Botos Churchill IP Law is a boutique Intellectual Property Law Firm located in New Providence, New Jersey.

1. Please explain how the current state of patent eligibility jurisprudence affects the conduct of business in your technology area(s). Please identify the technology area(s) in your response.

The current state of eligibility practice affects our practice by making it extremely expensive for clients to pursue IP Protection due to highly complicated office actions, more office actions and greater pendency and lower allowance rates. This makes our clients reluctant to file for IP Protection in certain fields such as life sciences and software. This has an especially acute effect on medical diagnostic devices where software serves to provide new and medically beneficial methods of diagnosing/identifying medical issues. In those areas clients are favoring a hold over their information as a trade secret if it is difficult to reverse-engineer. Thus, subject matter eligibility has become the antithesis of what the patent system was designed to achieve, the release of technology into the public in exchange for the limited exclusivity afforded by a duly issued patent. It also serves as a disincentive to develop such technologies since costs of development and testing are less likely to be recovered where protection of those developments cannot be obtained. Moreover, a disincentive to such diagnostic development then similarly suggests a disincentive to improving public health.

2. Please explain what impacts, if any, you have experienced as a result of the current state of patent eligibility jurisprudence in the United States. Please include impacts on as many of the following areas as you can, identifying concrete examples and supporting facts when possible:

a. patent prosecution strategy and portfolio management;

b. patent enforcement and litigation;

c. patent counseling and opinions;

d. research and development;

e. employment;

f. procurement;

g. marketing;
h. ability to obtain financing from investors or financial institutions;
i. investment strategy;
j. licensing of patents and patent applications;
k. product development;
l. sales, including downstream and upstream sales;
m. innovation; and
n. competition.

With regard to question 2(a), the tension between various inconsistent decisions by the Supreme Court, the Federal Circuit and various district courts, as well as the attempts to follow the logic of those decisions, has adversely impacted patent examination quality and consistency at the USPTO. Different Group Art Units, as well as examiners within an individual GAU, have vastly different interpretations as to what technology is properly eligible under the law. In addition, the recitation of boilerplate language used in stock rejections under 35 U.S.C. § 101 often fail to follow current USPTO guidelines (e.g., the April 19, 2018 "Berkheimer" memo and the December 20, 2018 memo re "2019 Revised Patent Subject Matter Eligibility Guidance"). Generally, the examiners have also ignored the patentable examples in the "Subject Matter Eligibility Examples: Abstract Ideas" documents circulated by the USPTO.

All of this has created uncertainty with applicants and patent practitioners. In an effort to predict what examiners will do in 1-3 years when they pick up a new case for examination, practitioners may include in the specification additional information about the benefits and applicability of the technology. Prophetic examples may also be helpful to underscore the differences between the technology and the known prior art. Furthermore, during prosecution it is often necessary to spend additional time explaining why the § 101 rejection fails to comply with the statue and current USPTO guidance.

For instance, it has been noted that examiners in GAU 3620 may generally assert ineligibility with unduly broad rejections founded in "methods of organizing human activity". Usually, it is

necessary to cite to the Manual of Patent Examining Procedure (MPEP), such as MPEP § 2106.04(a)(2)(II), which makes clear that "not all methods of organizing human activity are abstract ideas", and that "this grouping is limited to activity that falls within the enumerated sub-groupings". In contrast, examiners in GAU 2190 may instead assert ineligibility with reliance on a vague "mental processes" rejection. Here, it is typically necessary to explain in a response that claims "do not recite a mental process when they do not contain limitations that can practically be performed in the human mind, for instance when the human mind is not equipped to perform the claim limitations" per MPEP § 2106.04(a)(2)(III)(A).

Additionally, the "mental process" evaluation as applied, is an inappropriately out-of-context framework for evaluating claims such as when involving software in diagnostic devices with sensors and processors. Such an evaluation should not be permitted to ignore the reality of the technical structure in which they are claimed. Moreover, the evaluation conflicts with the draftsman's need to provide a humanly understandable description in written language. Indeed, technology is designed in the minds of humans and should be understandable in the mind. Nevertheless, understandable claims are too readily and simply characterized as mental processes because the technical context in which they are claimed can be simply ignored.

An example of a technologically founded claim held to be novel and inventive but abstract under §101 in such an out-of-context fashion can be considered in Appeal 2017-004809. The rejected claim is clearly directed to specific and useful technological device but was nevertheless deemed not patentable under §101.

