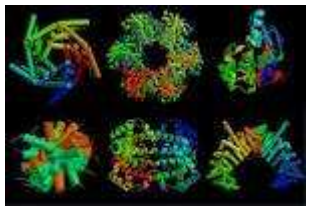
International Conference on IP and the Life Sciences

Friday, November 13 and
Saturday, November 14, 2015 Basel, Switzerland

– Patenting Human Genes in Europe-



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Introduction - I

- **Thousands of patents on gene-related technology since 1980's**
- **EU practice & legislation strongly influenced by US law & practice**
- **Patent practice did not quell public debate**
- **Since 2012 seminal changes in US law**
  (Supr. Court: *Prometheus, Myriad, Alice* & CAFC: *Ariosa v. Sequenom*)
- **Landmark decision by Austral. High Court in Oct. 2015**
  (*D'Arcy v Myriad*)
- **Game-changers for biomedical innovation framework?**

Introduction - II

- **How do these developments compare to current European law & practice?**
- **In how far may this influence European Law and Practice?**
- **What are the pros and cons of potential changes?**
- **Focus of this presentation:**

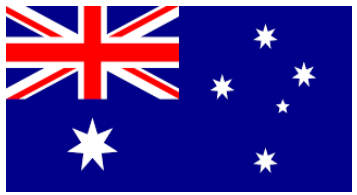
  Patent eligibility of isolated DNA and proteins in Europe!

Agenda

I. Patent-eligibility of human DNA on the EU national level.

II. Patent-eligibility of human DNA at the EPO.

III. Interim conclusions & brief comparison to US/Australia



IV. Open questions and points for debates

The controversy over full product patents for human DNA inventions

- DNA and traditional chemistry case law in the US and Europe.

- At the EPO and the USPTO full product protection had been the rule for claiming physical entities per se including DNA.

- Full product protection for DNA patents / effects on scope of protection?

Problem: **!New insights and special nature of DNA !**

- "Tragedy" of the Anticommons through full product patents on DNA & research tools ?

Basic Question: Traditional full product protection still appropriate for human DNA inventions ?

Problem: Any evidence regarding all checks and balances of patent system?

Many factors influencing type of claims scope of protection

1) Pre-grant effects on scope of the patent through basic patentability requirements

- eligibility (US and Australian approach)
- novelty
- inventive step
- industrial application
- disclosure requirement

2) Post grant effects on scope of the patent

→ doctrine of equivalence

→ enabling disclosure and clarity requirement (again)

→ competition law and other regulatory mechanisms [research exemption, compulsory licensing, reach through claims, patent period]

3) Legislative choice of the type of protection available

☞ **Focus of the debates in the MS when implementing the directive**

I. Patent-eligibility of *human* DNA on the EU national level

Context: The EU Legal Framework under the Biotech Directive (cf. Rules 26-29 EPC 2000)

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable **even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.**

2. Biological material **which is isolated from its natural environment** or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 5

……

2. An element **isolated from the human body** or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if **the structure of that element is identical to that of a natural element.**

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 9 (lex specialis / cf. Art. 8)

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material……in which the product is incorporated and in which the genetic information is contained and performs its function.

Various interpretations of i.a. Art. 5 & 9, as well as Recitals 8,12, 17, 22, 23, 24,25, 28, 46 & Art. 3.

Ambiguous wording of Art. 5 and recitals

- **Recital 8 points out that there is no need to introduce a specific law for biotechnological inventions**
  [lex specialis for sequences concordant to human DNA?]

- **Recital 3 and 7 emphasize the importance of an harmonized and effective patent protection in Europe**
  [Reciprocity in international patent law? Competitiveness?]

- **Recitals 23 & 24 leave room for speculation.**
  (*R 23* highlighting that a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention; *R 24* requiring – where DNA is used to express proteins - to specify which protein or part of a protein is produced or what function it performs;

⇨ **How should the objectives and article 5 of the Directive be interpreted?**

Short History of the Biotech Directive 98/44/EC

July 6, 1998

Directive was adopted by a large majority after nearly 10 years of discussions.

June 16, 1999

Administrative Council of the EPO decides to incorporate main provisions of the Directive into the Implementing Regulations to the EPC (Relevance of Dir confirmed by the Enl. Bl in 2001 Novartis decision)

July 30, 2000

Only four MS (GB, IR, FIN, DK) kept deadline for the implementation of the Directive under Art. 15.

October 9, 2001

ECJ confirmed validity and applica. of the Directive and dismissed 1998 action of the Netherlands.

July 01, September 09 & October 28, 2004

ECJ ruled that Fra, Bel, Lux, Ger and A had infringed their obligation under the Directive

April 23, 2006

Luxembourg was the last MS to implement the directive

Effective & harmonious patent protection achieved (recital 3 of Bio. Dir.) ???

Different Interpretations & Implementation of the Biotech Directive

MS adopted various types of implementations with several sub-types:

***Legislative approaches/prosecution*:**

1. **Still compound per se or absolute protection**
   [e.g. UK, Ir., DK, Fin. & Sw.]

2. **Various models of purpose- bound protection**
   [cf. Germany. (limited app.), France (broad), It., Sp. Lux. & Port.]

