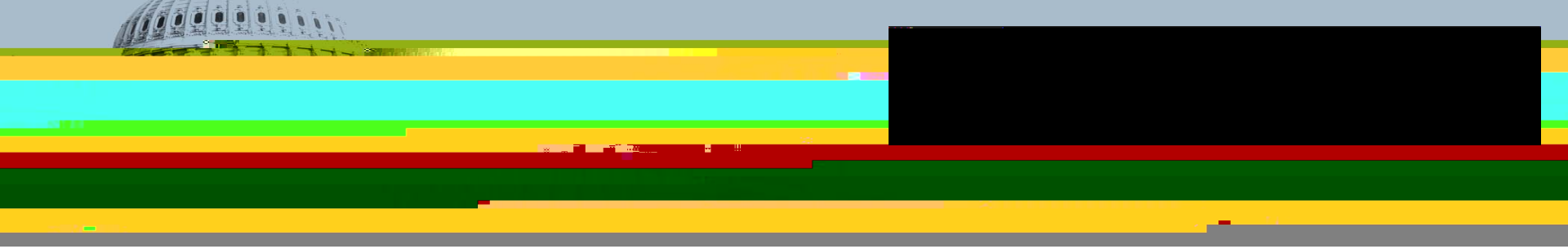

Potomac Research Group

Follow-On Biologic Market: Initial Lessons and Challenges Ahead

Paul Heldman

Friday, November 21, 2008

