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A review of developments in Intellectual Property Law

2019 Patent Trial and Appeal Board Key Practice Updates: A Year in Review



By Grantland G. Drutchas and George "Trey" Lyons, III

2019 has been an active year for procedural changes in the Patent Trial and Appeal Board ("PTAB"). These changes include not only the PTAB's issuance of a Trial Practice Guide July 2019 Update, but also a number of clarifications/

interpretations of procedures that the PTAB adopted in 2018 that have modified PTAB practice going forward. We explore a few key updates below.

The Ongoing Importance of Claim Construction

In late 2018, the PTAB did away with the broadest reasonable interpretation standard and finally adopted the litigation claim

construction standard from *Phillips v. AWH Corp.*¹ In spite of the industry attention that this received, there is reason for skepticism as to whether this is really a meaningful distinction. Although some decisions have clearly turned on which standard applies, some have suggested the change is likely to have little effect on validity determinations.² Either way, the PTAB's application of the *Phillips* standard is clear evidence of its efforts to promote greater predictability and uniformity of its opinions with U.S. courts.

As yet more evidence of the PTAB's efforts to promote uniformity with the courts, the PTAB's Trial Practice Guide July 2019 Update reiterated the importance of submitting evidence regarding this standard and constructions under this standard by other courts.³ For example, the PTAB noted: "Parties **should** submit a prior claim construction determination by a federal court or the ITC in an AIA proceeding **as soon as that determination becomes available.**"⁴ The PTAB also made

clear that such a submission is mandatory if the decision is "relevant information that is **inconsistent with a position advanced by the party during the proceeding.**"⁵ Procedurally, parties seeking to disclose claim construction determinations to the PTAB should preferably do so with the filing of a substantive paper (e.g., the petition or patent owner preliminary response/response, depending on the availability of the evidence). However, if that is not possible, parties may also include them in a submission of supplemental information, with the Board's permission.

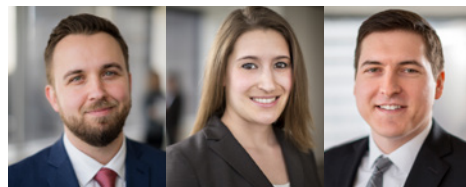
Provisional Claim Amendment Pilot Program Continues to Show Promise

Also in 2018, the PTAB made its *Western Digital* decision precedential, which addressed many important differences between amending

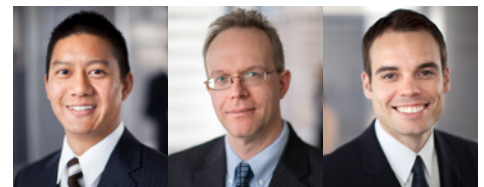
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claims in PTAB proceedings vs. other venues (e.g., the contingent nature of amendments, patent owner *does not* bear the burden of persuasion, “reasonable number” of substitute claims per challenged claim is presumed one-to-one, etc.). In March of this year, in order to strengthen the motion to amend practice and provide direction to Patent Owners, the PTAB launched the Pilot Program for Motion to Amend Practice. Through this Pilot Program, a Patent Owner may: (1) receive preliminary guidance from the PTAB regarding the motion to amend; (2) file a revised motion to amend after receiving (a) petitioner’s opposition to

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its original motion and/or (b) the Board’s preliminary guidance; or (3) pursue amendment under previous practice (at least for the time being).⁶

The effect this program has had on motion to amend practice this year has been dramatic, nearly tripling the grant rate of motions to amend. Specifically, as of March 31, 2018, in 4233 completed trials, motions to amend were filed only 305 times (approximately 7% of all IPRs). Of those motions, only 7 were granted in full, and only 18 were granted in part. Thus, up until that time, these 25 cases represented less than an 8% grant rate for cases where motions to amend were filed. Since the launch of the

Pilot Program, however, 17 out of 76 (22.4%) have been granted. In light of comments from the USPTO concerning the importance of amendment practice in PTAB proceedings,⁷ and the launch the Pilot Program itself, perhaps this dramatic increase is not too surprising. However, it is certainly encouraging for patent owners should they find themselves facing challenges in the PTAB.

The Continuing Impact of SAS

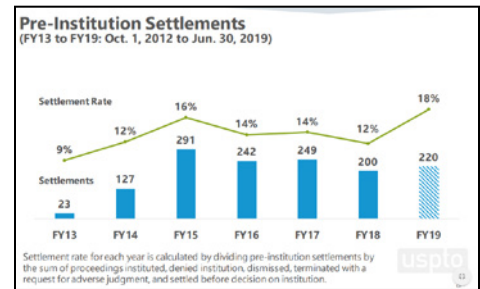
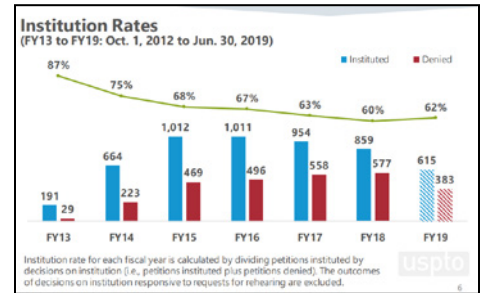
In April of 2018, the Supreme Court struck down the longstanding practice of issuing institution decisions on a ground-by-ground basis in *SAS Institute, Inc. v. Iancu*.⁸ Thus, prior to *SAS*, if a petition was instituted, not all grounds raised in the petition would necessarily become part of the instituted IPR, nor were those non-instituted grounds reviewable on appeal,⁹ nor did they create estoppel for non-instituted grounds.¹⁰

Now, post-*SAS*, there is no partial institution—instead, the PTAB must institute on all challenged claims or none. So, why does this matter? Ironically, under the previous practice, when the PTAB dismissed a challenger’s weakest grounds as not reasonably likely to establish that the claims are invalid, the challenger was free to re-assert that invalidity ground in litigation; only claims and grounds that the PTAB actually considered in a Final Written Decision were subject to AIA estoppel. Now, however, if the PTAB institutes an IPR, the PTAB must consider and decide all claim challenges/grounds in the final written decision, and, thus, estoppel applies to all claims and grounds that the challenger raised (or reasonably could have raised) in its petition. Thus, challengers face a much greater risk as to all challenges they make based on published prior art in post-grant proceedings.

