Australian Vioxx

By Richard Meeran and Andrew Baker

Vioxx was widely prescribed by millions of arthritis sufferers around the world from 1999 until it was withdrawn on 30 September 2004.

BACKGROUND

Rofecoxib, a type of anti-inflammatory drug known as a 'COX-2 inhibitor', was designed, developed, manufactured and marketed by New Jersey-based pharmaceutical giant, Merck, under the brand name 'Vioxx'. It was promoted as having greatly reduced risks of gastro-intestinal problems compared to other similar drugs.

Vioxx was widely prescribed to, and used by, millions of arthritis-sufferers worldwide from 1999 until 30 September 2004, when Merck's own (APPROVe) study indicated that Vioxx users suffered a significantly increased rate of heart attacks and strokes and the company recalled the drug worldwide. Around 250,000 Australians are estimated to have taken Vioxx.

Questions as to the cardiovascular safety of Vioxx had been raised even before it was released on to the market in 1999. In March 2000, the first major study into the drug, the 'VIGOR' trial, suggested that although Vioxx did demonstrate some reduction in gastro-intestinal problems, it also presented a risk of heart attacks and strokes that was five times greater than that of naproxen, another similar anti-arthritis drug. Merck argued that this finding was the result of the cardio-protective effects of naproxen, rather than a danger inherent in Vioxx. Others, however, rejected this hypothesis, observing that naproxen was incapable of producing a cardio-protective effect of such magnitude.

Merck resisted issuing any warnings about the potential cardiovascular risks of Vioxx for a further two years, and

Photo: Lisa Saad

even then the information provided on the subject was far from clear or obvious. As a result, doctors continued to prescribe Vioxx to their patients, oblivious to the cardiovascular risk.

To compound matters, evidence has emerged in the US that suggests that Merck may have gone to quite extraordinary lengths to continue proactively promoting Vioxx, despite increasing evidence of cardiovascular risk. In response to VIGOR, Merck produced a 'cardiovascular safety card' to give to doctors, which suggested that Vioxx was more than eight times safer than other anti-inflammatory drugs. Merck instructed its sales representatives not to initiate discussions on the results of the VIGOR study. A pharmaceutical training manual, entitled *Dodgeball Vioxx*, instructed them on how to 'dodge the ball' when questioned regarding the cardiovascular safety of Vioxx.

Most recently, editorials in the *New England Journal of Medicine* have claimed that Merck scientists deleted information on heart attack cases from disk files and omitted to include this data in the VIGOR study. Merck has vigorously denied these allegations.

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LEGAL ACTION

Not surprisingly, the circumstances of the recall, the nature of the adverse effects of the drug and the history of Vioxx, have resulted in class actions and individual suits being filed in the US on behalf of literally thousands of claimants. Merck has vowed to defend each case individually, and has set aside millions of dollars for this purpose. Of the three cases concluded so far, the plaintiff won the first (with a jury awarding the Vioxx user's widow US$253 million in damages), Merck won the second, and the third resulted in a mistrial. No clear pattern has emerged yet from these cases; however, none of the US cases tried so far has involved a significant or prolonged use of Vioxx – the category of case that analysts believe is most likely to succeed.

Foreign claims, including on behalf of some Australians, have also been filed in the US courts. Those claims are all currently subject to forum non conveniens motions, the first of which, relating to UK claims, is due to be heard on 31 March 2006.

In December 2005, a group proceeding was commenced in the Supreme Court of Victoria, and encompasses individuals who suffered heart attacks, strokes and other cardio- vascular injuries arising from arterial blood clots, following Vioxx consumption in Australia.

The defendants in the group proceeding are Merck Inc, the New Jersey-based parent company that made rofecoxib, and Merck Inc's NSW-based subsidiary, Merck Sharpe & Dohme, which made the Vioxx tablets from rofecoxib and also packaged, sponsored and marketed Vioxx in Australia.

In addition to alleging negligence against both defendants, the Statement of Claim alleges breaches of the *Trade Practices Act* 1974, viz: misleading and deceptive conduct (s52); defective product (s75AD); unfitness for purpose (s74B); unmerchantable quality (s74D).

Both Merck defendants are represented by Messrs Clayton Utz. They have raised three threshold issues that are scheduled for hearing before Justice Gillard on 10 April 2006.

First, they contend that certain of the *Trade Practices Act* claims are 'special federal' matters. Secondly, it is argued that the group definition includes claims that have no connection with Victoria, and over which the Supreme Court of Victoria has no jurisdiction. It is contended that these two reasons require that the action should therefore be transferred to the Federal Court.

Thirdly, the defendants state that the group definition includes individuals whose claims arose in Queensland, which ought to be governed by the law of Queensland, and thus required to comply with the *Personal Injuries Proceedings Act* 2002 (Qld), which lays down various procedural steps that are to be undertaken prior to the commencement of any proceedings. Since there has been no compliance with PIPA, it is contended that the group proceeding is invalid, at least insofar as it includes such claimants.

The PIPA argument has already been the subject of a hearing before Christmas in the NSW Court of Appeal, in an action brought by Messrs Shine Roche McGowan. Judgment is pending.

If and when the opportunities for procedural objections are exhausted, and the merits of the case come to be determined, individual causation is likely to be the key substantive issue. This will depend primarily on a combination of general epidemiological evidence derived from studies on Vioxx users, biological evidence as to the mechanism of action of Vioxx, and clinical evidence relating to the individual claimants themselves.

A significant proportion of the group comprises individuals who were elderly and frail and thus may have been at increased risk of cardiovascular injury in any event. Having said that, experts suggest that such individuals are precisely the type of people who may have been 'pushed over the edge' by Vioxx. Moreover, it appears that Vioxx usage increases the baseline risk, and that consequently the level of pre-existing risk of the individual in question is irrelevant to the statistical likelihood of causation of injury by Vioxx. ■

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