



Outline

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 - Practical application in the Myriad case
- Conclusion

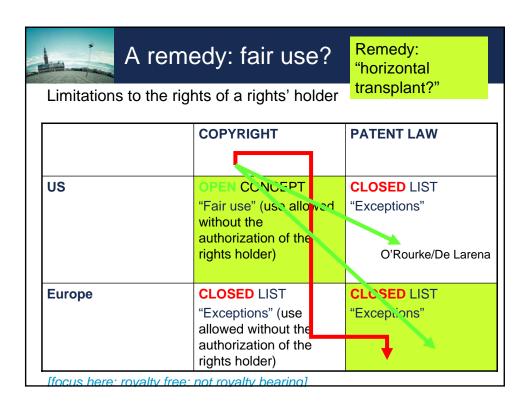


The problem

- (Coming into) *Existence* of human gene patents?
 - Settled by legislature or/and case law not discussed here

Explosion of human gene patents!

- Patent thickets and subsequent royalty stacking, may lead to tragedy of the anticommons; frustrating follow-on innovation
- Various remedies have been suggested not discussed here
- Exercise of patent rights related to genes/diagnostic tests!
 - Restrictive licensing behaviour + high license fees (2.400\$/test)
 may have a blocking effect on innovation + hamper access to
 health care
 - Current patent tools (research exemption, compulsory licence) nor current competion law (abuse dominant position) offer suitable remedy against "unreasonable" behaviour. Fair use?





Fair use in US copyright law

- The **open** list approach in the US
 - "In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include:
 - "the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
 - 2. the nature of the copyrighted work;
 - 3. the amount and substantiality of the portion **used** in relation to the copyrighted work as a whole; and
 - 4. the effect of the **use** upon the potential market for or value of the copyrighted **work**"



Exceptions in European patent law

- The closed list approach in European patent law
 - "The rights conferred by the Community patent shall not extend to:
 - (a) acts done privately and for non-commercial purposes;
 - (b) acts done for experimental purposes relating to the subjectmatter of the patented invention" [European Convention 1975]
- Application current closed list approach in the Myriad case



Fair use in patent law

- Legal basis
 - Safeguard "Social contract" [Hoffmann] balance private interest / public interest
 - article 31 TRIPs, artt. 7,8 TRIPs
- Problems
 - Legal transplants
 - Defense
 - Infringement costs



Fair use in patent law

- · Application in the Myriad case
 - 1. the purpose and character of the use the intent of the alleged infringer, in casu hospital/clinician: commercial: use = unfair; non commercial: use = fair

uncertain

- 2. the nature of the patented invention time, money and effort of the inventor/patent holder, in casu Myriad revolutionairy invention: use = unfair; incremental invention: use = fair
- 3. the amount and substantiality of the portion used type of use by alleged infringer, in casy clinician copy: use = unfair; transformative use: use = fair

uncertain

4. the effect of the use upon the potential market of the invention reasonable licence available: use = unfair; not available: use = fair uncertain



Conclusion

- Potential?
 - No added value to current European toolbox
- Future research: further explore horizontal transplants
 - Re-model four factors: compare 3-step test patent law with 4 factor test US copyright law
 - Design a more general, true fair use clause: lessons can be drawn from literature on 3-step test in copyright law
 - Examine application 'misuse of rights' doctrine



