

Patent Problems, and How To Pay For Them

**Controlled Release Society
India Chapter
2008 Annual Meeting**

Commercialization in the Regulated Markets

- Paragraph (iv)
- 505(b)(2)
- Paragraph (iii)
- Recent loss of freedom to pursue lower-cost alternatives
 - Pravachol
 - Sertraline
 - Carvedilol

Pravachol

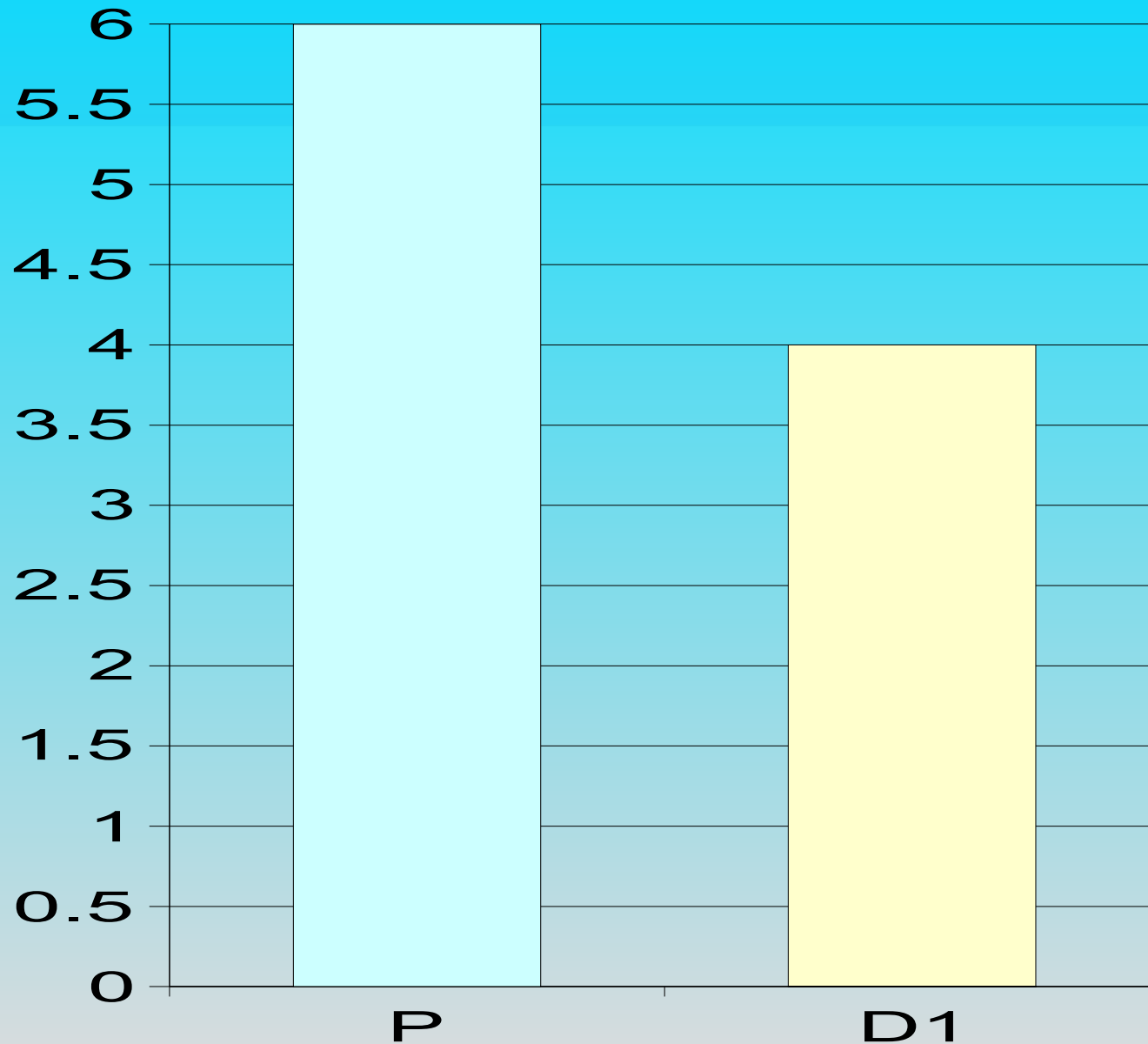
1. The sodium salt of pravastatin in a crystalline form wherein the crystals in the X-ray diffraction measurement produce distinct peaks having a half-value width below 2° measured at the reflection angle 2θ using $\text{CuK}\alpha$ radiation.