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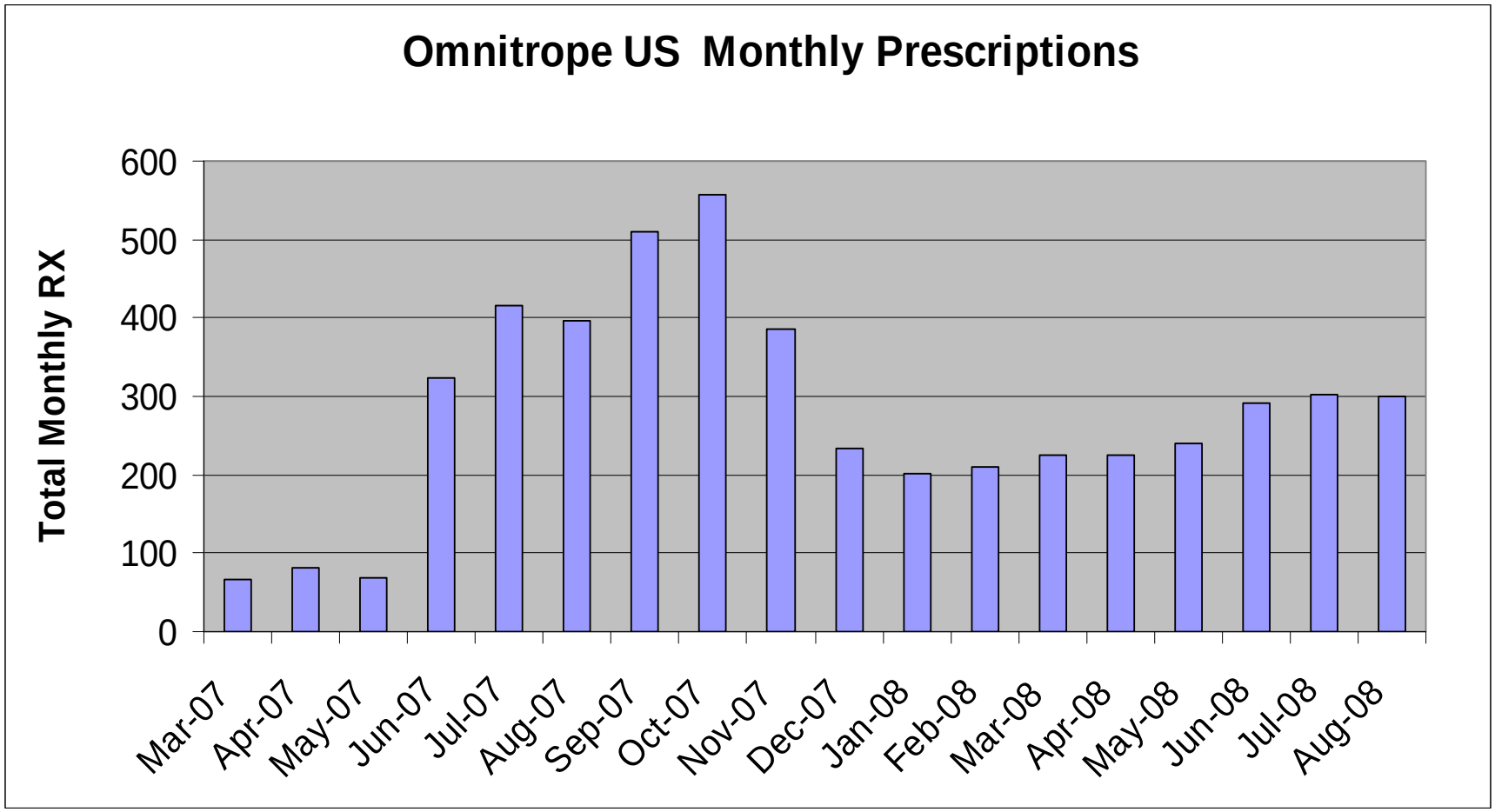
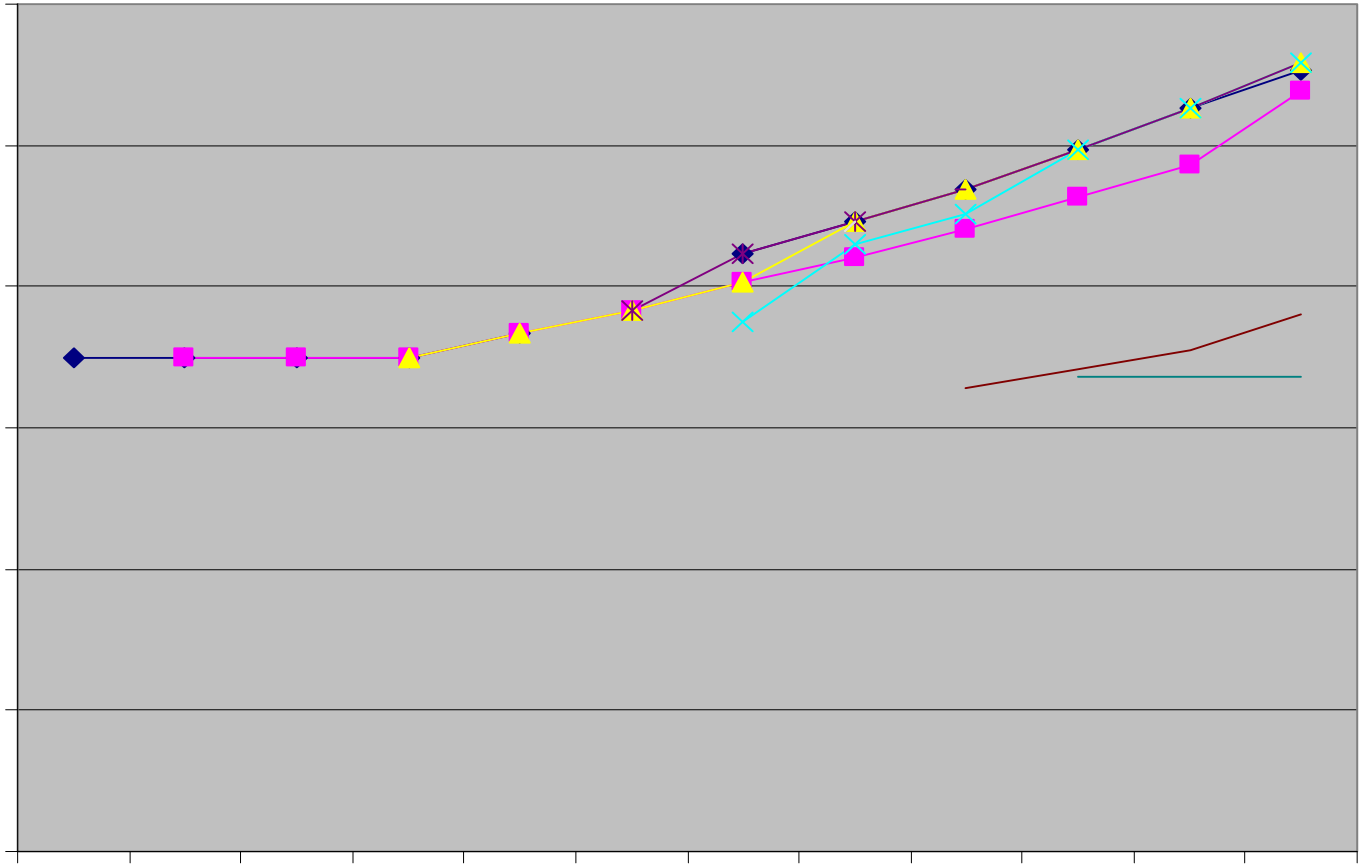
THERE IS A MARKET FOR BIOSIMILARS….



