PROTECTING SOFTWARE RELATED TO A MEDICAL DEVICE: A CASE LAW REVIEW AND STRATEGY GUIDE

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[1] This article results from a collaboration between members of the IPO's Software-Related Inventions Committee and the AI & Other Emerging Technologies Committee. Opinions stated in this article may not be consistent with the firms, corporations, or clients affiliated with the authors.

Introduction

Software has become increasingly intertwined with medical devices, serving to monitor, control, evaluate, extrapolate, etc.[2] In some instances, software now forms a medical device itself to not only guide a clinician in diagnosis and/or treatment but to form its own diagnosis and/or issue its own treatment. In fact, the International Medical Device Regulatory Forum (IMDRF) now defines the following four categories for medical device software[3]:

1. Software as a Medical Device (SaMD), which is standalone software that serves as a medical product in and of itself;
2. Software in a Medical Device (SiMD), which is software that is part of a medical device, such as implanted software in medical equipment;
3. Software as an accessory to a medical device; and
4. General purpose software that is not a medical product by itself.

In 2019, the FDA officially codified a regulatory framework for software to be certified as a medical device. Several artificial intelligence/machine learning-based technologies have since been approved by the FDA as regulated medical devices. Many more applications are under review.

Many considerations are involved in protecting innovation in such technologies – regulatory requirements of FDA 510(k) medical device clearance, prior art, and subject matter eligibility, to name a few. Against this backdrop, the reality of how *Alice* and *Mayo* have forced the USPTO and the courts to evaluate software- and biology-related inventions for subject matter eligibility poses a daunting task for companies trying to patent their SaMD and/or SiMD innovations. With software-related inventions often difficult to protect and diagnostic methods even more restricted, much medical device-related software faces questionable odds at the USPTO and in court.

The following paper explores the developing space of legal treatment of medical devices and related software under U.S. patent law, including by the courts as well as at the USPTO.

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[2] This paper assumes a basic knowledge of patent eligibility case law in the U.S. For a more extensive treatment of patent eligibility in the U.S. and globally, see the following papers published by IPO's Software-Related Inventions Committee: (a) https://ipo.org/index.php/a-global-perspective-on-patent-subject-matter-eligibility-and-software-related-inventions/ and (b) https://ipo.org/index.php/35-usc-101-subject-matter-eligibility-cases-involving-software-related-inventions/" .

[3] See, e.g., http://www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-170314-canada-presentation-wg-samd.pdf; *see also* https://www.johner-institute.com/articles/software-iec-62304/software-as-medical-device and https://www.fda.gov/media/119724/download.

Additionally, this paper extrapolates from the existing body of decisions to give practitioners a better understanding of what to expect when advising their clients and working to protect medical device-related software innovations from both in-house and law firm perspectives.

This is an important topic to IPO members, as many members are focused on medical device and software-related medical device technologies, whether in the health care and pharmaceutical sectors, software industry, or otherwise. It also is particularly timely in light of increased scrutiny of medical-related innovations and associated protection stemming from the COVID-19 pandemic, as well as continued debate from the *Alice* and *Mayo* Supreme Court decisions. This subject matter brings together software and electronics concerns with biotechnology and life sciences concerns like few others do.

Overview

Obviously, treatment of claims varies based on subject matter and style. For purposes of our analysis, claimed subject matter analyzed by the PTAB and the courts has been divided into the following categories for further examination in this paper. We have examined decisions, both precedential and non-precedential, in the following general areas of claim focus:

1. Guiding human actions;
2. Medical data processing;
3. Processing for output generation;
4. Medical device technology;
5. Law of nature.

We will address each grouping of cases individually followed by our overall conclusion and recommendations going forward[4].

Claims Directed Primarily to Guiding Human Actions

Courts will reject claims related to guiding human action if they qualify as abstract ideas under 35 U.S.C. § 101. One determination as to whether a claim is directed to an abstract idea is

[4] We note that this is a developing area, and many decisions are currently at the district court level, rather than coming from the Federal Circuit. We expect this analysis to further develop over the coming years as the Federal Circuit weighs in more in this area.

whether the claim purports to improve a computer's capabilities, or merely invokes the computer as a tool. *Enfish, LLC v. Microsoft Corp.,* 822 F.3d 1327, 1336 (Fed. Cir. 2016). This is true in the health care related software space, even when the claim describes automating a process that advances a health benefit.

In *DietGoal Innovations, LLC v. Bravo Media LLC*, 33 F.Supp.3d 271 (S.D.N.Y. 2014), the court found that a method for a person to plan a meal using a picture menu on a user interface was directed towards an abstract idea. The court found that the claims recited routine and conventional steps for meal planning and were not patent eligible simply because the steps were performed on a computer. The appellants argued that the method should not be considered abstract because the limitations describe a "highly particularized" display element. *Id.* at 287. However, the court found that the steps could be performed "in existing computers long in use, no new machinery necessary". Therefore, the computerized display element did not transform the claims from a mental process of meal planning into patentable subject matter.

