

# Patent Suit over Viagra

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Pfizer Inc. filed a suit against Watson Laboratories, on June 1, 2011 in the United States District Court for the Southern District of New York seeking to prevent Watson from commercializing sildenafil citrate tablets prior to the expiration of Pfizer's Viagra. Watson's sildenafil citrate tablets are a generic version of Pfizer Inc.'s Viagra, which is indicated for the treatment of erectile dysfunction (ED). Sildenafil citrate enhances the effect of nitric oxide, which plays a key role in creating erections, by inhibiting a chemical which can restrict its action. Pfizer's lawsuit was filed under the provisions of the Hatch-Waxman Act, resulting in a stay of final FDA approval of Watson's ANDA until November 6, 2013 or until final resolution of the matter before the court, whichever occurs sooner, subject to any other exclusivity. Pfizer also filed suit against companies, such as Actavis, Apotex and Mylan, in response to the companies' filing of an Abbreviated New Drug Application (ANDA) for the active ingredient in Viagra.

The Orange Book listing for Viagra contains two patents, one of which expires in March 2012, and the other in October 2019. Pfizer is trying to block generic sales until the 2019 patent expires. Details with respect to the two patents are provided.

<b>Patent No</b>	<b>Proprietary Name</b>	<b>Active Ingredient</b>	<b>Strength</b>	<b>Dosage Form; Route</b>	<b>Applicant</b>	<b>Expiry</b>
5250534	VIAGRA	SILDENAFIL CITRATE	EQ 25MG BASE; EQ 50MG BASE; EQ 100MG BASE	TABLET; ORAL	PFIZER IRELAND	<b>Mar 27, 2012</b>
<b>6469012</b>	VIAGRA	SILDENAFIL CITRATE	EQ 25MG BASE ; EQ 50MG BASE; EQ 100MG BASE	TABLET; ORAL	PFIZER IRELAND	<b>Oct 22, 2019</b>

Viagra sales are around \$1.9 billion per year, with one month's sales being close to \$158 million. Taking into consideration the jaw-dropping sales they are making, it is very natural that Pfizer would use all their muscle to prevent generics from entering the market before the expiration of Viagra. Some of the options available for Pfizer to guard their drug could be:

- Making Viagra available over-the-counter. However, this might not seem as a feasible option due to the contraindications they pose in patients with a weak heart. Patients suffering from cardio-vascular diseases need to consult a doctor prior to use of Viagra. Sildenafil is also known to lower the blood pressure, sometimes causing severe and sudden drops in blood pressure.
- Licensing the drug to generic companies and hence preventing the generics from filing for an ANDA application.
- By dropping the price of Viagra and hence reducing generic competition.
- Possibly, work around the patent and come up with an enhanced version with extended release.

As the suit over Viagra progresses, there would be many interesting things to look out for, such as the strategy that is going to be adopted by Pfizer in order to defend their drug; strategy adopted by the generics to invalidate the patent on Pfizer's drug and enter the market as early as possible. For all we know Pfizer, might even not be affected by the patent running into expiry taking into the fact that consumers would have got comfortable with the branded version and might doubt the generic versions reliability because of the vast side-effects it can have if not used under guidance. For now, all we can do is sit back and watch the drama unfold!!

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