Desonate disclosure could prove costly

The maxim that 'time is money' can easily be applied to US Hatch-Waxman patent-litigation cases. One of the major protections the system offers to brand owners in these patent conflicts is the statutory 30-month stay on the US Food and Drug Administration (FDA) approving the generic firm's abbreviated new drug application (ANDA). Such a 30-month stay starts running from the date that the patent holder receives a letter notifying it that a generics company has filed an ANDA containing a paragraph IV certification challenging one or more US patents listed in the FDA's Orange Book. The brand or patent holder has 45 days in which to file a patent-infringement suit if it wants to trigger a stay on final ANDA approval.

For blockbuster drugs with annual sales in the billions of dollars, each day a generic can be kept off the market is worth millions; any significant delay can pay the costs of litigation many times over. For smaller products, the stakes are correspondingly lower, but the basic premise still holds true. Any delay in generic entry is a boon for the brand and a lost opportunity for would-be generic competitors, not to mention the patients waiting for a cheaper version of a needed drug.

A recent paragraph IV challenge to the Desonate (desonide) 0.05% gel marketed by Bayer's Intendis unit illustrates how a deviation from standard timelines and practices could be costly.

Desonate gel is a low-potency topical corticosteroid for treating mild to moderate atopic dermatitis. While generic desonide 0.05% creams, lotions and ointments have been available for several years, Bayer's Intendis claims that two-thirds of dermatitis patients favour a hydrogel over other topical formulations. IMS Health reports that total US sales of desonide products in 2010 were just under $60 million.

In letters dated 15 and 16 March 2011, Intendis and patent-owner Dow Pharmaceutical Sciences received notification of an ANDA with a paragraph IV non-infringement certification for a generic version of Desonate gel. The letters did not, however, identify the ANDA applicant, as is required by the Hatch-Waxman Act.

Clarified date of notification receipt

On 5 April 2011, counsel for Intendis contacted Hultquist IP, the source of the letters, and learned that River's Edge was the ANDA applicant. Intendis and River's Edge later clarified that Intendis received the paragraph IV notification on 5 April 2011 and that the 45-day period to file suit commenced on that date. Suits were filed in district courts in New Jersey and the Northern District of Georgia on 18 May and 19 May 2011 respectively.

Under the Hatch-Waxman Act, the 30-month stay is calculated from the date the last relevant party receives the notification letter. "Typically, that date is not long after the letter is sent, and often not more than a day or two," observes Thomson Reuters, which compiles a database of paragraph IV challenges. But because of the confusion caused by notification letters that did not identify River's Edge, notification was delayed in this case by nearly three full weeks. That delay not only pushed back the expiration of the 30-month stay, but also held up the initiation – and presumably resolution – of the litigation by the same amount of time.

"Because sales of Desonate are modest, the cost to River's Edge of this delay is likely to be fairly small. But for other drugs, a similar delay could be worth millions of dollars," Thomson Reuters notes.

KEY DETAILS: DESONATE

Brand:	Desonate
Active ingredient:	desonide
Delivery form:	0.05% gel
Brand owner:	Intendis
Annual US brand sales:	Less than US$60 million
First paragraph IV filing submitted to FDA:	1 December 2010
Known paragraph IV filers:	River's Edge
Patents at issue – expiry dates:	6,387,383 – 3 August 2020
District court location:	New Jersey Georgia
Litigation references:	Intendis & Dow vs River's Edge 2:11-cv-02838 1:11-cv-01634
Other FDA Orange Book patents with expiry dates:	None

Figure 1: Key details of paragraph IV challenges to Intendis' Desonate (desonide) atopic dermatitis treatment in the US (Source – Thomson Reuters)

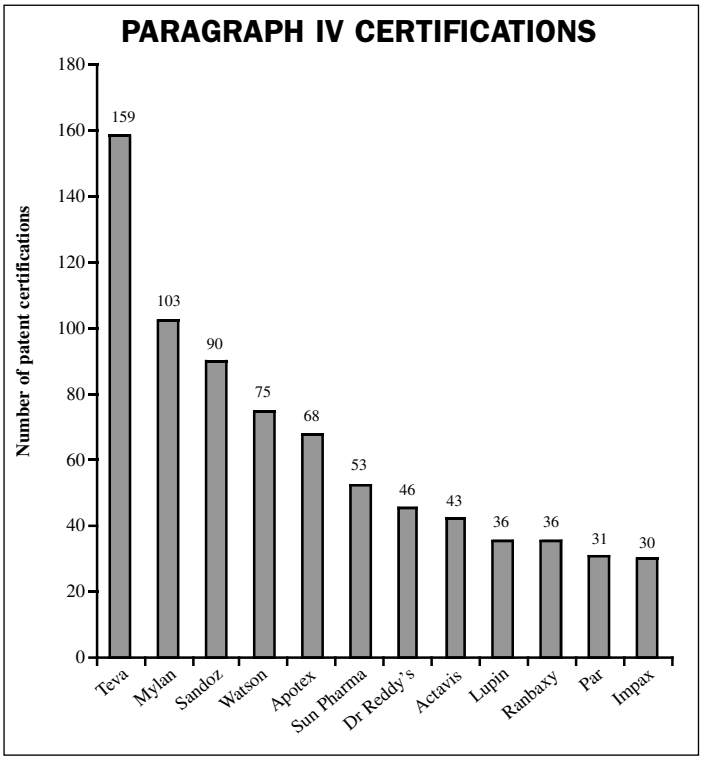

Figure 2: Numbers of paragraph IV patent certifications recorded by Thomson Reuters to 31 March 2011 (Source – Thomson Reuters)