Pharmaceutical battle in New Zealand

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New Zealand is a country with a small GDP, as of 2009, only US$100 billion, one-eighteenth the size of California's, and a small population of only 4.3 million, just one- ninth the size of California's.

To maintain the health of New Zealanders, the New Zealand government must therefore ensure that its limited funding available for pharmaceuticals is spent very carefully.

To facilitate this, the government in 1993 set up the Pharmaceutical Management Agency of New Zealand (Pharmac).[1] According to the Pharmac website, it has four main roles:

- managing the Pharmaceutical Schedule of over 2,000 government-subsidised community medicines (those medicines that your doctor prescribes)
- promoting the best possible (or optimal) use of medicines

- managing the subsidy of some medicines and products for public hospitals
- managing Exceptional Circumstance schemes (medicines funding for people with rare conditions) and other special access programs.

In performing these roles, Pharmac is required to negotiate with the major pharmaceutical suppliers. Inevitably, conflicts are going to arise and some of these will result in court proceedings. Sometimes, as happened recently, Pharmac becomes a party to the proceedings.[2]

Other times, Pharmac, as in the proceedings that are the subject of this commentary, is a very interested third party.[3]

The Case

Sanofi-Aventis Deutschland GmbH (Sanofi), (formerly Hoechst AG), was the proprietor of a New Zealand patent for leflunomide. The patent expired in 1999. However, Sanofi obtained a subsequent patent, New Zealand patent 331933, (see WO 97/34600), for a compound of leflunomide together with a metabolite of leflunomide, teriflunomide. This compound was sold under the trade mark ARAVA, principally for the treatment of rheumatoid arthritis. In April 2002, Pharmac agreed to fully fund ARAVA for five years, provided that it was prescribed only by rheumatologists and to a specified group of patients. During that five-year period the effective list price for 10 mg packets of ARAVA was NZ$101[4] and, for 20 mg packets, NZ$142.

The agreement between the parties was then extended in April 2007 with a further two-year contract but with the patient restriction removed and with the price reduced to NZ$79.27 for 10 mg packets and NZ$108.60 for 20 mg packets. Since 2007, however, the New Zealand pharmaceutical company AFT Pharmaceuticals Limited (AFT) had been importing from Canada, and marketing in New Zealand, a leflunomide product, under the trade mark AFTleflunomide. AFT knew that the Sanofi patent for leflunomide had expired but did not consider that it would be infringing the later patent for the combination of teriflunomide with leflunomide.

The intention of AFT to enter the New Zealand market with leflunomide had become public on 6 July 2006 and subsequently Sanofi received official notification in the form of the data sheet for AFT-leflunomide. In April 2007, Pharmac and AFT entered into a provisional agreement relating to the supply of AFTleflunomide and, in May 2007, all interested parties, including Sanofi, were notified of this and invited to respond. Similar to the terms of the provisional agreement, AFT would receive NZ$76 for a packet of 20 mg tablets and NZ$55 for a packet of 10 mg tablets, both substantially less than the payments being received by Sanofi. In response to this invitation, Sanofi merely pointed out that AFT was not supplying the 100 mg tablets that were required for the initial loading dose. Also, that AFT was not required to monitor foetal damage after treatment had ceased, which Sanofi was doing free of charge and Sanofi questioned whether AFT would be doing the same. Sanofi did not raise any issue

regarding possible infringement of its New Zealand patent. AFT's commercial launch was in July 2007 and by June 2009 it had 16.4% of the New Zealand market share.

Testing conducted by Sanofi in 2008 discovered that AFT-leflunomide included in excess of 0.3% teriflunomide. Sanofi's patent attorneys wrote to AFT regarding the Sanofi patent in February 2009. Proceedings were issued on 27 March 2009. Of relevance to this timing was the expiry in April 2009 of both the two-year contracts that Sanofi and AFT had with Pharmac. Prior to that expiry date, in December 2008, Pharmac had invited tenders for the sole supply of leflunomide. A further development was the potential entry into the New Zealand market of Novartis and its product Leflunomide Sandoz and Apotex NZ Limited and its product Apo-leflunomide.

In these proceedings, Sanofi was seeking an interim injunction to restrain AFT from manufacturing, importing or marketing AFT-leflunomide or any other leflunomide product. AFT, although not conceding infringement, did not contest that there was an arguable question as to whether AFT- leflunomide did infringe, in that its product contained in excess of 0.3% teriflunomide. However, its position was that this was not the result of the manufacturing process but the emergence of teriflunomide fractionally during the shelf life of the tablet. AFT also challenged the validity of Sanofi's patent on the grounds of lack of novelty, obviousness, inutility and fair basis.