- *Lek v BMS, Watson*
- Crystalline form patent
- BMS patent : spray drying (amorphous)
- Dec. 2006 filing
- June 2007 denial : pravachol crystals (i.e., dry API) is prior art
- Feb. 2008 : protective order entered

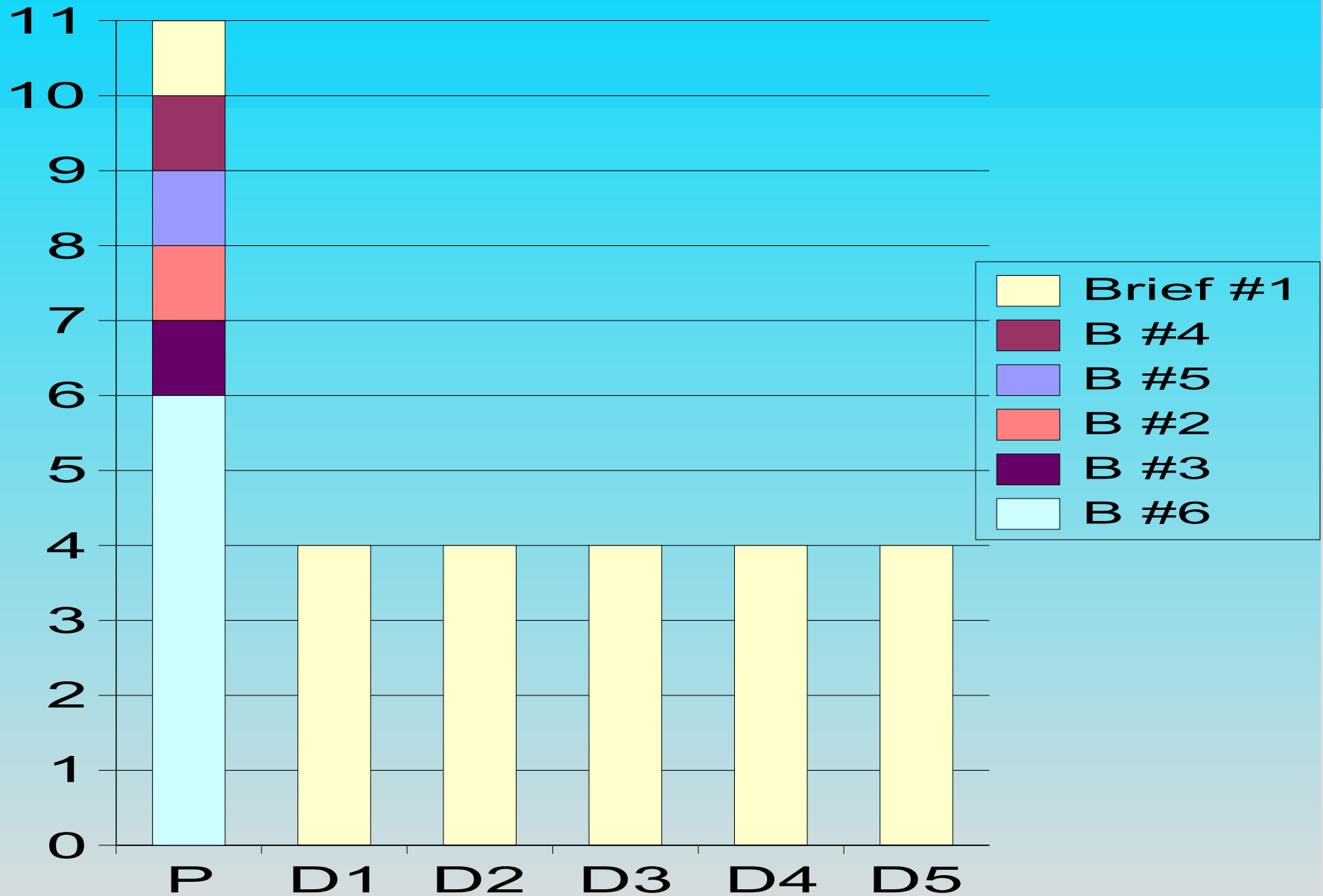
Sertraline, Carvedilol

- Litigation economics

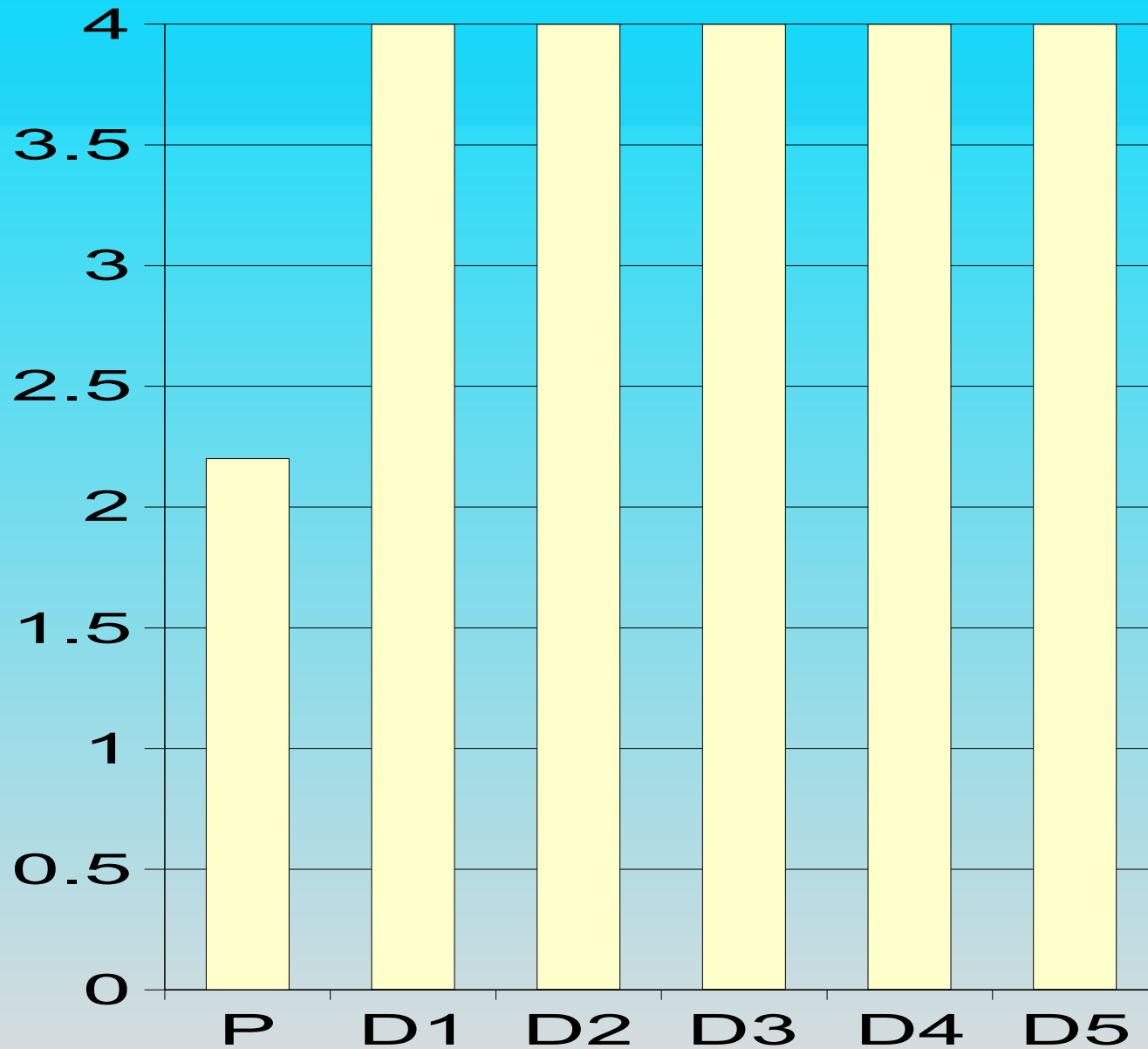
Class Litigation



Class Litigation



Cost per Litigant per Case



Sertraline

- Teva's 180 day exclusivity expired Feb 2007
- Dec 2006 – litigation notice letters
- DMFs for API
 - P (iii) filers
 - 505(b)(2) filers
- “Service of Process”
- Outcomes:
 - Default
 - Settlement (DRL)
 - One-way exclusivity
 - Temporarily withdraw suit (Zydus, Genpharm, Torrent)

Carvedilol

- June 2007: just before market opened to P. (iii) filers
- Teva vs. 14 DMF holders and Paragraph (iii) filers
- Results
 - Defaults (Moehs, Urquima, et cetera)
 - Temporary withdraw of case (Lupin et cetera)
 - Permanent withdraw of case (USV)

Benefits & Shortcomings

- Fast resolution
 - Compare Lupin (1 year) to USV (2 months)
- Permanent
- Cash-flow matching
- Limited availability

IPR and Stock Prices

- In the two days after announcement of a patent lawsuit, the combined market-adjusted value of the two companies falls by an average of 3.1 percent.
- Vonage : 25% drop in stock price on adverse court ruling.
- Lipitor patent fight: Deutsche Bank said that Ranbaxy faced a *25 percent* downside to its stock price if it failed in its patent fight

Recommendation

- Expect litigation (money, resources)
- Defensive Pre-planning
- Proactive Patent Filing
- Harr, Jonathan, A Civil Action (1996)
- - Pharmaceutical Patent Attorneys, LLC
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