In *University of Florida Research Foundation, Inc. v. General Electric Company, et al.,* 916 F.3d 1363 (Fed. Cir. 2019), the court found that a method for integrating physiologic data from a bedside machine was directed towards an abstract idea. The appellants contended that the method minimized human error and conserved resources. However, the court found that the method sought to "automate pen and paper methodologies", and that this was akin to a "do it on a computer patent". *Id.* at 1367. The appellants argued that the claim limitations include converting physiologic treatment data from a bedside machine-specific data format to a machine independent data format, and therefore the claims were directed towards an improvement of computer functionality. However, the court disagreed and found that the conversion step was claimed at a high level of generality that did not adequately describe the technological aspects of the conversion process.

The court in *University of Florida Research Foundation* contrasted the appellant's claims with *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253 (Fed. Cir. 2017), in which the claims recited "an enhanced computer memory system" that used "programmable operations characteristics configurable based on the type of processor" to "enable interoperability with multiple different processors". The court found that these claim limitations explained how the system improved computer functionality. In contrast, the court found that the appellant's claims

did not provide a technological description as to how a bedside machine data format is converted into a machine independent data format.

In *Vanda Pharmaceuticals Inc. et al. v. West-Ward Pharmaceuticals et al.* 887 F.3d 1117 (Fed. Cir. 2018), the court found that claims for treating a schizophrenic patient with iloperidone included patent eligible subject matter. The appellees argued that the claims were directed towards a law of nature, in particular a relationship between iloperidone, CYP2D6 enzyme metabolism, and heart rate rhythm. The appellee further suggested that the claims were analogous to the invalid claims in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S. 66 (2012). The court said that although the representative claim in *Mayo* did recite administering thiopurine to a patent, the claim was "not directed to the application of a drug to treat a particular disease". Furthermore, the *Mayo* claim's administering step was similar to a claim limitation that "asked an engineer to apply known natural relationship with a computer". In contrast, the *Vanda* court found that the appellant's claims were "directed to a specific method of using iloperidone to treat schizophrenia". *Vanda Pharmaceuticals Inc.*, 887 F.3d at 1135. Furthermore, even though the specification described the relationship between iloperidone, CYP2D6 enzyme metabolism, and heart rate rhythm, the claims were directed to a specific application of the relationship. In particular, the court noted that Vanda's claim 1 requires specific steps: (1) determining the patient's CYP2D6 metabolizer genotype by (a) obtaining a biological sample and (b) performing a genotyping assay; and (2) administering specific dose ranges of iloperidone depending on the patient's CYP2D6 genotype. *Id*. at 1134. Although this case does not include computer-based technology, the case is illustrative of the need for specificity and performance of an action in claims to confront subject matter eligibility issues.

In healthcare-related software claims, courts routinely reject claims as abstract ideas, where the claims recite collecting data, analyzing the data, and displaying the analysis, and where the steps are recited at a high level of generality such that they could practically be performed in the human mind. *Electric Power Group, LLC v. Alstom, S.A.,* 830 F.3d 1350, 1353-54 (Fed. Cir. 2016). Therefore, when practical, the claim limitations should include at least one of specific non-generic computing elements and their function, technical description of how a step is performed, and performance of an act.

Claims Directed Primarily to Medical Data Processing

Claims involving data processing have often been found ineligible under 35 U.S.C. § 101, and claims involving medical data processing are no exception. However, a review of cases in the software and medical device area shows that claims can be related to medical data processing and be found patent eligible under § 101. As we learned from a number of decisions in this area, simply gathering and storing data, applying known or general computer technologies to data processing, or performing general computer processing is not enough to make the claims patent eligible. A lack of definition of claim terms can also doom eligibility of the claims. However, a focus on the improvement (e.g., of an associated physical process, to overcome a technical challenge, to reduce errors, etc.), a detailed application of specifics, a particular solution to a clearly articulated problem or challenge, careful definition and explanation of terms in the specification, and the like can provide a path to subject matter eligibility under 35 U.S.C. § 101 and the *Alice*/*Mayo* line of case law.