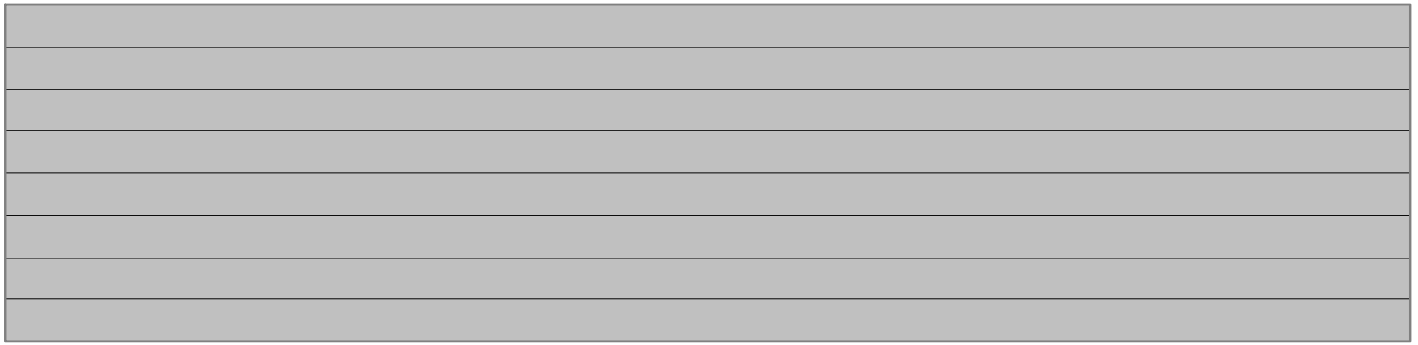
Source: IMS Health



Pricing of Somatropin

- Initial discount of about 30% for Omnitrope in comparison to Pfizer's Genotropin in 2006, based on wholesale acquisition cost (WAC).
- Discount widens to about 40% in 2008 as Omnitrope competitors raise prices, compared to 80% discounts in the market for traditional medicines.
  - Aggressive discounting not calculated in WAC may help innovators maintain market share

