IN THE COURT OF APPEAL OF THE REPUBLIC OF SINGAPORE

[2020] SGCA 84

Civil Appeal No 211 of 2019

Between

Zyfas Medical Co (Sued as a firm)

… *Appellant*

And

Millennium Pharmaceuticals, Inc

… *Respondent*

In the matter of Originating Summons No 1034 of 2019

Between

Millennium Pharmaceuticals, Inc

… *Plaintiff*

And

Zyfas Medical Co (Sued as a firm)

… *Defendant*

GROUNDS OF DECISION

[Statutory Interpretation] — [Interpretation Act] — [Purposive approach] [Patents and Inventions] — [Registration] — [Registration of therapeutic products]

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Zyfas Medical Co (Sued as a firm)
v
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Andrew Phang Boon Leong JA, Tay Yong Kwang JA and Woo Bih Li J
14 August 2020

27 August 2020

Tay Yong Kwang JA (delivering the grounds of decision of the court):

1 In the High Court, Millennium Pharmaceuticals, Inc ("Millennium") applied in HC/OS 1034/2019 ("OS 1034") for a declaration that Zyfas Medical Co ("Zyfas") had omitted to disclose to the Health Sciences Authority ("HSA") the existence of certain patents when it applied to register a therapeutic product. The High Court judge ("the Judge") granted the declaration and Zyfas appealed.

2 On appeal, Zyfas sought to advance a legal argument that it had conceded during the High Court hearing. In the special circumstances of this case, we granted leave for Zyfas to advance this legal argument. However, after hearing the parties, we dismissed the appeal with costs.

Background

3 Zyfas is a distributor of generic pharmaceutical, medicinal and healthcare products. On 2 February 2018, it applied to register an anti-cancer

drug known as "Myborte" with the HSA.[1] The active ingredient in Myborte is bortezomib,[2] a drug which is used in the treatment of multiple myeloma and mantle cell lymphoma.[3]

4 Bortezomib is not protected by any product patent in Singapore. However, Millennium is the registered proprietor of three patents for the processes relating to the manufacture of bortezomib. These three patents (the "process patents") were valid and subsisting at the material time.[4] It was undisputed that Zyfas did not declare the existence of the process patents when it applied to the HSA to register Myborte as a therapeutic product.

5 Zyfas's application was approved by the HSA on 5 July 2019.[5] Shortly thereafter, Millennium discovered that Zyfas had obtained registration for Myborte and contacted Zyfas to ask for a copy of its declaration made in its application to the HSA. Zyfas took the position that the manufacturing process for bortezomib in Myborte did not infringe the process patents and that there was therefore no need to declare the process patents.[6]

6 On 19 August 2019, Millennium filed OS 1034 seeking a declaration that Zyfas's declaration to the HSA under reg 23(2) of the Health Products

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1 (III) ROA 179 (Tahir's 1st affidavit, para 26).

2 (III) ROA 131 (InfoSearch for Therapeutic Products).

3 (III) ROA 177 (Tahir's 1st affidavit, para 20).

4 (II) ACB 11–12 (Yeung's 1st affidavit, paras 8–10); (III) ROA 79–129 (Patent Details from IPOS e-services portal).

5 (III) ROA 7 (Yeung's 1st affidavit, para 11); (III) ROA 131 (InfoSearch for Therapeutic Products).

6 (III) ROA 154–155 (Letter from Mirandah Law LLP to Eldan Law LLP dated 11 July 2019); (III) ROA 159–160 (Letter from Eldan Law LLP to Mirandah Law LLP dated 24 July 2019).

(Therapeutic Products) Regulations 2016 (S 329/2016) ("TPR") contained a statement that was false or misleading in a material particular or omitted to disclose a matter that was material to the application for the registration of Myborte. It also sought costs for OS 1034.

7 Therapeutic products are regulated under the Health Products Act (Cap 122D, 2008 Rev Ed) ("HPA") and the TPR. All therapeutic products must be registered before they can be supplied in Singapore. Regulation 23(1) of the TPR requires the HSA to consider, in dealing with an application for registration, whether a patent under the Patents Act (Cap 221, 2005 Rev Ed) ("Patents Act") is in force in respect of the therapeutic product. Regulation 23(2) stipulates that the applicant must furnish a declaration to the HSA stating whether there is a patent under the Patents Act in force in respect of the therapeutic product and whether the applicant is the proprietor of the patent. Where the applicant is not the proprietor of the patent, reg 23(3) states that it has to provide information about the proprietor of the patent and state certain things. Under reg 24(1)(*a*)(ii), where a court has determined that the applicant's declaration contains a statement that is false or misleading in a material particular or omits to disclose any matter that is material to the application, the HSA may cancel the registration of the therapeutic product.

