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MEDICAL/PHARMACEUTICAL INVENTIONS

A comparative study Europe – China

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SECOND THERAPEUTIC APPLICATION
ADMINISTRATION REGIMEN

China: *Swiss-type claim*:

“Use of a substance X for the manufacture of a medicament for a new and inventive therapeutic application”.

EPO “purpose-limited-product-claim”:

“Substance X for use in a novel and inventive medical treatment”.

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What are the conditions making a therapeutic application "novel"?

...there is a strong difference between the EPO a Chinese interpretation

EP PRACTICE
(AND EP CASE-LAW)

- A new disease
- A new type of patient
- A new administration way
- A new administration form
- A new administration regimen
NEW DISEASE

ACETYLSALICYLIC ACID

ANAolgic

CARDIO-VASCULAR DISEASES

FINASTERIDE

BENIGN PROSTATIC HYPERPLASIA

ALOPECIA

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NEW TYPE OF PATIENT

SERO-NEGATIVE PIGLETS

VACCINE

T 19/86

AUJESZKY'S DISEASE

SERO-POSITIVE PIGLETS

NEW TYPE OF PATIENT

HAEMOPHILIC PATIENTS

Factor Xa

T 893/90

BLEEDING CONTROL

NON-HAEMOPHILIC PATIENTS
New Administration Regimen

- Different timing for the same dosage;
- Different dosage with same timing;
- Different dosage and different timing

Nicotinic acid
1500 mg/day

Once/day prior to sleep

hyperlipidaemia

Two/three times a day
Finasteride

Androgenic Alopecia

1.0 mg/giorno

5-2000 mg/day

Merck & Co

EP 0 724 444

Merck & Co contro
Ratiopharm, Teva etc

Alendronate

osteoporosi

70 mg/week

10 mg/day
New technical effect

- Nicotinic acid once/day prior to sleep: 
  avoided heat flashes

- Alendronate 70 mg/week: 
  avoided esophagus ulcer

- Finasteride 1 mg/day: 
  activated a different receptor

COMPARATIVE STUDY
EUROPE – CHINA

PROPECIA® (Finasteride) (Merck & Co)

EP 0 724 444-B1

WO95/10284

CN ZL94194471.9 Aplld.
CN 1096861 Pat.granted
“Use of Finasteride for the preparation of a medicament for oral administration for treating androgenic alopecia of a person, wherein the dosage amount is about 0.05 to 1.0 mg/(day)”

“Use of “Finasteride” ... for treating androgenic alopecia of a person, wherein the dosage amount is about 0.05 to 3.0 mg/(day)”

CLOSEST PRIOR ART
very controversial!

Use of oral (?) Finasteride for treating androgenic alopecia (in human/animals?) with a dosage amount of 5 or more mg/(day)
United Kingdom

High Court of London: patent held **invalid** because the dosage regimen was not recognized as a technical feature (method of treatment by therapy).

Supreme Court of Judicature – Court of Appeal: Patent held valid because the dosage regimen, as any other feature of the “therapeutic treatment” characterizing a Swiss-type claim, was recognized as a technical feature.

ITALY

Three invalidity proceedings

The Tribunal Technical Experts, in first two proceedings, issued a positive **validity** opinion.

Both Tribunal Experts recognized that the dosage regimen was a technical feature suitable to make novel a therapeutic application.

All invalidity proceedings were withdrawn – patent is maintained as granted.
GERMANY AND SPAIN

The dosage regimen was recognized as an admissible technical feature capable of conferring novelty to the claimed use of Finasteride.

However the Tribunals held the patents invalid because the dosage regimen was considered not-inventive in the light of a prior-art documents.
CHINA
CN 1096861

SIPO

• Patent CN1096861 was granted;
• Submitted to invalidation procedure
• Re-examination Board held the patent invalid

...because the dosage regimen was not be considered as a limiting technical feature...
Accordingly it was disregarded

Merck instructed judicial proceedings before first instance Court.

The People’s Court of Beijing upheld the decision of invalidity of the Re-examination Board.

The dosage regimen was again not considered as a technical feature. Therefore disregarded.
Merck lodged an appeal
Higher People’s Court of Beijing

The Higher Court considered that the so-called “administration-related features”, such as dosage amount and dosage timing, …

…..had to be considered technical features relating to how to use a medicament, ….
…therefore capable of conferring novelty and inventiveness to a Swiss-type-claim.

Higher People’s Court of Beijing

Yet, the Higher People’s Court held the patent invalid because the administration-related features were considered lacking inventive step in the light of prior-art documents.
PRESENT SITUATION IN CHINA

Higher Court:
Administration
Regimens => YES

SIPO New Guidelines 2010:
Administration
Regimens => NO

CONCLUSIONS

At present the sole possibility to protect a medical invention based on a new and inventive administration-related feature is undertaking the judicial way up to the Higher Court...

...in the hope that it will confirm its previous opinion in the Merck Finasteride case!
The judgment of the Supreme Court was based on Section 101 of the US Patent Act, that provides:

- "Whoever invents or discovers any new and useful ... composition of matter ... may obtain a patent therefor...."

However, the isolated genomic DNA claimed by Myriad was indistinguishable from the natural genomic DNA and for this reason, the Supreme Court decided that it could not be regarded as a "new .. composition .. of matter", but only as a discovery.
Human Body and its elements: 
Art 5 Direttive 98/44/EC,
Rul 29 (2) EPC

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

Biological material
Art. 3 Direttive 98/44/EC; Rule 27 EPC2000

biological material which is isolated from its natural environment or produced by means of a technical process, may be patentable even if it previously occurred in nature
Rational of the EP rule is based on the very definition of “novelty”.

- EPC lays down in Art. 54(1) that:
  - (1) An invention shall be considered to be new if it does not form part of the state of the art.

Art. 54(2):

The criteria of being “made available to the public” is the element discriminating between known and unknown material.
May a genetic material be considered “available” to the public if …

... its very existence remains unknown or if it is hidden within its native environment made of a strand of genetic material comprising millions of other functional, structural or even silent genetic fragments all together making an entire genome? => NO!!

Thus adopting the criteria of “availability to the public”...

... the fact that an isolated genomic DNA is indeed indistinguishable from the natural DNA, as observed by the Supreme Court, becomes totally immaterial in assessing its patentability.
...DNA material is patentable if it is not in its natural state.

Shall an *isolated* DNA be considered a material “in its natural state” and therefore not patentable, or in a not-natural state, thus patentable??

THANK YOU FOR THE ATTENTION!

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