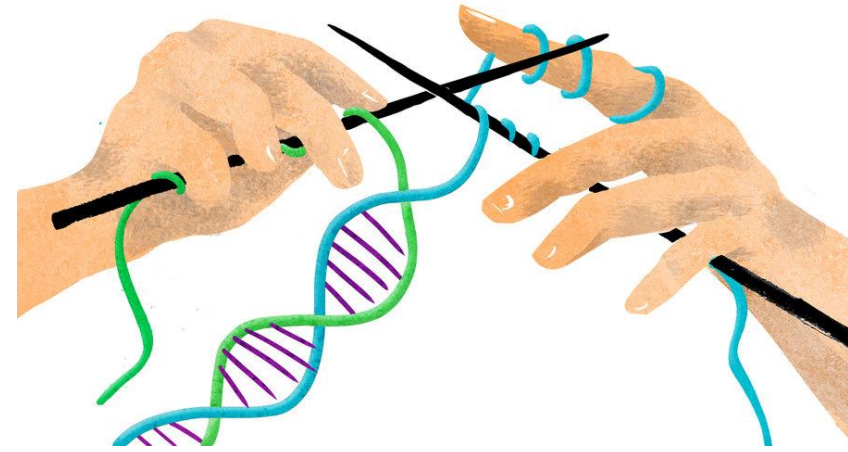


**Pharma 1:**



**In(gene)ious but not patentable?**

**Patentable Subject Matter.**

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**AIPPI 2016** September 16-20, 2016



# 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?**

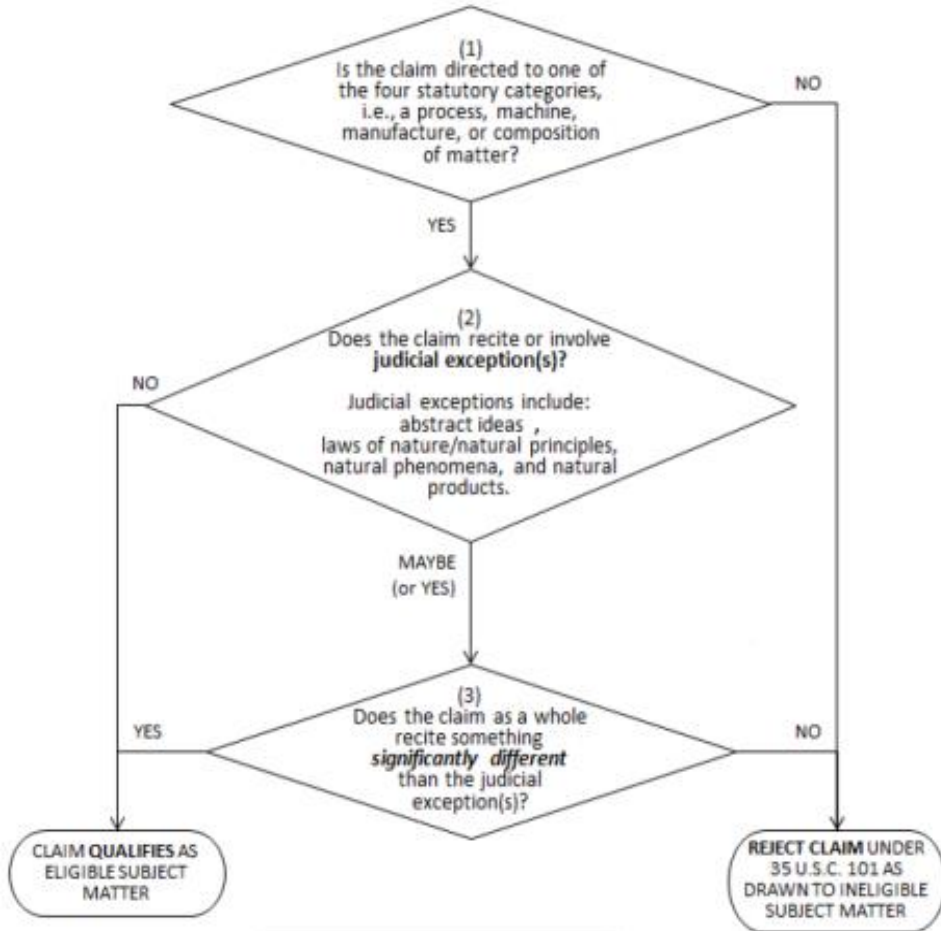
- What are the recent key cases?
- How has this affected the approach to patentability?

