

Patent Webinar Series

**Successful Patent Strategies for
Digital Health & Digital Therapeutics**

October 27, 2021

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Meet The Speakers



Christina McDonough
Principal



Patrick Darno
Associate

Overview

- **Topics**
 - Overview of digital health and digital therapeutic innovations.
 - Discussion of the eligibility of digital health and digital therapeutic innovations for patent protection.
 - Discussion of patent strategies for patenting digital health and digital therapeutic innovations.
- **Housekeeping**
 - CLE
 - Questions
 - Materials
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+ Complimentary CLE Webinar

Open Source Software and Patents:
Reconciling the Conflict

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DATE
Wednesday,
November 3, 2021

TIME
1:30 - 2:30 PM ET/
10:30 - 11:30 AM PT

**Webinar | Open Source Software and Patents:
Reconciling the Conflict**

Open source software (OSS) has become an integral part of the software development industry. Leveraging the combined skills of an open source developer community often leads to improved time-to-market and lower costs for both development and support. However, OSS communities have adopted a wide range of licenses and patent policies, some of which can conflict with business objectives. In addition, innovators often view open development and patenting as incompatible, which can create challenges for companies attempting to create strategic patent portfolios.

Complimentary Webinar
Wednesday, November 3, 2021
1:30 - 2:30 PM ET

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What are Digital Health and Digital Therapeutic Innovations?

Digital Health Innovations

▪ Digital Health Innovations

- Computer software and/or hardware innovations that process “medical information” related to an entity (e.g., a person or animal)
 - E.g., analysis of medical records, outcomes data, biomarkers, etc.
- Exemplary implementation:
 - E.g., a machine-learning model trained to predict “X” based on processing of “medical information”
 - Not only limited to software – e.g., FPGAs or ASICs configured to perform a series of operations on “medical information”
 - Example system:



Digital Therapeutic Innovations

- **Digital Therapeutic Innovations**

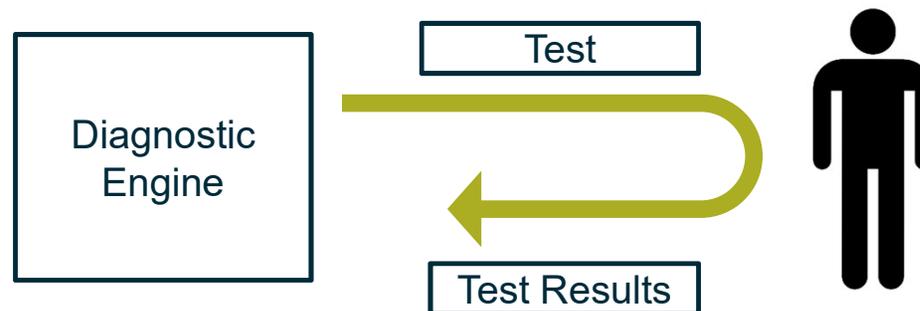
- Computer software and/or hardware innovations that provide therapeutic content to an entity (e.g., person or animal) that is configured to treat a symptom of the entity
 - Therapeutic content can include, e.g., textual content, audio content, video content, haptic feedback, or a combination thereof
- Exemplary implementation:
 - E.g., a treatment engine that selects therapeutic content and outputs the therapeutic content for consumption by an entity
 - Like the previous example, such implementations are not limited to software implementations
 - **Example system:**



