

# CHIRAL TECHNOLOGIES INC

#### DAICEL GROUP

Innovation Begins Here

## Chirality

## Asymmetric Enzymatic

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## Is There a Better Way?

Joseph M. Barendt, Ph.D.



## **Chiral Technologies Inc.**

<ul> <li>Discovery         <ul> <li>High volume of candidates</li> <li>Chirality of drug TBD</li> </ul> </li> <li>Key: Delivery of material</li> </ul>	<ul> <li>Process Development         <ul> <li>High attrition rate</li> <li>Chirality is known</li> </ul> </li> <li>Key: Speed</li> </ul>
<ul> <li>Clinical Trials         <ul> <li>Long-term focus</li> <li>Process feasibility</li> </ul> </li> <li>Key: Scalability</li> </ul>	<ul> <li>Commercial Production         <ul> <li>Process robustness</li> <li>Equipment availability</li> </ul> </li> <li>Key: Cost</li> </ul>



## **Chiral Technologies Inc.**

- Our only focus is enantiomeric purity
  - Custom purification from mgs to 100 kgs
  - Discovery through Phase II Trials
- Two Case Studies to exemplify capabilities
  - Process Development
  - Clinical Trials



## Case Study #1

- Process Development
- Initial focus was on API
  - Current process; classical resolution
  - Slow process, high cost, not scalable
- Reviewed prior intermediates
  - Developed process to obtain >98%ee
    - Faster than classical resolution
    - 25% of the cost

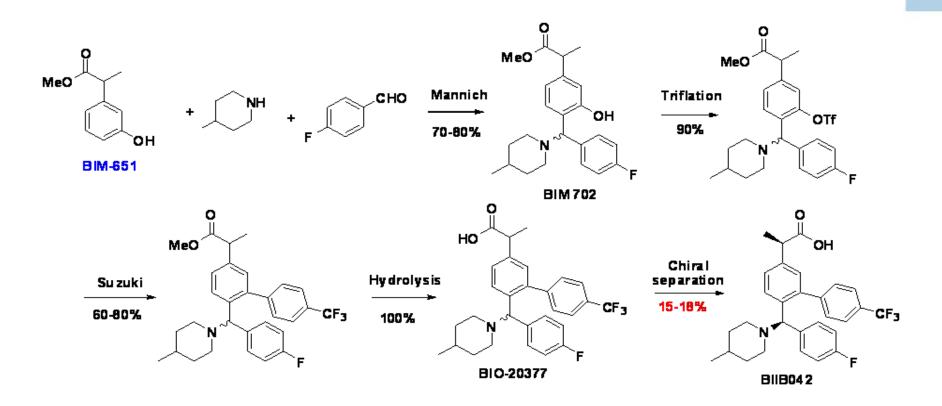


## Case Study #2

• Biogen Idec Drug



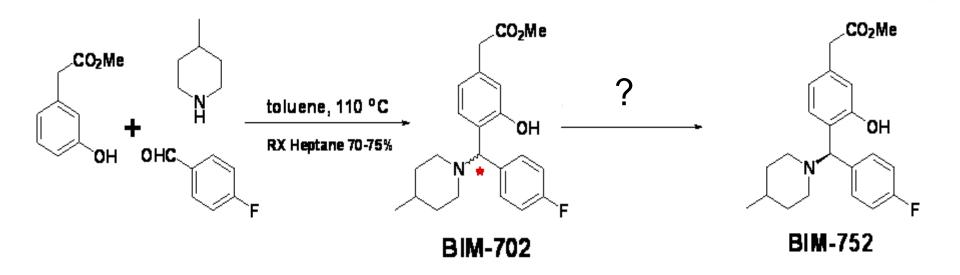
#### Initial Drug Discovery Approach to BIIB042



The Mannich reaction established the framework for **BIIB042** in the first step producing **BIM-702**, and chiral chromatography was employed to separate the four stereoisomers.

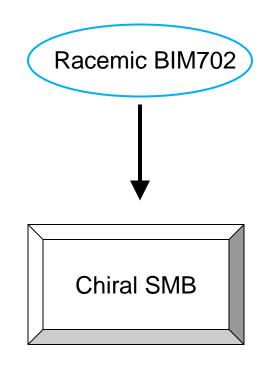


## **Formation of First Chiral Center**



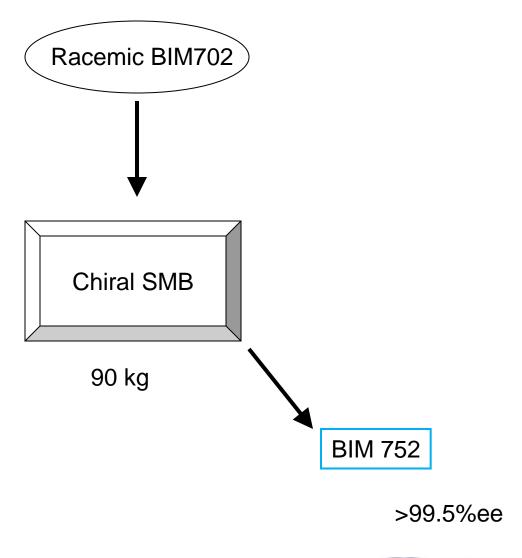
- Attempted both Enzymatic and Classical Resolution to no avail.
- Developed SMB route to obtain >99%ee BIM-752
- Ran 90kg campaign to prove it out



