A (very) brief guide to patenting diagnostic inventions

AOMB Intellectual property

From research & product development to market uptake within the diagnostics sector

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- Ph.D. in medicine
- Biochemistry, Genetics, Microbiology, Oncology, Immunology
- Cell biology, Food, Health
- Prosecution, Litigation and Strategy

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- 28 Patent attorneys
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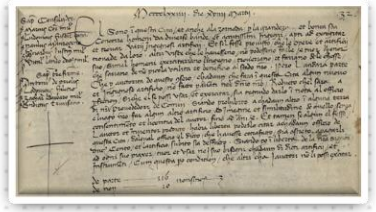
AOMB is member of AIPEX

Patent Basics - I

- Patent = legal monopoly
  - Incentive system - reward for disclosing new technology
  - Exclusion of competition/market power up to 20 years

- Right to exclude
  - Mere right to exclude others from making, using, offering, selling
  - **Not** ‘free pass’ or permit to enter market, make, use, offer, sell

- Form of intangible property - can be sold, bought leased, licensed, shared, enforced, marketed..
- Needs to be applied for!



The Venetian Patent Statute, one of the earliest patent systems in the world (1474).

Patent Basics - II

- Do we really need patents?
  - Expensive, long time to obtain…
  - Need to disclose invention – can we keep it a secret instead?
  - Some patents difficult to enforce
  - Need to applied for in each state: USA, JP, CN, EPO,

  - Yet: critical for tech that requires long and costly development/regulatory approval (pharma, biological, diagnostics)

New EPO building in The Hague: 85.000 m2 – 2000 employees.

Patent Basics - III

- Requirements (general)
  - **New** – anywhere, anyhow, anytime
  - **Inventive** – not obvious to the skilled person
  - **Sufficiently disclosed** – such that someone can ‘do’ the invention

- Additional requirements in the field of diagnostics, medical, health, life science:
  - Differences between jurisdictions
    - Interaction with the human body (EPO)
    - Natural phenomena (USA)
    - Plausibility

Skilled person: A fictional person considered to have the normal skills and knowledge in a particular technical field, without being a genius.

Patenting Diagnostics - Example

- Virtual example:
  - You identified:
    - a change or level of **Marker X**
    - in blood of human as predictive for
    - a **disease D** of for response to a **drug Y** in treatment of **disease D**
  - In order to make/measure the best relationship between **Marker X** and **disease D** you needed to improve measuring/isolation **Marker X**
  - **What may be protected at the EPO, what at the USPTO?**

Marker X is found relevant in relationship to disease D and drug Y

Patenting Diagnostics at EPO

- Methods practiced **on** human or animal body are **excluded** from patentability.
- Diagnostic, surgical and therapeutic methods are **excluded** from patentability, since these are "practiced on the human or animal body".
- **Only** if the diagnostic method can be carried out **separately** (*in vitro*, *ex vivo*) from the body, the method can be patent eligible.
- **Substances**, **devices** or **kits** that can be used in diagnostic methods can be patented.

Marker X is found relevant in relationship to disease D and drug Y

- "Practiced on the human or animal body" = a mere interaction with said body
- A device may not require a surgical method step.

Patenting Diagnostics at EPO

- To be excluded the diagnostic method must be practiced **<u>on</u>** the human or animal body:

    1. Examination phase – collecting data
    2. Comparison with standard values
    3. Finding of a deviation
    4. Attribution of deviation to a clinical picture (e.g., pathology, disease)
        - Diagnosis for curative purposes *stricto sensu*

Marker X is found relevant in relationship to disease D and drug Y

A claim to a diagnostic method in which ***at least one <u>technical step</u> is carried out separately from the body****, for example by carrying out a step in vitro on a sample of tissue obtained from the body, is therefore* ***<u>not excluded</u>*** *from patentability under Article 53(c) EPC*

Back to our Example at EPO

- Method that includes taking blood sample and measuring marker X: not allowed
- Method that includes measuring marker X in obtained blood sample: allowed
- Improved method to measure/isolate marker X from obtained blood: allowed
- Method that predicts response to drug Y by measuring marker X from obtained blood: allowed
- Drug Y for use in the treatment of disease D, wherein the treatment comprises measuring marker X from obtained blood: allowed
- Any kit or device that as such is patentable: allowed
- Use of the device to obtain blood from the subject: not allowed
- Making the actual decision to treat with Drug Y based on Marker X: not allowed

Marker X is found relevant in relationship to disease D and drug Y

And at the USPTO?

- In 2012 the U.S. Supreme Court decided on **banning** patents on methods of medical diagnosis (Mayo v. Prometheus)

- Diagnostic inventions were regarded to concern three types of subject matter that cannot be patented:
  - natural laws (e.g., relationship between **Marker X** and **disease D** or **drug Y**),
  - natural phenomena (e.g., genetic material such as cffDNA),
  - and abstract mental steps (e.g., obtaining diagnoses based on observations).

- **Substances**, **devices** or **kits** as such can be patented.

Marker X is found relevant in relationship to disease D and drug Y

THE END?

Patenting Diagnostics at USPTO

- Recent judicial developments in the US appear to have opened ways for patenting diagnostics and biomarkers, thereby **allowing**:
  - Methods of Treatment/Prevention tied to the test
  - Methods of preparation of a fraction comprising **Marker X**
  - Novel ways of measuring **Marker X**
  - Measuring **Marker X** without a diagnostic step
  - New diagnostic devices, new components or new methods of detection

Marker X is found relevant in relationship to disease D and drug Y

Our Example at USPTO

- Method that includes taking blood sample and measuring marker X as such: not allowed
- Method that includes measuring marker X as such in obtained blood sample: not allowed
- Improved method to measure/isolate marker X from blood: allowed
- Method that predict response to drug Y by measuring marker X: not allowed
- Method that predict response to drug Y by measuring marker X with improved method: allowed
- Method of treatment of disease D with Drug Y, wherein the treatment comprises measuring marker X: likely allowed
- Any kit or device that as such is patentable: allowed
- Use of the device to obtain blood from the subject: allowed

Marker X is found relevant in relationship to disease D and drug Y

Final Considerations

- Diagnostic patents need different approach for different jurisdictions
- USPTO more complex than EPO
- Consider not only the marker, but also the obtaining, measuring, isolation, preparing and use

- Do NOT claim overly broad – seriously hurt chances of success
- Do NOT claim speculations – can seriously hurt future perspectives

- Speak to a qualified patent attorney who is an expert in the technical field!
- A well considered decision to patent of not is important and valuable

Unravelling the diagnostic knot