FEDERAL COURT OF AUSTRALIA

Warner-Lambert Company LLC v Apotex Pty Limited [2017] FCAFC 58

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| Appeal from: | *Apotex Pty Ltd v Warner-Lambert LLC (No 3)* [2017] FCA 94  |
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| File number(s): | NSD 239 of 2017NSD 240 of 2017 |
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| Judge(s): | **JAGOT, YATES AND BURLEY JJ** |
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| Date of judgment: | 13 April 2017 |
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| Catchwords: | **PATENTS –** whether primary judge erred in finding that an application for Pharmaceutical Benefits Scheme (PBS) listing is not an infringement of patent – whether an application for PBS listing constitutes an offer to supply and an exploitation of the claimed invention  |
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| Legislation: | *National Health Act 1953* (Cth) ss 84(1), 84AF, 85(6), 87, 99AC, 99ACB, 99ACF, 99ACH, 99AEA, 99AEB, 99AEC, 99AED, 99AEE, 99AEF, 99AEG, 99AEH *Patents Act 1990* (Cth) s 13(1), Sch 1*Therapeutic Goods Act 1989* (Cth)*National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* (Cth) Reg 2.16(2)  |
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| Cases cited: | *Apotex Pty Ltd v Warner-Lambert Company LLC (No 2)* [2016] FCA 1238*Apotex Pty Ltd v Warner-Lambert Company LLC (No 3)* [2017] FCA 94*Gerber Garment Technology Inc v Lectra Systems Ltd* [1995] RPC 383  |
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| Date of hearing: | 22 March 2017 |
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| Registry: |  |
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| Division: |  |
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| National Practice Area: |  |
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| Sub-area: |  |
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| Category: | Catchwords |
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| Number of paragraphs: | 20 |
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| Counsel for the Appellants: | Mr A L J Bannon SC with Mr C Dimitriadis SC |
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| Solicitor for the Appellants: | Allens |
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| Counsel for the Respondent in NSD 239 of 2017: | Mr N Murray with Mr M Fleming |
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| Solicitor for the Respondent in NSD 239 of 2017: | Ashurst Australia |
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| Counsel for the Respondent in NSD 240 of 2017: | Ms A Bowne SC with Mr C Murphy |
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| Solicitor for the Respondent in NSD 240 of 2017: | Maddocks Lawyers |

ORDERS

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|  | NSD 239 of 2017 |
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| BETWEEN: | WARNER-LAMBERT COMPANY LLCFirst AppellantPF PRISM CVSecond AppellantPFIZER IRELAND PHARMACEUTICALS (and others named in the Schedule)Third Appellant |
| AND: | APOTEX PTY LIMITED ACN 096 916 148Respondent |

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| JUDGES: | JAGOT, YATES AND BURLEY JJ |
| DATE OF ORDER: | 29 March 2017 |

THE COURT ORDERS THAT:

1. The appeal be dismissed.
2. The appellants pay the respondent’s costs of the appeal as agreed or taxed.
3. The parties confer and file agreed proposed orders in respect of the cross appeal and notice of contention, including counsel’s details, the estimated length of hearing, available dates in the Full Court period for August 2017, and whether it is intended to submit any Full Court decision is wrong, within 14 days.

Note: Entry of orders is dealt with in Rule 39.32 of the *Federal Court Rules 2011*.

ORDERS

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|  | NSD 240 of 2017 |
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| BETWEEN: | WARNER-LAMBERT COMPANY LLCFirst Appellant**PF PRISM CV**Second Appellant**PFIZER IRELAND PHARMACEUTICALS** (and others named in the Schedule)Third Appellant |
| AND: | GENERIC PARTNERS PTY LTD ACN 132 833 777Respondent |

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| JUDGE: | JAGOT, YATES and burley jj |
| DATE OF ORDER: | 29 MARCH 2017 |

THE COURT ORDERS THAT:

1. The appeal be dismissed.
2. The appellants pay the respondent’s costs of the appeal as agreed or taxed.

Note: Entry of orders is dealt with in Rule 39.32 of the *Federal Court Rules 2011*.