Q2.



**Is there specific legislation, or are there specific rules, affecting the patentability of gene-based inventions in your jurisdiction?**

# USPTO Guidelines

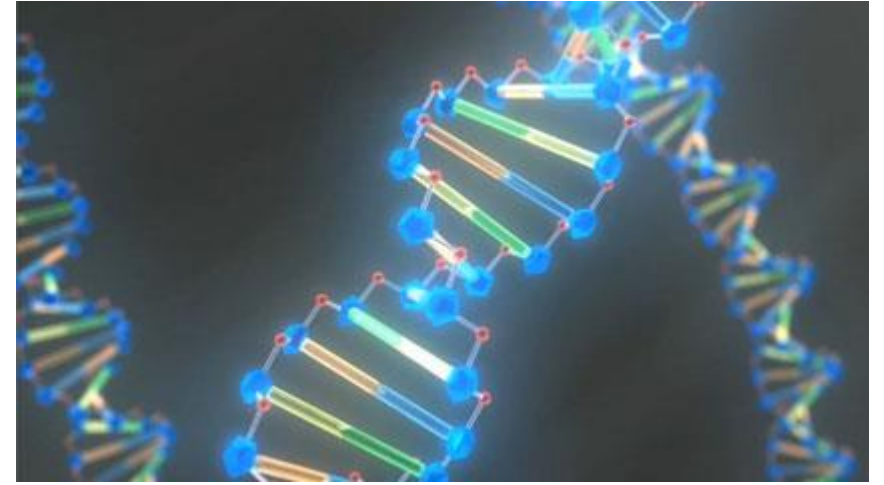


- **STEP 1**
  - 35 USC 101
- **STEP 2**
  - Part 1 of the 2-part test in *Alice/Mayo*
  - Judicial exceptions to patentability
- **STEP 3**
  - Part 2 of *Alice/Mayo* test
  - Claim elements, together or individually, amount to more than the exception

# 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

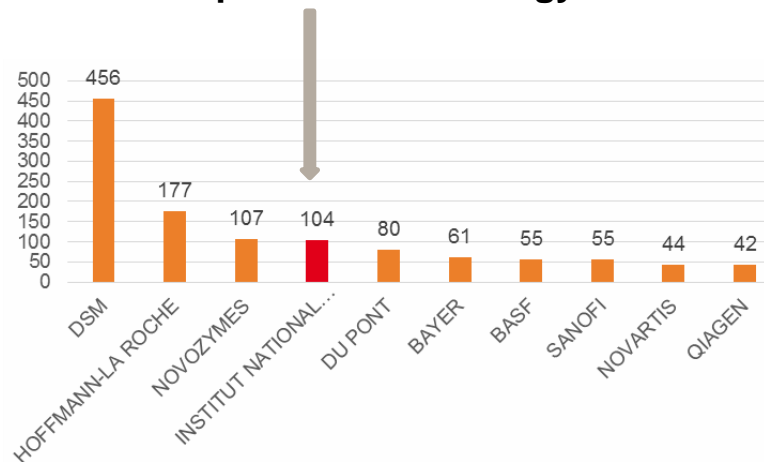
Return of experience of **Inserm** and other research  
organizations in human health

Denise Hirsch – AIPPI Congress – Milan – 16<sup>th</sup>-20<sup>th</sup> september 2016