Some Ineligible Examples

Generally, if a patent application describes and claims a specific improvement or a specific result, then such claims represent patent eligible subject matter. This can often be difficult when the medical data collected, processed, etc., was already available to be collected previously (e.g., using manual data collection). For example, a claim to collecting and comparing known information, which can practically be performed in the human mind, is ineligible under 35 U.S.C. § 101. *Classen Immunotherapies, Inc. v. Biogen IDEC,* 659 F.3d 1057, 1067 (Fed. Cir. 2011); *see also Electric Power Group, LLC v. Alstom, S.A.* at 1353-54 (Fed. Cir. 2016). A review of twelve recent decisions involving medical data in the software and medical device area reveals very mixed results on the issues of patent eligibility and overall patentability of claims. In some cases, method claims were held to be ineligible while apparatus claims were held to be eligible. In other cases, the form of the claim was not a factor.

For example, collecting, accessing, and managing health records through a user interface does not provide enough specificity and technological improvement to render the claims patent eligible under 35 U.S.C. § 101. *MyMedicalRecords, Inc. v. Walgreen Co.*, No. 2:13-cv00631, 2014 WL 7339201, at *3 (C.D. Cal. Dec. 23, 2014). Additionally, claims directed to data standardization around particular industry codes, without "a very specific and narrow technical process" represent general processes that are preemptive and not rooted in computer technology,

since organizing records is an "ancient issue". *HealthTrio, LLC v. Aetna, Inc.*, No. 1-12-cv-03229, at 7 (D. Colo. June 17, 2015). Similarly, calculating physician efficiency scores without a more specific recitation of how the data is analyzed, how the statistics are weighted, how the scores are determined, etc., results in a claim that is too general and has been found to be abstract. *Consulting Group, Inc. v. Truven Health Analytics Inc.*, 3:15-cv-02177, Op. at 1 (N.D. Cal. Dec. 22, 2016).

Further, controlling who has access to data has been found to be organizing human activity and, therefore, abstract. For example, use of a two-way firewall to control access, as set forth in the claims, was held to be conventional because very little structure or explanation was provided in the specification for this feature. *Preservation Wellness Techs., LLC v. Allscripts Healthcare Solutions, Inc.*, No. 2:15-cv01559, Op. at 12, 23 (E.D. Tex. May 10, 2016). By relying on "one of ordinary skill in the art would know how to do this" rather than explaining in more detail, the applicant can fall into the trap of conventionality. *Id*.

Maintaining and searching a library of information has also been found to be basic and abstract. *Cogent Med., Inc. v. Elsevier Inc.*, 70 F. Supp. 3d 1058 (N.D. Cal. 2014). In *Cogent Med.*, regarding step two of the *Alice* test, the court acknowledged that the "enhanced interface" provides related materials and concepts (i.e., preselected medical information) that are not literally within the search terms utilized by the user, but the resourcefulness of the human mind can manually preselect medical information that is not literally within the search terms supplied by the user. *Id*. However, simply performing manual activities using a general-purpose computer is not enough for patent eligibility.

Some Eligible Examples

If, instead, the claims go beyond a simple organization or calculation using medical data but result in a selection of particular features based on the calculation algorithm, such claims can be patent eligible. *Ex parte Evans*, Appeal 2019-002450 (Appl No. 14/318,500 Feb 25, 2020) (PTAB). Even where, as in *Ex parte Evans*, particular steps or details of an algorithm were not claimed, the claims could be held patent eligible based on the practical application of the known adaptive algorithm to select particular features based on certain resulting values. *Id*.

Correcting errors or improving a physical process also represents a path toward subject matter eligibility of claims involving medical data. For example, like *Diamond v. Diehr*, claims that improve upon previous methods and result in improved accomplishment of a physical

process (e.g., a more discriminating assessment of particles in a mixture) can be found patent eligible. *XY, LLC v Trans Ova Genetics, LC*, Appeal No. 1:17-cv-00944-WJM-NYW (D. Colo. July 31, 2020). In this case, claims also involved signal processors programed to detect differences including "rotational alteration, translation operation, scaling operation, any combination of these and the like." *Id*.

A claimed technical improvement to address errors in prior check data (e.g., resulting in increased detection of recurring errors) can also be patent eligible. *Koninkliijke KPN N.V. v. Gemalto M2M GmbH*, 942 F.3d 1143 (Fed. Cir. 2019, non-precedential). In this case, the Federal Circuit found that listing improvements to the prior art in the detailed description was sufficient to show a non-abstract improvement over prior technical processes to detect corrupted versus uncorrupted data. *Id*.

Further, including tangible elements, such as a scanning device, an alignment marker, etc., can take an otherwise ineligible claim outside the abstract idea of mere data collection and storage. *ContourMed Inc. v. Am. Breast Care LP*, No. 4:15-cv-02769, Op. at 6-7 (S.D. Tex. Mar. 17, 2016). In this case, these physical elements aid in building a model from image scans, rendering the claims patent eligible. *Id*.