One interesting question, however, is how does this change affect the Patent Owner’s strategy in these proceedings? Knowing now that institution decisions must be an all-or-nothing determination post-*SAS*, there may be reasons why a Patent Owner may *want* to have all published prior art challenges resolved in an IPR rather than in litigation. As such, there may be situations where a Patent Owner may prefer not to file a preliminary response at all, and allow the PTAB to decide if the proceeding should be instituted on its own, and preserve its arguments for the Patent Owner response.

In deciding to implement any strategy,

however, the institution rate trends must be taken into account. Specifically, since *SAS*, institution rates are at a historical low, while pre-institution settlement is at an all-time high.¹¹



Thus, preliminary responses are certainly recommended in the vast majority of situations, especially if focused on key issues (e.g., procedural arguments, key claim construction arguments, and attacking alleged prior art).

The Impact of Arthrex

Although not a PTAB update, *per se*, perhaps the single biggest decision impacting recent PTAB decisions came in the Federal Circuit’s opinion in *Arthrex, Inc. v. Smith & Nephew, Inc.*, in which the Federal Circuit held that an Appointments Clause defect exists in the statutes governing the constitutionality of empaneled APJs at the PTAB.¹² The Federal Circuit also held in *Arthrex* that such a constitutional defect may be cured by vacating decisions by such APJs and remanding them for new hearings before a new panel of constitutionally-appointed APJs.¹³ How the Federal Circuit has actually applied the *Arthrex* decision to other pending challenges, however, is less concrete.

For example, some Federal Circuit panels have held that the proper course under *Arthrex* is to vacate and remand these PTAB decisions,¹⁴ sometimes even without oral argument.¹⁵

Other panels, however, have been less

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convinced and/or quick to hold *Arthrex* binding. For example, some panels have denied the relief outright, noting that if not raised in opening briefing, *Arthrex* challenges are forfeited.¹⁶ Others have asked for additional briefing on the issue.¹⁷ Still others, even when granting *Arthrex* relief, have differences of opinion on what that relief would actually entail.¹⁸

In light of this uncertainty since *Arthrex*, what's next? We, like most, will be watching how the Federal Circuit responds to the inevitable request for rehearing *en banc*.¹⁹

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Endnotes

- 1 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*).
- 2 Compare, e.g., *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 734 (Fed. Cir. 2016) with *Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356 (Fed. Cir. 2015).
- 3 Trial Practice Guide Update (July 2019), available at <https://www.uspto.gov/sites/default/files/documents/trial-practice-guide-update3.pdf>.
- 4 *Id.* at 16 (emphasis added).
- 5 *Id.* (citing 37 C.F.R. § 42.51(b)) (emphasis added).
- 6 See *New Pilot Program Concerning Motions to Amend*, USPTO, <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/new-pilot-program-concerning-motions> (last updated Mar. 14, 2019).
- 7 Kelly G. Hyndman, *USPTO Director Iancu Announces New Day*, AIPPI, E-News Articles (Nov. 16, 2018), <https://aippi.org/no-show/uspto-director-iancu-announces-new-day/> (stating "[i]t is not in the interest of the patent system as a whole to invalidate a patent entirely if it actually describes patentable subject matter, and appropriately-scoped claims can be drafted.").
- 8 138 S. Ct. 1348 (2018).
- 9 35 U.S.C. § 319.
- 10 See, e.g., *Shaw Indus. Grp., Inc. v. Automated Creel Sys., Inc.*, 817 F.3d 1293, 1300 (Fed. Cir. 2016); *HP Inc. v. MPHJ Tech. Inv., LLC*, 817 F.3d 1339, 1347-48 (Fed. Cir. 2016).
- 11 See USPTO, Trial Statistics IPR, PGR, CBM, Patent Trial and Appeal Board (June 2019), at 6 and 8, available at https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_2019-06-30.pdf.
- 12 941 F.3d 1320, 1335, 1339-40 (Fed. Cir. 2019) ("APJs are principal officers under Title 35 as currently constituted," and "[a]s such, they must be appointed by the President and confirmed by the Senate; because they are

- not, the current structure of the Board violates the Appointments Clause.").
- 13 *Id.* at 1340.
- 14 See, e.g., *Bedgear, LLC v. Fredman Bros. Furniture Co.*, 783 F. App'x 1029 (Fed. Cir. 2019).
- 15 See *Image Processing Techs. LLC v. Samsung Elecs. Co.*, 2018-2156 (Fed. Cir. Dec. 5, 2019) (cancelling oral argument and vacating and remanding the IPR decisions based on the briefs, alone).
- 16 See, e.g., *Customedia Techs., LLC v. Dish Network Corp.*, 941 F.3d 1173, 1174 (Fed. Cir. 2019); but see *Sanofi-Aventis Deutschland GmbH v. Mylan Pharm. Inc.*, No. 2019-1368, 2019 WL 6130471, at *12 (Fed. Cir. Nov. 19, 2019) (Newman, J., dissenting) ("It is well established that when the law changes while a case is on appeal, the changed law applies. . . . Thus, Sanofi is entitled to the same benefit of the *Arthrex* decision as are the *Arthrex* parties. The foundation of a nation ruled by law is that the same rules, as well as the same law, will be applied in the same way to parties in pending litigation.").
- 17 *Polaris Innovations Ltd. v. Kingston Tech. Co., Inc.*, 18-1768 (Fed. Cir. Nov. 8, 2019).
- 18 See *Bedgear, LLC*, 783 F. App'x at 1032 (Judges Dyk and Newman indicated in their concurrence that there is no need for the remedy of remand and new hearing, and instead "the past opinions rendered by the PTAB should be reviewed on the merits, not vacated for a new hearing before a different panel.").
- 19 The deadline for the U.S. Government and/or the appellee in *Arthrex* to seek rehearing *en banc* is December 16, 2019. See Fed. R. App. P. 35(c), 40(a)(1). The mandate in *Arthrex* will issue no earlier than December 23, 2019. Fed. R. App. P. 41(b). The U.S. Government has indicated it intends to file a rehearing request. See *VirmetX Inc. v. Cisco Sys., Inc.*, No. 19-1671, Dkt. 25, at 2-3 (Fed. Cir. Nov. 13, 2019); *Steuben Foods, Inc. v. Nestle USA, Inc.*, No. 20-1082, Dkt. 15, at 2-3 (Fed. Cir. Nov. 13, 2019).

