Pharma 1:

In(gene)ious but not patentable?

Patentable Subject Matter.
The Panel

• **Moderator - Penny Gilbert**  
  Partner, Powell Gilbert (UK)

• **The Hon. Justice John Nicholas**  
  Federal Court of Australia

• **Gesheng Huang**  
  Partner, Zhongzi Law Office (China)

• **Manisha Desai**  
  Assistant General Patent Counsel, Eli Lilly (US)

• **Denise Hirsch**  
  Director Protection and Institutional Partnerships, InsermTransfert (France)

• And .....
Subject matter:

• Gene-based inventions

• Nucleic acid sequences
  • Encoding novel proteins
  • Diagnostics
  • Biomarkers
  • Gene-editing etc

→ Naturally occurring products
Q1.

Has there been much recent litigation on biotech patents in your jurisdiction?

- What are the recent key cases?
- How has this affected the approach to patentability?
Q2. Is there specific legislation, or are there specific rules, affecting the patentability of gene-based inventions in your jurisdiction?
USPTO Guidelines

- **STEP 1**
  - 35 USC 101

- **STEP 2**
  - Part 1 of the 2-part test in *Alice/ Mayo*
  - Judicial exceptions to patentability

- **STEP 3**
  - Part 2 of *Alice/Mayo* test
  - Claim elements, together or individually, amount to more than the exception
USPTO Guidelines: 2016 Life Sciences Examples

1. A method of detecting JUL-1 in a patient, said method comprising:
   a) obtaining a plasma sample from a human patient; and
   b) detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

2. A method of detecting JUL-1 in a patient, said method comprising:
   a) obtaining a plasma sample from a human patient;
   b) detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
   c) diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.
Q3.

How is the current approach of patent offices affecting grant of patents for gene-based inventions?

• Has there been any impact on the approach to patent prosecution?
• Is it becoming harder to obtain adequate patent protection?
• Is there greater clarity on what will be patentable?
IN(GENE)IOUS BUT NOT PATENTABLE? PATENTABLE SUBJECT MATTER

Impact of the Prometheus and Myriad decisions of the US Supreme Court on IP and licensing strategy

Return of experience of Inserm and other research organizations in human health

4th in Europe for biotechnology*

3rd in Europe for the pharmaceuticals sector*

1449 patent families (1/1/2016)
1st Academic research institution in Health in Europe

*European Patent Office (EPO) 2015 rankings
Where?
- Europe, Asia, USA

How many?
- 14 answers
- Representing roughly **5300 active patents and patent families**

What structures?
- TTOs / Research institutes / Law firms / Universities / Companies
- Half public / Half private companies or structures
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- 1449 patent families (1/1/2016)
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*European Patent Office (EPO) 2015 rankings
**IMPACT ON PATENTING**

All responders had an impact on their patenting strategy.

Which decision had a bigger impact on your IP strategy?

- The Prometheus decision: 57.1%
- The Myriad decision: 35.7%
- Both of them: 14.3%
- Neither of them: 78.6%

If so, in which domain:

- Diagnostic: 78.6%
- Therapeutic: 14.3%
- Other: 35.7%
Q4.

How have changing standards of patentability impacted business?

- Is licensing/valuing/investing in gene technology-based businesses becoming more difficult?
- What are your experiences/concerns?
Is your licensing activity impacted by:

- The Prometheus decision
- The Myriad decision
- Both of them
- Neither of them

When asked which topics were most impacted for licensing:
- Biomarkers of diagnosis, prognosis or stratification
- Biomarkers for response to treatment
- To some extent, companion diagnostics seem to be affected too

When asked how the licensing activity was impacted:
- There were lesser new deals, and new deals with lower value
- Deal structures do not seem to be changed
- On the contrary, there was no substantial decrease in existing license incomes nor termination of existing licenses
Q5.

Are there issues that limit the scope of protection / enforceability of gene-based inventions?

- Claim construction issues?
- Litigation strategies?
Thank you for joining us!