8 Regulations 23 to 25 of the TPR, which form part of the registration scheme, are set out below:

> **Whether therapeutic product subject to patent**
>
> **23.**—(1) In dealing with an application for the registration of a therapeutic product, the Authority must consider whether a patent under the Patents Act (Cap. 221) is in force in respect of the therapeutic product and, if so —
>
> > (*a*) whether the applicant for the registration of the therapeutic product is the proprietor of the patent; or

(*b*) if the applicant is not the proprietor of the patent, whether —

(i) the proprietor has consented to or has acquiesced in the grant of the registration of the therapeutic product to the applicant; or

(ii) the patent is invalid or will not be infringed by the doing of the act for which the registration of the therapeutic product is sought.

(2) Unless the Authority otherwise determines, the applicant must, at the time of the application and at such other time before the determination of the application as the Authority may require, make and furnish to the Authority a declaration in the form specified on the Authority's website, stating —

(*a*) whether a patent under the Patents Act is in force in respect of the therapeutic product; and

(*b*) whether the applicant is the proprietor of the patent.

(3) If the applicant is not the proprietor of the patent in respect of the therapeutic product and there is such a patent in force, the applicant must further state in the declaration mentioned in paragraph (2) —

(*a*) the name and address of the proprietor of the patent;

(*b*) whether —

(i) the proprietor has consented to or has acquiesced in the grant of the registration of the therapeutic product by the applicant; or

(ii) in the opinion of the applicant and to the best of the applicant's belief, the patent is invalid or will not be infringed by the doing of the act for which the registration of the therapeutic product is sought; and

(*c*) such other information as the Authority may require in any particular case.

(4) For the purposes of paragraph (1), the Authority may rely upon, and need not be concerned to inquire into the truth of, any statement made in the declaration furnished under paragraph (2).

(5) Where the applicant is not the proprietor of a patent under the Patents Act that is in force in respect of the therapeutic product, the Authority may require the applicant to serve, in accordance with section 67 of the Act, on the proprietor of the

patent, a notice in the form specified on the Authority's website, and within such time as the Authority may determine, if —

> (*a*) the applicant has declared that, in the applicant's opinion and to the best of the applicant's belief, the patent is invalid or will not be infringed by the doing of the act for which the registration is sought; or
>
> (*b*) the Authority considers it appropriate in any particular case for the applicant to do so.

(6) The applicant must furnish to the Authority such evidence of the service of the notice mentioned in paragraph (5) as the Authority may require.

(7) The Authority need not determine the application until the applicant has complied with paragraph (2) and, where applicable, paragraphs (5) and (6), to the reasonable satisfaction of the Authority.

(8) If the Authority is satisfied that the notice mentioned in paragraph (5) has been served on the proprietor of the patent, the Authority may register the therapeutic product if the proprietor does not, before the 45th day after the date that notice is served on the proprietor —

> (*a*) apply to —
>
> > (i) a court for an order restraining the act for which the registration of the therapeutic product is sought; or
> >
> > (ii) a court or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act, for a declaration that the patent is valid or will be infringed by the doing of the act for which the registration of the therapeutic product is sought; and
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> (*b*) give written notice to the Authority stating that such application in sub-paragraph (*a*) has been made, accompanied by evidence of the application.

(9) The Authority may register the therapeutic product without further notice to the proprietor of the patent, if no order or declaration mentioned in paragraph (8)(*a*) has been made at the end of 30 months after the date of the application for the order or declaration.

(10) If, before the end of the period mentioned in paragraph (9), the proprietor of the patent submits to the Authority a copy of

the order or declaration mentioned in paragraph (8)(*a*), the Authority may refuse to register the therapeutic product.