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Supreme Court Expands Trade Secrets Exemption from FOIA

By Joshua R. Rich

Businesses often worry that the information they provide to the government will be disclosed, and with good reason – such information is presumptively available to the public under the Freedom of Information Act (FOIA).¹ There is an exemption for “trade secrets and commercial or financial information obtained from a person and privileged or confidential” (Exemption 4),² but courts have generally construed this exemption narrowly. Specifically, decisions under Exemption 4 have long required a showing of a likelihood of substantial competitive harm resulting from the disclosure of information before the government could withhold the information.³ However, in *Food Marketing Institute v. Argus Leader Media*,⁴ the Supreme Court considered the scope of Exemption 4 and found that no such showing of harm is required. Rather, to the relief of parties providing information to the government, the Supreme Court ruled that the only requirements for information to be withheld under Exemption 4 are (i) that a person outside government had provided it, (ii) that it be customarily and actually treated as private by the party providing it, and (iii) that the government customarily provide assurances that the information would remain secret.⁵

The earlier additional requirement that the disclosure of information would have to cause competitive harm to qualify under Exemption 4 arose out of a case from the U.S. Court of Appeals for the District of Columbia, *National Parks & Conservation Assn. v. Morton*.⁶ Unlike the Federal Circuit, whose patent precedent has binding statutory authority over the district courts and U.S. Patent and Trademark Office, the D.C. Circuit’s precedent is not binding on any court or administrative agency other than the D.C. district court. However, its expertise in the administrative law forum is so respected that the *National Parks* test had not only been adopted by every other Court of Appeals and district court that had considered it, but it had also been implemented by the FOIA offices of Federal administrative agencies. Thus, under the *National Parks* test, FOIA required an agency to turn over information unless it

showed that the information was not only secret, but also “likely . . . to cause substantial harm to the competitive position of the person from whom the information was obtained.”⁷

Here, the case arose in 2011 when the *Argus Leader* newspaper of Sioux Falls, South Dakota began working on an article on food stamp fraud. It had learned of concerns of “retailer trafficking” of benefits under the Supplemental Nutrition Assistance Program

In view of *Food Marketing Institute*, parties submitting information to the government should maintain a focus on whether there is an obligation for the government to keep their information secret and should make it clear in their submissions that they consider the information confidential.

(SNAP), where retailers exchange SNAP benefits for cash. Under SNAP, program participants generally use electronic benefit cards to buy food from eligible retailers; the sales information is then electronically transferred to a state electronic benefits processor who approves or denies the transaction. The state processor subsequently reports the information to the U.S. Department of Agriculture (which administers the SNAP program for the federal government). To support the article, the reporter working on the story submitted a FOIA request to get store-level data for every store in America that accepted SNAP benefits.⁸

The USDA refused to produce the store-level information on grounds including Exemption 4. Eventually, when the Exemption 4 issue became ripe, the district court applied the *National Parks* test (which had been adopted by the U.S. Court of Appeals for the Eighth Circuit) and indicated that the USDA would have to show that disclosure of the information would likely “cause substantial harm to the competitive position of the person from whom the information was obtained.”⁹ The district court held a trial where witnesses for the USDA testified that retailers closely guard their store-level data and that disclosure would harm their stores’ competitive positions by allowing competitors to model consumer behavior better. While the district court found that revealing the information would create a risk of harm to the stores, it found the risk was only incremental, not “substantial.” Thus, the district court ordered the USDA to turn over the information.¹⁰

The USDA alerted retailers who take part in the SNAP program that it would not appeal the district court’s ruling, and the Food Marketing Institute stepped in on behalf of the retailers to try to prevent the documents from being disclosed. In the meantime, the USDA provided assurances (and notice to the district court) that it would not turn the documents over until all appeals were exhausted. However, on appeal, the Eighth Circuit affirmed the district court’s decision finding that the potential harm — while real — would not be substantial, rejecting any argument that confidentiality alone would be sufficient to satisfy Exemption 4 and reaffirming the application of the *National Parks* test in the Eighth Circuit.¹¹

The Supreme Court reversed on a six-to-three vote. Justice Gorsuch, writing for the Court, started his consideration of the scope of Exemption 4 with the language of the statute itself. The meaning of the key statutory term, “confidential,” was the same when FOIA was enacted in 1966 as it is today, “private” or “secret.”¹² Contemporary dictionaries suggested that confidentiality might therefore require two conditions. First, it must customarily be kept private (or at least closely held) by the person imparting it. Second, the person receiving the information must customarily provide an assurance that it will stay secret. Certainly, the first condition must

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be satisfied for information to be considered “confidential,” it is less clear that the second must also be satisfied.¹³

In this case, Justice Gorsuch felt no need to provide clarity on that point because he found that the requested data in this case unquestionably met both conditions to qualify as “confidential” under Exemption 4. The Food Marketing Institute had intervened specifically because the individual stores wanted to keep the information secret, and customarily had. And the USDA had promised the stores that it would keep the information secret unless it was ordered to turn it over. Thus, the Court found that the information need not be provided under FOIA, regardless of what test would be applied under Exemption 4.¹⁴

Despite the clarity of the dictionary definitions on which it decided the case, the majority still decided to address the *National Parks* test. It found no basis for requiring that a disclosure result in “substantial competitive harm” in the statutory language, early case law, or any “other usual source.”¹⁵ The D.C. Circuit had cited certain legislative history for FOIA in support of this test, but Justice Gorsuch referred to that as a “selective tour through the legislative history.”¹⁶ To the majority, the plain language of the statute itself was sufficient to allow interpretation of Exemption 4. And there would be no good reason for applying the *National Parks* test when the information was required to be provided to the government, but not in cases where the information was provided voluntarily (as the D.C. Circuit had subsequently found in *Critical Mass Energy Project v. NRC*).¹⁷ Thus, the majority rejected the D.C. Circuit’s *National Parks* decision in favor of the plain language of Exemption 4.

