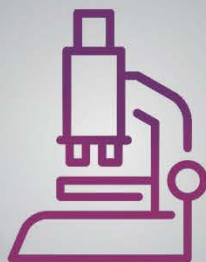


THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES



POST MYRIAD:

5 PATENT PROSECUTION TIPS



THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

MEET THE PRESENTERS



Robin Chadwick

- Principal Patent Attorney
- I have 20 years of experience handling all types of biotechnology.

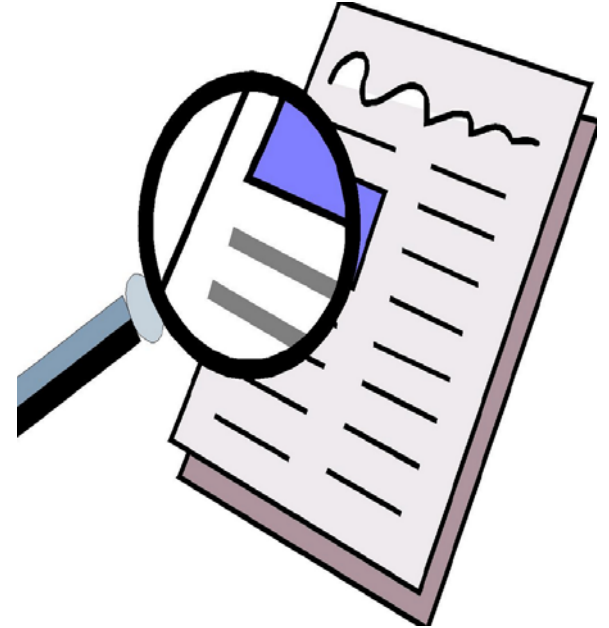


Ricardo Moran

- Principal Patent Attorney
- Main focus is small molecule pharmaceuticals and strategy and management of large and diverse pharma portfolios.

Patent Office Report (July 2017) – case list

- Examiners may find this information useful in identifying cases that may require detailed analysis...
- 82 Fed. Cir. Cases listed – 12 have at least one patent-eligible claim (13.7%)
- 10 life-sciences cases out of 82 – 3 had at least one patent-eligible claim (30%)



Patent Eligible Subject Matter

- What works:
 - *Natural Product Claims.*
 - Diagnostic Claims.



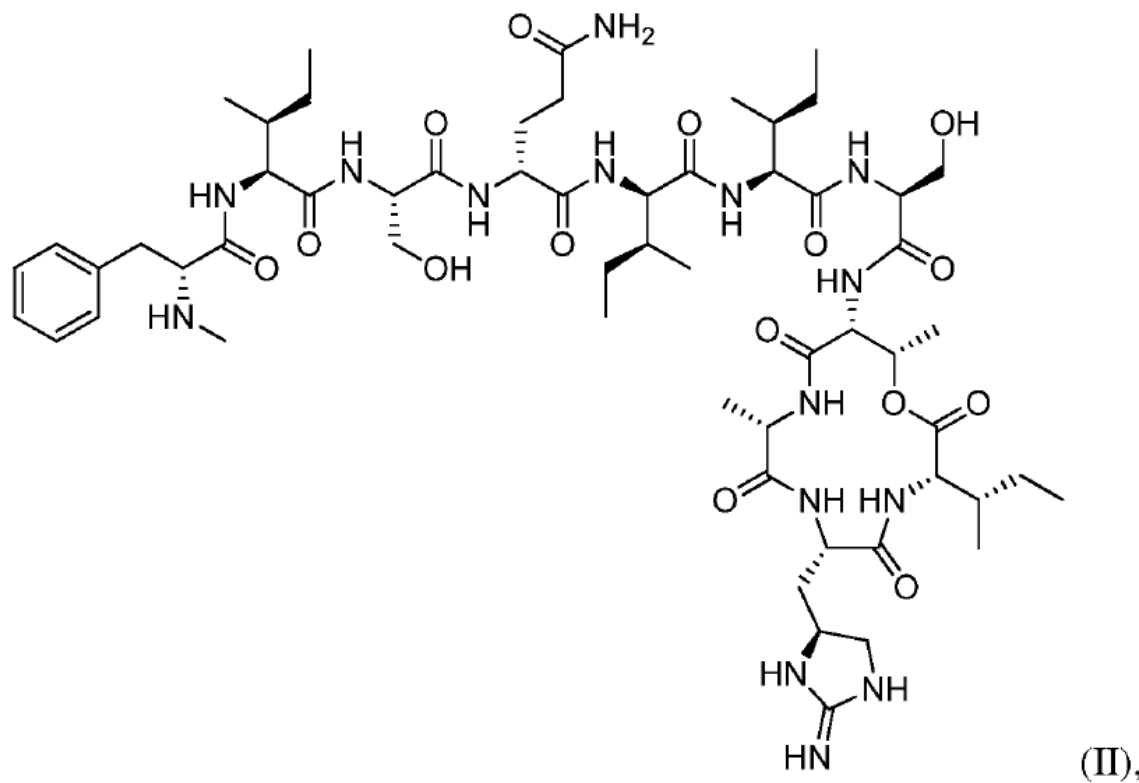
Two-Part Test for Patent Eligibility

- (1) Are the claims are directed to a product of nature or a natural correlation?
- (2) If so, do the claims recite an inventive concept that is significantly more than the law of nature to render the claims patent eligible.



