-use cancellations that do not end in default, but that have a relatively simple set of facts that nonetheless demand adjudication by the TTAB on whether a registrant has abandoned rights to the mark by not using the mark.

Current Accelerated Case Resolution Procedures at the TTAB:

The TTAB has long offered parties procedures by which to accelerate opposition and cancellation proceedings that involve claims other than just non-use claims. Known as “Accelerated Case Resolution” (or “ACR”), these procedures can be used to fast-track any case in which both parties agree to the procedures. ACR procedures can apply to almost any claim that could be raised during a cancellation or opposition proceeding.

ACR procedures can vary, but the process generally takes the form of stipulated facts, limited discovery and limited testimony witnesses, cross-motions for summary judgment, and accompanying evidentiary submissions. The parties must agree on, and the Board must approve, the procedures, which generally take the place of a traditional trial record and traditional briefs at a final hearing. In ACR, the TTAB seeks to render a decision within 50 days from completion of briefing, and TTAB guidance contemplates (although does not require) parties choosing 11-month, 14-month, 17-month, or 18-month ACR track options.

Expedited Non-Use Cancellation Proceedings:

Focusing on ways to expedite non-use cancellation proceedings specifically, the USPTO initially published on May 16, 2017, proposed rules under a Request for Comments on a Possible Streamlined Version of Cancellation Proceedings on Grounds of Abandonment and Nonuse. The USPTO indicated that the proceedings would require certain evidence be submitted with the pleadings (such as a declaration or other evidence of non-use), very limited discovery only for good cause shown, an abbreviated schedule, no oral hearing, and an expedited issuance of a decision by the TTAB. Fees would be lower, with $300 per class contemplated.

(continued on page 5)
The USPTO received a number of comments to the proposed rules, both in favor and raising concerns. Based on these comments, the Office decided instead to implement the current pilot program. The pilot has two main goals: (i) identify the types of non-use cancellation cases that would be most suitable for expedited proceedings; and (ii) identify expedited procedures that can be used in such cases.

Under the pilot, beginning in March 2018, the TTAB began attempting to identify cancellation proceedings that solely involve non-use or abandonment claims and that do not involve a registrant in default. In a number of such identified cases, once an answer is filed, the TTAB advises the parties that it will participate in the initial discovery conference, and that the parties should be familiar with ACR and be prepared to discuss potential ACR options prior to the conference.

In the conference, the interlocutory attorney for the case, as well as one of the designated administrative law judges at the TTAB (not one of the presiding judges, however), participate. The interlocutory attorney and judge then discuss with the parties potential options for expediting the cancellation, including potential fact and evidentiary stipulations, options for limiting discovery, and use of the “summary judgment ACR model,” in which the TTAB treats summary judgment motion filings and accompanying evidence as the final record and briefing, and in which the TTAB decides disputed issues of fact.

Even if not contacted by the Board to do so, the parties themselves may choose to participate in the expedited program. If interested, agreeable parties should coordinate at any point in the case and discuss options for expediting with their interlocutory attorney.

For cases that are part of the program, the Board seeks to issue final decisions within 50 days of briefing being complete. One recent expedited cancellation proceeding terminated with a final decision of cancellation issued exactly nine months after the filing of the petition for cancellation.

The USPTO intends to continue the pilot program until it has enough information to assess the following points (largely raised in the comments to the proposed rule):

- The frequency of parties’ willingness to agree to ACR in some form.
- Concerns expressed about ACR.
- The types of ACR measures preferred.
- How effective such measures are in developing the record and issues.
- The progress and timing of ACR pilot cases.
- The rates of default judgment.
- Withdrawals and settlements.

The USPTO also intends to learn how to best and how to quickly identify cases that would be appropriate for expedited non-use cancellation proceedings.

Once it has completed the pilot program, the USPTO will likely provide another notice of proposed rulemaking with lessons learned from the pilot program.

**Other Steps Being Taken By the USPTO:**

Along with considerations related to expedited cancellation proceedings, the USPTO has implemented several other procedures to try to keep the register clear from marks not currently in use. One is a post-registration specimen audit program, which requires certain registrants who submit post-registration declarations of use to submit additional specimens or proof of use on certain identified goods or services beyond those submitted in the original declaration of use. Another is reformatted declaration and signature portions of allegations and declarations of use forms, to more clearly advise applicants and registrations of use in commerce requirements for federally registered U.S. trademarks.