Justice Breyer, joined by Justices Ginsburg and Sotomayor, dissented from the decision based primarily on both the uniformity of decisions below and policy issues.¹⁸ While the courts below had adopted somewhat different tests under Exemption 4, they had all required some showing of competitive harm for the exemption to apply. Thus, the majority’s decision differed more from all of the lower court precedent than any two lower courts differed from one another. It also increased the scope of Exemption 4 far more broadly than any lower court had previously. That was a fundamental concern for the dissenting Justices: that Exemption 4 might ultimately

swallow FOIA whole. That is, the goal of FOIA has always been disclosure of information to increase the transparency of government functions (at least as balanced against certain specific, narrow policy exceptions). But if the question is just whether the parties providing information and the government agency working with those providing parties want to keep the information secret especially when the government is potentially subject to “capture” by the providing party, the providing parties and government may work together to shield any information from disclosure under FOIA. Thus, the dissenting Justices fear that the decision will substantially narrow the beneficial effects of FOIA as a whole.

The *Food Marketing Institute* case should allow parties submitting information to the government to breathe a sigh of relief, but it reflects a sea change in the application of FOIA to confidential information. Previously, even trade secrets (as defined by the traditional definition under the Uniform Trade Secrets Act or Defend Trade Secrets Act) could be subject to disclosure under FOIA if the trade secret owner could not prove that the disclosure would cause it substantial competitive harm.¹⁹ Now, Exemption 4 covers not only all traditional trade secrets, but also merely confidential business information that has been shared with the government under an expectation of secrecy. For example, even information that has not been subject to reasonable measures to protect its confidentiality may be shielded under Exemption 4. Thus, in many cases, information that previously would have been disclosed under FOIA will now be withheld under Exemption 4. In view of *Food Marketing*

Institute, parties submitting information to the government should maintain a focus on whether there is an obligation for the government to keep their information secret and should make it clear in their submissions that they consider the information confidential. By contrast, parties seeking FOIA disclosures should scour the statute to find indications that the government does not intend the information to be held as confidential.

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Endnotes

- ¹ For example, utility patent applications remain confidential until publication, either at 18 months after filing or upon issuance (whichever comes first, unless there is a request for non-publication until issuance in accordance with the statute). See 35 U.S.C. § 122.
- ² 5 U.S.C. § 552(b)(4).
- ³ See *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2367 (2019) (Breyer, J., concurring in part and dissenting in part) (“Since 1974, when the District of Columbia Circuit decided *National Parks and Conservation Assn. v. Morton*, 498 F.2d 765, nearly every lower court has imposed some kind of harm requirement. See *New Hampshire Right to Life v. Dep’t of Health & Human Servs.*, 136 S. Ct. 383, 384 (2015) (Thomas, J., dissenting from denial of certiorari) (noting that “every Court of Appeals to consider Exemption 4 has interpreted it [using] *National Park(s)*”); *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 876 (CA DC 1992) (en banc) (collecting cases).”)
- ⁴ 139 S. Ct. 2356 (2019).
- ⁵ *Id.* at 2366.
- ⁶ 498 F.2d 765 (D.C. Cir. 1974).
- ⁷ *Id.* at 770.
- ⁸ See *Argus Leader Media v. U.S. Dep’t of Agric.*, 224 F. Supp. 3d 827, 829-31 (D.S.D. 2016).
- ⁹ See *Argus Leader Media v. U.S. Dep’t of Agric.*, 889 F.3d 914, 915 (8th Cir. 2018).
- ¹⁰ See *Argus Leader Media*, 224 F. Supp. 3d at 835.
- ¹¹ See *Argus Leader Media*, 889 F.3d at 917.
- ¹² *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2363 (2019).
- ¹³ *Id.*
- ¹⁴ *Id.* at 2366.
- ¹⁵ *Id.* at 2363.
- ¹⁶ *Id.* at 2364.
- ¹⁷ 975 F.2d 871 (D.C. Cir. 1992).
- ¹⁸ *Food Mktg. Inst.*, 139 S. Ct. at 2366-69 (Breyer, J., concurring in part and dissenting in part).
- ¹⁹ See *id.* at 2367 (discussing potential “serious harm” associated with disclosure that would not have been recognized under the *National Parks* test).



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U.S. Canna-Patents After the 2018 Farm Bill

By George “Trey” Lyons, III, Nicole E. Grimm, and Brett W. Scott

Almost one year ago, the 2018 Farm Bill was signed into law, and, for the first time, hemp and hemp-derived cannabidiol (CBD) were federally legalized. Under the statute, legal hemp is defined as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.”¹ This law was an important first step in legitimizing a large sector of the cannabis industry under federal law, marking an important step forward for companies that produce or cultivate hemp and/or manufacture, market, and sell CBD products derived from hemp. In the months following the enactment of the 2018 Farm Bill, the United States Patent and Trademark Office (USPTO) issued guidelines on how it will examine federal trademark applications for CBD, which previously had no legal use in commerce due to CBD falling under the Schedule I classification of the Controlled Substances Act.² However, there have also been developments on the canna-patent side in the past year, perhaps fueled by hemp legalization.

U.S. Canna-Patents

By way of a brief background, the USPTO grants patents for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”³ However, unlike some other federally granted intellectual property rights (e.g., federal trademarks), U.S. patents do not confer a right *to use the invention*, rather they confer the right *to exclude others from making, using, and selling the invention in the United States*.⁴ Thus, although many patented cannabis inventions are currently illegal to practice under federal law, the USPTO has had a long history of granting all types of U.S. cannabis-related patents (utility and design), as well as patents on the cannabis plant itself.

Because the subject matter of many such canna-patents is still illegal to practice under federal law, there is a litany of potential issues with enforcing them in U.S. federal courts. However, with the passing of the 2018 Farm

Bill, many prior-issued canna-patents may no longer have enforcement issues in federal courts. As such, the industry may expect to see an increase in the filing of patents directed to hemp-derived CBD as well as patent infringement lawsuits to enforce canna-patents involving legal CBD products.