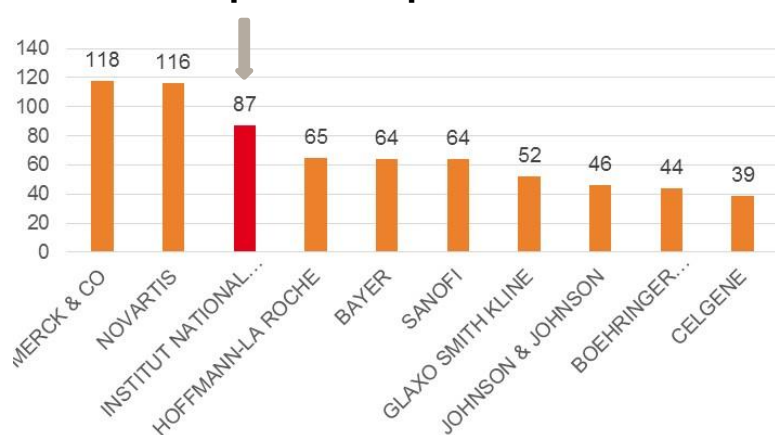
**Inserm** **Transfert**



### 4th in Europe for biotechnology\*



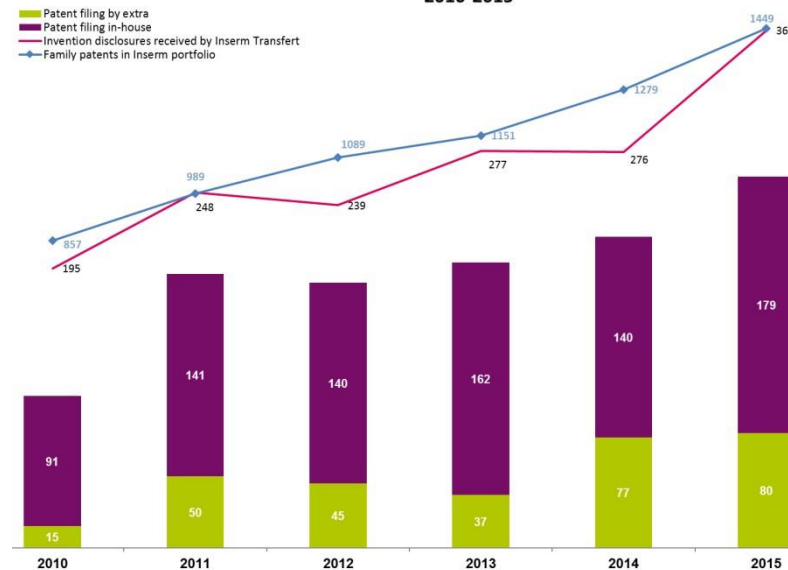
### 3rd in Europe for the pharmaceuticals sector\*



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

\*European Patent Office (EPO) 2015 rankings

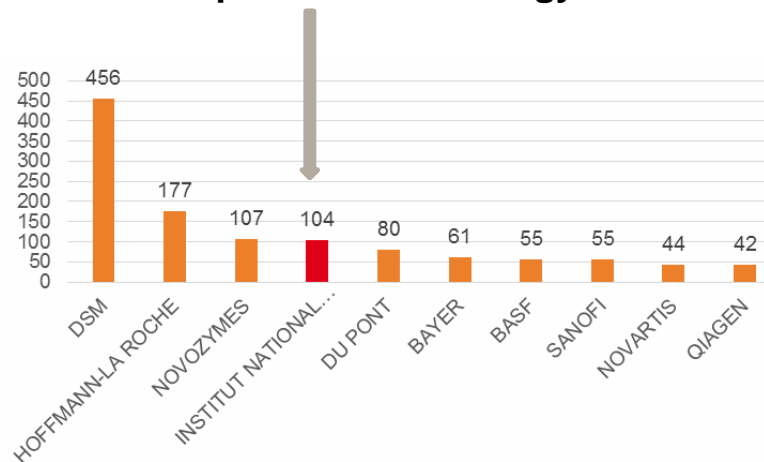
Intellectual property : Inserm Patent Portfolio 2010-2015