Digital Health Diagnostic Innovations

- **Digital Health Diagnostic Innovations**

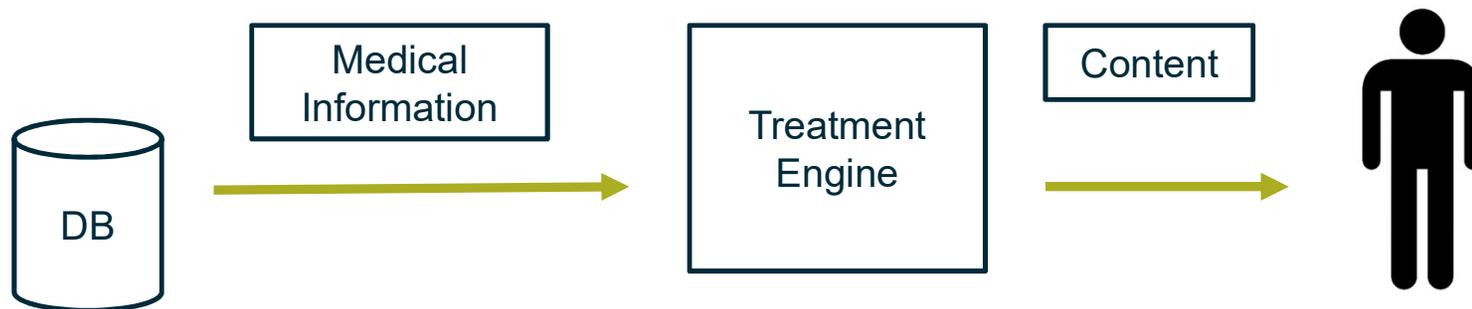
- Computer software and/or hardware innovations that measure an attribute of an entity (e.g., a person or animal)
 - E.g., measuring a biological attribute of an entity or measuring a change of a biological attribute of an entity
- Exemplary implementation:
 - E.g., a system that measures a biological attribute of a user responsive to an administered test or treatment
 - Like the previous innovations, these innovations are not limited to software innovations
 - Diagnostic engine may be embodied in a wearable device(s)
 - **Example system:**



Hybrids?

- **Hybrid Systems**

- Certain innovations may be hybrid systems – i.e., a system that includes digital health innovations and digital therapeutic innovations
 - E.g., such systems may process “medical information” and generate or select therapeutic content based on the processing of “medical information”
- Example System:



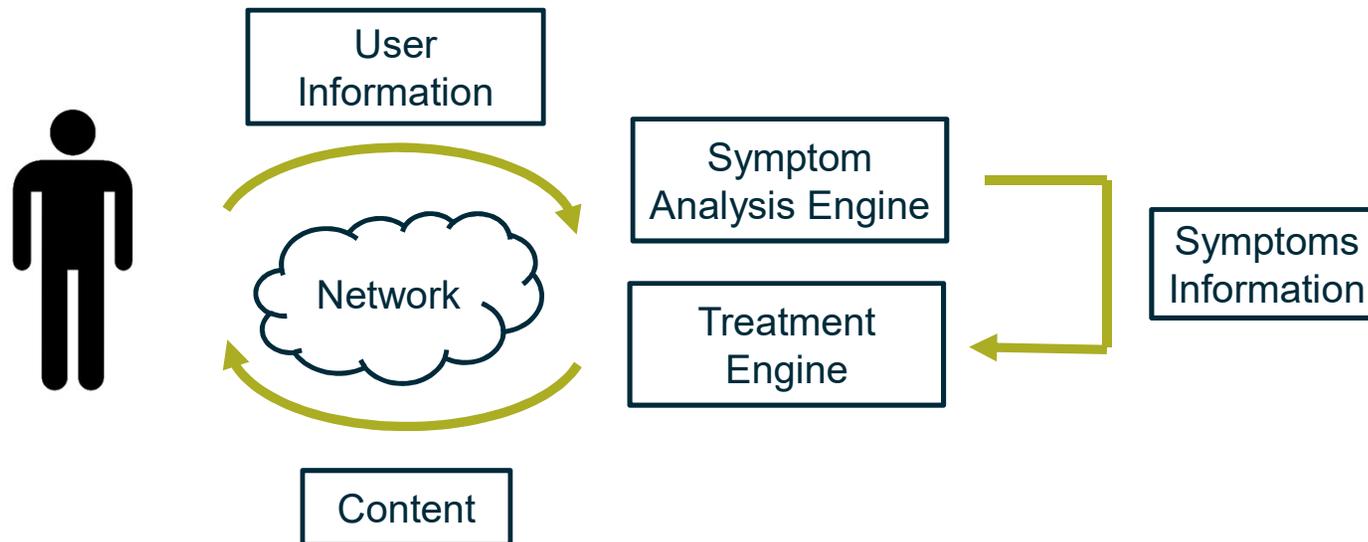
Other Natural Evolutions of The Technology?

