



Second Medical Use Claims

...the story continues...

Marleen H.J. van den Horst

Session 5A Fordham IP Conference NY – 1 April 2016



Second medical use claims

- Introduction
- Update on status proceedings in NL
(*Novartis vs Sun Pharma - zoledronate*)
 - PI proceedings before Supreme Court
 - Final relief proceedings before District Court
(interlocutory decision 25 Nov 2015 – further substantiation on basis of direct infringement)



Key issues for infringement

- Intent/knowledge/forseeability
- What kind of (precautionary) measures are patentee / generic supplier / others required to take to prevent infringement?
- How far do you go? Send letters, take legal action, stop delivery altogether?



Legal actions against various stakeholders and remedies sought

- MEB (Netherlands)
- Pharmacies (Denmark)
- Health insurers (Germany)
- Ministry of Health (UK, Portugal, Denmark)
- Generic suppliers (Austria, Denmark, France, Germany, Netherlands, Portugal, Spain and UK)



Remedies against generic supplier

- Injunction based on (in)direct infringement
- Order not to participate in tenders, unless
 - It is made explicit that offer is not for patented indication
 - Health insurers/hospital pharmacies guarantee that product is not delivered for patented indication
- Order to restrict generic supply to certain amount (based on assessment market for free indications)
- Order to open books for patentee to check sales



Remedies against generic supplier

- Are such remedies:
 - Effective
 - Reasonable and proportionate
 - Allowed (EU competition law; EU Charter of Fundamental Rights)



Enforcement 2nd medical use claims

- Requires changes in the regulatory framework (AIPPI Q 238)
- Patent Court is not equipped to fully enforce 2nd medical use claims
- Balance between patent rights / rights of competition on free indications
- Financial compensation for patentee on different basis?

Thank you for your attention.

CONTACT DETAILS

Lange Voorhout 3
2514 EA The Hague
P.O. Box 30457
2500 GL The Hague
The Netherlands
T +31-(0)70-376 06 06



Marleen H.J. van den Horst
T: +31-(0)70-376 0621
M: +31-(0)6-1621 0392
marleen.vandendorst@barentskrans.nl