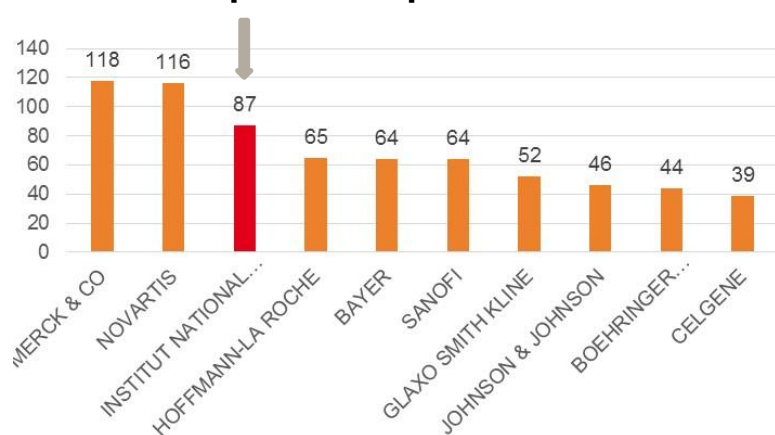
## INFORMATION ABOUT THE SURVEY

- ❖ 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

### 4th in Europe for biotechnology\*



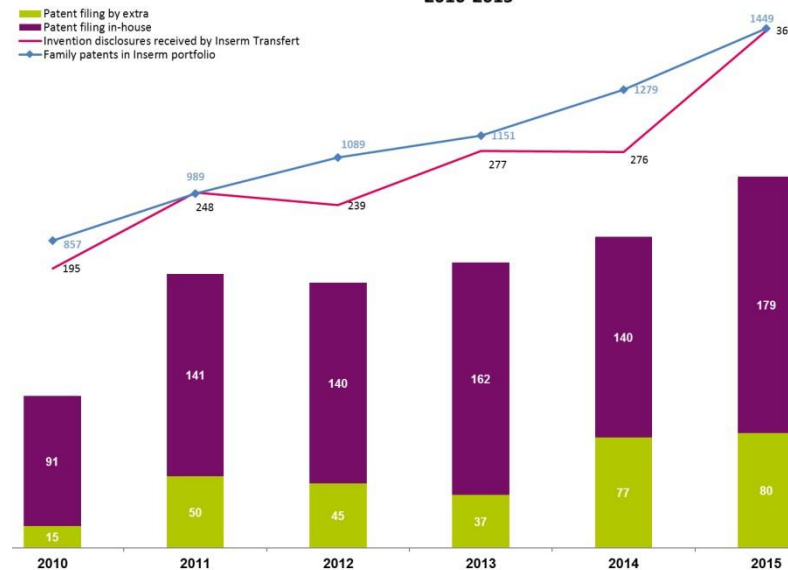
### 3rd in Europe for the pharmaceuticals sector\*



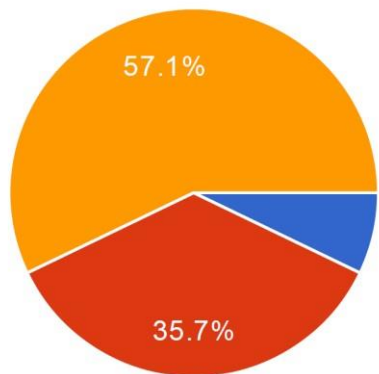
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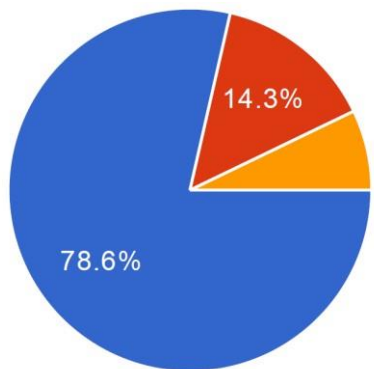


ALL RESPONDERS HAD AN IMPACT ON THEIR PATENTING STRATEGY  
 WHICH DECISION HAD A BIGGER IMPACT ON YOUR IP STRATEGY?



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

IF SO, IN WHICH DOMAIN:



- Diagnostic
- Therapeutic
- Other

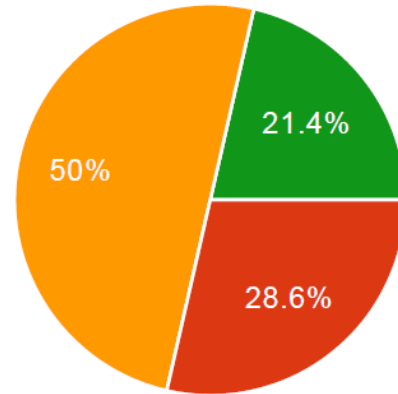


Q4.

## **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

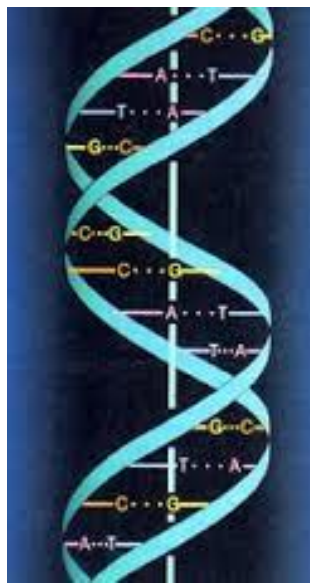
❖ When asked which topics were most impacted for licensing:

- ❖ 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!



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