Cancellation of registration of therapeutic product subject to patent dispute

24.—(1) Without prejudice to the generality of section 37(1) of the Act, the Authority may, upon an application by any interested person, cancel the registration of a therapeutic product, if the Authority is satisfied —

(*a*) that —

(i) a court or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act has determined that the doing of an act authorised by the registration infringes a patent under the Patents Act; or

(ii) a court has determined that the declaration made under regulation 23(2) contains a statement that is false or misleading in a material particular or omits to disclose any matter that is material to the application; and

(*b*) that the determination mentioned in sub-paragraph (*a*)(i) or (ii) is final.

(2) For the purposes of paragraph (1)(*b*), a determination is final if it is not subject to further appeal.

Offences for making false patent declaration

25. A person who, when making a declaration under regulation 23(2) —

(*a*) makes any statement or furnishes any document which the person knows or has reason to believe is false in a material particular; or

(*b*) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

9 Recently, this court considered the above registration scheme in *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd and*

another appeal [2019] SGCA 31 ("*Drug Houses of Australia*"). In that case, the same patent proprietor, Millennium, commenced an action against Drug Houses of Australia Pte Ltd ("DHA") for obtaining registration of bortezomib as a therapeutic product without declaring the existence of the process patents. DHA's position was that its process for manufacturing bortezomib did not infringe Millennium's patents and the patents therefore did not have to be disclosed. DHA applied to strike out Millennium's statement of claim on the ground that it disclosed no reasonable cause of action and the High Court judge permitted certain claims to be struck out.

10 On appeal, this court restored the claims and held that Millennium's patents fell within the description set out in reg 23(2)(*a*) of the TPR (*Drug Houses of Australia* at [2]). Although DHA averred that its product did not infringe the processes protected by Millennium's patents, this court held that DHA had to declare the existence of the patents and then state that the patents were invalid or would not be infringed by the doing of the act for which the registration was sought. It was then for HSA to decide whether to invoke reg 23(5) to require DHA to serve a notice on Millennium as the proprietor of the patents (*Drug Houses of Australia* at [3]). The suit in *Drug Houses of Australia* was eventually discontinued before trial.

The proceedings in the High Court

11 As mentioned above, OS 1034 sought a declaration that Zyfas's declaration under reg 23(2) "contains a statement that is false or misleading in a material particular or omits to disclose any matter that is material to its application(s) for registration of its therapeutic product".[7] At the hearing in the

[7] (II) ROA 7 (Prayer 1 of OS 1034).

High Court, however, it was accepted that it was sufficient for the Judge to grant the declaration sought if he found that Zyfas's declaration omitted material facts. The parties therefore did not proceed on the issue of whether Zyfas's declaration contained a statement that was false or misleading.[8]

12 In the High Court, Zyfas also conceded expressly that process patents were patents in force in respect of the therapeutic product and had to be declared under reg 23(2)(*a*) of the TPR.[9] Although Zyfas submitted that the statement in *Drug Houses of Australia* on this point was made *obiter dicta*, it accepted that the *dicta* represented the law correctly and that the Judge was bound by the decision.[10] It also conceded that the existence of the process patents was a matter which was material to its application for registration.[11] Zyfas's sole argument in the High Court was that it did not knowingly or intentionally omit to declare material information because it had applied to register Myborte a year before the judgment in *Drug Houses of Australia* and it genuinely did not know that the process patents had to be declared at that time.[12]

13 The parties' submissions before the Judge were therefore confined to the single issue of whether Zyfas's omission had to be done knowingly or intentionally before the court could grant a declaration under reg 24(1)(*a*)(ii). The Judge concluded that there was no such requirement (see *Millennium Pharmaceuticals, Inc v Zyfas Medical Co (sued as a firm)* [2020] SGHC 28 ("GD") at [22]–[26]). There was nothing in reg 24(1)(*a*)(ii) that required the

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8 (III) ROA 223–224 (NEs 23 October 2019, pp 4–5).

9 (III) ROA 222–223 (NEs 23 October 2019, pp 3–4).

10 (III) ROA 265, 270 (Zyfas's submissions in OS 1034 at paras 23, 43–44).

11 (III) ROA 222–223 (NEs 23 October 2019, pp 3–4).

12 (III) ROA 271–272 (Zyfas's submissions in OS 1034 at paras 50–51).

mental elements of knowledge or intention. In contrast, reg 25, which creates offences, referred to such mental elements because of the use of words such as "knows", "reason to believe" and "intentional". This difference in language was justified based on the respective purposes of the provisions. While reg 24 was intended as an administrative process by which a registered therapeutic product could be cancelled, reg 25 was a provision that imposed criminal liability. All that Millennium was required to show was that Zyfas failed to disclose any matter that was material to its application. As there was no dispute that Zyfas failed to declare that Millennium's process patents were in force and as it had conceded that this information was material, the Judge granted the declaration. On 21 November 2019, Zyfas filed this appeal.