U.S. Plant Patent PP30,639

In July 2019, a new plant patent, U.S. Plant Patent PP30,639, entitled “HEMP PLANT NAMED ‘CW2A’” was granted to CWB Holdings, Inc. (aka “Charlotte’s Web”). CWB

Because the subject matter of many such canna-patents is still illegal to practice under federal law, there is a litany of potential issues with enforcing them in U.S. federal courts. However, with the passing of the 2018 Farm Bill, many prior-issued canna-patents may no longer have enforcement issues in federal courts.

Holdings markets itself as “an industry-leading pioneer creating whole-plant hemp health supplements.”⁵ This plant patent was granted within the year following the enactment of the 2018 Farm Bill. The claimed invention of this patent covers “[a] new and distinct cultivar of hemp plant named ‘CW2A’ substantially as shown and described herein.”⁶

PP30,639 recognizes the nuances of the Farm Bill and the USPTO’s guidelines on the same. It notes that federal law requires protectable hemp contain “no more than three-tenths of one percent (i.e., 0.3%) concentration of tetrahydrocannabinol (THC),” and that the claimed invention “relates to a new and distinct hemp (*Cannabis sativa* L.) cultivar designated as ‘CW2A’.”⁷ As described by the patent, the extracts of CW2A

“contain an assortment of phytocannabinoids (e.g., CBD), terpenes, flavonoids and other minor but valuable hemp compounds that work synergistically to heighten effects of products produced from ‘CW2A.’”⁸ The patent also specifies that “[t]he primary goal of the breeding program [for CW2A] was to develop a new hemp variety with high cannabidiolic acid (CBDA) concentrations and low tetrahydrocannabinolic acid (THCA) concentrations in its mature female flowers.”⁹

But, importantly, with the described growing conditions, the patent notes that the following THC and CBD contents of CW2A can be achieved at harvest maturity: “(i) Total THC content: 0.13% to 0.27%; (ii) Total CBD content: 4.50% to 6.24%.”¹⁰ As a comparison, the cannabis plant, “ECUADORIAN S4711/A,” which is described by U.S. Plant Patent No. 27,475, contains 12.45% total THC content.¹¹ Thus, at maturity, the claimed invention in the CW2A patent appears to comport with the carve out requirements of the 2018 Farm Bill, and, thus, also appears to be federally legal to practice, which could prove beneficial if CWB Holdings ever attempts to enforce the patent in U.S. federal courts.

However, this patent does not wholly foreclose the path forward for other hemp producers seeking to develop and protect other varieties of high-CBD/low-THC cannabis. That is, by its very nature, U.S. Plant Patent PP30,639 only covers the specific plant it claims. It is not, for example, a utility patent that could potentially broadly cover several different varieties of hemp plants depending on the breadth of the claims and disclosure in the specification.

U.S. Hemp-Related Patent Enforcement

Although one of the first cannabis patent infringement lawsuits is still underway in the U.S. District Court for the District of Colorado, *United Cannabis Corp. v. Pure Hemp Collective Inc.* (1:18-cv-01922), patent infringement litigations involving patents covering cannabis plant-touching products (e.g., CBD/THC formulations) or methods (e.g., CBD/THC extraction techniques) are still rare.

However, there was at least one example

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of a hemp-related patent infringement lawsuit that was filed this past year. On September 25, 2019, *AFAB Industrial Services, Inc. v. Apothio, LLC* was filed in the U.S. District Court for the Eastern District of California involving techniques and equipment for extracting CBD from hemp. In that case, Plaintiffs AFAB Industrial Services, Inc., NewBridge Global Ventures, Inc., EcoXtraction, LLC, and CleanWave Labs, LLC (collectively, AFAB) sued Apothio, LLC, Apothio, Bakersfield, LLC, and one of Apothio's managing members (collectively, Apothio) for patent infringement of six utility patents related to hemp/CBD oil processing methods and equipment.¹² Of the six patents asserted in this case, U.S. Patent No. 10,011,804 (the "'804 patent"), entitled "Method of Extracting CBD, THC, and Other Compounds From Cannabis Using Controlled Cavitation," explicitly disclosed cannabis extraction methods. Claim 1, the only independent claim of the '804 patent, recites:

1. A method of extracting oils from the cannabis plant comprising the steps of:
 - (a) drying the cannabis plant;
 - (b) chopping or grinding the dried cannabis plant into pieces;
 - (c) combining the pieces of cannabis plant with a fluid to form a mixture;
 - (d) passing the mixture through a cavitation zone;
 - (e) causing cavitation events in the fluid that produce shock waves and pressure variations in the cavitation zone, the cavitation zone being defined between the outer peripheral surface of a rotor and an interior surface of a housing within which the rotor is rotatably mounted, the rotor having cavitation inducing structures on its outer peripheral surface, and wherein the step of causing cavitation events comprises rotating the rotor within the housing as the mixture passes through the cavitation zone;
 - (f) as a result of step (e), liberating oils from the pieces of the cannabis plant, the liberated oils becoming entrained within the fluid; and
 - (g) separating the oils from the fluid; where in step (e), the shock waves and pressure variations are controlled by varying the rotation rate of the rotor to reverse hornification caused by step (a).

The remaining patents in the case related more broadly to cavitation devices and methods for biomass processing.

According to the Complaint, NewBridge and Apothio entered into a business arrangement whereby Apothio would grow hemp crop and NewBridge would produce CBD oil using the patented equipment and extraction methods.¹³ In particular, the patented technology involved processing hemp "in a continuous oil extraction process using water as a medium, rather than batch extraction using ethanol and CO2 as is currently used today."¹⁴

Following a change in the business arrangement, AFAB demanded that Apothio return the hemp extraction equipment, which at the time was contained in a facility operated by Apothio, and Apothio refused.¹⁵ AFAB then sued Apothio for patent infringement as well as filed a motion for a temporary restraining order (TRO) and preliminary injunction to permit AFAB to access and seize the equipment that could be used by Apothio to infringe the patents.¹⁶ In response, Apothio argued, in part, that there was no proof that it had infringed (or will infringe) because the equipment at issue had been idle during the dispute.¹⁷ While the court preliminarily concluded based on AFAB's filings that they demonstrated a likelihood of success on at least one of their patent claims, the court ultimately denied the AFAB's motion and vacated the prior TRO Order. The court was persuaded by Apothio's arguments that the equipment was in a "shuttered" state and that a key component of AFAB's equipment was not present at the facility, and therefore, the situation did not "indicate use or threatened use" of the patented technology.¹⁸ Shortly after the Order denying the TRO and preliminary injunction, the parties settled the case.¹⁹

