

Patent Valuation Case study

TEVA Vs NATCO & others

**Patents that prevent others from practicing
something
“Sustainable competitive advantage”**

June 2012

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1. Copaxone

COPAXONE is the brand name for glatiramer acetate (formerly known as copolymer-1).

COPAXONE is a synthetic polypeptide analog of myelin basic protein (MBP) which is a natural component of the myelin sheath. Glatiramer acetate is approved by the U.S. Food and Drug Administration (FDA) to reduce the frequency of relapses in patients with relapsing-remitting MS. It is also approved for use in individuals who have experienced a first clinical episode (clinically-isolated syndrome) and have MRI features that are consistent with multiple sclerosis. (<http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/medications/glatiramer-acetate/index.aspx>)

2. Multiple sclerosis (MS),

Multiple sclerosis also known as "disseminated sclerosis" or "encephalomyelitis disseminata", is an inflammatory disease in which the fatty myelin sheaths around the axons of the brain and spinal cord are damaged, leading to demyelination and scarring as well as a broad spectrum of signs and symptoms

TEVA Vs Sandoz/Momenta & Mylan/Natco

3. About Teva

Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's leading generic drug maker, with a global product portfolio of more than 1,300 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on CNS, oncology, pain, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 46,000 people around the world and reached \$18.3 billion in net revenues in 2011. (www.tevapharma.com)

- I. TEVA is the proprietor of multiple patents covering the chemical composition of COPAXONE®, methods of using the product and processes for manufacturing the product.
- II. The patents-in-suit are U.S. Patent Nos. 5,981,589, 6,054,430, 6,342,476, 6,362,161, 6,620,847, 6,939,539 and 7,199,098 ("the Orange Book Patents") and U.S. Patents Nos. 5,800,808, and 6,048,898, which are not listed in the Orange Book. The seven Orange Book Patents and U.S. Patent No. 6,048,898 are set to expire on May 24, 2014 a U.S. Patent No. 5,800,808 is set to expire on September 1, 2015. (<http://www.mondaq.com/canada/x/183576/Patent/COPAXONE+Patents+Infringed+Valid+And+Enforceable+US+District+Court>)

4. Timelines

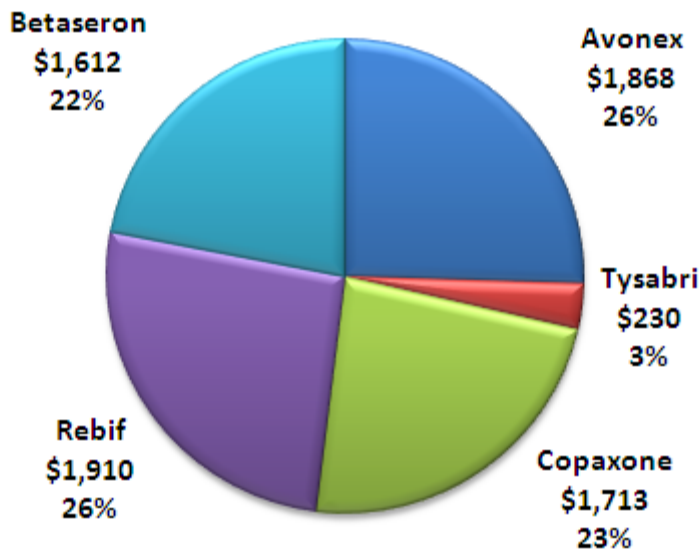
- I. NATCO, a Hyderabad-based company had filed an ANDA for Copaxone with its partner, Mylan Inc, in June 2008 and obtained a Para IV certification which challenged the existing patents held by Teva.
- II. In response to paragraph IV notice letters, Teva files Infringement suit against Sandoz/Momenta in 2008 and Mylan/Natco in 2009 and the two proceedings were consolidated.
- III. June 22, 2012 US District Court judgement rules in favour of TEVA (detailed judgement soon to be released)
- IV. TEVA stock rises to a 12 year high.

5. War to sustain in the MS drug market

- I. 25 November 2011: Report predicts multiple sclerosis drug market will reach \$15.8bn in 2015' says visiongain report (http://www.visiongain.com/Press_Release/112/%27Report-predicts-multiple-sclerosis-drug-market-will-reach-15-8bn-in-2015%27-says-visiongain-report)
- II. Sanofi reported positive results from a late-stage trial of its Aubagio multiple sclerosis drug. Brand expects Aubagio to generate peak sales of \$1.8 billion in 2018, taking around 11 percent of volume market share. (<http://www.reuters.com/article/2012/06/01/us-sanofi-study-idUSBRE85008820120601>)