> 1. A snoring detection device comprising:
> a sensor configured to detect sounds during a breathing cycle; and a processor configured to:
> detect a noise level during an inspiration phase of the breathing cycle with said sensor;
> detect a noise level during an expiration phase of the breathing cycle with said sensor;
> determine an occurrence of a snore based on a difference in the noise levels detected during inspiration and expiration, the difference comprising a subtraction of the noise level during expiration from the noise level during inspiration.

It is inexplicable how the eligibility evaluation process under §101 has abandoned all reasonable perspective such that the above claim was held to not be a "new and useful process, machine, manufacture, or composition of matter."

From client counseling and portfolio management perspectives, it has been found helpful to recommend to clients to conduct examiner interviews with both the examiner and their supervisor, no matter how experienced the examiner is. This allows practitioners to hear multiple perspectives from the examiners. This is particularly helpful since it has been found that examiners and their SPEs often do not have equivalent understandings of patent eligibility requirements. Supervisors will often make suggestions for minor tweaks to the claims to address purported eligibility issues, and these suggestions can be applied to other cases in the portfolio.

Such approaches can increase the length and complexity of the specification and/or responses to Office Action, which may increase cost to applicants. Additional rounds of prosecution have been experienced, which also drives up cost and delays protection. Applicants may also be forced to appeal when no agreement with the examiner can be reached, in the hope that the PTAB panel that eventually hears the appeal will have a more complete understanding of current patent eligibility jurisprudence.

3. Please explain how the current state of patent eligibility jurisprudence in the United States impacts particular technological fields, including investment and innovation in any of the following technological areas:

a. quantum computing;

b. artificial intelligence;

c. precision medicine;

d. diagnostic methods;

e. pharmaceutical treatments; and

f. other computer-related inventions (e.g., software, business methods, computer security, databases and data structures, computer networking, and graphical user interfaces).

There is great uncertainty with regard to quantum computing and artificial intelligence, due to the lack of coherent caselaw and little to no guidance from the USPTO. As best understood, none of the eligibility examples actually focus on these types of technologies. There are legitimate concerns that claims will be rejected under a "mental steps" approach, even though that approach would seem to run afoul of the fact that the technology as claimed would not contain limitations "that can practically be performed in the human mind". MPEP § 2106.04(a)(2)(III)(A).

In particular, with quantum computing innovative aspects may involve how the system is "trained" via exposure to different types of signals/inputs. While this is akin to training machine learning (ML) models, it is unclear how an examiner will interpret quantum computing system or method claims that may not expressly require an output action or other "use" of the technology. And for artificial intelligence-related innovations, there is a legitimate concern that the claimed technology would not be patentable *per se* because it is unclear who is the inventor. There is at least one portfolio being prosecuted in the US and other jurisdictions where courts in the different jurisdictions are coming down on different sides of the artificial intelligence inventorship issue.

There is also great uncertainty with regard to diagnostic methods. Our clients have developed unique and innovative techniques for detecting sleep disorders (*see, e.g.*, Appeal Nos. 2017-004809 and 2018-001367), identifying and/or classifying bacterial growth (*see, e.g.*, Appeal Nos. 2017-005815, 2017-005963, and 2017-007200), and detecting disease outbreaks (*see, e.g.*, Appeal No. 2020-005479). However, unless those methods conclude with a physical action or transformation, it is often very difficult to obtain patents for such methods. In many of the above-noted appeals, the examiner conceded that the claims were both novel and inventive. In some cases, the examiner and the appeal board even acknowledged that the claims may provide certain advantages over the prior art. However, ultimately, the rejections under § 101 were affirmed in all of the above-noted appeals. This has caused our clients to be much more hesitant about filing patent applications directed to diagnostic methods that cannot practically conclude with a physical action or transformation.

It is unclear where the supposed requirement for a physical action or transformation comes from. None of the recent caselaw from Supreme Court or the Federal Circuit has indicated that there is such a requirement. In fact, there are numerous examples of cases involving patent-eligible claims that do not include a physical action or transformation. *See, e.g.*, *Visual Memory LLC v. NVIDIA Corporation*, 867 F.3d 1253 (Fed. Cir. 2017); *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017); *Amdocs (Israel) Limited v. Openet Telecom, Inc.*, 841 F.3d 1288 (Fed. Cir. 2016); *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (Fed. Cir. 2016); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016). Moreover, the updated guidance from U.S.P.T.O. does not mention any such requirement. *See* M.P.E.P. § 2106. Additionally, the U.S.P.T.O. has released several examples of patent-eligible claims that do not include a physical action or transformation. *See Subject matter eligibility*, U.S.P.T.O., https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility. Nonetheless, as demonstrated by Appeal No. 2018-001367, it is sometimes viewed as a requirement.