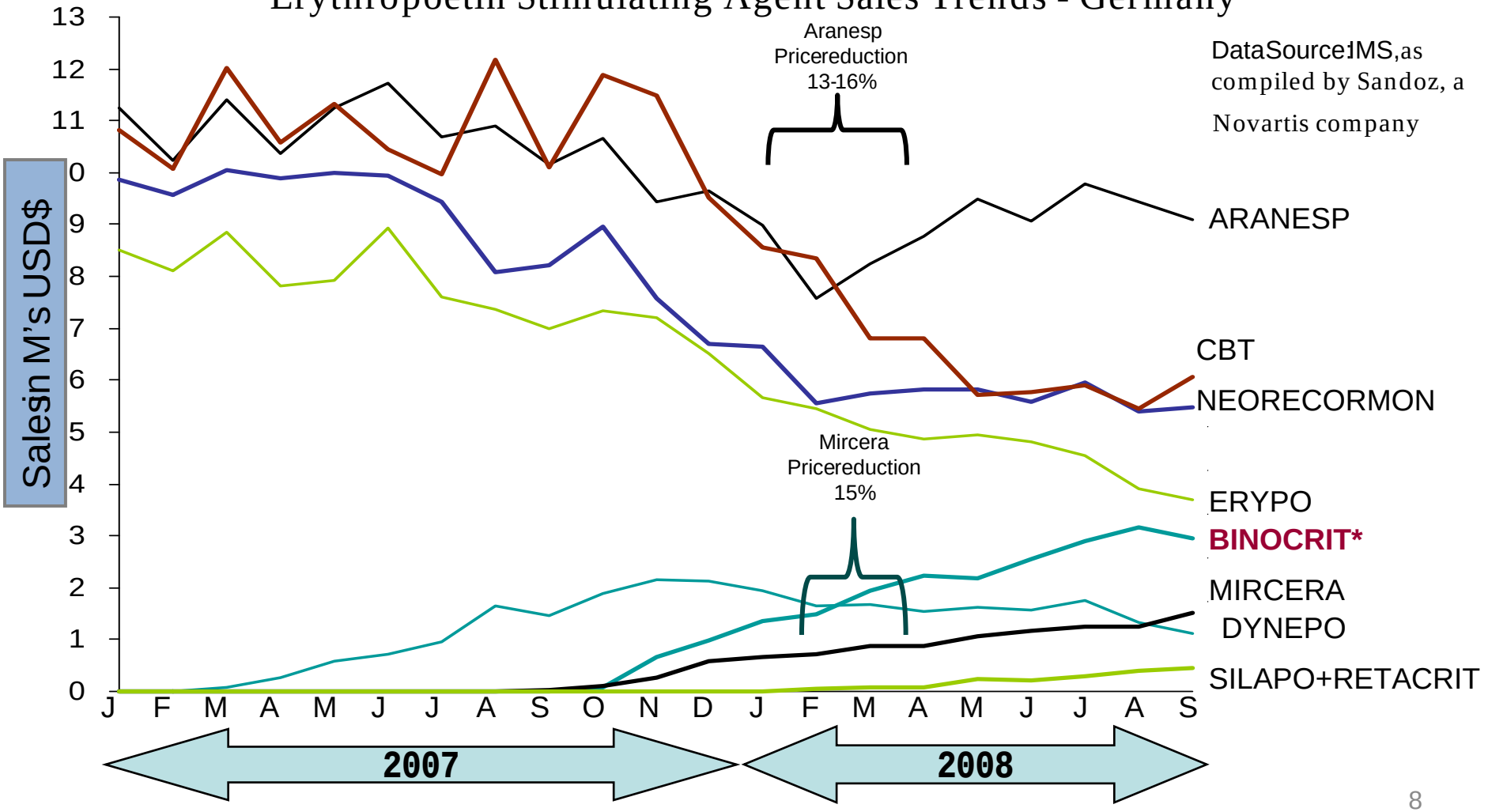
ESA BIOSIMILAR MARKET STARTS SLOWLY AS WELL



Source: IMS Health and companies

*Biosimilar market share just in Germany and UK.
**Dynepo being phased out by year end.

