Challengers eye bimatoprost patents

Just because two brands share the same active ingredient – and to some extent the same US patents – it does not necessarily mean they will attract the same generic challengers.

Allergan originally obtained US approval to market bimatoprost as an ophthalmic solution for treating glaucoma, or ocular hypertension, under the Lumigan brand name. But several years after Lumigan's market entry in March 2001, Allergan capitalised on the drug's effect of increasing the pigmentation and growth of eyelashes to secure approval for bimatoprost eye drops in December 2008. The originator introduced its treatment for eyelash hypotrichosis as Latisse early in 2009.

According to Allergan's latest quarterly '10-Q' filing, Lumigan's global sales in the first six months of 2010 increased by 14.7% to US$250.5 million. In the same period, Latisse's turnover climbed by 68.3% to US$42.7 million, driven in part by direct-to-consumer advertising. Annual global brand sales in 2009 were US$457 million and US$73.7 million respectively.

"Such sales are unlikely to go unnoticed by generics companies – indeed, both Lumigan and Latisse are the subject of paragraph IV patent challenges," observes Thomson Reuters.

Referring to its Newport Premium database, Thomson Reuters says it appears Teva's Barr was the first firm to file an abbreviated new drug application (ANDA) containing a paragraph IV certification for a generic version of Lumigan ophthalmic solution. The brand is protected by US patents 6,403,649 and 5,668,819, which expire on 21 September 2012 and 19 August 2014 respectively (see Figure 1).

Having sued Barr for alleged infringement of both patents in a Delaware district court in May 2009, Allergan in December last year received notification of Sandoz' ANDA and soon after filed a similar suit in the same court (**Generics *bulletin***, 1 February 2010, page 15). The two cases were consolidated in April this year and a trial is scheduled to start on 1 February 2011.

Different approaches to invalidity

Thomson Reuters notes that while Barr has alleged some of the '819 patent's claims are invalid, and the rest not infringed, Sandoz has asserted the invalidity of all of the claims – which it would, in any case, not infringe. Both generics firms have said the '649 patent is invalid.

The '649 patent also protects Latisse, which is covered by another two patents in the Orange Book maintained by the US Food and Drug Administration (FDA): 7,388,029, expiring on 21 January 2022, and 7,351,404, which expires on 25 May 2024. The brand's new product exclusivity runs out on 24 December 2011.

Having received notification of Apotex' ANDA for a rival to Latisse in July this year, Allergan in September alleged infringement of all three patents in a North Carolina district court (see Figure 2).

According to Allergan's complaint, Apotex' notification letter indicated challenges to the '029 and '404 patents, but insisted the '649 patent was – for an undisclosed reason – "not relevant". Thomson Reuters noted that the 30-month stay on ANDA approval would end in January 2013, several months after the '649 patent expires in September 2012. "Since Hatch-Waxman cases typically take longer than 30 months, it's unlikely that Apotex expects to resolve the other patent disputes before the '649 patent expires in September 2012," maintains the strategic intelligence specialist. G

KEY DETAILS: LUMIGAN

Brand:	Lumigan
Active ingredient:	bimatoprost
Delivery form:	0.03% ophthalmic solution
Brand owner:	Allergan
Annual US brand sales:	US$457 million*
First paragraph IV filing accepted by FDA:	22 December 2008
Known paragraph IV filers:	Barr/Teva and Sandoz
Patents at issue – expiry dates:	6,403,649 – 21 September 2012 5,668,819 – 19 August 2014
District court location:	Delaware
Litigation references:	Allergan vs Barr Laboratories 1:09-cv-00333
Other FDA Orange Book patents with expiry dates:	None

* global brand sales in 2009. Allergan generated 65.4% of its net product sales in the US last year.

Figure 1: Key details of paragraph IV challenges to Allergan's Lumigan (bimatoprost) ophthalmic solution in the US (Source – Thomson Reuters)

KEY DETAILS: LATISSE

Brand:	Latisse
Active ingredient:	bimatoprost
Delivery form:	0.03% topical solution/drops
Brand owner:	Allergan
Annual US brand sales:	US$73.7 million*
First paragraph IV filing accepted by FDA:	3 May 2010
Known paragraph IV filers:	Apotex
Patents at issue – expiry dates:	6,403,649 – 21 September 2012 7,388,029 – 21 January 2022 7,351,404 – 25 May 2024
District court location:	North Carolina (Middle District)
Litigation references:	Allergan vs Apotex 1:10-cv-00681
Other FDA Orange Book patents with expiry dates:	None

* global brand sales in 2009. Allergan generated 65.4% of its net product sales in the US last year.

Figure 2: Key details of paragraph IV challenges to Allergan's Latisse (bimatoprost) topical solution in the US (Source – Thomson Reuters)