In some cases, we have successfully compared pending claims to the claims at issue in the above-noted cases and/or examples from the U.S.P.T.O. to overcome a rejection under 35 U.S.C § 101. However, usually the outcome is highly dependent upon the examiner's understanding of 35 U.S.C. § 101 and/or his or her supervisor's understanding. Some examiners are very helpful when it comes to providing guidance for how to overcome a rejection under 35 U.S.C. § 101 and others have simply stated that it is impossible to overcome such a rejection. This has produced wildly inconsistent results and has made it very difficult to effectively counsel our clients. Some of our larger clients are occasionally willing to move forward with a patent application directed to a diagnostic method without a physical action or transformation. However, due to the lack of predictability in this area, the overall number of such filings has been reduced. Moreover, many of our smaller clients cannot afford to take the risk of filing such an application.

Even when it is possible to include a physical action or transformation step in a diagnostic method, the resulting coverage may not be enough to warrant the filing or continued pursuit of a patent application. For example, while there may be situations where it is useful to configure a sleep therapy device to react in a particular manner based on the detection of a sleep disorder, there are

also many situations where the mere reporting of such a detection is useful. For example, a user may not even realize that he or she has a sleeping disorder. Therefore, technology capable of enabling, for example, a cell phone to provide a user with an indication that he or she may have a sleeping disorder is extremely useful and may encourage that user to seek necessary treatment. Unfortunately, due to the limited number of outputs available to cell phones, some examiners are unwilling to allow such claims. This leads to a scenario where a client may only be able to secure patent protection for a small number of the possible applications of the technology they developed. In some cases, this limited coverage may be enough to justify the filing or the continued pursuit of a patent application. In other cases, a client may abandon the patent application or forgo the filing of a patent application altogether.

4. Please explain how your experiences with the application of subject matter eligibility requirements in other jurisdictions, including China, Japan, Korea, and Europe, differ from your experiences in the United States.

The rules are more consistently applied in other countries and they are not filled with vague standards like “substantially more” or “significant part” which can be used an applied by Examiner’s with no guidance or standard for their application. The standard is really whatever the Examiner thinks the standard is. There is no required analysis for an Examiner to establish that something is or is not “substantially more.”

5. Please identify instances where you have been denied patent protection for an invention in the United States solely on the basis of patent subject matter ineligibility, but obtained protection for the same invention in a foreign jurisdiction, or vice versa. Please provide specific examples, such as the technology(ies) and jurisdiction(s) involved, and the reason the invention was held ineligible in the United States or other jurisdiction.

We have many examples where we were able to secure intellectual property protection for earlier patents only to be denied later patents under 101. One such example is US Patent No. 8,660,854 which we were able to secure for our client back in 2014. However, claims quite similar

in nature have been rejected as ineligible. The invention has been acknowledged during prosecution to be novel and inventive. The methods are directed to detection of disease outbreaks, and it was particularly galling that the USPTO rejected the claims solely on 101 during a pandemic. We appealed the rejection and showed the parallels between the claim and example 42 of the guidance:

Claim 13 of the Present Application	**Claim 1 of Example 42**
A method for providing rapid syndrome analysis comprising: receiving, using a set of instructions stored on a computer readable medium of a computer, syndromatic surveillance count data for a plurality of past time blocks within a plurality of moving baseline intervals from a plurality of computer devices over a network; calculating, using the set of instructions, for each moving baseline interval, a trimmed moving weighted means and sigma of the received syndromatic surveillance count data of the past time blocks within that moving baseline interval; receiving, using the set of instructions, syndromatic surveillance count data for a current time block from a plurality of computer devices over the network; calculating, using the set of instructions, a plurality of cumulative sums (CUSUMs) using (a) the received syndromatic surveillance count data for the plurality of past time blocks, (b) the calculated trimmed moving weighted means and sigmas, and (c) the received syndromatic surveillance count data for the current time block, wherein each of the CUSUMs are calculated using at least one of a different moving baseline interval or a different predetermined threshold value within a first set of threshold values stored on the computer readable medium; comparing, using the set of instructions, the calculated CUSUMs with a plurality of predetermined threshold values within a second set of threshold values stored on the computer readable medium; and when the comparison indicates that a magnitude of one or more of the calculated CUSUMs exceeds a magnitude of one or more of the predetermined threshold values within the second set of threshold values: generating, using the set of instructions, one or more flag signals; and sending, using the set of instructions, an indication of a seriousness or an unusualness of a disease outbreak to a computer device over the network based on the one or more generated flag signals.	A method comprising: a) storing information in a standardized format about a patient's condition in a plurality of network-based non-transitory storage devices having a collection of medical records stored thereon; b) providing remote access to users over a network so any one of the users can update the information about the patient's condition in the collection of medical records in real time through a graphical user interface, wherein the one of the users provides the updated information in a non-standardized format dependent on the hardware and software platform used by the one of the users; c) converting, by a content server, the non-standardized updated information into the standardized format, d) storing the standardized updated information about the patient's condition in the collection of medical records in the standardized format; e) automatically generating a message containing the updated information about the patient's condition by the content server whenever updated information has been stored; and f) transmitting the message to all of the users over the computer network in real time, so that each user has immediate access to up-to-date patient information.

