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November 4, 2019

VIA FEDEX

Laura A Peter
Deputy Under Secretary of Commerce for
Intellectual Property and
Deputy Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
Madison Building
600 Dulany Street
Alexandria, Virginia 22314

Re: Artificial Intelligence Issues

Dear Director Peter:

I recently organized a meeting at Massachusetts Institute of Technology's McGovern Institute for Brain Research in which I presented on patent issues relating to inventions derived from artificial intelligence and on trademark issues relating to artificial intelligence. I have enclosed the draft slide deck from my presentation as I understand that your office is now considering many of the issues that I raised.

I hope you will find these materials helpful and would welcome the opportunity to discuss this topic with you if you believe that would be of some assistance in your consideration of these issues.

Very truly yours,

Joseph R. Robinson
Registration Number 33,448

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McGOVERN INSTITUTE
FOR BRAIN RESEARCH AT MIT

Artificial Intelligence Is Driving Life Science Law

October 29, 2019

AI Issues in Intellectual Property

Joseph R. Robinson, Esq.

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Corpus Diem

Those of us in the field must proactively determine our destiny

Do NOT leave it to our legislators

340,000 AI patent applications have been filed since the 1950s – more than 50 percent since 2013 (WIPO Technology Trends 2019 – Artificial Intelligence Report)

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Too many have called AI a disruption of intellectual property law.

BUT

"A pessimist sees the difficulty in every opportunity;
an optimist sees the opportunity in every difficulty."
Winston Churchill

"The most reliable way to predict the future is to create it."
Abraham Lincoln

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Two Types of AI Inventions

- The AI itself
- Inventions "derived" from the AI
- Life science companies have both

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Several Pressing Issues

- **Are inventions or works made by AI protectable IP?**
  - Patent
  - Copyright
  - Trade Secret
- **Who owns the property rights?**
  - Inventorship
  - Conception
  - Reduction to Practice
- **How does the company assure ownership of AI invented IP?**
  - Additions to employment and consulting agreements
- **How can AI change patent preparation and examination?**
  - Examples
  - Declarations (Inventor, Rule 131, Rule 132)
  - Duty of Disclosure
  - Objective Indicia of Non-Obviousness
  - Prior Art Searching
  - Rejections – Who Is the Person of Ordinary Skill in the Art
  - Interviews
- **How can the company enforce AI invented IP or protect against charges of infringement?**

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Are inventions/works made by AI protectable subject matter? YES!

- Patent – Inventions
  - AI generated inventions are patentable subject matter
  - In life science, we can talk about the output of algorithms, not necessarily the algorithms - compounds, compositions, methods of treatment, methods of synthesis (35 U.S.C. 101)
  - The term "invention" means invention or discovery (35 U.S.C. 100)
  - The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material (35 U.S.C. 100)

- Copyright – Software and databases
  - The US Copyright Office employs a "human authorship requirement."
  - Databases may be copyrightable subject matter.
    - A collection of data that is selected or arranged in a unique way may constitute a compilation and may be protected under the United States Copyright Act (17 U.S.C. § 101)
  - Computer programs are copyrightable subject matter as literary works (17 U.S.C. 102(a)(1))
    - "Computer program" - set of statements or instructions to be used in a computer in order to bring about a certain result (17 U.S.C. 101)
    - "Literary works" - works, other than audiovisuals, expressed in words, numbers, or other verbal or numerical symbols or indicia, such as books, periodicals, manuscripts, phonorecords, film, tapes, disks, or cards, in which they are embodied (17 U.S.C. 101)

- Trade Secret – Perhaps the best way to protect the underlying AI
  - All states have adopted the *Uniform Trade Secrets Act (UTSA)* (except NY)
  - *Economic Espionage Act (EEA) of 1996* (18 U.S.C. 1831–183)
  - *Defend Trade Secrets Act of 2016 (DTSA)* (18 U.S.C. 1836 *et seq.*)

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Who owns the property rights?

- Patent Ownership
  - Patents shall have the attributes of personal property (35 U.S.C. 261)
  - The inventor is assumed to be the original owner of a patent.
  - **But who is the inventor of an invention made by AI?**
    - Machine, programmer, data provider, problem provider?
  - **Can a machine assign?**
- Inventorship
  - "Inventor" means the individual or, if a joint invention, the individuals collectively, who invented or discovered the subject matter of the invention. 35 U.S.C. 100(f).
  - *"Making the invention requires conception and reduction to practice." Solvay S.A. v. Honeywell International, 742 F.3d 988, 1000 (Fed. Cir. 2014).*
  - Because the invention process is largely a mental process, we have never really understood it anyway.
  - **Can a machine be an inventor under the patent statute?**
- Conception
  - *"While conception is the formation, in the mind of the **inventor**, of a definite and permanent idea of a complete and operative invention, reduction to practice requires that the claimed invention work for its intended purpose." Solvay S.A. v. Honeywell International, 742 F.3d 998, 1000 (2014).*
  - This refers to an inventor which currently means an individual.
  - **Can a machine conceive of an invention?**
- Reduction to Practice
  - There are currently two types of reduction to practice – *actual* and *constructive.* Contributors to only a reduction to practice are not inventors.
  - **Do we need a new machine reduction to practice?**
- The Declaration and Oath
  - Each individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application (35 U.S.C. 115)
  - **Who will execute the declaration?**

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How can a company assure its ownership of an invention made by AI?

