Protecting Therapeutic Inventions
US and European Perspectives

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Common Issues

- Inherency
- When to file

Inherency EPO

- No “doctrine of inherency”

  - "Gold standard" disclosure required for lack of novelty
  - Prior art must disclose claimed subject-matter **directly and unambiguously** , including any features **implicit** to a person skilled in the art
  - “Implicit" only if it is immediately apparent to the skilled person that **nothing other than the alleged implicit feature forms part of the subject-matter disclosed**

Narrow definition....**BUT**

Inherency EPO

- New discovery about mode of action not enough for novelty
- Need **new technical effect** which is novel and inventive

  - New indication
  - Treatment of a different pathology/clinical situation
  - New patient sub-group; or
  - Mode of administration/dosage regimen

Europäisches Patentamt
European Patent Office
Office européen des brevets

The Doctrine of Inherent Anticipation

- Single reference must disclose every claim element; can be explicit, implicit or **inherent**. M.P.E.P.

Courts	Learnings
Inherent: previously unappreciated property of a known composition	Claim unexpected uses; functional fragments
Inherent: property does not have to be recognized when published	But property must be recognized by POSITA when filed – find art that teaches away
Inherent characteristic must be necessarily present	Define sub-groups; dosing; formulation; exclude prior art Use evidence to show characteristic not necessarily present

U.S.: The Doctrine of Inherent anticipation or inherent obviousness

Courts	Learnings
Species always “inherently” anticipates genus, but not the other way around	File genus application first then species
Clinical trial plan “inherently” anticipates a method of treatment	File before publishing clinical trial protocols
Newly identified compound is “inherent” if found using old process	Claim isolated, purified, stable compounds; pharmaceutical compositions and formulations

Case Study: IL-18BP USPTO

PCT claim 22
Method of treatment of a peripheral vascular disease (PVD), comprising administering to a **host in need thereof** an **effective inhibiting amount** of an IL-18 inhibitor.

- IL-18BP known for treatment of diabetes by anti-inflammatory mechanism
- Discovery: IL-18BP induces angiogenesis -> new use for treatment of PVD
- USPTO rejection: diabetes patients often suffer from PVD, therefore, prior IL-18BP treatment inherently treats PVD

Case Study: IL-18BP USPTO

- Law: missing descriptive matter must be (1) necessarily present, and (2) should be so recognized by POSITA
- Counter arguments and evidence:
  - (1) Evidence: not all diabetes patients have PVD – prior method does not necessarily treat PVD
  - (2) Evidence: prior art taught IL-18BP is an angiogenesis inhibitor - POSITA would not recognize the new property based on art
  - (3) Claim limitations: added mechanism of action; added patient sub-group; added dependent claim to local administration

Case study

Allowed US Claim
A method for **stimulating angiogenesis** in an individual **affected with a peripheral vascular disease** comprising administering to the individual an effective amount of a composition comprising an IL-18 binding protein (IL-18BP) and a pharmaceutically acceptable carrier

- **Learning:** Cannot patent discovery of mechanism of action, UNLESS it leads to unexpected use in a sub-group of patients

Case Study: IL-18BP EPO

- Claims initially rejected for lack of novelty over documents disclosing atherosclerosis
- Applicant provided evidence that PVD is **a distinct cardiovascular condition** to atherosclerosis. Thus claims novel
- Examiner argued PVD caused by atherosclerosis and claims obvious
- Prior art taught IL-18BP is **anti**-inflammatory when used to treat atherosclerosis, whereas neovascularisation requires **pro-**inflammatory effects
- No expectation of success that the anti-inflammatory IL-18 BP would promote neovascularisation and be suitable for PVD treatment
- Patent granted with broad claims to treatment of PVD

- **Learnings**: Define subset of disease; evidence of efficacy; no expectation of success

Case Study: New Clinical Situation EPO

Claim:

"One or more antioxidants for use in **enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract** of an animal having or at risk for inflammatory bowel disease (IBD)."

- Prior art disclosed treatment of IBD using vitamin E
  - Reduces the expression of endothelial cell adhesion molecules in the vasculature of the bowel wall
  - No mention of dysbiosis
- Patentable?
  - Same disease, same animal

Case Study: New Clinical Situation EPO

Claim:

"One or more antioxidants for use in **enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract** of an animal having or at risk for inflammatory bowel disease (IBD)."

Indirect effect on IBD by modulating gut flora provided a novel treatment of IBD compared to the direct effect on gut wall disclosed in prior art (T2251/14)

- Patent maintained!

- **Learning:** Focus claim on the new clinical situation; provide evidence of efficacy in application results **from the new technical effect**

Case Study: US20070178078

Claim in US limited to:

Enhancing balance of bacteria by administering specific dose of antioxidants to animal having or ***at risk*** of **having IBD**, “wherein the food increases certain bacteria and decreases others.”

Case Study: US20070178078

- Examiner argued “at risk” includes any animal, and rejected claim as inherently anticipated by a pet food label listing same antioxidants as additives. Rationale: even if the reason for administration differs, it **necessarily yields the same results** as those required by the "wherein" clause in claim 1

Case Study: US20070178078

- On appeal, Board disagreed and ***held "IBD" target group limitation was valid.*** Would have reversed the examiner… but found that the pet food label listed IBD and thus claim was explicitly anticipated. Wherein clause "result" was considered inherent

U.S. Claim:

A method of enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal track of a canine or feline **animal having or at risk for having inflammatory bowel disease** (IBD) comprising **administering to the animal a composition comprising** vitamin E in a total tocopherol amount of about 50 to about 1000 μg, vitamin C … and β-carotene … per gram of food on a dry matter basis consumed by the animal, **wherein the enhancement comprises an increase in the level of beneficial bacterial comprising one or more of … and a decrease in the level of deleterious bacteria comprising**…

When to File?

- What data do you have?
- Clinical trial disclosures

Drafting Tips

- Set out mechanism of action and how it affects the disease or treatment
- Discuss likely label with clinical team
- Define a sub-set of patients
- Include basis for excluding certain groups of patients
- Set out how to show physiological/pathological status
- Include data to show treatment is plausible
- Consider narrower fall backs e.g. dosage regimens, mode of administration…

Other Considerations

- Enforcing the patent claim
  - Can claim be policed and enforced?
  - Who infringes?

- Validity
  - EPO case law has evolved to be patentee friendly

  BUT
  - National courts are not bound by the EPO so be prepared for challenges!

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