- **Symptom Detection and Analysis**

- A hybrid system that (i) uses a diagnostic test to detect “medical information” including one or more entity attributes (e.g., user symptoms) and then (ii) determines a treatment for the user based on the user symptoms, determines a modification to a treatment for the user based on the user symptoms, or any combination thereof

- E.g., can infer symptoms based on user interaction with user device

- Example System



Are Such Evolutionary Systems Science Fiction?

- A review of recent headlines suggests such systems are science fact.



Your Phone Knows You're Depressed— Here's What to Do About It

By Gina Ng | October 6th, 2021

New wearable tech is being designed to detect depression with more than twice the accuracy of your average human psychiatrist — and prompt users to make lifestyle changes that boost their mental health.

- See: <https://www.beingpatient.com/smartphone-depression-tech/> (October 6, 2021)

Apple Is Working on iPhone Features to Help Detect Depression, Cognitive Decline

Company is working with UCLA, Biogen to see if sensitive data like facial expressions, typing metrics could signal mental-health concerns

- See: <https://www.wsj.com/articles/apple-wants-iphones-to-help-detect-depression-cognitive-decline-sources-say-11632216601> (September 21, 2021)

Could your smartphone hold clues for diagnosing and treating Depression?

By Niel Smith - September 30, 2021

- See: <https://www.myhealthyapple.com/could-your-smartphone-hold-clues-for-diagnosing-and-treating-depression/> (September 30, 2021)

Strategic Planning

- Consider current **and** future business needs
 - E.g.,
 - **Does your company currently have a digital health and/or digital therapeutic unit?**
 - If yes, are you taking steps to protect intellectual property rights in your innovations in this space?
 - If no, should your company start a digital health and/or digital therapeutic unit?
 - **Thinking about today is important – but also think about where this technology is headed in the next 5, 10, 15, and 20 years?**
 - Do not sacrifice the future by **only** focusing on today
 - There is no requirement for an invention to be reduced to practice in order to file a patent application
 - Accordingly, perform creative exercises such as identifying innovations that could be achieved assuming an unlimited team and unlimited budget – and then file one or more prophetic patent applications covering those innovations
 - **Work with a team that develops creative approaches to patent application preparation that give you the best opportunity for success**

Strategic Considerations – A Two Tiered Approach

- The ***first tier*** of a strategic approach is to look ***inwards*** at your company's innovations
- **Identify early streams of products and services from which:**
 - Your company derives revenue
 - Your company plans to derive revenue from in the future
- **Prepare and file at least one patent application for new and useful of each of the identified streams of products and services**
 - Maintain correct mix of trade secret and paten protection
- **Patent strategy should not only focus on what can currently be done by your company**
 - Think about improvements to current products and services
 - Think about new products and services that can launch in the future
- **Monitor public disclosures**
 - Evaluate the subject matter of planned disclosures for new and useful “blocking features” and file accordingly
 - Employ strategic uses of NDAs as appropriate

Strategic Considerations – *A Two Tiered Approach*

- The second tier of a strategic approach is to look outwards in an attempt to patent a competitive differential
- **Gather competitor intelligence related to your competitor's products**
 - Determine key features of your competitor's current products and/or services
 - Determine natural evolutions to your competitor's current products and/or services
 - Determine improvements that can be made to your competitor's products and/or services
- **File patent applications for “blocking features” related to features of your competitor's products and/or services in any one of the above categories to build an economic moat**
- Example: Determine what your competitors would need to do to take your business (Comp. Diff., then patent that)

Strategic Considerations – *When To File?*

- **It is generally recommended to file a patent application for key innovations as soon as possible**
- **No requirement to reduce the invention to practice**
 - Filing can proceed when the invention can be described in a manner that enables one of skill in the art to make and use the invention
 - For digital therapeutic inventions:
 - There is no requirement at the patent office for FDA approval of the method
 - There is no requirement at the patent office that a digital therapeutic has to satisfactorily perform in one or more clinical trials
- **There are drawbacks to expedited filing**
 - Subsequent clinical trials may show that a digital therapeutic does not work
 - The FDA may not approve a digital therapeutic treatment that has been patented
- **Be cautious of disclosing a digital therapeutic treatment prior to filing**
 - Processes for seeking FDA approval or participating in a clinical trial may require disclosure, which could lead to the loss of patent rights if no prior filing