- Patents
  - Applications for patents, applications, or any interest therein, are assignable in writing (35 U.S.C. 261)
  - Addition to assignment and employment agreements - obligation to assign all inventions derived or invented by AI that the employee or consultant created, invented, or used or for which the employee or consultant furnished information, data, or direction.
- Copyrights
  - Copyright ownership may be transferred by conveyance, operation of law, will, or intestate succession (17 U.S.C. 201(d)(1))
  - Copyright vests initially in the author or authors of the work (17 U.SC. 201(a))
  - Works Made for Hire — Employer or other person for whom the work was prepared is considered the author, and, unless the parties expressly agree otherwise in writing, owns all of the rights in the copyright (17 U.S.C. 201(b))
  - Contributions to Collective Works — Copyright in each separate contribution to a collective work is distinct from copyright in the collective work as a whole, and vests initially in the author of the contribution. I n the absence of an express transfer of the copyright, the owner of copyright in the collective work is presumed to have acquired only the privilege of reproducing and distributing the contribution as part of that particular collective work, any revision of that collective work, and any later collective work in the same series (17 U.S.C. 201(c))
    - "Compilation" - work formed by collection and assembling of preexisting materials or of data selected, coordinated, or arranged so the resulting work as a whole constitutes an original work of authorship. The term "compilation" includes collective works.
    - "Work made for hire" (1) work prepared by an employee within the scope of his or her employment; or (2) a work specially ordered or commissioned for use as a contribution to a collective work ..., if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire.
  - Addition to assignment and employment agreements - obligation to assign all inventions derived or invented by AI that the employee or consultant created, invented, or used or for which the employee or consultant furnished information, data, or direction.
- Trade Secrets
  - There are no statutes governing initial ownership of a trade secret.

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How can AI change patent preparation and examination?

- AI generated examples - working or prophetic?
  - **Are AI generated examples enabling?**
    - Enablement - Lack of a working example is a factor in unpredictable and undeveloped arts (MPEP 2164.02)
    - Correlation will be the key. For example, an *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a "working example" if that example "correlates" with a disclosed or claimed method invention. (MPEP 2164.02(II))
  - **Is an AI generated genus enabled?**
    - "Predictability or lack thereof" will be the key. The ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention.
- Declarations (Inventor, Rule 131, Rule 132)
  - **Who is the inventor?**
    - The inventors must execute a declaration or oath
- Duty of Disclosure (Rule 56)
  - **Will a machine owe a duty of disclosure?**
  - **Does the machine know all of the published literature?**
  - **Can a machine or a person working the machine maintain a conscious ignorance of prior art?**
  - **Should Rule 56 be eliminated?**

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How can AI change patent preparation and examination?

- Objective Indicia of Non-Obviousness
  - **How do we deal with AI generated surprising and unexpected results?**
  - **How do we deal with AI generated comparative data?**
- Prior Art Searching
  - **Will advanced machine searching can give better examination or simply find everything anticipated or obvious?**
- Rejections – Who Is the Person of Ordinary Skill in the Art?
  - **Can AI be the POSA?**
  - **How does one determine the skill level of different AI programs?**
- Interviews
  - **Who gets interviewed if AI does the examination?**

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How can the company enforce AI invented IP or protect against charges of infringement?

- AI developers should teach their software to respect the rights of third parties.
- Presently, an AI system lacks legal personality – it cannot be sued under patent or copyright laws
  - **Do we need to create a new AI "person"?**
- Some AI systems store information in a form that cannot be read by humans or reverse engineered – it can be impossible to discover why a system made a particular decision or produced a particular output.
  - **How can we determine intent or willfulness?**
  - **Do we need strict liability IP laws for AI?**
- All agreements with consultants and vendors should include strong indemnification clauses against infringement of 3d party IP
- The company must know from where the data AI uses came
- The company must step up cybersecurity – a new, higher standard of care
  - **Should this be the subject of legislation?**

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Trademark Law Must Adapt to AI

- Current trademark law is human-centric
  - Visual similarity
  - Likelihood of confusion
  - Typical consumer
  - Accommodates characteristics/faults of humans
    - Reasonably well-informed
    - Circumspect
    - Observant
    - Imperfect recollection
    - Varying level of attention

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Trademark Law Must Adapt to AI
Up to 85% of customer interactions will be impacted by AI by 2020

- Trademark law must also become machine-centric to remain relevant
  - Will AI consider a mark at all when making a purchasing decision?
  - Can AI be confused at all?
  - AI's recollection can be perfect, not imperfect.
  - Who is the average consumer – AI or human?
    - Is AI always a sophisticated consumer?
  - When AI suggests purchasing an infringing/counterfeit product or service, is AI a secondary infringer?
    - What if AI only considers price, features of goods and services, speed of delivery, etc?