The related proceedings

14 At the time of filing OS 1034, Millennium also filed HC/S 817/2019 ("Suit 817") against Zyfas seeking a declaration that Zyfas had infringed its patents and an injunction to restrain Zyfas from continuing to infringe the patents. Millennium does not manufacture, market or supply bortezomib in Singapore but its exclusive licensee in Singapore, Johnson & Johnson Pte Ltd ("J&J"), has supplied bortezomib in Singapore before. Accordingly, J&J was added as the second plaintiff to Suit 817, which is pending before the Judge.

15 On 29 January 2020, Millennium and J&J filed HC/SUM 430/2020 in Suit 817 seeking an interlocutory injunction to restrain Zyfas from performing any of the acts for which registration of Myborte had been obtained until the conclusion of the suit. The focus of the injunction was the fact that Zyfas had been awarded a tender on 1 November 2019 to supply bortezomib to public hospitals in Singapore. Due to the present appeal, Millennium could not apply to the HSA for cancellation of the registration of Myborte. Millennium therefore

sought the interlocutory injunction to restrain Zyfas from supplying Myborte under the tender and from participating in any further tenders.

16 On 2 April 2020, the Judge granted the application for the interlocutory injunction only in part. He made an order to restrain Zyfas from any future acts for which registration of Myborte had been obtained but permitted Zyfas to continue to supply Myborte to the public hospitals pursuant to the tender. The Judge held that in the context of this tender, damages would be an adequate remedy and the balance of convenience lay in favour of permitting the continued supply of bortezomib to the public hospitals. Millennium's application for leave to appeal to the Court of Appeal was refused by the Judge on 15 June 2020. Its further application to the Court of Appeal for leave to appeal was dismissed on 21 July 2020 without oral arguments pursuant to O 57 r 2B of the Rules of Court (Cap 322, R 5, 2014 Rev Ed) ("Rules of Court").

17 On 4 March 2020, Millennium filed CA/SUM 30/2020 to expedite the present appeal due to its concerns about Zyfas's supply of Myborte to the public hospitals.[13] Its application was dismissed on 6 April 2020.[14]

The parties' cases on appeal

Leave to raise a new point on appeal

18 In this appeal, Zyfas abandoned its sole argument before the Judge that the omission had to be a knowing or an intentional one. Instead, Zyfas sought

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13 (II) ACB 30–31 (HC/SUM 30/2020 Summons), (IV)(C) ROA 13–17 (Yeung's 1st affidavit, paras 23–38).

14 (II) ACB 47–48 (Correspondence from court dated 6 April 2020).

to argue that process patents did not fall within the scope of reg 23(2)(*a*) of the TPR as it covered only product patents.[15]

19 Zyfas accepted that leave of court was required to advance this point. It submitted that leave should be granted as this was a point of law that did not concern factual disputes and no fresh evidence was required.[16] The holding in *Drug Houses of Australia* that Millennium's process patents were within the meaning of "patent" in reg 23(2)(*a*) of the TPR was *obiter dicta* and, in any event, that holding was wrong and this court was not bound by its own decision.[17]

20 Millennium submitted that Zyfas should not be granted leave to raise the new argument as it had conceded expressly and unequivocally in the High Court that process patents were within the ambit of reg 23(2)(*a*).[18] In any event, this court had already determined the issue in *Drug Houses of Australia* and there were no reasons to justify overruling or departing from that decision.[19] If leave was not granted for the new argument, the appeal would fail in its entirety.[20]

21 The parties filed their submissions on 13 July 2020. On 16 July 2020, this court released its decision in *JWR Pte Ltd v Edmond Pereira Law Corporation and another* [2020] SGCA 68 ("*JWR*"). That decision included guidance on the relevant principles when applying for leave to introduce a new

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15 AC para 33.

16 AR para 5, 17.

17 AR paras 18–35.

18 RC paras 23–24.

19 RC paras 25–37.

20 RS para 6.

point on appeal. We therefore invited the parties here to submit on this case if they wished. They did so on 11 August 2020.