Mixed Messages from the Courts

In some cases, the court found that the form of the claim mattered for patent eligibility. For example, where a method claim was found invalid as merely "acquiring and processing medically informative data from two different, known sources in a chosen human subject", the apparatus claim was found patent eligible because it was "specifically limited to a particular machine made from specific elements." *Brain Synergy Institute LLC v. UltraThera Techs., Inc.*, No. 1:13-cv01471, Op. at 15-18 (D. Colo. Jan. 28, 2016). Here, the claimed machine is an "apparatus useable in relation to a chosen human subject for acquiring medically informative data," which includes a "chosen-subject manipulation structure for establishing different spatial orientations (positions) for a chosen subject" and a first and second "data-stream structure." *Id*.

Courts additionally look at the sufficiency of definition and explanation in the specification and claims to evaluate subject matter eligibility. One court has evaluated "the weight of the claim" to determine whether it is directed to an abstract idea. *Immerson Corp. v. Fitbit, Inc.*, No. 5-17-cv03886 (N.D Cal. Mar. 5, 2018) (finding some claims eligible and some claims ineligible). Just because the claim includes an abstract idea does not mean that the claim

is ineligible if the weight of the claim is to a tangible, non-abstract device. *Id*. If the claim is just gathering information and the claimed analysis is a high-level functional result, that is not enough to make the claim patent eligible. Rather than gathering data and providing a result, the claim should tell how to provide that result, overcome a technical challenge, and/or set forth a tangible, non-abstract device. *Id*.

A lack of definition can also doom the claims to vagueness and lack of eligibility. *Ameritox, Ltd. v. Millennium Health, LLC*, No. 3:13-cv-00832, Slip Op. at 5-6 (W.D. Wis. Apr. 24, 2015) (finding some claims eligible and some claims ineligible). Without definition, it can be difficult to assign meaning or importance to claim terms. *Id*. As such, it is important to be clear on definitions in the specification that will be relied on in the claims. Being clear as to the value of a combination or improvement on existing steps, as well as lack of preemption, can help argue for subject matter eligibility of the claims.

Practice Tips for Eligible vs. Ineligible Claims

As such, if a claim is manual, sets forth undefined actions, or merely collects, organizes and analyzes medical data, then the claim is likely to be found directed to an abstract idea and, therefore, subject matter ineligible. However, claims that set forth specific, defined actions, technical improvement over prior processes, and/or involve tangible devices should provide arguments for the subject matter eligibility of those claims under 35 U.S.C. § 101.

Claims Directed Primarily to Processing for Output Generation

Like inventions involving medical data, claims for inventions that involve data processing to generate an output can also be challenging with regard to patent eligibility. In *Electric Power Group, LLC v. Alstom, S.A.,* the Federal Circuit stated that the claims at issue were ineligible because "[t]he advance they purport to make is a process of gathering and analyzing information of a specified content, then displaying the results, and not any particular assertedly inventive technology for performing those functions." 830 F.3d 1350, 1354 (Fed. Cir. 2016). The patent office and district courts generally interpret this broadly in finding claims that recite data processing alone to be ineligible. However, combining data processing with meaningful use of a generated result can tip the scales in favor of eligibility.

In *Zircore, LLC v. Straumann Mfg., Inc.*, the district court found that a process for manufacturing custom crown copings was patent eligible despite the use of computer modeling

to design the manufactured product. No. 2:15-cv-01557 (E.D. Tex. Jan. 20, 2017). The court noted that the process as a whole resulted in the creation of a physical object and merely including some computerized data collection and processing steps did not render the whole claim abstract. *Id.* Significantly, the creation of the physical object was claimed broadly as "manufacturing said core and said coping." Thus, when claiming novel data processing techniques focusing on an output, it may be helpful (where feasible) to include explicit steps of manufacturing or modifying a physical product using the results generated by the data processing.

Similarly, eligibility is more likely to be found where a claim recites processing data generated by a device and using the results for operation of the device. In *Ex Parte Fautz*, the Patent Trial and Appeals Board (PTAB) found a claim to a magnetic resonance tomography apparatus eligible despite the fact that a significant proportion of the claim was mathematical equation. The PTAB reasoned that the equations calculate properties of physical components of the apparatus which are then used to improve the output image relative to prior art approaches. The PTAB took note that the connection between the equations and the improved output from the apparatus was explicitly laid out in the specification. Thus, practitioners should make sure that any connections between data processing techniques used and improved performance of a scanner of other device are clearly explained in the specification.