Strategic Considerations – *Software or Therapeutic?*

- **Certain digital health applications will inherently focus on the software aspects**
 - E.g., a machine learning model trained to predict an outcome based on processing “medical information”
- **For others, such as digital therapeutic applications, a determination as to whether to focus on the software or therapeutic aspect may not be so clear**
- **What is the *focus* of the application?**
 - E.g., whether the application is described using **predominantly computer software terminology / figures** and is classified in a computer science classification (e.g., class 707: database, data structure, file management) **vs.** using **predominantly therapeutic terminology** and is classified in a therapeutic classification (e.g., class 607 surgery: light, thermal, and electrical application)
- **Focus of application can dictate battles to be fought during prosecution**
 - Claims with either *focus* are likely to encounter *Alice* rejections under § 101
 - However, the focus of the application will dictate the background of the examiner for the application
 - a software focus will likely result in greater scrutiny under § 101 and less scrutiny under § 112
 - a therapeutic focus will likely result in greater scrutiny under § 112 and less scrutiny under § 101

Strategic Considerations – *Software or Therapeutic?*

- **Ultimately, the *focus* should be decided on a case-by-case basis**
 - This includes weighing technology considerations and strategic considerations
- **Technology Considerations**
 - Where is the novelty of the digital therapeutic invention?
 - **Is it found in the selection and/or generation of the therapeutic content?**
 - If yes, then a software focus may be best suited for the application
 - **Is it found in the effect that generated content has been discovered to have on an entity when consumed by the entity according to a particular dosing regimen?**
 - If yes, then a therapeutic focus may be best suited for the application
- **Strategic Considerations**
 - Do you want greater scrutiny of § 101 or §112 during prosecution?
 - Are certain examiners (e.g., in a therapeutic class) more familiar with certain §101 strategies (e.g., “method of treatment” claims)
 - Is there data (e.g., clinical data) to support effectiveness of a digital therapeutic?



Are Digital Health and Digital Therapeutic innovations eligible for patent protection?

The *Alice* Question ...

- **General Requirements To Obtain A U.S. Patent**

- Eligible for patenting
- Novel
- Non-obvious

- **Eligibility is typically the most difficult hurdle to overcome for digital medicine and digital therapeutic innovations**



- Software and/or Hardware innovations in this technology space likely to receive *Alice* rejection under 35 U.S.C. 101

- **This challenge can be met in one of two ways:**

- The easy approach: *Alice* proposes too high of a barrier of entry so we should not pursue digital health / digital therapeutic / digital diagnostic patents for our innovations – let's forego patenting
- The hard approach: Digital health / digital therapeutic /digital diagnostic patents covering our innovations can be valuable to the future of our company. Let's think creatively as to how strong patents can be obtained for these innovations – and work with a creative team to achieve that goal

Tackling *Alice* (and related precedent)

- **First – accept reality**
 - Software and/or Hardware innovations in this technology space are likely to receive *Alice* rejection under 35 U.S.C. 101
- **Second – have a plan**
 - *Alice* does not have to be viewed as death blow to patents in any software space – much less the digital health / digital therapeutic / digital diagnostic space
 - Instead, *Alice* (and related precedent) should be viewed as a road map providing guidance on how to prepare a patent application to evolve into a strong patent
 - This road map should be employed from start (e.g., technology mining sessions) to finish (e.g., receipt of a notice of allowance)
 - **Thinking critically and planning adequately to address *Alice* issues at the onset of the patent application process (e.g., technology mining sessions and invention disclosure calls) will provide you with the best chance of success**

Tackling *Alice* (and related precedent)

- **What is the law and what does *Alice* say?**
 - The law is that “whoever invents or discovers ***any*** new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore...” (35 U.S.C. 101, emphasis added)
 - *Alice* says that certain processes, machines, manufactures, compositions of matter, or improvements thereof are ***not*** patentable if they are directed towards a judicial exception to eligible subject matter (i.e., an abstract idea, natural phenomena, or law of nature)....
 - ***UNLESS***: the claimed judicial exception provides a technological solution that is something significantly more than the alleged abstract idea
- **Key rebuttals to *Alice* rejections include pointing out that the claimed subject matter:**
 - (1) Is not directed to a judicial exception to patent eligible subject matter (e.g., abstract idea, law of nature or physical phenomena); or
 - (2) Provides a technological solution that is something significantly more than an alleged abstract idea