Erythropoetin Stimulating Agent Sales Trends - Germany

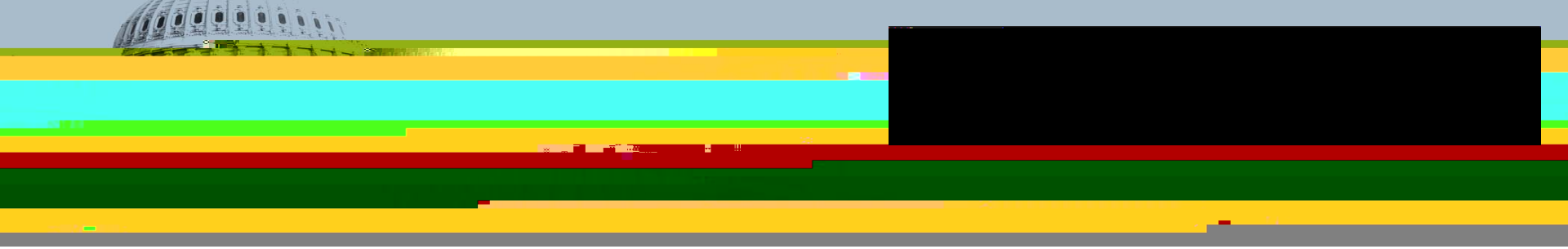


* Represents Binocrit, Epoetinalfa Hexal and Abseamed

Biosimilar Discounts Significant

- ESA brand-name competitors reduce prices before and after introduction of biosimilars in Germany and UK.
- Amgen reduces price 13% to 16% in early ’08 in Germany. However, Amgen says it maintains a 15% to 30% price premium to first generation ESAs in Europe. Other data suggest price premium is narrower in Germany.
- ESA biosimilars priced at about 25% discount to innovator product.

Sources: IMS and companies



Causes of More Limited Biosimilar Market

- Clinical development and marketing costs.
- Biosimilar NOT substitutable for reference product at retail pharmacy level
  - State generic substitution laws may not provide for biosimilar or biogeneric substitutability.

One Man’sTech Gain is Another’s Evergreening

- Introduction of 2nd generation product threatens to limit potential of biosimilars to save money by retaining reference product market share and price premium.

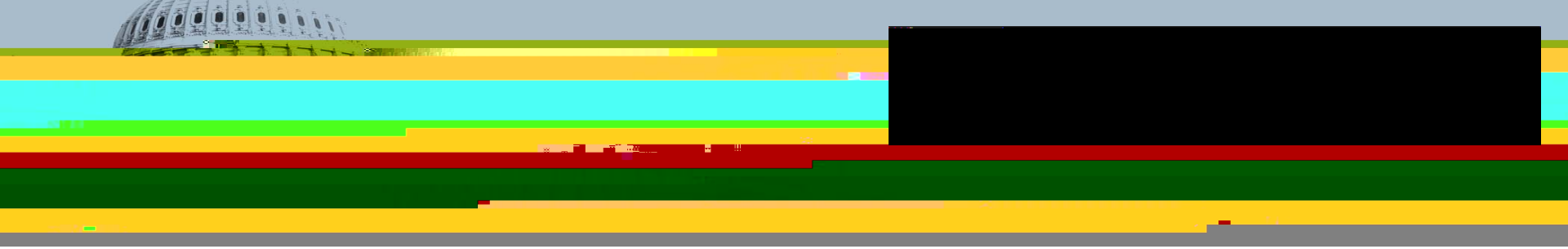
  Aranesp:

  - Still commands a premium price to first-generation ESAs, according to Amgen, although that premium is narrower in Germany.
  - Remains market leader in sales, with less market-share erosion in Germany than first-generation ESAs.

- Caveat: Biosimilar may improve on the reference product.

Biosimilar Impediment: Reimbursement Incentives

- 64% of biotech drugs are used in a physician's office which limits effectiveness of retail pharmacy substitution (if its even possible9Ds



Some Insurance Incentives in Place

- Dialysis bundling (although payments not yet set)
- Insurance plan formularies
- Medicaid preferred drug lists

Conclusions

- First biosimilars in Europe and US show potential for price discounts, but more modest than with small-molecule generics.
- Federal and state legislative issues of substitutability, public and private reimbursement incentives and coverage, and coding authority are key to future of biosimilars.

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For more information contact Paul Heldman at 202-266-7289.

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