REASONS FOR JUDGMENT

THE COURT:

1. The only issue in these appeals is whether the primary judge was right to conclude that an application by the respondents for the listing of their products on the Pharmaceutical Benefits Scheme (**PBS**) would not infringe a patent.
2. The primary judge had found that the respondents’ generic pregabilin products (used to treat pain), which were manufactured overseas, would infringe the first appellant’s Australian standard patent 714980 if imported into Australia for the purpose of sale (*Apotex Pty Ltd v Warner-Lambert Company LLC (No 2)* [2016] FCA 1238). The relevant claims, so-called Swiss claims, involve use of pregabilin to make a medicament for treating pain. The primary judge considered that it was not the manufacture of the products outside Australia that would infringe the patent, but the importation and sale of the products in Australia which had been made using the patented method which would do so. This, the primary judge said, would involve the exploitation in Australia of the invention within the meaning of sub para (b) of “exploit” in the *Patents Act 1990* (Cth) (**the Patents Act**). In Sch 1 to that Act “exploit” is defined as follows:

***exploit***, in relation to an invention, includes:

(a) where the invention is a product–make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or

(b) where the invention is a method or process–use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

1. By s 13(1), it is the patentee (the first appellant) who has the exclusive right to exploit the invention and to authorise another person to exploit the invention during the term of the patent.
2. While a number of these conclusions are challenged in cross-appeals by the respondents, the issue in these appeals involves the orders the primary judge made, consequential on subsequent reasons for judgment in *Apotex Pty Ltd v Warner-Lambert Company LLC (No 3)* [2017] FCA 94. The orders included an injunction restraining the threatened infringements (order 5 in each case) and order 6 as follows:

6. For the avoidance of doubt, the terms of the injunction imposed by order 5 do not prevent the Applicant/Cross-Respondent from taking any steps required to obtain listing of the [Apotex/Generic Partners] Generic Pregabalin Products under the pharmaceutical benefits scheme (“PBS”) maintained by the Australian Government Department of Health under the *National Health Act 1953* (Cth).

1. The primary judge made order 6 because he rejected the appellants’ contention that an application to obtain listing of the products on the PBS involved an exploitation of the patent by reason of offering to sell a product resulting from using the method or process the subject of the claims of the patent.
2. It is common ground that in reaching this conclusion the primary judge identified the right question (at [26]) and the relevant statutory provisions (at [6] to [18]). It is also common ground that the primary judge was correct to decide that any offer of sale in Australia of a patented product or product made by a patented process or method during the term of the patent would infringe the patent, even if the offer involved sale after the term of the patent. In so concluding at [25], the primary judge diverged from the reasoning in *Gerber Garment Technology Inc v Lectra Systems Ltd* [1995] RPC 383 (***Gerber***). Because this conclusion was not in issue in the appeals, we do not venture any opinion about it other than to note that the contrary view expressed in *Gerber* would have been a complete answer to the appeals because it is also common ground that the respondents’ propose to seek listing of their products on the basis that the products will not be made available for sale to wholesalers or pharmacists until after the term of the patent, which expires on 16 July 2017.
3. The appellants’ case is that the primary judge was in error in [33] to [35] in concluding that the respondents’ proposed actions fell short of offering to sell or otherwise dispose of the products. According to the appellants, the primary judge failed to recognise that, by reason of the requirements of the statutory scheme for PBS listing, the respondents necessarily entered into a statutory bargain in which they offered to the relevant Minister to sell the products to wholesalers and pharmacists, albeit that sale would take place after the listing on the PBS. As the appellants put it, an offer to one party (the Minister) to sell products to another party (wholesalers and pharmacists) is nevertheless an offer. Given the primary judge’s unchallenged conclusion that an offer to sell or otherwise dispose of products made during the term of a patent involves infringement, even if the sale or disposal is to occur after the term of the patent, the appellants contended that the primary judge erred in failing to characterise the respondents’ proposed actions as an offer within the meaning of “exploit” in s 13 of the Patents Act.
4. The reason these appeals have been determined separately from the cross-appeals is that, by reason of administrative arrangements established by the Minister, the respondents must request a listing of their products on the PBS by 1 May 2017 to obtain the first available listing date after expiry of the patent (1 August 2017). If the respondents do not request listing by 1 May 2017, the next possible listing date is 1 December 2017. As the appellants noted, these administrative arrangements are irrelevant to the proper characterisation of the respondents’ proposed actions but they do explain why these appeals are being heard and determined in advance of the cross-appeals.
5. Recitation of the statutory provisions which create and regulate listing on the PBS should be avoided. For present purposes it is sufficient to identify the following. The actions the respondents propose to take are directed towards obtaining a Ministerial determination under s 85(6) of the *National Health Act 1953* (Cth) (**the National Health Act**), which provides that the Minister may, by legislative instrument, determine a brand of a pharmaceutical item. To obtain such a determination, an application must be made in accordance with the approved form under reg 2.16(2) of the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* (Cth). Pursuant to a document *Procedure guidance for listing medicines on the Pharmaceuticals Benefits Scheme* (Version 1, October 2016) the respondents will have to provide a cover letter with their application which “must include a signed supply assurance undertaking that sufficient stock of the product to meet demand will be available to allow for delivery to PBS dispensers (eg pharmacies, hospitals or other dispensers) in time for the PBS listing day…”.
6. This “signed supply assurance undertaking”, required as a matter of administrative procedure as part of the application, reflects those provisions of the National Health Actunder which:
7. The Minister may determine that a person is the responsible person for the brand of a pharmaceutical item which is a listed brand, the responsible person being the person who will be the supplier to wholesalers and approved pharmacists (s 84AF).
8. On the coming into force of a determination that a brand of a pharmaceutical item is a listed brand, a so-called guaranteed period starts within which the listed brand becomes a guaranteed brand of a guaranteed item (ss 99AEA, 99AEC and 99AED) and under s 99AEB:

The responsible person for a guaranteed brand of a guaranteed item must supply the guaranteed brand of the guaranteed item during the guaranteed period for the guaranteed brand of the guaranteed item.

1. By s 99AEG the responsible person for a listed brand must notify the Minister if that person forms a belief that the person will fail to supply or be unable to supply the guaranteed brand of the guaranteed item during the guaranteed period. Failure to notify is an offence under s 99AEG(3). Sections 99AEE and 99AEF define “fails to supply” and “unable to supply” respectively. Both definitions depend on a failure or inability to supply after receipt of a request by a wholesaler or an approved pharmacist.
2. By s 99AEH the Minister is vested with various powers if a responsible person fails to supply or is unable to supply a guaranteed brand of a guaranteed item during the guaranteed period. Those powers do not include a capacity to require supply but do include revocation or variation of the determination under s 85(6) or, indeed, any determination in relation to any brand of any pharmaceutical item of the responsible person. Suffice to say the range of powers in s 99AEH is intended to ensure that there is no failure or inability to supply during the guaranteed period. The reason for this is that the coming into force of a determination under s 85(6), by which a generic version of a pharmaceutical item becomes subject to the statutory scheme, has price and payment consequences. As to price, as explained by s 99AC the listing of a pharmaceutical brand results in a price reduction of that item of at least 16% (s 99ACB), including such a price reduction of the originator brand (ss 99ACF and 99ACH). As to payments, the price which a consumer may be charged for the supply of a listed pharmaceutical brand is capped by s 87. The supplier of that listed pharmaceutical brand, however, is entitled to claim payment from the Commonwealth of the difference between the amount able to be charged under s 87 and the so-called Commonwealth price (which is the price as provided for in the definition of that term in s 84(1)). By this method, when a generic version of a pharmaceutical item becomes subject to the statutory scheme (that is, is listed on the PBS), consumers obtain the pharmaceutical items at prices which are both subsidised by the Commonwealth and reduced compared to the price when only the originator brand is available.
3. The appellants’ case is that a person who wishes to take advantage of the statutory scheme by the making of an application for listing enters into a bargain with the Minister. Under that bargain, the responsible person (which will be each of the respondents) offers to the Minister to guarantee supply of the product to wholesalers and pharmacists during the guaranteed period which starts on the coming into force of a determination under s 85(6). The fact that the coming into force of a determination post-dates the term of the patent is immaterial. The offer to supply the product is made on the making of the application. The fact that the offer is to the Minister to supply the product to wholesalers and pharmacists is also immaterial. The law has always recognised that an offer may be made to one party to supply another party. The fact that the definition of “exploit” in the Patents Act is inclusive rather than exhaustive supports these propositions. It reflects the scheme of that Act under which it is the patentee alone which may exploit the invention during the term of the patent. Any act which enables another person to take advantage of the invention for commercial or economic benefit is liable to be found to have exploited the invention. Applying for listing on the PBS during the term of the patent, and thereby gaining a springboard for PBS listing, is to the commercial or economic benefit of the respondents and an intrusion into the first appellant’s monopoly rights. It is an infringement which the primary judge ought not to have permitted in order 6.
4. The respondents’ case is that this mischaracterises the scheme established by the National Health Act. Their products have been listed on the Australian Register of Therapeutic Goods under the *Therapeutic Goods Act 1989* (Cth) as a result of which they may lawfully be supplied in Australia. The proposed application for a determination under s 85(6) is to enable the products to be sold subject to the subsidy arrangements which PBS listing provides. Even without PBS listing, immediately upon expiry of the patent, the respondents could each supply their products to wholesalers and pharmacists and pharmacists could sell those products to consumers. However, the price to the consumer would not be capped and the pharmacist would not be entitled to the payment by the Commonwealth by which the cost to the consumer is subsidised for products which are listed on the PBS. The fact that, in making an application, an applicant must provide a guarantee of supply and, on listing (but not before), will be subject to the guaranteed supply provisions in Div 3C of Pt 7 of the National Health Act does not mean that the applicant is offering to the Minister to supply the product to wholesalers and pharmacists within the meaning of the definition of “exploit” in the Patents Act.