While the *AFAB Industrial Services v. Apothio* patent infringement case ended quickly, it is likely one of many hemp-related lawsuits to unfold over the next few years. Put simply, now that companies comporting with the 2018 Farm Bill have far more opportunities to leverage U.S. court systems based on the legality of their products and services under federal law, it will be exciting to see how hemp-related patents begin to play a bigger role in disputes between companies in this space. And, with CBD sales projected to reach \$20 billion in the U.S. by 2024, patent protection

of new hemp plant varieties and hemp-derived CBD inventions is as important as ever for canna-businesses to stake (and protect) their place in this expanding industry.²⁰

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Endnotes

- 1 7 U.S.C. 1639o(1).
- 2 See George "Trey" Lyons, III et al., *USPTO Issues CBD Trademark Guidelines in Light of 2018 Farm Bill: Key Takeaways*, PATENT DOCS (May 8, 2019), <https://www.patentdocs.org/2019/05/uspto-issues-cbd-trademark-guidelines-in-light-of-2018-farm-bill-key-takeaways.html>.
- 3 35 U.S.C. § 101.
- 4 See 35 U.S.C. § 154.
- 5 *Our Company*, CHARLOTTE'S WEB, <https://investors.charlottesweb.com/our-company/default.aspx> (last visited Dec. 8, 2019).
- 6 Like all plant patents, PP30,639 has a single claim drawn narrowly to the specific plant variety disclosed in the patent. Here, the claim specifically calls out "hemp," another likely reference to the Farm Bill.
- 7 Hemp Plant Named 'CW2A', PP30,639, col. 1, ll. 14-16, ll. 26-27.
- 8 *Id.* at col. 1, l. 28 – col. 2, l. 3.
- 9 *Id.* at col. 2, ll. 22-25.
- 10 *Id.* at col. 19, ll. 43-45.
- 11 *Id.* at col. 16, ll. 25-31.
- 12 See Complaint, *AFAB Industrial Servs., Inc. v. Apothio, LLC*, No. 19-01355 (E.D. Cal. Sept. 25, 2019). The patents asserted in this case were Method of Extracting CBD, THC, and Other Compounds From Cannabis Using Controlled Cavitation, U.S. Patent No. 10,011,804, Continuous Hydrodynamic Cavitation Crystallization, U.S. Patent No. 9,469,548, Method of Extracting Starches and Sugar from Biological Material Using Controlled Cavitation, U.S. Patent No. 8,430,968, Controlled Cavitation Device with Easy Disassembly and Cleaning, U.S. Patent No. 7,507,014, Highly Efficient Method of Mixing Dissimilar Fluids Using Mechanically Induced Cavitation, U.S. Patent No. 6,627,784, and Method and Apparatus for Hydrogenating Substances Using Controlled Mechanically Induced Cavitation, U.S. Patent No. 10,220,365.
- 13 See Complaint, *AFAB Industrial Servs., Inc. v. Apothio, LLC*, No. 19-01355 at ¶¶ 16-17.
- 14 *Id.* at ¶ 17.
- 15 *Id.* at ¶ 29.
- 16 See Plaintiffs' Notice of Motion and Motion for Temporary Restraining Order, Preliminary Injunction and Expedited Discovery, *AFAB Industrial Servs., Inc. v. Apothio, LLC*, No. 19-01355, (E.D. Cal. Oct. 2, 2019).
- 17 Defendant's Opposition to Motion for Temporary Restraining Order, Preliminary Injunction, and Expedited Discovery, Memorandum of Points and Authorities in Support Thereof, *AFAB Industrial Servs., Inc. v. Apothio, LLC*, No. 19-01355, at 2 (Oct. 6, 2019).
- 18 Order Denying Motion for Temporary Restraining Order and/or Preliminary Injunction and Vacating Prior TRO Order in its Entirety, *AFAB Industrial Servs., Inc. v. Apothio, LLC*, No. 19-01355, at 2 (E.D. Cal. Oct. 7, 2019).
- 19 See Order, *AFAB Industrial Servs., Inc. v. Apothio, LLC*, No. 19-01355 (E.D. Cal. Nov. 26, 2019).
- 20 Iris Dobrian, *CBD Market Could Reach \$20 Billion By 2024, Says New Study*, FORBES (May 20, 2019), <https://www.forbes.com/sites/irisdobrian/2019/05/20/cbd-market-could-reach-20-billion-by-2024-says-new-study/#5041c2a49d05>.

Artificial Intelligence-based Patents: Perspectives for Practitioners and Patent Owners

Aaron Gin, Michael Borella, and Joseph Herndon

Innovations involving artificial intelligence (AI) and machine-learning (ML) are being developed at an ever-accelerating pace. For example, as illustrated in Figure 1, the number of patent applications published by the United States Patent and Trademark Office (USPTO) including the phrase “artificial intelligence” or “machine-learning” has increased from 406 publications in 2009 to 4,091 publications in 2019 (projected from statistics available on September 11, 2019).

As evidenced by such increasing patent activity, AI/ML-based inventions and applications are emerging in every area of technology, including robotics,² integrated circuit design,³ and health care,⁴ to name just a few. Such a burst of discovery may be comparable to only a few past developments, such as the integrated circuit and the combustion engine.

As ever more patent applications are being drafted in this technology space, this article provides practitioners with best practices for drafting and claiming AI/ML-based inventions, as well as guidance to patent owners for building a valuable AI/ML patent portfolio.

Practitioner Perspective: Drafting Effective AI/ML-based Patent Applications

From the outset, practitioners should try to obtain as much publicly-disclosable information as (reasonably) possible about the AI/ML-based invention. In particular, practitioners should gather information on the novel, non-obvious aspects of the given invention including, but not limited to:

- **Input data preparation** – how is data gathered, pre-processed, handled, or parsed upon use by the AI/ML model? Is the data obtained from a specific type of sensor (e.g., a camera or radar device)? What does the data represent (e.g., letters, words, Boolean values)?

