

**Senate Community Affairs Committee**

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

**Budget Estimates 2013-14, 5/6 & 7 June 2013**

**Question: E13-226**

**OUTCOME:** 2 – Access to Pharmaceutical Services

**Topic:** Patent Litigation

**Type of Question:** Written Question on Notice

**Senator:** Heffernan

**Question:**

Is there a list of other things which you could provide on notice where evergreening issues are impacting on the Budget?

**Answer:**

The Department of Health and Ageing notes that the independent Pharmaceutical Patents Review Panel stated in its Draft Report that “the term ‘evergreening’ has no generally agreed definition and is often used in literature to describe the utilisation of patent law and regulations, in order to maximise or extend the protection surrounding intellectual property” (IP Australia- Pharmaceutical Patents Review Secretariat, *Pharmaceutical Patents Review Panel Draft Report*, 2 April 2013, p. 119)

The Department understands this question was asked in the context of litigation between pharmaceutical patent holders and generic manufacturers.

Injunctions preventing the listing on the Pharmaceutical Benefits Scheme of a generic medicine have been granted in various cases since 2007, including those cases in the attached list. This list has been divided into two categories:

- 1) cases where the generic company was successful and no further appeals are pending; and
- 2) cases pending final determination.

The list is based on publicly available information on cases initiated in the Federal Court of Australia and was last updated on 23 October 2013.

Any delay to the entry of a generic medicine into the market has an impact on the Budget due to delayed price reductions and implementation of price disclosure arrangements.

## Patent Litigation

Case Name	Drug
Cases where generic company successful, no further appeals pending	
<i>Apotex Pty Ltd and others v Sanofi and others</i>	clopidogrel
<i>Sigma Pharmaceuticals (Australia) Pty Ltd and others v Wyeth and others</i>	venlafaxine
Cases pending final determinations	
<ul style="list-style-type: none"> <li>• <i>Ranbaxy Australia Pty Ltd and others v AstraZeneca AB and others</i></li> <li>• <i>AstraZeneca AB and Anor v Alphapharm Pty Ltd</i></li> </ul>	esomeprazole
<i>Apotex Pty Ltd and others v AstraZeneca Pty Ltd and others</i>	rosuvastatin
<i>Otsuka Pharmaceutical Co Ltd and Bristol Myers Squibb v Generic Health Pty Ltd</i>	aripiprazole
<i>Eli Lilly and others v Apotex Pty Ltd</i>	raloxifene
<i>Apotex Pty Ltd v Pfizer Ireland Pharmaceuticals &amp; Anor</i>	sildenafil
<i>Novartis Pharmaceuticals Australia Pty Ltd and others v Hospira Pty Ltd and others</i>	zoledronic acid
<i>Sanofi and others v Apotex Pty Ltd and others</i>	leflunomide
<i>Apotex Pty Ltd v Les Laboratoires Servier and others</i>	perindopril arginine
<i>Apotex Pty Ltd v F. Hoffman-La Roche AG</i>	valganciclovir
<i>Merck Sharpe &amp; Dohme and others v Apotex Pty Ltd</i>	mometasone
<i>Apotex Pty Ltd v Merck Sharp &amp; Dohme and others</i>	desloratadine
<i>Les Laboratoires Servier v Apotex Pty Ltd</i>	gliclazide