***Judicial approaches/litigation*:**

3. **Third type: Leave the scope of protection to the Courts in litigation**
   [Swiss patent law (2007)(not form. bound by Dir.)]

§ 1 a German Patent Act (unofficial Engl. translation, deviation fr. Directive in red)

1. The human body, at the various stages of its formation and development, **including germ cells** and the simple discovery of one of its element, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be **concretely** disclosed in the application **by indicating the function fullfilled by the sequence or partial sequence**.

4. **If the subject matter of the invention is a sequence or partial sequence of a gene the structure of which is concordant to the structure of a natural sequence or partial sequence of a human gene, then its use, for which the industrial application is concretely described in accordance with subsection 3, has to be included into the patent claim.**

Reasons of the Legal Committee of the German Federal Parliament for & 1 a (4) GPA

According to the reasons of the legal Committee subsection (4) was added to § 1 (a) GPA with clear intent to only allow purpose bound product protection for certain nucleic acids.

✋ **Farewell to absolute compound protection under GPA at least for naturally occurring human DNA sequences and their complements, even if they would fulfill all patentability criteria for chemical compounds/compounds of nature. ✋ (Compare i.e. Italy and France, and on the other Hand Sweden)**

But, subsection (4) only applies to certain nucleic acids, it does not apply to other classes of substances, particularly not to encoded proteins.

Unclear implications for the practitioner and applicant at the GPO: Legal uncertainty

- **P 1:** How to disclose a sufficient "concrete function"?
- **P2:** How to sufficiently define the purpose to which the compound protection is to be limited in the claim [cancer ?] ?
- **P3:** Does purpose limitation of compound protection in GPA only apply to DNA or also to RNA ?[Risk of circumvention]
- **P4:** What does "concordant to" really mean? [cDNA ?]
- **P5:** Does § 1 a (4) GPA only apply to genes actually occurring in human genome or does it also refer to structurally similar ones from other organisms/primates or engineered ones (Def. of gene)?
- **P6:** What about other DNA which could also be bottle neck resources and proteins. They fall outside scope of subsection 4.

No direct effects on EPC patents but what about CJEU & Unitary Patent System?

- **Only applies to Ger. patent appl. filed as of Feb. 28, 2005 at GTPO**
- **No direct effect on the German part of European EPC patents and EPC patent applications (cf. Article 69 EPC).**
- **But, influences jurisdiction of German Courts on disclosure criteria for industrial applicability (Ger. patents & Ger. parts of EPO patent).**
- **CJEU in C-428/08 *Monsanto v Cefetra* indicates support for German approach but unclear wording and different facts.**

II. The EPO approach

- **Article 52(1) EPC & R. 42 & 43**
- **Early case law: T 272/95 Relaxin (full product protection)**
- **R. 29 (2) EPC corresponds to Art. 5 (2) Biotech Dir.**
- **R. 29(3) EPC fully corresponds to Art. 5(3) Biotech Dir.**
- **EPO "Myriad" decision in T 1213/05 (2007); T 0666/05 (2008) & T 0080/05 (2008), limit claims but do not generally require obligatory purpose bound protection.**
- **Exception: 2nd and further medical use claims [Art. 54 (4) & (5)].**

Full product protection for genomic and cDNA & proteins possible at EPO if all other criteria fulfilled.

III. Interim conclusions & comparison to US/Austral.



- **Articles 3 and 5 (2) of EU Biotech Dir. & EU case law regard isolated biological material principally as patent-eligible.**
- **This encompasses <u>both isolated genomic and complementary DNA</u>.**
- **EPC, Imp. Reg. and EPO case law follow similar approach**
- **EPO case law also more permissible reg. diagnostic methods**
- **Legal status in Europe contrary to US decisions in *Prometheus, Myriad & Alice* & Australian *D'Arcy v Myriad Genetics* decision.**
- **Yet, different implementations of Biotech. Dir, & CJEU in Monsanto**
- **EU approach often <u>more restrictive reg. types of claims & scope of protection for DNA & protein-related patents</u>.**

IV. Open questions & points for debates

unified patent court

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- **Reg. National implementations of Biotech Directive:**

- **Violation of Biotech Directive & Art. 27 (1), 30 TRIPS?**
- **Was it (with benefit of hindsight) necessary?** (scientific advances and mitigating effects of traditional patent criteria)
- **Had broader economic impact been sufficiently considered?**
- **What would the CJEU decide considering its judgment in Monsanto?**

- **Reg. US/Australia comparison and Unitary Patent**

- **Will these developments lead to changes in Biotech Dir.?**
  (proposed by Commission committee)
  - Pro: Contrast to US & Australian Approaches; various implementations and contrasts to EPO approaches (ex. DNA & plant patents –Broc. & Tomato II) , CJEU in Monsanto.
  - Contra: History of Biotech Directive & number of MS.
- **More debates on framework for biomedical innovation**
- **Increased significance of complementary incentives in some R&D.**
- **Increased focus on better IPR governance**
- **What do recent foreign developments teach us reg. Unitary Patent system?**
- **Procedural risks & benefits of specialized patent courts and general courts.**

Any questions or comments?

Thanks you for attention!

Any questions or comments?

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