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pharmaceutical patent litigation in France  
Montreux, October 23, 2008

## FRENCH PATENT

- no full examination
- a full and quick enforcement (?)

## EUROPEAN PATENT

- full examination (after opposition)  
full and quick enforcement in France
- product                      - process  
active ingredient         - formulation :
  - prolonged release
  - dissolution profile

# PROHIBITED ACTS

- 1/ a)
  - i. manufacturing, using ...  
offering, selling ...
  - ii. product – product obtained by process  
process
  
- b) no threat

## prohibited acts (continued)

### 2/ « BOLAR exception »

#### a) all acts :

- such as studies and trials
- required for Marketing Authorization (MA)

- #### b)
- ready to be on the market  
the day after the expiration of the patent (SPC)
  - quick enforcement  
the day before the expiration of the patent (SPC)

# EVIDENCE OF INFRINGING ACT

- 1/ a) burden on plaintiff  
dismissal
  
- b) i. reversal for process  
ii. injunction from Judge for additional information

## evidence of infringing act (continued)

### 2/ saisie-contrefaçon

- a) to collect judicial evidence  
not to get information on potential infringements
  
- b) plaintiff entitled to get :
  - ex parte
  - authorization from the Judge
  - to have a bailiff assisted by a patent expert

## evidence of infringing act (continued)

### 2/ saisie-contrefaçon (continued)

- c) the bailiff is able :
  - i. to visit any facility
  - ii. to collect :
    - - all documents / information related to infringement claim
    - even though confidential (except legal opinions)
    - such as extracts from MA dossier
    - no document / information not related to infringement claim

## evidence of infringing act (continued)

### 2/ saisie-contrefaçon (continued)

d) in a case of a dispute :

i.

- documents placed in sealed envelope
- selection of relevant information :
  - by Judge
  - or by judicial expert
  - with assistance only of lawyers

ii. adversary debate before the Judge  
w. / wo. modification of his first decision



## evidence of infringing act (continued)

### 2/ saisie-contrefaçon (continued)

- e) obligation to bring a main action within one month

## MAIN ACTION ON THE MERITS

1/ 7 French Patent Courts  
(Paris – Lyons)

2/ a) same Judge for :

- validity
- scope
- infringement

b) between 9 and 15/18 months

## PRELIMINARY INJUNCTION (PI)

1/ a) conditions now removed:

- quick and serious
- action on the merits

b)

- based on a patent application (?)
- before any action on the merits
- ex parte (?)

## preliminary injunction (continued)

### 2/ validity of the patent :

- a) to be presumed when :
  - granted, maintained by EPO
  - without new :
    - prior art
    - ground for invalidity

## preliminary injunction (continued)

### 2/ validity of the patent (continued)

- b) i. to be decided by the Court  
within the main action on the merits
  
- ii. except :
  - when the patent is obviously null and void...  
because of lack of novelty ...
  
  - when the main action looks unsuccessful (?)  
because of new :
    - relevant prior art
    - relevant ground for invalidity
    - relevant foreign decision

## preliminary injunction (continued)

### 3/ Infringing object :

a) i. clear evidence

(see “*saisie contrefaçon*”)

ii. any doubt / ambiguity

in favor of the defendant

b) i. an identical reproduction of a claim

ii. an equivalent reproduction :

- in mechanics

(different form but same function

with technical result of the same nature)

- in chemistry (?)

any doubt in favor of the defendant

## preliminary injunction (continued)

4/ in case of threat :

a) more than :

- MA
- decision from Pricing Committee

b) additional circumstances :

- - manufacturing within Europe
- - selling around France
- - offering to deliver in France  
before the expiration of the patent
- - public decision to launch  
the day after the decision of Pricing Committee

c) French Judge aware of irreparable harm to the brand-name drug  
when a generic at a lower price is launched  
even though for a short time  
(just before the expiration of the patent)

## preliminary injunction (continued)

### 5/ Cross border :

- a) by the French Judge:
  - of the domicile
  - of the main defendant
  
- b) by applying :
  - foreign law
  - to foreign acts

(despite Primus / Roche – GAT / LuK)



# REMEDIES

## 1/ injunction

- a) • inevitable
  - enforceable (despite appeal)

### b) accompanied by:

- civil fine
- - call back
- confiscation

### c) outside France

## 2/ publication

in 2-5 periodicals

(to be confirmed by the Court of Appeals)

## remedies (continued)

### 3/ financial damages

- a)
  - i. loss of profits,  
if capable of selling the infringing mass
  - ii. if not,  
indemnifying royalty
  
- b)
  - i. no punitive damages
  - ii. profits by the infringer  
to be “taken into consideration”
  
- c) also foreign damages:
  - by the Judge  
of the domicile of the main defendant
  - by applying foreign law

## COSTS FOR FIRST INSTANCE

- a) - 50 to 100,000 € for patent litigator  
- 50 to 100,000 € for patent attorney
  
- b) lump sum as reimbursement  
(20 to 70,000 €)

# APPEALS

- 1/ before Court of Appeals
  - a) de novo litigation
  - b) confirmation  
within 1-2 years
  
- 2/ before Supreme Court
  - a) legal issues
  - b) within 2 years

NB: criminal proceedings available

## EU PATENT

- wished by SMEs
- in three languages (?)  
(London protocol)

## EUROPEAN JUDGE

- local for first instance  
central for second instance
  
- pool of Judges

thank you  
for your attention