

**A (very) brief guide to patenting diagnostic
inventions**

The logo for AOMB is written in a large, white, cursive script. The letters are fluid and interconnected, with a period at the end of the word.

AOMB Intellectual property

From research & product development to market uptake within the diagnostics sector
Online Seminar 21 April 2022



René J. Raggers

Partner,
European patent
attorney

r.raggers@aomb.nl

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



**Tim van
Beelen**

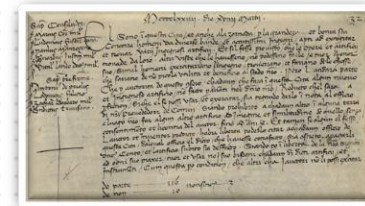
Dutch
patent
attorney



- 5 Offices
- 28 Patent attorneys
- 6 Trademark attorneys
- 3 Plant breeders' rights attorneys

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** or 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 **on** 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 technical step 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 **not excluded** 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 or not is important and valuable



Unravelling the diagnostic knot

Thank you !

AOMB.

AOMB Intellectual property

Rene J. Raggars
r.raggars@aomb.nl