Eligibility can also be established by claiming a specific approach to producing an improved model. This is particularly the case where the specification identifies a problem with existing models and the claim captures the described solution to that problem. However, there can be a fine line between specific improvements to a model (eligible) and improvements that naturally arise from computer-implementation of existing technique (ineligible). A good illustration of this is provided in *Align Technology, Inc. v. 3Shape A/S*, No. 1-17-cv-01646 (D. Del. Sept. 7, 2018). In *Align Technology*, the court evaluated the eligibility of four patents relating to computer-aided dental techniques, finding two eligible and two ineligible. The two patents found eligible both identified a specific problem with existing techniques in the specification and claimed a specific set of data processing steps that solve the identified problem. In contrast, the court viewed the improvements realized by the ineligible as presenting data in a convenient way, which it viewed as merely generic application of computer technology. Thus, when claiming data processing techniques, it may be helpful to clearly lay out in the

specification how the claimed technique improves the model itself and goes beyond mere presentation of data in a convenient format.

Claims Directed Primarily to Medical Device Technology

Examples of medical device technology, as considered by courts, include cardiac monitors, infusion pumps, catheter navigation system, biometric devices, etc. Because claims directed to medical device technology typically include, or include the use of, these specialized tangible devices (i.e., "particular machines"), courts have been reluctant to find that such claims are patent-ineligible. This is because tangible devices, themselves, are not merely laws of nature, natural phenomena, or an abstract ideas. In view of this, where applicable, practitioners should draft claims that focus, at least in part, on a tangible device. Courts have also looked to a patent's written description to determine whether a given medical device technology-based claim describes an improvement to an underlying medical device or its technical field. Showing such improvement can further demonstrate that a related claim is patent eligible.

In *CardioNet, LLC v InfoBionic*, for example, the Federal Circuit considered whether claims directed to a "cardiac monitoring device" were patent eligible. 955 F.3d 1358 (Fed. Cir. 2020). According to the *CardioNet* court, the claims recited that the cardiac monitoring device "*detects beat-to-beat timing of cardiac activity, detects premature ventricular beats, and determines the relevance of the beat-to-beat timing to atrial fibrillation or atrial flutter, taking into account the variability in the beat-to-beat timing caused by premature ventricular beats identified by the device's ventricular beat detector*." *Id.* The district court had found such claims ineligible because they were "drawn to automating basic diagnostic processes that doctors have long used." The *CardioNet* court, however, disagreed. Instead it found that the claims focused on a specific means or method that improves cardiac monitoring technology, and that such claims were not merely "directed to a result or effect that itself is the abstract idea and merely invoke[d] [by] generic processes and machinery." *Id.* In reaching its finding, the *CardioNet* court referred to the written description that described an improvement to cardiac monitoring device technology, where an underlying cardiac monitoring device, using the invention, would more accurately detect the occurrence of atrial fibrillation and atrial flutter—as distinct from V-TACH and other arrhythmias—that allows for a more reliable and immediate treatment of those two medical conditions. *Id.* Thus, even though the cardiac monitoring device involved a computing

device that monitored "data" (e.g., heartbeat data), the claims of the cardiac monitoring device fit into the class of claims that focus on "an improvement in computers [and other technologies] as tools." *Id.* Thus, the claims at issue were "directed to a patent-eligible improvement to cardiac monitoring technology and [were] not directed to an abstract idea." *Id.*

Similarly, in *Baxter Int'l, Inc. v. CareFusion Corp.*, the Northern District of Illinois found eligible patent claims directed to a specific device and a method of using that device. No. 1:15-cv-09986, Op. at 22, 24-25, 28-29 (N.D. Ill. May 13, 2016). In *Baxter*, two patents were asserted that were each directed to an "infusion pump." The first patent claimed standard "circuits" for monitoring voltage and triggering alerts upon detection of a low battery. The second patent claimed an "algorithm" for automatically controlling a level of a patient's medication. For each patent, the *Baxter* court found that the respective claims were "directed to a concrete and tangible form, expressly limited to specific intravenous pumps." According to the *Baxter* court, this "concrete and tangible form, and discrete field of application," distinguishes the patents "from the broad, disembodied 'data collection' or 'data processing' patents held ineligible by a number of courts in recent years." Accordingly, the *Baxter* court held that each patent was directed to patent-eligible subject matter.

A Note on Motion Practice

In addition, district courts have shown reluctance to grant case dispositive motions for Medical Device Technology related claims.

