SPC's IN THE EU – ARE THE REGULATIONS FIT FOR PURPOSE?

Moderator: Francesco Paolo Vatti

FUMERO STUDIO CONSULENZA BREVETTI

Vienna

FUMERO STUDIO CONSULENZA BREVETTI

Congress in Vienna

FUMERO STUDIO CONSULENZA BREVETTI

Vienna's influence on my Country

FUMERO STUDIO CONSULENZA BREVETTI

Vienna caput Europae

FUMERO STUDIO CONSULENZA BREVETTI

Drugs

After the filing of a patent referred to a drug, an authorisation to marketing should be got for drugs falling under the umbrella of the patent.

The authorisation to marketing is a time consuming process

Difficult tests: in vitro, in vivo, toxicologic tests,..., tests on patients.

Italy as an example

Patent law issued in 1939, as a revision of the previous 1934 law.

Health is a major, social issue: drugs, as surgical processes, were exceptions to patentability.

A strong pharmaceutical industry developed in Italy

EPC

Italy joined EPC and amended its patent law in 1979

In particular, the prohibition of drug patenting was removed

Drugs became products of research as any other one!

Authorisation to marketing and patenting

Patents are he reward for the inventive effort

A patent lasts 20 years

Protection lasts as long as the patent itself, ***but***

This does not apply to drugs or drugs for plants: the authorisation path lasts for years, normally

Therefore, the research effort in the

Drug patents in Italy

For these reasons, a sort of SPC (Certificato di Protezione Complementare) was introduced in Italy in 1991

Accordingly, a drug could enjoy of a time extension for the patent protection, the duration of which is as long as the time between the patent and the first authorisation.

Balance in patent systems is like a pendulum

FUMERO STUDIO CONSULENZA BREVETTI

FICPI work

FICPI presented a survey

On the basis of its results, a position paper was issued

EU directive

SPC was regulated in the EU in 1992, by introducing the relevant legislation

But the pendulum has gone further....

EU situation

The situation in Europe is rather complicated.

SPC: recent developments and CJEU referrals

Critical issues

There is a better world

Perspectives and possible interactions with the UP/UPC

How innovators and genericists see the

FUMERO STUDIO CONSULENZA BREVETTI

Thanks!

Dr. Francesco Paolo Vatti
Fumero S.r.l.
Milan, Munich, Ancona, Varese
fpv@fumero.it

FUMERO STUDIO CONSULENZA BREVETTI