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AI Will Change the Trademark Landscape

- Voice searching *v.* visual impact of a mark
  - Design marks, spelling, etc. become less important
- Product rankings on search engines
  - The impact of the mark becomes less important than buying space.
- Delegation of purchasing to an AI assistant that does not get confused
- Recommendation of drugs by AI
  - Labeled and off-label indications
  - Dosing
  - Interactions with other medicines
  - Brand or generic

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Think about this

***Fact Pattern*:**

Adam invents **Eureka**, an AI program for discovering drug candidates based upon disease.

Barbara discovers **PEAREC-1**, a receptor instrumental in anaphylaxis from peanut allergy.

Charlie discovers the primary, secondary, and tertiary structure of **PEAREC-1**.

Dara invented a large molecule, **Impedio**, that blocks **PEAREC-1** but it is not solubleand is toxic in an art-accepted mouse peanut anaphylaxis model.

None of **Adam**, **Barbara**, **Charlie**, nor **Dara** work together, collaborate, or is employed by any related companies.

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Think about this

Scenario 1:

Adam asks **Eureka** to find a large molecule candidate to treat peanut allergy. **Adam** does not provide any further information to **Eureka**. **Eureka** has access to the internet. **Eureka** proposes ten novel and non-obvious compounds as lead candidates.

Who *is* the inventor of the ten compounds, Eureka or Adam?

Who *should be* the inventor?

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Think about this

Scenario 2:

Barbara asks **Eureka** to find a large molecule candidate to block **PEAREC-1**. The ten lead candidates and **PEAREC-**1 is now in the prior art, but the structure of PEAREC-1 is unknown. Neither **Adam** nor **Barbara** provide any further information to **Eureka**. **Eureka** has access to the internet.

Eureka proposes the novel and non-obvious compound **Obscuro**. **Obscuro** has solubility and potential toxicity issues but still is potentially effective in a small population of patients.

Who *is* the inventor of Obscuro - Eureka, Adam, or Barbara?

Who *should be* the inventor?

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Think about this

Scenario 3:

Charlie provides the structure of **PEAREC-1** to **Eureka** and asks **Eureka** to find a soluble, non-toxic large molecule candidate to block **PEAREC-1**. **PEAREC-1** and its structure, the ten lead candidates, and **Obscuro** are in the prior art. Neither **Adam**, **Barbara**, nor **Charlie** provide any further information to **Eureka**. **Eureka** has access to the internet.

Eureka proposes the novel and non-obvious compound **Presto**. **Presto** has solubility and potential toxicity issues but still is potentially effective in a small population of patients.

Who *is* the inventor of Presto - Eureka, Adam, Barbara, or Charlie?

Who *should be* the inventor?

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Think about this

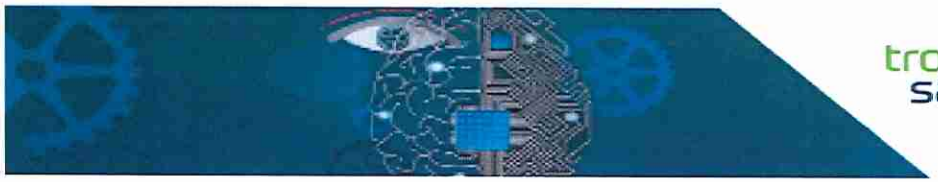
Scenario 4:

Dara invents the large molecule candidate, **Impedio**, an insoluble, toxic, but extremely effective analog of **Presto.** **Dara** provides **Impedio** to **Eureka** program and asks **Eureka** to find an analog of **Impedio** that as therapeutically effective as **Impedio** but is non-toxic and soluble. The ten lead candidates, **PEAREC-1** and its structure, **Obscuro**, and **Impedio** are now in the prior art. Neither **Adam**, **Barbara**, **Charlie**, nor **Dara** provide any further information to **Eureka**. **Eureka** has access to the internet.

Eureka proposes the novel and non-obvious compound **Ifoundit**. **Ifoundit** is more effective than **Impedio**, is soluble, and is non-toxic in all patients.

Who *is* the inventor of Ifoundit - Eureka, Adam, Barbara, Charlie, or Dara?

Who *should be* the inventor?



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