For example, in *Xoran Technologies, LLC v. Planmeca USA, Inc.*, the Northern District of Illinois denied a Rule 12(b)(6) motion to dismiss where the claims-at-issue directed to a scanner with structural improvements over the prior art. No. 1-17-cv-07131 (N.D. Ill. May 22, 2018). The *Xoran* court looked to the patent's written description describing that the claimed invention overcame the prior art's requirement of using several cameras to generate a 3D external image. According to the patent, the use of such cameras was difficult and error prone. To solve the problem, the claims-at-issue recited a camera mounted to a first arm section and a second arm section with a motor that rotated a gantry about an axis of rotation to capture images. In this way, a single camera could take a plurality of external images as the gantry rotated. The *Xoran* court found that, because of this, the claims-at-issue were directed to more than just the idea of taking and displaying images. Instead, the claims recited a scanner with specific improvements relating to the structure of the scanner. The court found that the claims would not

somehow preclude others from taking, and displaying, X-ray and external images of a patient. Instead, the claims were specifically directed to a scanner with specific structural limitations. Accordingly, the *Xoran* court denied the motion to dismiss, instead finding that the claims were directed to patent eligible subject matter.

As a further example, in *Fitbit, Inc. v. AliphCom d/b/a Jawbone*, the Northern District of California denied a motion for judgment on the pleadings where the claims-at-issue directed to portable biometric devices and portable biometric device pairing. No. 5:15-cv-04073 (N.D. Cal. Feb. 9, 2017). All of claims-at-issue recited a method or system for pairing that involved three discrete entities: a portable monitoring device, a "client," and a "server." The *Fitbit* court focused on the "character as a whole" of the claims and found that the claims were not merely directed to device pairing generally, but rather a specific "flavor" (i.e., implementation) of portable device pairing. Such specific flavor involved the combination of the use of user account information, regulating a list of eligible devices with a server, and "tapping" as the means of user validation. The *Fitbit* court found that "tapping" overcame a problem experienced generally by wearable devices, where such devices typically lack a keyboard or buttons. More specifically, tapping provided an inventive (and an improved) way to achieve pairing because tapping provided, and relied on, advantages inherent to technical capabilities of a portable monitoring device—its ability to detect motion with a motion sensor—to provide a manner of validating the device. Such functionality was different from traditional forms of input (i.e., buttons and keyboards). Moreover, the *Fitbit* court found that such functionality was similar to the inventive concept in *Bascom*, which found that taking advantage of a technical feature of certain ISP servers improved an existing technological process. In this sense, and according to the *Fitbit* court, the claims-at-issue analogously "improve[d] an existing technological process" by expanding the scope of devices that can be paired. Accordingly, the *Fitbit* court found that the claims were directed to eligible subject matter and denied the motion for judgement.

Likewise, in *Femto Sec Tech, Inc. v. Lensar, Inc.*, the Central District of California found eligible patent claims directed to a specific device and a method of using that device. No. 8:15-cv-01689, Op. at 9, 11–12 (C.D. Cal. June 8, 2016). In particular, the claims-at-issue were directed to the field of "ultrashort pulse duration laser systems suitable for material and biological tissue processing." The patent's written description described improvements in the use of lasers, as therapeutic and preventive tools, in various fields, such as surgery. According to the

patent, the improvement provided by the invention included increasing ablation efficiency while minimizing collateral damage to adjacent material (e.g., tissue). The defendant had motioned the court under Rule 12(b)(6) to dismiss the case, alleging that claims were invalid for lacking subject matter eligibility. According to the defendant, the claims of the patent were ineligible because the claims were merely directed toward natural phenomena and the laws of nature. The *Femto* court disagreed, finding instead that the claims were specifically directed to an improved method and system of using laser beams of ultrashort duration. The *Femto* court summed up its finding as follows: "[i]n short, the '894 Patent does not monopolize the use of laser beams for research or medical applications; instead, it discloses an improvement as to which laser beams and which qualities of laser beams lead to an advantageous material removal process." Accordingly, the *Femto* court held that the claims were directed to patent eligible subject matter and denied the defendant's motion to dismiss.

Treatment at the PTAB

The Patent Trial and Appeal Board (PTAB) also has considered claims directed to Medical Device Technology. Like the Federal Circuit and district courts, the PTAB has also found persuasive, arguments for patent eligibility where the claims recite a particular machine. For example, in *Ex parte Olson*, the PTAB reversed an Examiner's subject matter eligibility rejection where the claims were directed to a particular machine. Appeal 2017-006489, 2019 WL 4297780 (July 1, 2019) (PTAB) (designated Informative). In particular, the claims directed to a "method and system for locally deformable registration of a catheter navigation system to an external model or external image data." The claimed systems and methods operated "to transform the coordinate system of [a] catheter navigation system to the coordinate system of [an] external model or external image data." The Examiner had rejected the claims, contending that "[t]he claims essentially cover[] a general algorithm to be executed on a general purpose computer that is cited with [a] generic catheter navigation system and generic catheter/tool that are well-known, conventional systems/devices in the field of medical imaging." The Examiner further contended that the Applicant/Appellant did not "claim any new and novel structures for the catheter and catheter navigation system." The PTAB found that the Examiner erred in rejecting the claims as being directed to patent-ineligible subject matter without more. The PTAB explained that the claimed limitations "apply the mathematical concepts with a particular machine, i.e., the catheter navigation system." *Id.* The PTAB also explained that, although the

claims recited mathematical concepts, such claims nonetheless improved the technical field of catheter devices. Because of this, the PTAB found that the claims were integrated into a practical application and, therefore, are not ineligible.

