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## **Roche: Boniva patent prosecution history and repeated challenges on biphosphonate class expected to make patent more vulnerable to invalidation**

Roche's Boniva could be more vulnerable to a patent invalidation given its patent prosecution history and repeated challenges on the biphosphonate class of drugs, a number of lawyers agreed.

Court documents reveal that Roche received notice of the challenges for the Boniva 150mg tablet formulation patent from a number of generic manufacturers including Gate (Teva) (on 27 July 2007), Mutual (on 30 July 2007), Dr Reddy's (07 August 2007), Orchid (13 August 2007) and Genpharm (on 15 August 2007). Gate appears to be the first to file and would therefore be entitled to a 180-day exclusivity once the 30-month stay of execution expires, as per the Hatch Waxman proviso.

The patents being challenged are the '196 (pharmaceutical composition containing diphosphonic acid or salt thereof) and '938 (method of treatment using bisphosphonic acid) patents which expire in 2019 and 2023 respectively.

Court documents reveal that the '814 patent - which is the active ingredient patent - and refers to "diphosphonate derivatives, pharmaceutical compositions and methods of use" is however not being challenged by any of the generic manufacturers. As the patent expires in 2012, **Neil Di Spirito, Esq at The Law Offices of Larry M Roth, PA**, said it makes sense to wait for the patent to expire rather than challenge it, given that the 30-month stay of execution on the generics will expire not long before 2012.

Boniva's patent prosecution documents show that there was a final rejection of the '196 patent based on a number of prior arts: European patent (EP252505) and a Schofield reference which were deemed too close to the current invention submitted by Roche. More specifically, according to patent prosecution documents in the first non-final rejection the examiner pointed out that "the present application's bisphosphonic acid (broad) encompasses the copending application's ibandronic acid (narrow) species". In other words the patent submitted by Roche was too close to a prior art present in a pending application of a European patent.

**Di Spirito** also agreed that patent prosecution documents, which highlight the reasons why the patent was rejected by the Examiner for being too close to prior arts, may anticipate how strong the claims in the light of an obviousness argument are in the ensuing patent litigation. A rejection does not necessarily imply that the patent is weak, he added, as this could be due to a number of reasons including - for example, the inability to have the technology to measure the patent claim.

Similarly **William Youngblood, attorney at Caesar, Rivise, Bernstein, Cohen & Pokotilow** agreed on the same points and further agreed that the rejection in the patent prosecution history relating to Schofield and the European patent actually makes the patent stronger as it shows that the Examiner gave these prior arts due consideration.

More importantly, he noted, any part of the claims disclaimed in the prosecution history cannot later be broadened during the litigation process, so Roche would need to show the strength of their patent claims based on their current wording.

After numerous rejections the Examiner agreed that the disclosure of the European patent provided no expectation that "once monthly oral administration of about 100 to about 150mg of bisphosphonate would be safe, tolerable, or effective to treat osteoporosis. It is believed that agreement was reached on all matters, with the Examiner indicating that the claims, amended as proposed, would be allowed".

In the same class of drugs, Actonel (Procter & Gamble), Reclast (Novartis) and Fosamax (Merck) have equally being challenged and a generic version of Fosamax is already available.

Both **Di Spirito** and Youngblood agreed that given the fact that other drugs in the same class have been challenged or have already gone generic, this could favour an out of court settlement between the parties - subject to other commercial considerations.

**Di Spirito** also pointed to the recent Pulmicort case where an out-of-court settlement was reached after Teva had launched at risk. Given Teva's history, he commented, and in view of the fact that the biphosphonate class has been heavily challenged already, there is a strong chance that Teva would entertain an at-risk launch.

The fact that Boniva is the only drug in the class with a monthly administration dosage - a clear advantage, it could give Roche some reason to consider a settlement with Teva as an authorised generic in order to maintain market share.

Boniva constituted approximately 1.7% of Roche's 2007 revenues.

by *Mintoi Chessa-Florea in London*