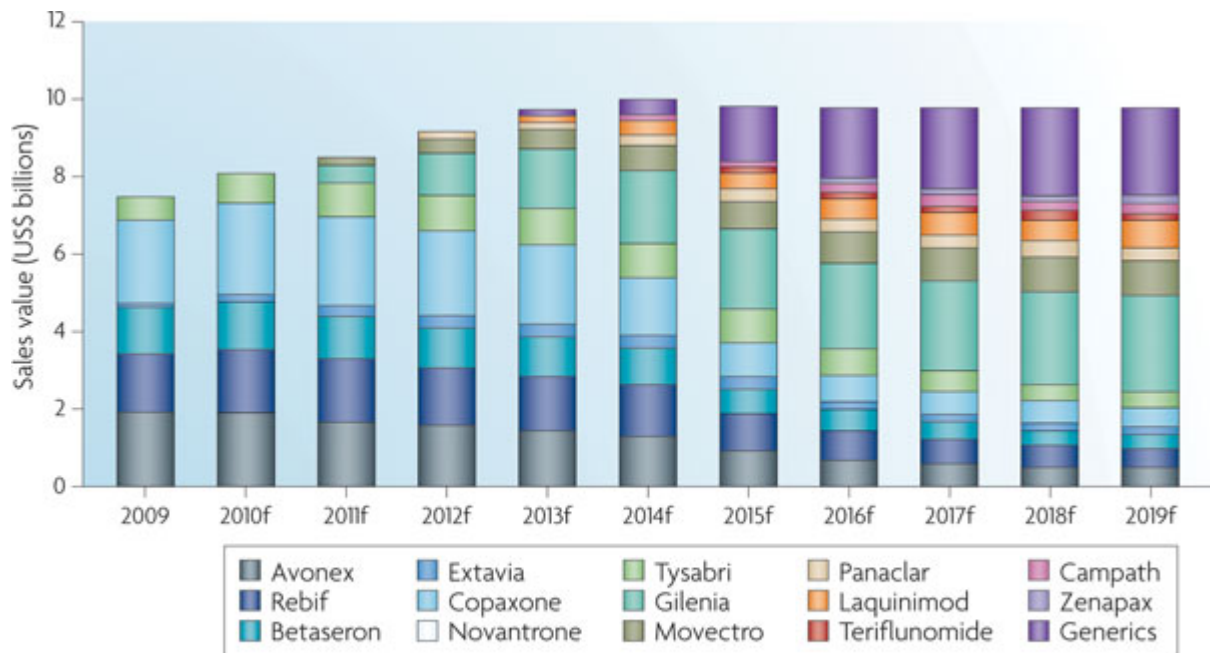
Figure1: Multiple Sclerosis drug market in 2007

Top 5 Multiple Sclerosis Drugs in 2007 (in millions of US\$)



http://www.wikinest.com/concept/Multiple_Sclerosis_%28MS%29_Drug_Market

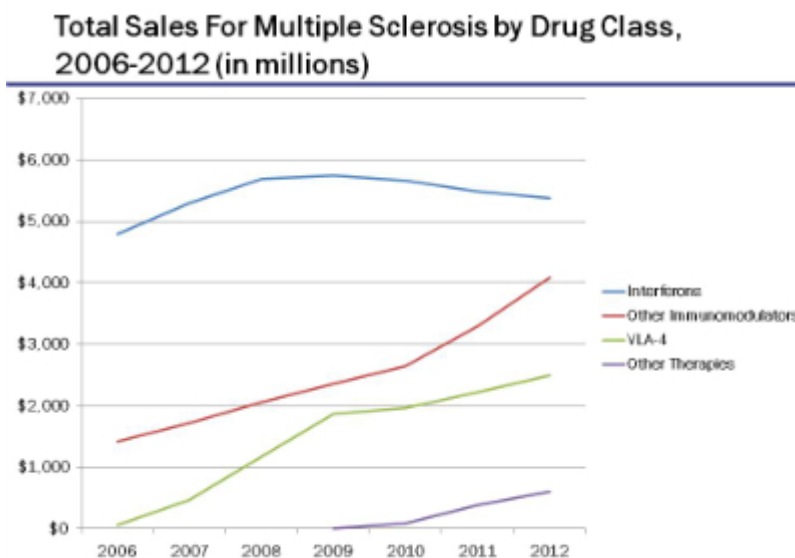
Figure 2: Projected sales



Nature Reviews | Drug Discovery

http://www.nature.com/nrd/journal/v9/n10/fig_tab/nrd3272_F1.html

Figure 3: Total Sales of MS by Drug Class



<http://www.cuttingedgeinfo.com/research/market-intelligence/neurodegenerative-forecast/>

The Generic Approval Process

In 1984, Congress passed The Drug Price Competition and Patent Term Restoration Act that came to be known as the “Hatch-Waxman Act.” The Hatch-Waxman rules created processes and incentives for both branded and generic companies involving challenges to patents.

- Branded pharmaceutical companies are required to list patents involving composition of matter (substance), formulation, and method of use in the Food and Drug Administration “s (FDA) *Approved Drug Products with Therapeutic Equivalence Evaluations* , also known as the Orange Book.
- When applying to enter the market with a generic form of a reference product, the generic company files an Abbreviated New Drug Application (ANDA) and certifies against patents listed in the Orange Book. The certification states that either (a) FDA should approve of its generic version after the date the last patent expires (a “Paragraph 3” filing) or (b) that its generic product does not infringe on the listed patents or that those patents are not enforceable (a “Paragraph 4” filing actually called a Paragraph IV filing.¹
- If the generic company files an ANDA with a Paragraph IV certification, then the branded company is notified. After the notice, the branded company has 45 days to file a patent infringement action against the generic company. After the suit has been filed, the FDA cannot approve of the application until the generic company successfully defends the suit or until 30 months, whichever comes first.

The Regulations also allow for two other types of certifications that are not relevant for The Paragraph Four Report. A Paragraph 1 certification states that there are no patents listed, and a Paragraph 2 certification states that the listed patents have expired.

(<http://www.paragraphfour.com/explained/process.html>)