**Conclusion:**

Although the pilot program may only be temporary, we advise trademark clients to consider this and other ways to expedite cancellation proceedings at the USPTO. Doing so can achieve quicker results with reduced costs, and, if successful, can clear “abandoned” registrations to allow new marks to register.

---

**Endnotes**

2. 2017-00856
3. See id.
4. See id. at 702.04 (2018).
8. See id.
9. See id.
11. See Expedited Cancellation Pilot Program, supra note 3.
12. See id.
13. See id.
14. See id.
15. See id.
16. See id.
17. See id.
18. See id.
19. See id.
20. See Expedited Cancellation Pilot Program supra note 3.
21. See id.

---

**Eric R. Moran**, an MBHB partner, has experience in all areas of intellectual property law, with particular emphasis on litigating and counseling clients on patent, trademark, and domain name issues. He is Chair of the firm’s Trademark, Unfair Competition, Advertising Law & Copyright Practice Group. moran@mbhb.com

---

**Patent Docs**

The authors and contributors of “Patent Docs” are patent attorneys and agents who hold doctorates in a diverse array of biotech and chemical disciplines.

Visit www.patentdocs.org to gain insight and information on a topics important to you and your business.
Protecting Trade Secrets with Restrictive Covenants:
The Question of Consideration in Illinois

By Joshua R. Rich

Employers have a number of tools they can use to protect against their employees walking off with trade secrets; among them, restrictive covenants or non-compete agreements can be extremely powerful. Such agreements avoid the threat of trade secret misappropriation by prohibiting a former employee from working for a competitor (and thereby potentially using the employer’s trade secrets against it) for some period after his or her employment ends. But they can be too powerful, locking unhappy employees into their current jobs, and courts generally refuse to enforce them if the geographic or temporal scope is too great. Many businesses – and lawyers – enforce them if the geographic or temporal scope their current jobs, and courts generally refuse to enforce them if the geographic or temporal scope is too great. Many businesses – and lawyers – are aware of that threat and pay close attention to the limitations they place on departed employees. But few pay attention to another aspect of restrictive covenants that can be just as fatal to enforcement: whether the employer has provided adequate consideration in exchange for the agreement.

In most contract cases, courts do not pay attention to the consideration provided by the parties. Rather, they give the parties the latitude to strike any lawful deal they desire and will not look at the fairness of the deal. Restrictive covenants are one of the few exceptions in which courts will look to the bargain and weigh the adequacy of consideration. They do so because restrictive covenants can give employers overwhelming negotiating power and prevent employee mobility; thus, many courts will look at the quid pro quo that the employer provides in exchange for the employee agreeing not to compete. The consideration necessary can vary widely, depending on which state’s law governs, when the deal is struck, and even which court is asked to enforce the agreement.

Illinois may be the most notable state where the adequacy of consideration may depend on which court is asked. The difference is stark: while the State courts of Illinois have adopted a bright line rule regarding the term of at will employment required for a restrictive covenant to be enforced, the U.S. District Court for the Northern District of Illinois has concluded that there is no such bright line rule and, potentially, a shorter term of at will employment may suffice. Thus, the enforceability of a non-compete agreement may very well hinge upon the Court in which the case is heard.

The Illinois Court of Appeals for the First District, the appellate court that considers all appeals from the Circuit Court of Cook County (which includes Chicago), has established a rule that adequate consideration requires at least two years of at-will employment or some other form of compensation. In Fifield v. Premier Dealer Services, Inc., the declaratory judgment plaintiff had been employed by the defendant’s predecessor-in-interest. As the business was transitioned from one owner to the next, the new owner required Fifield to sign an employment agreement (with a non-compete provision) in order to stay in his job. Although Fifield negotiated that the non-compete would not apply if he was terminated without cause within one year, he received no additional compensation for signing the agreement. He then voluntarily left his employment after less than four months and filed a lawsuit to have the non-compete provision found unenforceable, especially because he never had access to confidential information.

Because restrictive covenants are restraints on trade, they are carefully considered by Illinois courts. The terms therefore must be reasonable, but even before considering the terms, a court must make two required findings: (1) that the restrictive covenant is “ancillary to a valid contract”; and (2) that “the restrictive covenant is supported by adequate consideration.” With regard to the second finding, Illinois courts have long held that continued at-will employment for a substantial period of time can constitute adequate consideration. Surveying the cases (especially the Brown & Brown, Inc. v. Mudron case from the downstate Illinois Court of Appeals for the Third District), the Fifield trial court found that two years of continued employment was considered adequate. It also found no distinction in the required consideration between restrictive covenants entered into prior to beginning employment and those entered into after employment had begun. And because it found no consideration had been provided to Fifield beyond continued employment for less than four months, it held the non-compete provision in the employment agreement unenforceable. The Court of Appeals agreed with the trial court’s analysis, holding that “Illinois courts have repeatedly held that there must be at least two years or more of continued employment to constitute adequate consideration in support of a restrictive covenant,” even if the employee cuts the term of employment short by resigning before the two year threshold. Since that time, the Illinois Court of Appeals has repeatedly applied the two year bright line rule to determine whether consideration for a restrictive covenant is adequate.