Practice Tips for Eligible vs. Ineligible Claims

As provided above, claims directed to Medical Device Technology should, where applicable, be drafted to focus on the structural components and/or functional steps of a device, at least in part. Claims that are directed to mere provision or use of a device may be found ineligible under *Alice.*

For example, in *Puget BioVentures, LLC v Biomet Orthopedics LLC*, two dependent claims (claims 45 and 47 of the patent-at-issue) were found to be directed to an abstract idea without more and, therefore, not patent eligible. No. 3-10-cv-00465 (N.D. Ind. July 2, 2018). Specifically, the claims-at-issue recited mere use of a "cutting tool," where, e.g., for claim 45: "*wherein cutting the end of the one of the femur or the tibia* ***by moving the cutting tool*** *in a direction along the long axis* …." With respect to step 1 of the *Alice* test, the *Puget* court found that such claims were directed to the abstract idea of merely "providing" instrumentation, implants, and information for a total knee arthroscopy procedure. Also, with respect to step 2 of the *Alice* test, the *Puget* court found that such claims lacked an inventive concept sufficient to transform their nature into a patent-eligible application of that abstract idea. Accordingly, the *Puget* court granted the motion to dismiss claims 45 and 47, finding that such claims were directed to patent ineligible subject matter.

Claimed Directed Primarily to a Law of Nature

Courts have repeatedly held that a newly discovered law of nature or natural phenomenon cannot by itself amount to patentable subject matter, no matter how novel. *See Exergen Corporation v. Brooklands Inc.*, 125 F.Supp.3d 307, 316 (D. Mass. 2015). "[G]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013). Such claims would be overly broad, tying up future use of laws of nature.

For example, in *Mayo*, the Supreme Court held that claims relating to measuring metabolite levels as an indication of how to adjust drug dosage "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged

in by those in the field". *Mayo Collaborative Services*, 566 U.S. at 79-80. However, as discussed above, the court in *Vanda* contrasted *Mayo* and held treatment claims patent eligible due to the level of specificity and performance of action required.

In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, even though the discovery of parentally inherited cell-free fetal DNA (cffDNA) in maternal plasma was new and useful and enabled non-invasive prenatal testing, the claimed steps of amplifying and detecting cffDNA were deemed "well-understood, conventional and routine" and insufficient to "transform[] the natural phenomenon of cffDNA into a patentable invention". 788 F.3d 1371, 1376-77 (Fed. Cir. 2015).

In *Genetic Techs. Ltd. v. Merial L.L.C.*, the district court's ineligibility-based dismissal of infringement claims under Rule 12(b)(6) was affirmed. 818 F.3d 1369, 1380 (Fed. Cir. 2016). As in *Ariosa*, the court held that the claimed steps relating to amplifying (non-coding) genomic DNA and analyzing the amplified DNA were well known, routine, and conventional in molecular biology, and relied on the seemingly novel yet naturally occurring discovery of linkage disequilibrium between coding and non-coding regions of DNA to detect an allele. *Id*. at 1374, 75, 79-80. Moreover, the court disagreed with Genetic Technologies' argument that analyzing the amplified non-coding DNA "to detect the allele" did not recite the linkage disequilibrium discovery and provided sufficient inventive concept, instead holding that the "to detect the allele" is a mental process. *Id*. at 1378.

In *Athena Diagnostics, Inc. v. Mayo Collaborative Services*, claims related to detecting MuSK autoantibodies, which are an indicator of the neurological disorder myasthenia gravis for a subset of patients, using for example a radioactive isotope of iodine in one dependent claim at issue. 915 F.3d 743, 747 (2019). The Federal Circuit affirmed the ineligibility-based 12(b)(6) dismissal, because the claims involved only observing or detecting a natural law (even if the method used man-made molecules). *Id*. at 752.