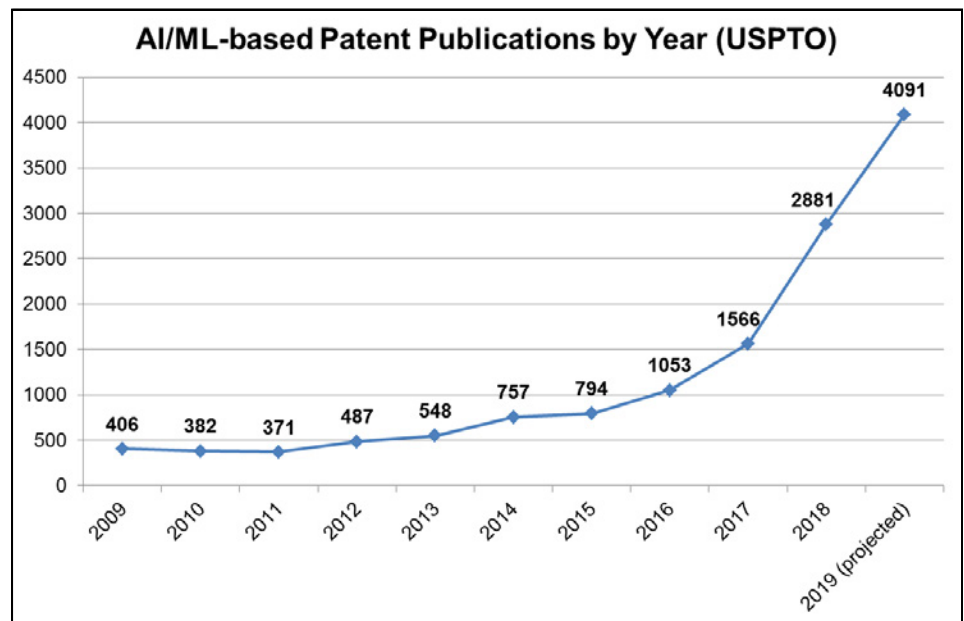


Figure 1¹

- **Model structure** – does the model have specific non-generic features (e.g., a neural network with non-conventional number of nodes at given layers, multiple hidden layers, etc.) and how is the input data mapped to this specific structure?
- **Training phase process** – how is the model trained, and in what manner (e.g., tagged input-output pairs, unsupervised learning, etc.)?
- **Execution phase process** – what weights are used with respect to what variables? What advantages result from execution of the AI/ML model?
- **Output data post-processing / analysis** – how are the outputs utilized and what do they represent (e.g., classification, recommendation, likelihoods, etc.)? Is the data used to control a specific device (e.g., a speech synthesizer or an autonomous vehicle)?
- **Locus of AI/ML processing** – is the substantive computing performed locally (e.g., “AI on the edge”), in the cloud, and/or elsewhere?
- **AI/ML-based hardware** – does the innovation utilize AI-specific integrated

circuits, such as AI-optimized graphics processing units (GPUs)? How does the model structure map to such hardware?

After obtaining this information, but prior to investing a significant amount of time and resources to draft a full patent application, inventors and their organizations should consider conducting a prior art search based on a brief, written disclosure summary and one or more sample claims. Such a search may help “short circuit” over-ambitious AI/ML-based applications or overly-broad claim scope, and can almost always provide helpful context about related prior art in a given technical area. In the near term, a prior art search can help save the client money if close prior art is found. Furthermore, in the longer term, the references produced in such a search may help practitioners and companies work around certain competitor filings.

Since the patent claims define the scope of the future legal right, practitioners should take special attention to properly capture the full intent and various embodiments of the

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invention whenever possible. For example, when drafting AI/ML-centric patent claims, practitioners should:

- Include a “**patentable hook**” in each independent claim, which hopefully relates back to the AI/ML-based nature of the invention.
- **Separate training phase processes from execution phase processes** by utilizing independent claim families directed to the respective methods. Doing so may help avoid split infringement issues down the road.
- Try to incorporate as much **physical structure** (e.g., controller, computation unit, circuits, etc.) as possible into the claims to obviate issues with 35 U.S.C. § 101 (patentable subject matter). This structure can include both special hardware used for the training and execution phases, as well as physical devices that provide input data or receive output data.
- **Utilize patent analytics** by “testing” sample claim language to predict art unit assignments and iteratively adjust claim terms to actively **avoid business method type art units** (e.g., art unit 3600) or other low-allowance-rate art units.

While drafting the patent application, practitioners should strive to describe a primary embodiment in depth while exploring several alternative embodiments to help broaden the overall disclosure. Breaking the patent specification into multiple sections that correspond to the major elements of the AI/ML-based invention (e.g., input data preparation, model structure, training phase, etc.) can compartmentalize the disclosure and may help ensure that each novel, non-obvious detail is described thoroughly. Patent drawings should expressly illustrate each substantive claim term in a schematic-type diagram or a method flowchart. Ideally, the drawings should be organized and illustrated so that another patent practitioner might be able to identify the patentable hook upon a brief inspection of the drawings.

Patent Owner Perspective: Developing an Intentional AI/ML- based Patent Portfolio Strategy

Companies are time and resource limited. Meanwhile, building and maintaining an AI/ML-based patent portfolio can be expensive and time-consuming. Accordingly, pursuing an *intentional, introspective* patent portfolio strategy may help maximize return on investment for a company by 1) focusing on the company’s core needs and strengths and 2) considering the company’s competitors and industry to help maximize its competitive advantage. From a high level, a central question to a patent owner is: “Would you care if someone copied this AI/ML-based invention?” However, the answer can involve many further details and potential considerations. When an invention satisfies many of the factors in the checklist below, it may indicate that preparing and filing a patent application may be in line with the company’s interests.

A. BUSINESS AND PATENT PORTFOLIO GOALS

First, consider the invention and how it relates to the business and patent portfolio goals of the company.

- Consider key industry players (competitors, partners, customers)
 - Is this AI/ML-based invention directed to technology related to the key industry players?
 - Is anyone outside of your company (and notably, any key industry players) using this invention or a related technique?
 - Does this particular AI/ML-based innovation represent a new approach within your industry?
- Consider this AI/ML-based invention with respect to your own company
 - Is this invention directed to a fundamental/core technology and/or product of your company?
 - If so, consider filing an “omnibus” provisional application in the United States with many (e.g., 30-50) multiply-dependent claims and as much disclosure as possible to obtain an early priority date. This can provide maximum express support for future Patent Cooperation Treaty (PCT)/international filings and retain

options for claim scope/direction at the US conversion stage.