After initially appearing to agree with the state courts’ bright line rule, the U.S. District Court for the Northern District of Illinois has more recently rejected it for a test based on the totality of the circumstances. Other Federal district courts in Illinois have also rejected the bright line two year standard. Under the Erie doctrine, a Federal court sitting in its diversity jurisdiction and applying state substantive law – as the district courts were doing here – must apply the law as it believes the state supreme court would apply it.
In addition, a careful employer may wish to provide some form of consideration beyond at will employment in exchange for the signing of a no-competition agreement. As the McInnis court indicated, any additional consideration may be considered even in State courts. Thus, a signing bonus, new bonus plan, or even a change in employment conditions may allow a restrictive covenant to satisfy the consideration requirement in State court. In Federal court, any such additional consideration would go onto the scales of the totality of the circumstances to support enforcement of the restrictive covenant as well. Thus, if an employer is concerned that its employment agreement will not be fully enforced, it would do well to provide something to the employee beyond at will employment and call that additional consideration out in the agreement itself.

Joshua R. Rich, an MBHB partner, serves as MBHB’s General Counsel and Chair of MBHB’s Trade Secrets Practice Group. He has successfully litigated in Federal and state trial and appellate courts throughout the United States, in cases involving patent, trade secret, trademark, copyright, and other commercial issues. rich@mbhb.com

Endnotes
1. California simply will not enforce restrictive covenants at all under Cal. Bus. Prot. Code § 16000. New Hampshire and Vermont are both considering bills that would prohibit restrictive covenants as well. Most other states will refuse to enforce a restrictive covenant that is too onerous, while some states will “blue pencil” the terms of an invalid restrictive covenant to narrow its terms.
3. Id. at 940. The lack of disclosure of any confidential information to the employee made the Fifield case unusual. Indeed, the employer may not have had a protectable interest to support the restrictive covenant. However, because of the inadequacy of the consideration, the court did not need to address that issue.
4. Id. at 942.
6. Fifield, 993 N.E.2d at 943.
7. Id. at 943.
8. Id.
9. Id.
10. See, e.g., Prairie Rheumatology Assocs., S.C. v. Francis, 24 N.E.3d 58, 63-64 (Ill. App. Ct. 2014); McInnis v. OGI Motorcycle Ventures, Inc., 35 N.E.3d 1076, 1081 (Ill. App. Ct. 2015). In McInnis, the Court considered whether there was any other consideration provided beyond continued at will employment. That is, it suggested that there would be an exception to the bright line rule if there were some other form of consideration.

In the Instant Technology case, the U.S. Court of Appeals for the Seventh Circuit did not consider the question of what test would determine the adequacy of consideration in enforcing. In Russell-Dan, Inc. v. Alder, No. 17-C-0440, 2018 WL 4679557 (N.D. Ill. Sept. 28, 2018), Judge Fenner rejected a defendant’s argument that the consideration had been inadequate without addressing what the proper test would be. Citing both State and Federal cases, the Court stated, “Illinois generally regards two years of continued employment as adequate consideration for a restrictive covenant.” Id. at 7. The defendant had been employed for five years after executing the employment agreement. Id.
13. See 35 N.E.3d at 1007.
Beyond Patents—FDA Regulatory Approval of Medical Devices and the Software Precertification Program

By Aaron V. Gin, Ph.D. and Bryan G. Helwig, Ph.D.

Artificial Intelligence (AI) and Machine Learning (ML) are poised to revolutionize the field of healthcare. For example, researchers are leveraging deep learning methods to find new ways to efficiently diagnose and treat diseases. Although lacking a well-articulated AI strategy, the United States invested an estimated $2 billion on research and development for AI-based technologies in 2017. Since that time, the Department of Defense has also committed to providing up to an additional $2 billion per year in spending for AI technology and infrastructure over the next five years.

