

Antitrust & Pharma

Seeking a Balance

AIPPI, Milan

19 September 2016

16:00 to 17:30

Speakers

Gabriella Muscolo

Commissioner of the Italian Competition Authority

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General Manager – IP, Takeda Pharmaceutical Co. Ltd.

Michael Carrier

Distinguished Professor at Rutgers Law School

PAY FOR DELAY

Early entry deals

P and G settle patent litigation

Patent expires in 2 years

P's profits from exclusivity = \$100M/year

A: plus payment

P allows G to enter 6 months prior to expiry

P pays G \$50M (i.e. 6 months of profits)

B: patent term split

P allows G to enter 1 year prior to expiry

P pays G nothing

The size of the payment

P and G settle patent litigation

G agrees not to launch until expiry

P agrees to pay G the sum of X

A: nuisance value

$X = \$3M$

B: large payment

$X = \$100M$

Non-cash value transfers

P and G settle patent infringement **in country X**

A: licence

P grants G a **licence** to enter the market

B: no-AG

P allows G to launch 6 months before expiry

P agrees **not to launch an AG** until expiry

C: cross-border

G agrees not to launch **in country X**

P allows G to launch **in country Y**

MISUSE OF THE PATENT SYSTEM

Patent term extensions (PTEs)

P applies for a PTE to protect its successful product A

A: misleading information

P provides **misleading information** to the patent office to obtain a **longer term** for the PTE

B: divisionals

P obtains a PTE on a **divisional patent** rather than on the parent case

Secondary patents

Compound protection for P's successful product A has nearly expired

A: filing strategy

P files many secondary (process, polymorph, formulation, dosage regime) patents relating to product A

B: acquisitions

P acquires from third parties a number of secondary patents relating to product A (alternative production methods and formulations)

MISUSE OF THE REGULATORY SYSTEM

Product hopping

Product A is nearing the end of patent protection

P launches its improved product A+

A: soft switch

Inform prescribers of the
benefits of A+ over A

Offer discounts on
product A+

Stop promoting product A

B: hard switch

Withdraw product A from
the market

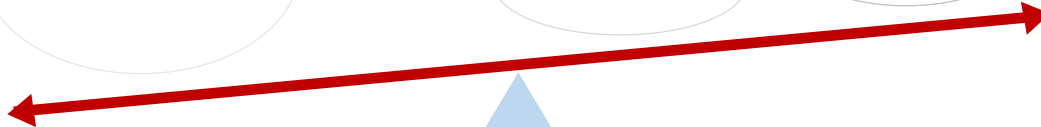
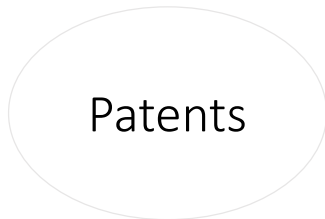
De-register product A and
remove it from drug
databases

Seeking a balance

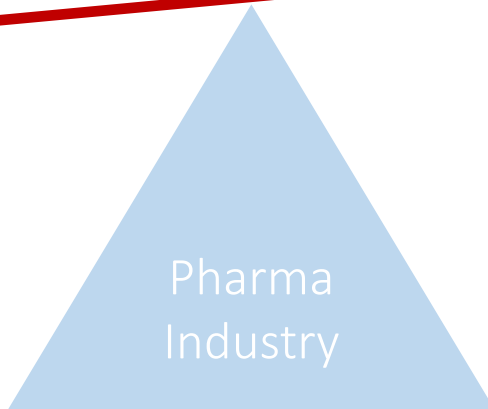
Consumer benefit

Innovation

10



Pharma
Industry



10



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Questions