Tackling *Alice* (and related precedent)

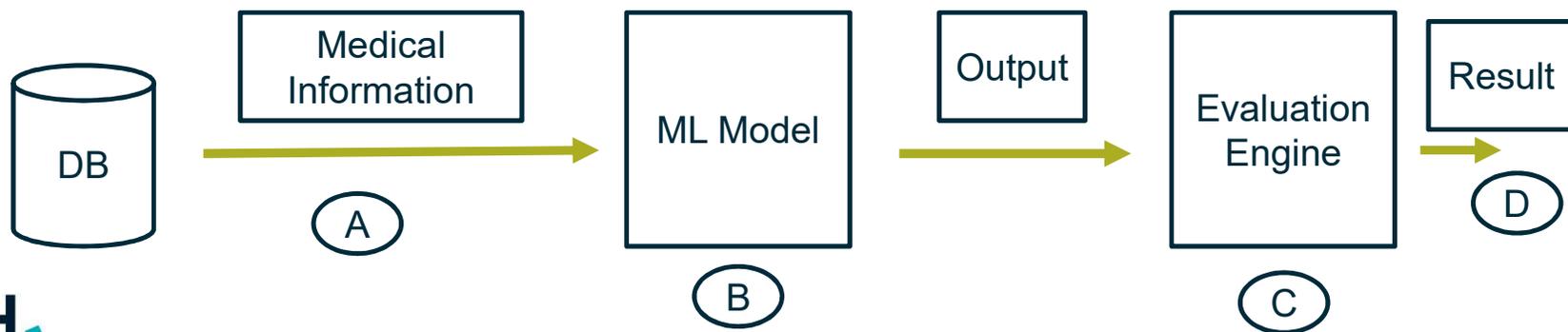
- **The Outliers – *Digital Therapeutics and Digital Diagnostics***
 - These types of innovations can provide for narrowly tailored approaches to rebut an *Alice* rejection
 - “Method of Treatment” Claims
 - Uniquely suited for *Digital Therapeutic* innovations
 - Have been found to be patent-eligible subject matter in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited*, 887 F.3d 1117 (2018)
 - The Question:
 - » Is content consumed by an entity a therapeutic treatment?
 - “Unconventional diagnostic method”
 - A helpful strategy suited for *Digital Diagnostic* claims
 - Has been found to be patent-eligible subject matter in *Exergen Corp. v. Kaz USA, INC.*, 725 Fed. Appx. 959
 - See also *McRO, Inc. v Bandai Namco Games America, Inc.*, 837 F.3d 1299
 - » E.g., using a computer to perform a task in a different manner than conventionally performed by a human



Examples Of Claim Strategies For Digital Health and Digital Therapeutics Innovations

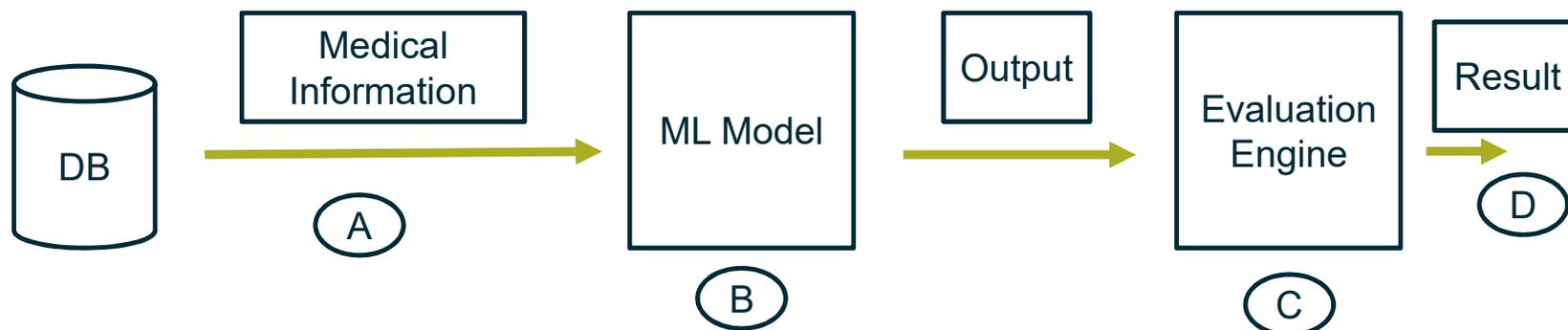
Effective Alice Strategies – Digital Health Innovations