In line with such increased investments, there has been substantial growth in AI-based medical device patent applications over the last decade. A Juristat review of classes related to surgery, x-ray systems, and prosthetics under the United States Patent Classification system returned over 1800 published AI-related medical device patent applications since 2000, as well as a sharp and monotonic increase in such filings since 2010. However, many AI and ML-based software as a medical device (SaMD) applications commonly receive claim rejections under 35 U.S.C. §§ 101 and 112. While the USPTO has recently released updated guidance on patentable subject matter, it is not yet clear whether such guidance has actually mitigated issues relating to the patentability of inventions involving abstract ideas.

Furthermore, bringing a patented product to market is often delayed because of the hurdles involved in the Food and Drug Administration (FDA) regulatory approval process. In recognition of this inefficiency, retiring FDA Commissioner Scott Gottlieb recently led the establishment of the Software Precertification Program, which is intended to streamline the FDA approval process for AI and ML-based medical technologies.

FDA Regulatory Oversight of Medical Devices

The conventional FDA approval process for marketing new medical devices is an arduous and conservative pathway, driven by policies and procedures that are intended for hardware-based medical devices. The approval process can be broken down into the following steps:

1. Device Discovery and Proof of Concept.
2. Preclinical Research that includes building a prototype of the medical device to assess risk and safety.
3. FDA Device Classification (Class I-III) based on the level of control necessary to ensure safety of the device. The FDA-required regulatory controls increase with increased class number.
4. FDA Device Review based on safety and effectiveness of the device. Upon approval the device is cleared for public use.
5. FDA Post-Market Device Safety Monitoring to ensure device safety and effectiveness.

Overall, the entire FDA medical device approval process, shown in Figure 1 below, takes an average of 3 to 7 years. FDA Device Review can take anywhere from 3 to 12 months or longer, dependent upon the medical device category and data supporting safety and effectiveness. The process is also expensive, with typical costs to bring a device for FDA review (Steps 1-3) ranging between $10 and $20 million.

This FDA review process is intended for all medical devices requiring FDA approval, including those involving AI and ML technologies. Thus, FDA oversight of AI and ML is far-reaching and even applies to SaMD. Such devices include most software and mobile apps intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions as medical devices under the Federal Food, Drug, and Cosmetic Act. However, this rigid framework is ill-equipped to deal with AI-based software technology that changes in near real-time based on responses to real-world performance. AI creates a further unique problem under the current regulatory scheme because there is often lack of a tangible device. Instead, the FDA regulatory framework requires the evaluation of software code to assess the accuracy, reliability, and safety of AI-based healthcare. However, such code typically does not directly address the specific FDA metrics (e.g., safety, efficacy) required for FDA approval. Furthermore, a significant advantage of AI and ML medical devices is that they are frequently updated, in some cases in near-real-time, based on real-world data. However, the current FDA approval process is designed for devices that may be updated quarterly, annually, or even less frequently.

Software Precertification Program

The Software Precertification Program (Program) is a voluntary pathway that embodies a regulatory model tailored to assess the safety and effectiveness of AI-based software technologies without inhibiting patent access to the technologies. The foundation of the Program is identification of medical device

(continued on page 9)
manufacturers that have demonstrated a robust culture of quality and organizational excellence and are committed to monitoring real-world performance of their AI-based technologies.14

The Program launched in 2017 as part of the Digital Health Innovation Action Plan, and was limited to FDA-regulated SaMD, defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.15 Instead of the traditional FDA approval process of focusing on the eventual product, the Program focuses on the software or digital health technology developer.16 The developer/company-first approach should, in theory, remove traditional regulatory hurdles and permit trusted companies to harness the advantages of AI to quickly and effectively address safety concerns and respond to adverse events when they arise.

In response to a notice seeking voluntary participation, over one hundred companies applied to be included in the Program. The FDA used selective metrics such as product quality, patient safety, clinical responsibility, cybersecurity responsibility, and proactive culture to identify companies that exhibited organizational excellence.17 Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool, and Verily were selected as the initial nine trusted SaMD manufacturers to participate in the Program.18 Voluntary participation required the companies “to provide access to measures they currently use to develop, test, and maintain their software products,” including methods for post-market data collection, and allowance for FDA site visits.19

Earlier this year, Director Gottlieb announced the release of the three key initiatives that outline the next phase of the Program.20 First, the FDA released guidance intended to explain the framework for the Program under the FDA’s current regulatory authorities.21 Specifically, the Program will be implemented under the De Novo pathway, traditionally used for approval of lower risk medical devices. The Program is in its infancy, but its goal is to “determine the contours of a possible regulatory model that provides efficient regulatory oversight of certain software-based medical devices from manufacturers who have demonstrated a robust culture of quality and organizational excellence (CQOE) and are committed to monitoring real-world performance while assuring that these devices are safe and effective.”22