5. We agree with the respondents and the conclusion of the primary judge. It may be accepted, as the primary judge did at [31], that “offer” in the definition of “exploit” is not confined to its contractual meaning. It takes its ordinary meaning whether that be “to present or tender for acceptance or refusal” (Oxford English Dictionary Online item 4) or to “propose or express one’s readiness (to do something) if the person assents” (Oxford English Dictionary Online item 3). It cannot be denied that on making an application the respondents will be required to present or propose or express their commitment to ensure that they will be able to supply their products during the guaranteed period. But in our view this is not an offer to the Minister to supply the products to a third party.
6. The assurance required to be provided in the form of an undertaking to the Minister is that “sufficient stock of the product to meet demand will be available to allow for delivery to PBS dispensers (eg pharmacies, hospitals or other dispensers) in time for the PBS listing day…”. No doubt this is done in recognition of the fact that until a determination is made and in force, s 99AEB does not operate. The assurance is a practical way of ensuring, insofar as possible, that a person who will become a responsible person under s 84AF will be able to comply with s 99AEB if and when a determination under s 85(6) comes into force.
7. In any event, it is not this assurance which the Minister accepts or rejects. The Minister accepts or rejects the application for listing by either determining the brand of a pharmaceutical item or not under s 85(6). The Minister, it is apparent, will not make such a determination without the assurance, but the assurance itself is not being proposed, tendered, presented or expressed for acceptance or rejection by the Minister. It is being proposed, tendered, presented or expressed as a pre-condition to the Minister deciding to determine a brand of a pharmaceutical item. Acceptance or rejection by the Minister is of the determination of the brand of a pharmaceutical item. If the determination is made and is in force, then the statutory provisions operate and the respondents as the responsible person under s 84AF will be subject to the guarantee of supply obligation in s 99AEB. At that time, they will each have to supply on request or risk the consequences in ss 99AEG and 99AEH.
8. Characterising these circumstances as involving an offer to the Minister to supply the products to third parties, being wholesalers and pharmacists, during the guaranteed period overlooks the nature of the assurance required to be provided and the fact that the statutory guaranteed supply provisions operate from the coming into force of the determination which will be after the term of the patent. An assurance to the Minister that sufficient stock of the product to meet demand will be available to allow for delivery to PBS dispensers (eg pharmacies, hospitals or other dispensers) in time for the PBS listing day is not an offer to the Minister to supply those third parties during the guaranteed period. It is an assurance that the responsible person will be able to supply those third parties during the guaranteed period if requested to do so. The guaranteed supply provisions do not operate on the making of an application. As is apparent from the definition of “guaranteed period” in s 99AEA, which cross-refers to ss 99AEC(3) and 99AED(3), it is the coming into force of a determination which starts the guaranteed period. It is during that period that the responsible person guarantees supply under s 99AEB. Until that time, however, there is merely the application accompanied by the required assurance.
9. Characterising the application as involving a statutory bargain, as the appellants urge, does not advance the matter. If there be a bargain, it is an assurance by the applicant for listing that the applicant will have sufficient stock to meet demand on the listing day (the coming into force of the determination) in exchange for a listing which will enable the product to be part of the PBS. An assurance of this kind is not an offer to the Minister to sell or otherwise dispose of the products to wholesalers and pharmacists. It is nothing more than what it purports to be, an assurance that stock will be available to meet demand. To adopt the appellants’ approach of arguing by way of analogy, party A does not offer to supply to party B merely by assuring party C that, when the relevant time comes, party A will be able to supply party B.
10. For these reasons, the primary judge was correct and the appeals should be dismissed.

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| I certify that the preceding twenty (20) numbered paragraphs are a true copy of the Reasons for Judgment herein of the Honourable Justices Jagot, Yates and Burley. |

Associate:

Dated: 13 April 2017

SCHEDULE OF PARTIES

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|  | NSD 239 of 2017 |
| Appellants |  |
| Fourth Appellant: | PFIZER ASIA PACIFIC PTE LTD |
| Fifth Appellant: | PFIZER AUSTRALIA PTY LTD ACN 008 422 348 |
|  | **NSD 240 of 2017** |
| **Appellants** |  |
| Fourth Appellant: | PFIZER ASIA PACIFIC PTE LTD |
| Fifth Appellant: | PFIZER AUSTRALIA PTY LTD ACN 008 422 348 |