The premise exemplified in these genetic testing cases appears to also be true for laws of nature and natural phenomena implemented in software or device-based diagnostic inventions. Exergen Corporation is assignee of a patent relating to measuring skin surface temperature or radiation of the forehead and converting those measurements to body temperature. Claims were held invalid on summary judgment under § 101 in both *Exergen Corporation v. Brooklands Inc.*, 125 F.Supp.3d 307 (D. Mass. 2015) and *Exergen Corp. v. Thermomedics, Inc.*, 132 F.Supp.3d 200 (D. Mass. 2015). Exergen argued that because it was previously believed to be impossible

to correlate skin temperature to internal body temperature (pointing to a statement by the American Society for Testing and Materials), the claim as a whole is transformed into eligible subject matter. Since the parties did not dispute that the claimed processing step was directed to a mathematical formula, the only additional step was a measuring step, which the *Brooklands* court found was "hardly be considered unconventional in the field of thermometry" and merely provided the necessary input into the mathematical formula. *Exergen Corporation v. Brooklands Inc.*, 125 F.Supp.3d 307, 315-16 (D. Mass. 2015).

Often, these types of cases are analyzed against the archetypes of *Parker v. Flook*, 437 U.S. 584 (1978) (adjusting alarm limits based on measured variable was not patent eligible) and *Diamond v. Diehr*, 450 U.S. 175, 188 (1981) (measuring temperature of rubber in mold to recalculate curing time and open the mold at the proper time was patent eligible). It is clear that claims that use known means of observation or detection of a natural law or phenomenon are not patent eligible.

However, there are fewer cases illustrating how to successfully incorporate medically-related natural laws or phenomena into eligible claims. A few guideposts exist. The court in Athena stated that a claimed advance can "harness[] a natural law to produce a technological improvement that [is] patent eligible" (*Athena* at 751 (citing *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1046, 1048-50 (Fed. Cir. 2016) (natural law of cells surviving multiple freeze-thaw cycles was harnessed into a new way to preserve hepatocyte cells for later use)). That court also said that "claiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law". Id. at 753. The *Brooklands* court contrasted the claims at issue with *Diehr*, stating "[u]nlike in *Diehr*, the formula is not used to affect a physical transformation." *Exergen Corporation v. Brooklands Inc.*, 125 F.Supp.3d. at 315. Additionally, cases discussed above appear to indicate that claims specifically directed to modifications of a physical product or improvements to a machine (e.g., medical device technology) may be patent eligible.

As another observation, it may appear that diagnostic inventions may have a more difficult time of meeting subject matter eligibility requirements than therapeutic inventions, which may skew more towards *Diehr*. *But see Mayo Collaborative Services*, 566 U.S. 66. Regardless, diagnostic inventions may be eligible if claiming non-conventional or unexpected methods for detecting the natural law or transformative elements.

Conclusion

Thus, inventions directed to SaMD, SiMD, and other medical device-related software can be patented, but such inventions must address challenges faced by software, diagnostic methods, treatment methods, and biologics to help ensure patentability in the eyes of the USPTO and the courts. Claims directed to guiding human actions or reflecting laws of nature are very difficult to find patent eligible. If a computer is involved as a tool to merely leverage generic computing capabilities in a well understood, routine, and conventional manner, then such claims are likely ineligible. In contrast, providing a high degree of specificity in the claim and using the computer to perform a particular action could be patent eligible. Similarly, simply observing, measuring, gathering, and/or storing data using general computer processing functionality is likely ineligible. However, careful, clear definition of terms, functions, and benefits can change such a claim to be subject matter eligible. Further, if data processing results in an improvement to a physical process or other physical system, such a claim is likely patent eligible. Merely displaying results of data processing is likely insufficient, while creation of a physical output is likely eligible subject matter. Improvements to a physical device itself are most often patent eligible, as long as the claims are directed specifically enough to the improvement. Unconventional or unexpected results can also provide a path to subject matter eligibility of SaMD or SiMD claims under 35 U.S.C. § 101.

So far, many of the decisions in this area remain at the district court level. As these decisions are appealed, we expect to hear more from the Federal Circuit regarding claims directed to SaMD, SiMD, and other medical device-related software. For example, Cybergenetics Corp. recently appealed a decision by the Northern District of Ohio that held its patent claims, directed to "computer-based systems and methods for analyzing a DNA sample comprising a mixture of DNA from multiple sources in order to determine a likelihood that a particular person's DNA is, or is not, contained within the mixture" were abstract and ineligible. *Cybergenetics Corp. v. Institute of Environmental Science and Research et al.*, No. 5:19-cv-01197-SL (N.D. Ohio 2020) (granting defendant's Rule 12(b)(6) motion to dismiss). Additionally, as more and more companies are active in this area, more patent applications, issued patents, and associated decisions will arise. As more companies seek FDA approval of software as a medical device and are obligated to disclose software functionality as part of that

process, such companies may seek patent protection since they can no longer keep such functionality as a trade secret. This increase may drive pressure to examine these cases differently, and it will certainly spur practitioners to be mindful of subject matter and other potential pitfalls when drafting, prosecuting, and litigating in this area.