Second, the FDA released a Pre-Cert Test Plan for 2019 that outlines testing related to refinement and implementation of the Program.23 The goal of the Pre-Cert Test Plan is to determine how the Program can ensure safe and effective products.24 The FDA will compare parallel submissions made to the De Novo route and to the traditional route in an effort to determine whether the Program might provide efficiencies over the conventional FDA medical device approval process.25

Third, the FDA launched an updated working model that incorporates the Regulatory Framework and Test Plan.26 The working model describes the proposed implementation approach and future vision for the Program.

The Program appears to be a concerted effort to streamline the regulatory process for software-based medical devices. However, many questions remain. For instance, it is not immediately clear where the bar will be set for companies to achieve the necessary CQOE required to participate in the Program. The initial slate of companies includes well-known global businesses with substantial product portfolios and a wealth of data to address the criteria for inclusion. Thus, it remains an open question whether, and how, startups and other less established companies might become certified. In addition, it is unclear whether the FDA will have authority to force
(continued from page 9)

a recall on companies and/or their products in the Program. Also, the FDA will need to consider situations where companies should have implemented a recall, but failed to do so. Furthermore, the protection of private information will be an important concern for AI and ML innovations that utilize large datasets that involve numerous patients and their sensitive personal information. Such privacy issues will likely represent substantial hurdles that the FDA must address moving forward.

Importantly, the U.S. currently lacks a well-defined AI strategy to address the rapid rise of Big Data and its impact on health technologies. As a result, full adoption of the Software Precertification Program appears to be years off, with only traditional FDA approval methods currently available for AI-based health technologies. Other FDA AI-based qualification programs, such as the Medical Device Development Tools (MDDT) Program, remain in the nascent stages and have not been widely utilized by AI and ML developers. Thus, today’s AI-based medical technologies continue to be subjected to lengthy regulatory timelines and risk being outdated by the time they are approved for commercialization.

Accordingly SaMD manufacturers currently face risks to their product pipeline at the USPTO as well as at the FDA. In the patent realm, despite potential pitfalls related to rejections under 35 U.S.C. §§ 101 and 112, experienced practitioners have developed effective strategies for patenting AI and ML-based technologies. On the regulatory side, innovative AI-based medical device manufacturers will likely leverage the Software Precertification Program, or other similar FDA pilot pathways, to reduce delays to marketing approval.

Aaron V. Gin, Ph.D., an MBHB partner, has broad experience in preparing and prosecuting U.S. and foreign applications for patents and trademarks. He provides advice in support of patent validity, infringement, patentability analyses, and litigation matters in the electrical and computing technology areas.

gin@mbhb.com

Bryan G. Helwig, Ph.D., an MBHB associate, concentrates his practice on intellectual property law matters, including patent prosecution, as well as providing infringement and patentability analyses in the biotechnology, pharmaceuticals and medical device and diagnostic areas.

helwig@mbhb.com

Endnotes


3 Id.


8 Id. at 279.

9 Id. at 279.


12 Developing a Software Precertification Program, supra note 10 at 6.

13 Id.

14 Id.


17 Developing a Software Precertification Program, supra note 14 at 11.

18 FDA Selects Participants for New Digital Health Program, supra note 17.

19 Id.


22 Regulatory Framework for Conducting the Program, supra note 22 at 1.


24 Id. at 2.

25 Id.

26 Developing a Software Precertification Program, supra note 14.


McDonnell Boehnen Hulbert & Berghoff LLP recognizes the ever-increasing importance of intellectual property. Our mission is to enhance the value of our clients’ businesses by creating and defending their intellectual property assets. We have built our reputation by guiding our clients through the complex web of legal and technical issues that profoundly affect these assets. We are keenly aware of the trust placed in us by our clients — Fortune 100 corporations, universities, individuals, and start-up companies — and we always remain focused on their ultimate business goals.

With offices in Illinois, California and North Carolina, MBHB provides comprehensive legal services to obtain and enforce our clients’ intellectual property rights, from navigating the U.S. Patent and Trademark Office procedures to litigating complex infringement actions. We don’t merely procure rights and litigate cases; we craft winning strategies that achieve our clients’ business objectives.

Our entrepreneurial spirit, combined with the wealth of our legal experience and technological expertise, gives McDonnell Boehnen Hulbert & Berghoff LLP the power to achieve success for our clients.