- Is the AI/ML-based invention currently in use at your company?
If so, is it successful?
- Is this AI/ML-based invention a customer driver for your company (i.e., generates more customers, makes platform more user friendly, a reason why customers would choose your product/company over a competitor, etc.)?
- Does this AI/ML-based invention provide a competitive advantage?
- Consider your company’s investment in this AI/ML-based invention
 - Has a substantial amount of money been invested in the research and development of this invention? Patents are a form of insurance, so more money invested leads to higher interest in patenting.
 - Have a substantial amount of employee hours been invested in the development of this invention?
- Consider the impact of the AI/ML-based invention
 - Does the invention work (or work well) (e.g., AI-based invention reduces power usage by 10%)?
 - Is a prototype made and working?
 - Does this invention provide a disruptive solution to an existing problem in the industry?
- Consider the “shelf life” of the AI/ML-based invention
 - Does the invention have a short product life (e.g., software revisions likely to occur within 1-2 years)?
 - Does the invention have a long product life (e.g., disruptive, fundamental new idea)?
- Consider publicizing the AI/ML-based invention
 - Are you okay with making this invention available for the world to inspect?
 - Consider whether to file a non-provisional application in the United States along with a non-publication request to prevent publication.

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A rescission of the non-publication request can then be filed at the PCT stage, if necessary.

- Does the invention relate to or contain any sensitive/confidential information (a patent will be publicly available for anyone to read)?
 - Weigh eventual patent right against potential adverse impact to existing trade secret portfolio.
- Consider patent ownership
 - Will the company be able to claim full or partial ownership over the patent application?
 - Was the AI/ML-based invention jointly developed in combination with a supplier, vendor, independent contractor, customer, or other third party who may have rights?
 - Does the AI/ML-based code include third-party code and/or open-source code?
 - Open-source software licenses vary widely and can, in some instances, prevent patenting of software that implements it.
- Consider the potential market for this patent and monetization potential
 - Is there a potential for licensing revenue?
 - Consider utilizing different independent claim families to separate training phase and execution phase to keep licensing compartmentalized.
 - Is there a potential for sale of the patent (and return license)?
 - Is there an interest in enforcing the patent for monetary damages?
 - If enforcement is a primary interest, use claim charting and infringement analysis to streamline independent claim elements and method steps.
- Consider whether you would like to be able to prevent competitors from using the invention
 - Would you like to have control over who can use the invention?
 - Is the invention easily detectable?
- Consider copying and reverse-engineering of the invention

- Is the invention very difficult to reverse-engineer (e.g., AI-based application running on private cloud server - perhaps maintain as trade secret)?
- Is the invention relatively easy to reverse-engineer (e.g., AI-based application deployed on 100,000+ mobile devices - may need patent protection to stop copying)?
- Consider international market/competitors
 - Would you like to protect the AI/ML-based invention in foreign jurisdictions?
 - Consider filing in countries with the most AI/ML development. (e.g., China, Europe, South Korea, Japan, India, Singapore, Taiwan,⁵ etc.)

B. PATENT LAW CONSIDERATIONS

Second, consider the AI/ML-based invention and whether the legal requirements to obtain a patent can be satisfied.

- Consider the prior art
 - When considering the technology that exists today, is the AI/ML-based invention clearly/substantially different than conventional methods/systems (e.g., a convolutional neural network with novel structure and/or novel input data mapping, etc.)?
- Consider the potential claim scope in light of the prior art
 - Is the possible claim scope valuable to your company?
 - Would the possible claim scope be too narrow?
 - Too narrow and hard to enforce?
 - Too narrow and easy for a competitor to design around?
- Consider enforcement of patent rights
 - Is it easy for you to identify when someone is using the AI/ML-based invention (i.e., identify infringers)?
 - Does the invention find use only internally or internal to a company (e.g., company is running AI-based models on a private server, for test purposes only)?
 - Does the invention find use by customers (e.g., customers are deploying trained models to provide recommendations or classifications)?

- Consider patent eligibility
 - Is the invention “directed to” laws of nature, mathematical theories, etc.?
 - An algorithm (e.g., a neural network or support vector machine) in and of itself is not patentable subject matter.
 - However, for an algorithm utilized in a broader method or utilized in a system, the method or system generally could represent patentable subject matter.
 - Does the invention involve non-generic hardware (e.g., AI-optimized GPUs, FPGA trained with machine learning model, etc.)?
 - Claiming an AI/ML-based model that interacts with non-generic hardware is an ideal scenario.
- Consider whether the invention is sufficiently developed
 - Is the invention past the “idea” stage (e.g., AI/ML-based code has been developed and implemented in internal tests, training phase has been completed, etc.)?
 - A working prototype is not necessary, but the patent applicant must be able to describe how to make and use the invention in detail.

AI/ML-based patent filings will continue to rise for the foreseeable future as artificial intelligence takes a larger role throughout our lives and within society more generally. However, such patent applications should be drafted with special considerations tied to the underlying AI/ML-specific subject matter and claims. Furthermore, patent owners should strive to employ an intentional strategy aligned with their company’s business interests when building their AI/ML-based patent portfolio.

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Endnotes

- 1 Yearly totals of USPTO-published patent applications with disclosures that include the phrase "artificial intelligence" or "machine-learning." GOOGLE PATENTS, <https://patents.google.com> (accessed Sept. 11, 2019).
- 2 See, e.g., Intelligent Robot Based on Artificial Intelligence, U.S. Pat. App. Pub. No. 2019/0111566.
- 3 See, e.g., Machine-learning Circuit Optimization Using Quantized Prediction Functions, U.S. Pat. App. Pub. No. 2019/0228126.
- 4 See, e.g., Artificial-intelligence-based Facilitation of Healthcare Delivery, U.S. Pat. App. Pub. No. 2018/0182475.
- 5 Note that Taiwan is not a signatory of the Patent Cooperation Treaty and direct filings are due in that country within 12 months of the earliest priority date.

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