Teixobactin Claim = Product of Nature?

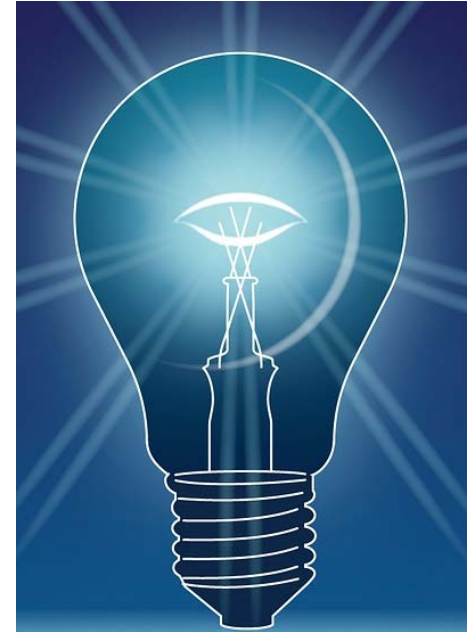
54. (New) A pharmaceutical composition comprising a compound of Formula (II):



or tautomer or pharmaceutically-acceptable salt thereof, and a pharmaceutically-acceptable carrier that efficiently solubilizes the compound.

Teixobactin Claim = Product of Nature?

- Applicant argued claim 54 was eligible for patenting:
 - Claim 54 is analogous to claim 6 of Example 3 of the 2014 Nature-Based Product Examples provided by the Patent Office.
 - **PTO Example 3, claim 6:** stable aqueous composition comprising: amazonic acid; and a solubilizing agent.



Teixobactin Claim = Product of Nature?

- **US Patent Office:** Claims 51-65 are rejected under 35 U.S.C. 101 because the compounds are directed to a naturally occurring compound and composition.
- The compound can still be solubilized in “pyrogen-free” water, which is still a naturally occurring composition of matter.



Teixobactin Claims Allowed

- Methods for treating bacterial infections in parent application, U.S. Appl. Ser. No. 14/095,415 (U.S. Patent No. 9,163,065).
- Composition of matter claims issued in “child” application, now U.S. Patent No. 9,402,878. Claims were identical to claim 54 presented in the parent case.
- No indication on record as to what got the child application over the finish line.
- Methods of making claims pending in second child case. Claims are surprisingly rejected under 101 (August 2017).

Product of Nature – what to do?

- Compound + pharmaceutically-acceptable carrier “that efficiently solubilizes” the compound appear to be patent-eligible.
- Evidence (e.g., inventor declaration) that it is difficult to solubilize compound in water appears to be important.
- Non-naturally-occurring modifications of compound should be patent-eligible (e.g., prodrugs and salts).

Patent Eligible Subject Matter

- What works:

- Natural Product Claims.

- Add something 'unnatural'
 - Combine products not found together in nature
 - Chemically modify natural product

- *Diagnostic Claims.*



Patent Office Report (July 2017) – case list

- 10 life-sciences cases out of 82 – 3 had at least one patent-eligible claim (30%)
 - *Classen Immunotherapies Inc. v. Biogen IDEC* (Fed. Cir. 2011) – eligible methods re immunization scheduling.
 - *Cellzdirect* (Fed. Cir. 2016) – 10 claims eligible (method of producing multi-cryopreserved hepatocytes)
 - *Myriad* (Fed. Cir. 2012) – one (1) claim eligible (method of screening therapeutic agents); methods of analyzing / comparing BRCA sequences ineligible



Two-Part Test for Patent Eligibility

- (1) Are the claims are directed to a product of nature or a natural correlation?
- (2) If so, do the claims recite an inventive concept that is significantly more than the law of nature to render the claims patent eligible.



Diagnostic Claim –Eligible?

- **Cleveland Clinic Claim 14:** A method of assessing a test subject's risk of developing a complication of atherosclerotic cardiovascular disease comprising:
 - determining levels of myeloperoxidase (MPO) ...
 - wherein elevated levels of MPO indicate that the test subject is at risk of developing a complication of atherosclerotic cardiovascular disease.



Diagnostic Claim – Not So Eligible

- **Court:** The claims merely allow one to “see” the natural correlation of MPO correlated with cardiovascular risk, and
- do not add “something more” that transforms the natural correlation into a patent eligible invention.