- **Most likely rejection:**
 - Claimed subject matter is directed to an abstract idea without significantly more
- **Rebuttal Strategy #1**
 - Assert claim is not directed to an abstract idea
 - E.g., because one or more claim features cannot be performed in the human mind
- **Practice Tips**
 - Identify key targeted portions of a system that can be claimed in a manner that is not *abstract*
 - **E.g.**, see (A), (B), (C), and (D) below
 - Draft a claim feature on (A), (B), (C), and/or (D) describing actions that cannot be performed in human mind



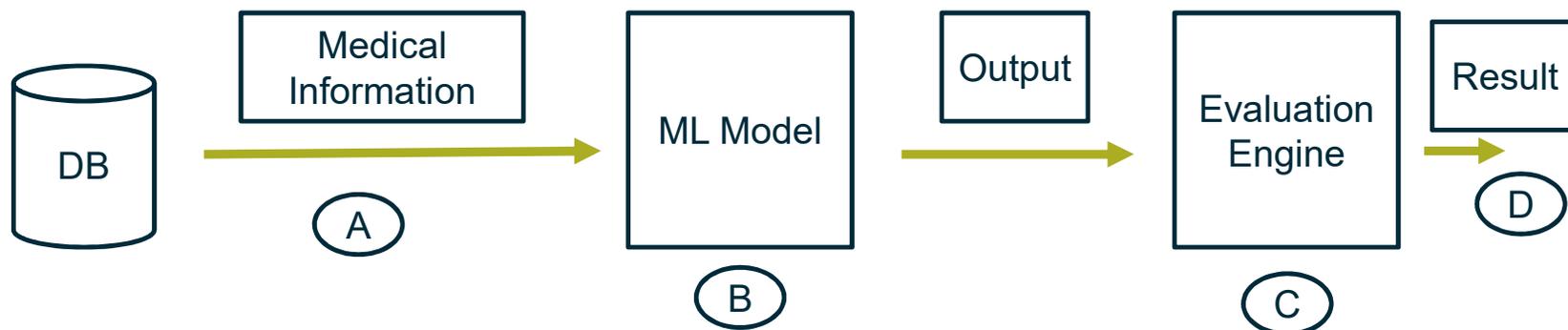
Effective Alice Strategies – Digital Health Innovations

Targeted Feature	Bad	Good
(A) Generating input data	“generating, based on obtained medical information, data for input to a machine learning model”	“generating, based on obtained medical information, a data structure that is formatted to be processed through one or more layers of a machine learning model, the data structure having one or more fields structuring data that includes X, Y, and/or Z...”



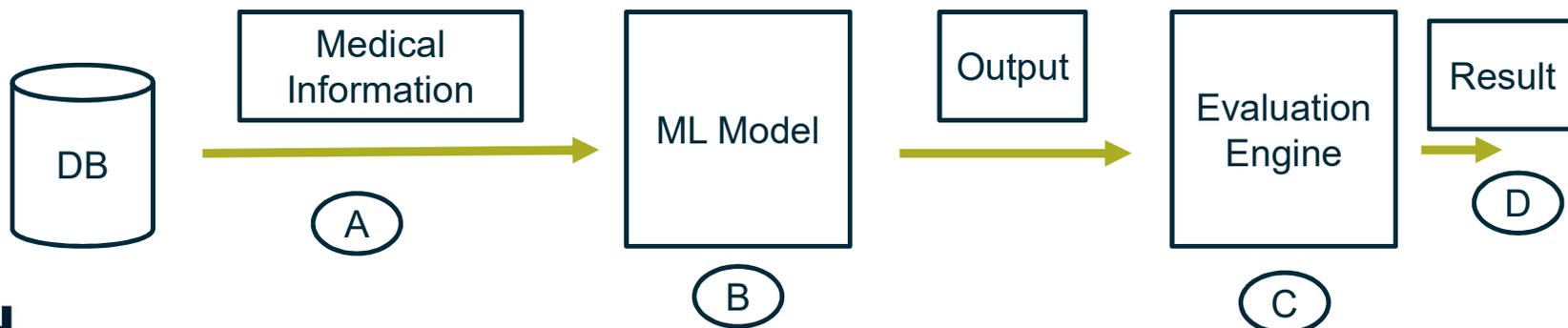
Effective Alice Strategies – Digital Health Innovations