The panel and USPTO is perfectly willing to deny patents on significant advances in technology because of a very dogmatic view of 'abstract ideas" and use of a very flawed rubric for what can actually be performed by the human mind and what is "substantially more" than the judicial exception. In the decision on appeal of the subject matter eligibility rejection of all the pending claims, the panel stated: "[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). And here, we agree with the Examiner that"[w]hile Appellant[']s algorithm *may be more accurate than the prior art,* it is an improvement to the abstract idea and not an improvement to a functioning of a computer or other technology." Ans. 4-5. "It has been clear since Alice that a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention 'significantly more' than that ineligible concept." *BSG Tech LLC v. BuySeasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018).

According to this logic, a substantial improvement in the speed and accuracy for detecting a disease outbreak is not eligible because it does not improve the operation of the processor that is receiving the data from which the outbreak determination is made. If the operation of a mechanical device is improved by a bearing, the bearing itself is certainly patentable. Why is an algorithm treated differently than any other component? If running an improved algorithm in a system that determines disease outbreaks results in an improved system to detecting disease outbreaks, how is that not patent eligible subject matter? The operation and performance of the system is improved by what is claimed, and the office conceded as much.

What we find is that, once the office has made an ineligibility determination, it jumps through as many hoops and makes as many logical leaps as it needs to in order to uphold that determination. There is no careful consideration of applicant's counter arguments, and no assistance offered in identifying "significantly more" than the judicial exception.

An example of an application that was determined to be ineligible in the United States yet broadly patentable elsewhere in the world is Patent Application Number 12/918,011, which was filed in February 19, 2008. Although that application was denied on eligibility grounds, counterpart patent applications granted in other countries with relative ease:

Type	Country	Status	Application Number	Filed Date	Patent Number

Utility - DIV	European Patent Office	Issued	15161700.8	Feb 19, 2008	2913404
Utility - DIV	Japan	Issued	2014-096250	May 7, 2014	5901689
Utility - EPPAT	Germany	Issued	60 2008 054 741.8	Feb 19, 2008	2913404
Utility - EPPAT	Spain	Issued	15161700.8	Feb 19, 2008	2913404
Utility - EPPAT	France	Issued	15161700.8	Feb 19, 2008	2913404
Utility - EPPAT	United Kingdom	Issued	15161700.8	Feb 19, 2008	2913404
Utility - EPPAT	Italy	Issued	15161700.8	Feb 19, 2008	2913404
Utility - NSPCT	Canada	Issued	2,715,566	Feb 19, 2008	2715566
Utility - NSPCT	India	Issued	3138/KOLNP/2010	Feb 19, 2008	331258
Utility - ORG	China	Issued	200880128140.X	Feb 19, 2008	ZL0880128140.X
Utility - ORG	Germany	Issued	08779567.0	Feb 19, 2008	EP2250281
Utility - ORG	European Patent Office	Lapsed	08779567.0	Feb 19, 2008	EP2250281
Utility - ORG	Spain	Issued	08779567.0	Feb 19, 2008	EP2250281
Utility - ORG	France	Issued	08779567.0	Feb 19, 2008	EP2250281
Utility - ORG	United Kingdom	Issued	08779567.0	Feb 19, 2008	EP2250281
Utility - ORG	Italy	Issued	08779567.0	Feb 19, 2008	EP2250281
Utility - ORG	Mexico	Issued	MX/a/2010-009028	Aug 17, 2010	336963

The Office has empowered the Examiner and the PTAB to be disdainful of improvements that the Office has identified as "ineligible subject matter." In the decision on appeal, note that the PTAB is dismissive of all of the advantages that the applicant noted regarding its discovery and why it was "substantially more" than the judicial exception.