Treatment Method Claim

- **Cleveland Clinic '260 Claim 1:** A method for administering a lipid lowering agent ... comprising:
 - (a) performing ELISA assay ... to determine MPO activity in the serum or plasma sample;
 - (b) selecting a patient who has elevated levels of MPO compared to control levels of MPO; and
 - (c) administering a lipid lowering agent to the selected human patient.



Cleveland Clinic- Infringement of '260 Claim 1?

- **Contributory Infringement of '260 Claim 1:**

Contributory infringement occurs if a party sells, or offers to sell, a material or apparatus for use in practicing a patented process... 35 U.S.C. § 271(c).



- **Induced Infringement of '260 Claim 1:**

“Whoever actively induces infringement of a patent shall be liable as an infringer.”
35 U.S.C. § 271(b).

Treatment – No Infringement

- **Court:**

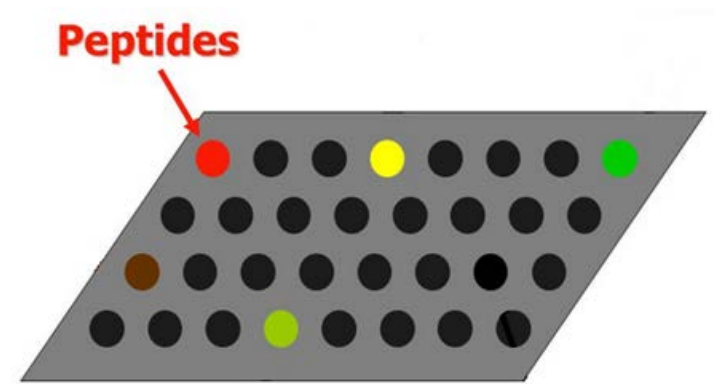
- **No Contributory Infringement:** Lab reports are not a “material or apparatus” that True Health sells.
- **No Induced Infringement:** True Health does not sell or prescribe lipid lowering drugs to patients.



Diagnostic Claims – Eligible?

US 8507211 claim 1: A method for *diagnosis of Mycobacterium tuberculosis* infection, comprising:

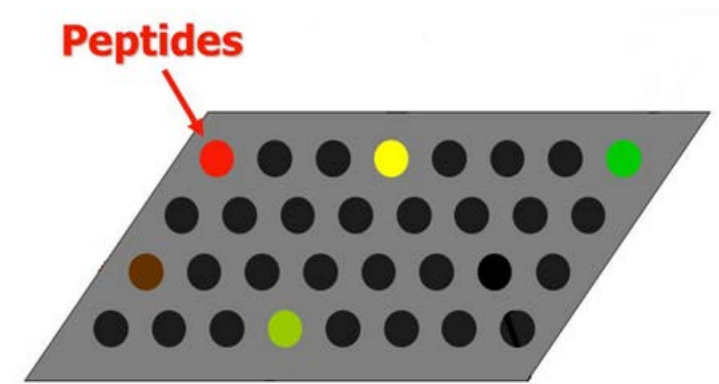
- (a) incubating host T cells with a panel of peptides, and
- (a) detecting T cell recognition of the peptide panel.



Diagnostic Claims – Eligible?

Court: The patented invention improves on existing methods for diagnosing TB by making diagnosis

- more convenient,
- less dependent on a physician's subjective interpretation of results,
- more accurate.



Motion to Dismiss denied.

Diagnostic Claims – what to do?

- Write claims as an assay. Avoid ‘diagnosis’ & information being the focus of the claim. Use active step, e.g., ‘measuring’?
- If claim includes a correlation or algorithm, then add ‘significantly more’ such as:
 - Specific (new) reagents / assay steps
 - Improved results over existing technologies



AIPLA Proposes Amendment of §101

- 101(a) ELIGIBLE SUBJECT MATTER (deletes “new”)
 - Whoever invents or discovers any useful process, machine, manufacture, composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title.
- 101(b) SOLE EXCEPTION TO SUBJECT MATTER ELIGIBILITY
 - A claimed invention is ineligible under subsection (a) only if the claimed invention as a whole exists in nature independent of and prior to any human activity, or can be performed solely in the human mind.
- 101(c) SOLE ELIGIBILITY STANDARD
 - The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to the requirements or conditions of sections 102, 103, and 112 of this title, the manner in which the claimed invention was made or discovered, or whether the claimed invention includes an inventive concept.

Takeaways: 5 Tips for Patent Prosecution

Natural Product Claims

1. Add something 'unnatural'
 - Combine products not found together in nature
2. Chemically modify natural product

Diagnostic Claims

3. Draft them like assay claims
4. Use new reagents / steps
5. Improvement over existing technologies

QUESTIONS & DISCUSSION



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**October 5
1:00 PM (Central)**