

IBC's 20th Conference on Biotech & Pharmaceutical Patenting 2012

Paediatric Extensions – Issues and Challenges



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Overview of this Session

- Problem/Solution
- Opportunity/Threats
 - Complicated Regulatory System
 - Timing
 - Competitor Patentees
 - Enforcement and Challenge
 - Legislative Reviews
- Conclusions

Problem/Solution

- Problem: “market forces alone have proved insufficient to stimulate adequate research into, and the development and authorisation of, medicinal products for the paediatric population”
- Solution (US): 1997, introduce 6 month extension of protection to encourage studies
- Solution (EU): 1997, start talking about it
Paediatric Regulation 1901/2006
2007, introduce 6 month extension of protection to encourage studies
(also: 2 year extension for orphans;
data exclusivity for PUMAs)

Opportunity/Threats

- Opportunity: 6 month extension covers all indications, not just paediatric indications; true SPC extension
- Threats:
 - Complicated regulatory system
 - Timing is critical
 - Studies required in any case for new authorisations (2008) & indications where SPC available (2009)
 - Competitors may rely on your studies
 - Need to enforce and high likelihood of challenge
 - Reviews planned in 2013 and 2017

Complicated Regulatory System

- Reward only applies where SPC available
 - C-125/10 *Merck Sharp & Dohme*, negative term SPCs available
 - For new indications, no study obligation if no SPC available
- Need to agree studies with the EMA's Paediatric Committee (PDCO) as a Paediatric Investigation Plan (PIP) – Arts 15-19
- Need to complete studies – Art. 7
- If PIP includes pre-2007 studies, need to show that new studies are “significant” – Art.45(3)
- Need to vary authorisations; competent authorities will consider whether studies complete and, if necessary, significant - Art.28(3) [Art.29 possibility]
- Need to apply for SPC extension – national patent offices

Timing

- Application for SPC extension must be made to national patent offices 2 years before expiry of the SPC
 - 6 months transitional period expired on 26 January 2012
- Before that, you need to:
 - Agree the studies with PDCO/EMA as part of the PIP
 - Complete the studies
 - Vary authorisations in all Member States
- *Du Pont v UKIPO* (English Court of Appeal, 17 September 2009) – there may be some flexibility to file early, but not unlimited
- Where mandatory, unlikely to be a problem
- Where optional, need to start work several years before SPC expiry

Competitor Patentees

- Reward is available to the SPC holder, who may be different from the marketing authorisation holder
- Can obtain a regular SPC based on competitor's authorisation (C-181/95 Biogen v SKB)
- Similarly, can obtain an extension based on competitor's PIP
- Question: does competitor's SPC also trigger Art.8 obligation to conduct PIP for new indications?

Enforcement and Challenge

- Generics hate the regime and lobbied hard against it, complaining that the reward can outweigh the costs
- Highly likely to challenge important SPC extensions in next few years
- Various challenges possible:
 - Attacking PIP decision
 - T-52/09 *Nycomed v EMA* (General Court, 14 December 2011)
 - Attacking authorisation/variation or statement of compliance
 - Attacking SPC extension
 - Launching/threatening to launch and claiming extension invalid
 - Antitrust/competition claims?

Legislative Reviews

- During 10 year legislative process there were divergent opinions
- Compromise: reviews of legislation under Art 50
 - 26 January 2013, report on experience
 - 26 January 2017, further report with analysis of economics and public health (to be provided in 2013 if sufficient data available)
- Still in early stage, difficult to review in 2013
- In any case, changes to legislation likely to be heavily lobbied

Conclusions

- Potentially very valuable reward
- However, many issues and challenges in (a) obtaining and (b) enforcing that reward
- Major developments likely over next few years as generics attack extensions
- Key is early consideration and communication as part of overall product strategy

Any questions?

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