> As to part two of the test, the remaining elements are directed to equipment and steps that are well known in the art. This is best demonstrated by Appellant's own statement that by "using the novel systems, methods, and apparatus of the present invention, an

incubating system, such as the BACTEC® blood culture system, can be programmed to determine the microorganism type in a culture before manual tests, such as a Gram stain or a subculture, are performed." Spec. 2 (emphasis added). Thus, the present invention involves programming for known blood culture systems. The presence of a generic blood culture system, including all of its elements, is not unlike using a generic computer to implement software and does not constitute something significantly more than the judicial exception. See, Alice, 134 S.Ct. at 2357.

Appellant contends that the claims recite an improvement to a technical filed [sic], specifically determination of a microorganism type. Appeal Br. 17-18, Reply Br. 7-8. We are unpersuaded [sic]. As the Examiner points out, there is no evidence of record that shown [sic] that the claimed method offers an improvement over the prior art. Ans. 4.

In support of his argument, Appellant argues that the present method "may 'obviate any need to perform a Gram test or subculture in order to identify the microorganism type that is infecting the culture.'" Appeal Br. 18, Reply Br. 7. We find this unpersuasive. As stated in the background of the invention, "A drawback with [prior art] microorganism detection approaches is that they do not always detect microorganism type in such cultures." Spec. 2. This does not appear to be any different from the claimed system which may avoid the need for further procedures.

Moreover, all inventions can be said to be an improvement over what was known before. However, not every improvement constitutes patentable subject matter. See, Intellectual Ventures I LLC v. Capital One Bank (USA), 792 F.3d 1363, 1367 (Fed. Cir. 2015) (claims to improved speed of efficiency did not render claims patentable).

Appellant next argues that the invention includes unconventional steps that confine the claim to a particular useful application. Appeal Br. 19. Appellant point to the fact that the claims are directed to more than just mathematical concepts but are tied to "a vessel with a culture disposed therein to automatically determine the type of microorganism in the culture." Id.

We find this argument unpersuasive. As noted above, lack of preemption alone does not support a finding that the claims are directed to patent eligible subject matter. In addition, the use of a vessel to grow the microorganism as well as acquiring data as the microorganism grows, are conventional steps. Only the application of various mathematical concepts to that data is different.

Appellant argues that the "invention does not simply append well-understood, routine and conventional activities known to the industry, specified at a high level of generality to a judicial exception." (emphasis and title caps omitted) Appeal Br. 20. We remain unpersuaded. The instant invention is one that can be accomplished by programming the recited mathematical concepts or steps into an existing blood culture machine. Spec.

> 2, Appeal Br. 18, Reply Br. 6. Thus the invention appears to be nothing more than using an existing blood culture machine to obtain data about the culture and then using various mathematical concepts to manipulate the data. This is an application of a judicial exception to a well-known and conventional activity.
>
> Finally, Appellant argues that the present claims are similar to those in SiRF where our reviewing court found the claims to be patentable. Appeal Br. 22. Appellant contends that like the system in SiRF, the claimed method requires the use of specific components, namely a sensor that gathers information about the conditions in the culture vessel over time or a culture vessel. Appeal Br. 22-23.
>
> We have considered Appellant's argument and are unpersuaded. As our reviewing court noted in SiRF, "[i]n order for the addition of a machine to impose a meaningful limit of the scope of a claim, it must play a significant part in permitting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more quickly." SiRF, 601 F.3d at 1333. In SiRF, a GPS receiver was found to be essential to performing the claimed method. Id at 1332. In the present case, as the Examiner has found, the claimed sensor and culture vessel are not essential to the performance of the claimed mathematical calculations. Ans. 7.

So, it is not enough for the applicant to identify an improvement; it is not enough for the applicant to limit the scope of the invention to the context in which the improvement is achieved and the improvement cannot be just any improvement, it must play a "significant part" in performing the method. If the invention affords an improvement of any sort, how is this not significant. On what objective basis does the Office quantify "significant?" to determine whether the improvement is "enough" to overcome the eligibility hurdle? The Office has lost the ability to consistently address the issue of eligibility with applicants.

6. Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to modify or shift investment, research and development activities, or jobs from the United States to other jurisdictions, or to the United States from other jurisdictions. If so, please identify the relevant modifications and their associated impacts.

We counsel holding inventions as trade secrets if we think there will be significant eligibility challenges. What is the point of broadcasting what you are doing if all you are doing is giving your competitor's a roadmap to your technology in exchange for nothing. The Office should

be more deferential on the eligibility question if what is claimed offers a real improvement in the art.

Respectfully submitted,

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