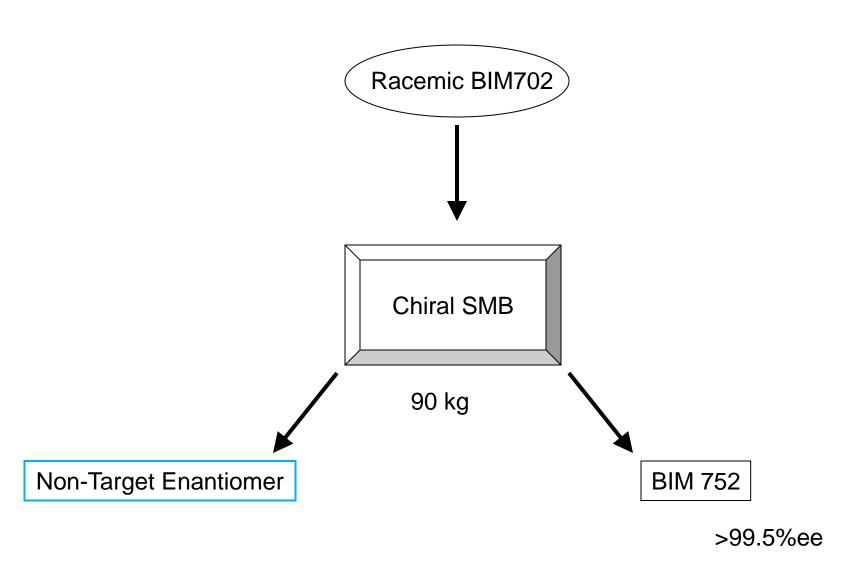


90 kg

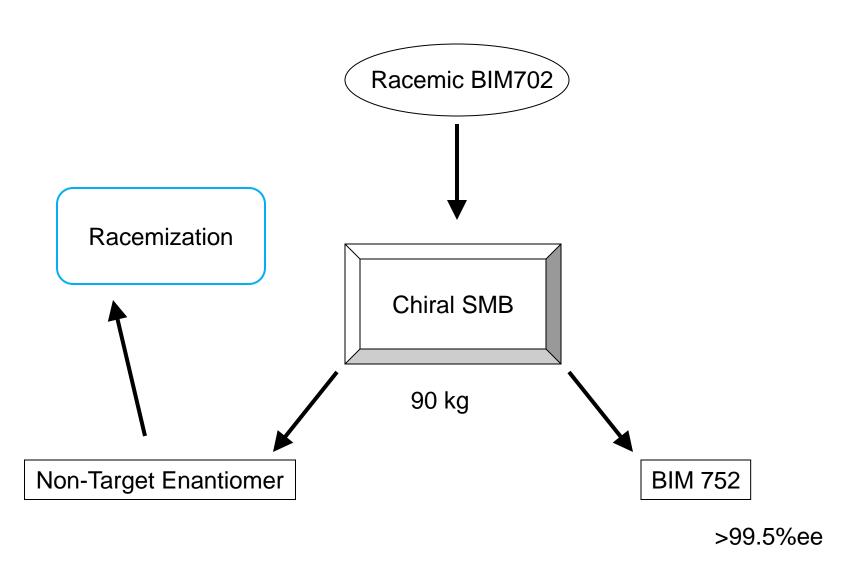




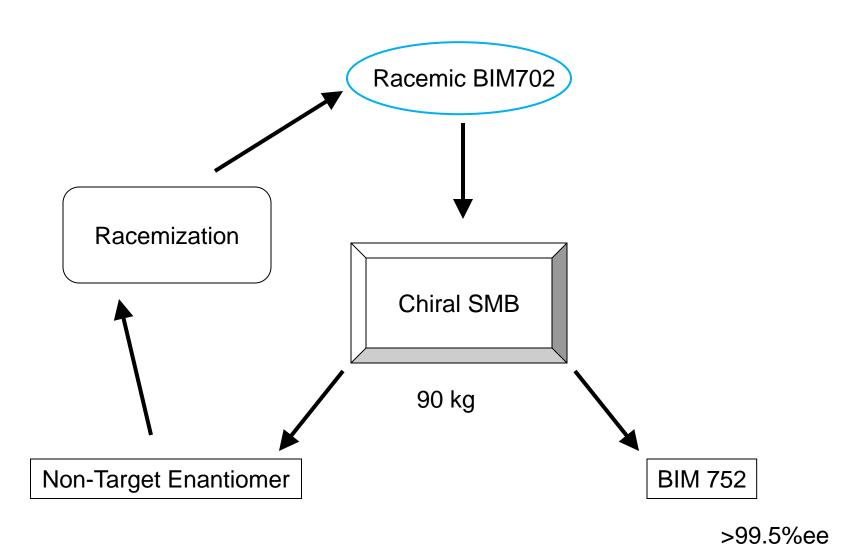








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## **Global Capabilities**











