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The Lyrica saga continues: Australia's Full Federal Court dismisses Warner-Lambert's argument that an application for PBS listing is an infringing act

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Since Warner-Lambert successfully defended its pregabalin patent and obtained injunctions against generic market entry in *Apotex Pty Ltd v Warner-Lambert Company LLC (No 2)* [2016] FCA 1238 (see our coverage of the case in 'Carving out the principles: a comparative review of the Australia and UK Lyrica cases'), the Australian Lyrica dispute has continued through various appeals and cross-appeals. A number of cross-appeals still remain to be finalised.

Recently, the Full Federal Court of Australia considered Apotex's applications to list products on Australia's Pharmaceutical Benefits Scheme (**PBS**) before the expiry of a patent in *Warner-Lambert Company LLC v Apotex Pty Limited* [2017] FCAFC 58. The Full Court upheld the first instance decision of Justice Nicholas and clarified that an application by a generic for PBS listing does not, of itself, infringe a patent. In doing so, the Full Court also shed further light on the meaning of "exploit" in the Patents Act.

PBS listing and the meaning of "offer"

As part of Australia's reimbursement system pharmaceutical companies must first obtain a marketing approval apply and then apply for a PBS listing. The PBS listing, once granted, carries with it various mandatory obligations in connection with supply of the listed products. In the Lyrica case, Apotex had applied for PBS listing during the term of the patent, but with actual supply to commence from a date after expiry of the relevant patent.

The question was one of statutory interpretation – does an application for PBS listing constitute an "offer" to the Minister to supply the product to wholesalers and pharmacists within the meaning of "exploit" in the Patents Act? Warner-Lambert submitted that the generic's application for PBS listing during the term of the pregabalin patent (allowing them to gain a "springboard" for PBS listing ahead of other generics) was such an offer because it was to their commercial and economic benefit.

The Full Court held that it was not such an offer. The Court found that "offer" in this context had its ordinary meaning, such as "to present or tender for acceptance or refusal" or to "propose or express one's readiness (to do something) if the person assents". The Full Court recognised that an application for PBS listing carries with it an obligation to demonstrate that sufficient stock of the product must be available to PBS dispensers in time for the PBS listing day. This may require a

generic company to import product into Australia before the PBS listing date, and this conduct may well infringe an unexpired patent. However, the Court held the application was still not an offer under the Act. For an "offer" to constitute exploitation of a patent, it must be an offer to supply products to a third party, not simply to the Minister. The Minister is merely the regulator of the supply scheme and the application for PBS listing is a pre-condition for such supply to be reimbursed. The Court noted that products could be supplied to the market absent PBS listing, and the application process was therefore not the commercial activity that Warner-Lambert insisted it was. The obligation to supply was, in the words of the Full Court, "*nothing more than what it purports to be, an assurance that stock will be available to meet demand*."

One less leg – but there are plenty of others

The Full Court decision means that rights holders will have greater difficulty asserting infringement at an earlier stage of the generic approval/PBS listing process. However, the fact that most generics will be required to import commercial quantities of products to fulfil their PBS listing obligations, and such importation may well occur before patent expiry, means that rights holders may not be particularly disadvantaged by this decision. However, one thing is sure – Warner-Lambert's decision to seek special leave to appeal to the High Court of Australia from the Full Court's decision means that the Lyrica saga is far from over.

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