Targeted Feature	Bad	Good
(B) Machine Learning Model	“providing the generated input data as an input to a machine learning model”	“processing, by one or more computers, data that includes a data structure having one or more fields structuring data that includes X, Y, and Z through each of a plurality of layers of a machine learning model that has been trained to predict a likelihood of a particular patient characteristic “



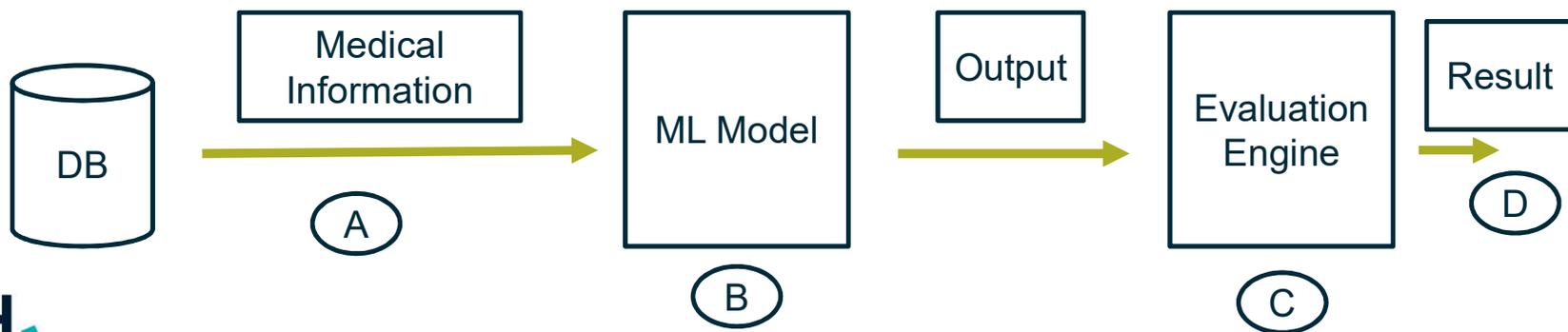
Effective Alice Strategies – Digital Health Innovations

Targeted Feature	Bad	Good
(C) Evaluation Engine	“determining whether the output data satisfies one or more thresholds”	“processing, by one or more computers, an output data structure generated by an output layer of the machine learning model to determine whether data organized by one or more fields of the output data structure satisfies one or more predetermined thresholds, wherein the output data structure includes fields structuring data indicating a likelihood that a particular patient has a particular characteristic”



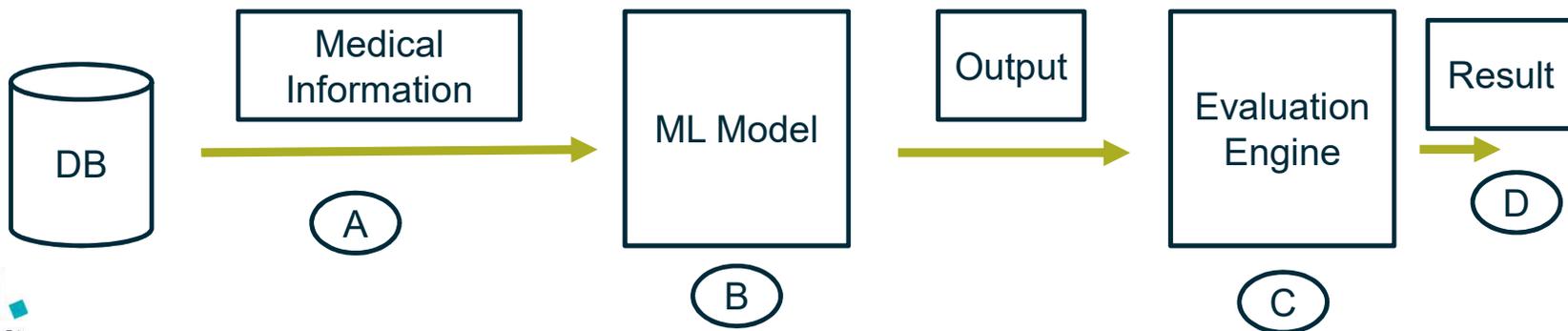
Effective Alice Strategies – Digital Health Innovations