One day before the hearing, Pharmac undertook that, until the proceedings were resolved either by judgment or settlement, it would not reference price ARAVA to AFT-leflunomide, or award sole supply to AFT and also confirmed that Pharmac would not subsidise Apotex's product. On the day of the hearing, Pharmac gave a further undertaking. This would extend for 12 months but was capable of being extended, provided Sanofi undertook to meet Pharmac's lost savings after 12 months, if these proceedings were still in train. This undertaking was on the following terms: "[Pharmac] would not use any of its mechanisms to remove the subsidy of ARAVA solely as a result of the presence of AFT-leflunomide on the Pharmaceutical Schedule until the present litigation has been resolved"

Subsequent to the hearing, further undertakings were given by Pharmac that:

"To avoid any doubt, we confirm that the reference…to any of the mechanisms available to Pharmac covers all mechanisms available to Pharmac to adjust or remove the subsidy for ARAVA, solely as a result of the presence of AFT leflumonide on the Pharmaceutical Schedule, including, but not limited to, reference pricing, parity pricing and delisting."

Also, as far as Apotex and Novartis were concerned:

"For the avoidance of doubt…these brands are unrelated to these proceedings and thus, Pharmac's undertaking…does not extend to mechanisms available to

Pharmac to adjust or remove the subsidy for ARAVA in the event that one or other of those other brands is listed on the Pharmaceutical Schedule."

Further, Pharmac's solicitors stated in a letter on behalf of Pharmac:

"Pharmac does not consider the possible impact of AFT-leflunomide's listing on the Pharmaceutical Schedule on the subsidy pricing offered by suppliers of other brands of leflunomide that are not currently listed, to be relevant to these proceedings."

Also, the solicitors said in the same letter that:

"All Pharmac's undertakings will be withdrawn immediately Sanofi is granted an interim injunction against AFT."

In his decision, Keane, J. referred to the usual basis for interim relief being granted, namely that there is a serious question to be tried and that the balance of convenience lies in favour of granting relief. Reference was made by Keane, J. to Pharmac's pivotal role and the distinction between the present case, and an earlier case[5] where Pharmac was also involved, namely that in the present case AFT is already in the New Zealand market and Pharmac has made its position clear.

Regarding the patent, there was the concession by AFT that there was an arguable question of infringement. Also, as far as validity, in the judge's view, the

expert evidence on behalf of Sanofi was decisive at this stage on the obviousness question. However, in respect of fair basis, Sanofi had only tested in the range 1–11% of teriflunomide, whereas claim 1 was for 0.3–50% of teriflunomide. AFT alleged that the claim was therefore too wide and not fairly based. The conclusion of the judge was that the challenges that AFT had made to the validity of the patent:

“apart from that as to obviousness, seemed to me to be seriously arguable and indeed to set the issue as to validity in equipoise with that as to infringement, given the way in which the infringement is said to have arisen.”

As to the issue of the balance of convenience, the judge did not consider that Sanofi would suffer irreparable harm if AFT remained on the market and was also not convinced that AFT could be compensated in damages if interim relief was granted and it succeeded at trial. Additionally, Pharmac had made its position clear regarding the potential entry into the market by other generic suppliers, and, in respect of those suppliers, Sanofi had the option of asserting its rights in its patent in seeking interim injunction relief, which it had failed to do when AFT publicly notified its intention to enter the market in 2006.

For these reasons, Sanofi’s application for an interim injunction was declined. What is clear from this case is that, whether Pharmac is involved directly or indirectly, in New Zealand court proceedings, complex issues will arise. In circumstances such as these, however, where Pharmac has declared its position,

this can make the decision of the court, especially in any interim injunction proceedings, much easier.

Notes

1. www.pharmac.govt.nz.

2. Astrazeneca Limited v Commerce Commission & Pharmaceutical Management Agency (SC) 26/8/2009; Elias, C J, Blanchard, Tipping, McGrath & Wilson J J, CA 91/2008 [2009] NZSC 92.

3. Sanofi-Aventis Deutschland GmbH & Anor v AFT Pharmaceuticals Limited (HC, 3/8/2009; Keane J, Auckland, CIV 2009-404-1795).

4. As at 29 October 2009 – NZ$1 = US$.72.

5. Novartis New Zealand Limited v Aktiebolaget Hassle [2004] 2 NZLR 721 CA.