Targeted Feature	Bad	Good
(D) Providing Result data	“generating result data based on the output of the evaluation engine; and providing the generated result data to a user device”	“generating, by one or more computers, result data based on data generated by the evaluation engine, wherein the generated result data includes rendering data that, when rendered, causes a user device to display X, Y, or Z; and providing, by one or more computers, the generated result data to a user device using one or more networks, wherein the provided result data, when rendered by the user device, causes the user device to display X, Y, or Z.”



Effective Alice Strategies – Digital Health Innovations

- Rebuttal Strategy #2
 - Assert that one or more claim features provides a technological improvement that provides something significantly more than an abstract idea.
 - Bigger, faster, stronger
 - Requires a case-by-case approach
 - Practice Tips
 - Identify key targeted portions of a system that provide a technological benefit.
 - E.g., see (A), (B), (C), and (D) below
 - For each feature, include a description in the specification that explains the technological benefit of that claim feature at the time of filing.
 - If possible, include experimental data that shows evidence of the technological benefit.



Effective Alice Strategies – Digital Therapeutics

- **Digital therapeutic innovations will likely encounter similar *Alice* rejections**
 - E.g., office action asserting that claims are directed to an abstract idea and do not provide something significantly more than the alleged abstract idea
 - In such instances, the same rebuttal strategies we previously discussed can also be applied to digital therapeutic claims:
 - **(1) draft claim features describing actions that cannot be performed in the human mind**
 - **(2) argue that the claimed subject matter provides a technological improvement**
 - Additional reasoning:
 - » E.g., the administered treatment reduces one or more symptoms of a patient
- **In addition, the unique nature of digital therapeutic innovations provides another strategy for satisfying the patent eligibility requirement**
 - Method of Treatment Claims
 - See *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited*, **887 F.3d 1117 (2018)**.

Effective Alice Strategies – Digital Therapeutics

- **Example – Method of Treatment Claim**
- A method for treating a sleep disorder comprising:
 - obtaining content for treating a sleep disorder [description of the content]; and
 - treating, using the one or more computers, the entity using the obtained content, wherein treatment comprises rendering, by the one or more computers, the content on the graphical user interface, when the entity is viewing the graphical user interface, according to a predetermined dosing schedule.
- **Points of novelty and/or non-obviousness can potentially include:**
 - Types of visualizations, spatial relationships between visualizations and/or accompanying audio outputs, temporal relationships between the visualizations and/or audio outputs, dosing schedule, or any combination thereof
 - The dosing schedule
 - The argument for novelty / non-obviousness can be bolstered by evidence of content causing symptom reduction

Effective Alice Strategies – Digital Health Diagnostics

- **This technology class is likely to be more difficult to patent than the other technology classes described today**
 - But not impossible
- **Digital health diagnostic innovations need to be evaluated on a case-by-case basis**
- **Practice Tip:**
 - Evaluate digital health diagnostic innovations to determine whether they require performance of an “unconventional diagnostic method”
 - **E.g., detecting body temperature by moving a radiation detector over a temporal artery three times (See *Exergen*)**
 - **E.g., does a computer perform the diagnostic method differently than a human would perform the diagnostic method (See *McRO*)**
 - Also, claim the diagnostic method using detailed language that can only be performed by a computer and not within the mind of a human



Questions?



Christina McDonough
Principal
mcdonough@fr.com



Patrick Darno
Associate
darno@fr.com

Thank You!

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Any questions about the webinar, contact Makayla Mainini at mainini@fr.com

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