22 Millennium submitted that *JWR* bolstered its case that Zyfas should not be granted leave to make the new argument. Zyfas was abandoning its arguments before the Judge and seeking to make an entirely new argument on appeal. As there were no exceptional circumstances here, leave ought to be refused to prevent the abuse of the appeal process.[21] On the other hand, Zyfas submitted that *JWR* could be distinguished. There was no prejudice to Millennium as all the relevant evidence was already in the record of appeal and its argument was not entirely new.[22]

The interpretation of reg 23(2)(a)

23 If Zyfas was permitted to raise the new point on appeal, both parties agreed that the purposive approach to statutory interpretation as set out in *Tan Cheng Bock v Attorney-General* [2017] 2 SLR 850 ("*Tan Cheng Bock*") should apply to reg 23(2)(*a*) to determine if "a patent under the Patents Act… in force in respect of the therapeutic product" referred solely to product patents or to all patents, including process patents. We refer to these alternative interpretations as the "Narrow Interpretation" and the "Broad Interpretation" respectively.

24 Zyfas submitted that the Narrow Interpretation was supported by the text and the statutory context. Regulation 23 and Form 1 of HSA's patent declaration forms, which an applicant had to use, referred repeatedly to the word "product". In contrast, save for a reference to "manufacturing process controls" in reg 22,

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21 RS dated 11 August 2020 paras 4–5.

22 AS dated 11 August 2020 paras 10–11.

the word "process" did not appear in the relevant part of the regulations or in Form 1.[23] The First Schedule of the HPA defined "therapeutic product" as "any substance that… has as a constituent any of the following active ingredients", which included any chemical element and this meant that a relevant patent which had to be declared was a patent over the active ingredient itself.

25 The Parliamentary debates on the predecessor provision, which was s 12A(2) of the Medicines Act (Cap 176, 1985 Rev Ed), revealed that its purpose was to provide a patent linkage scheme to ensure that generic products were not granted marketing approval prior to the expiration of the patent term of the innovated product unless the patent owner consented.[24] Process patents were not mentioned in the Parliamentary debates.[25] Singapore's patent linkage scheme was implemented following the United States–Singapore Free Trade Agreement (6 May 2003), <https://www.enterprisesg.gov.sg/non-financial-assistance/for-singapore-companies/free-trade-agreements/ftas/overview> ("USSFTA") and was modelled on the scheme in the United States of America ("the US").[26] As process patents were excluded from the US scheme, Zyfas submitted that the Singapore scheme was also intended to protect product patents only.[27]

26 On the other hand, Millennium submitted that the ordinary meaning of the text was only capable of the Broad Interpretation.[28] There was no express

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23 AC paras 51–54; (II) ACB 18–20 (Form 1).

24 AC paras 74–75.

25 AC para 83.

26 AC paras 86–88.

27 AC pars 94–97.

28 RC para 45.

qualification of the word "patent" and the text simply meant a patent that was relevant to the therapeutic product.[29] Millennium's process patents fell within the definition of "patent" in s 2 of the Patents Act.[30] The other provisions of reg 23 also made it clear that "patent" referred to any patent that might be infringed by the doing of the acts for which the registration of the therapeutic product was sought and process patents were capable of being infringed by the supply, manufacture, importation or wholesale of the product in Singapore.[31] Form 1 was merely an administrative form and the absence of the word "process" did not suggest necessarily that "patent" excluded process patents.[32]

27 The purpose of reg 23 was to provide a mechanism by which patent proprietors could be notified of pending applications for the registration of therapeutic products that might infringe their patents so that they could intervene.[33] The Broad Interpretation was consistent with this purpose as process patents could be infringed by the acts for which registration was sought. The Narrow Interpretation meant that process patents would enjoy a lower level of protection than product patents.[34] No distinction was drawn between product patents and process patents in the Parliamentary debates or in the obligations under the USSFTA.[35] Although process patents were excluded from the US patent linkage scheme, this was due to an express exclusion in the subsidiary

29 RC paras 46–47.

30 RC para 49.

31 RC paras 55–60.

32 RC paras 61–62.

33 RC paras 67–68.

34 RC paras 69–70.

35 RC paras 76–78.

legislation there. Parliament would have been cognizant of the scheme in the US and must have made a choice not to exclude process patents.[36]

Our decision

Leave to raise a new point on appeal

28 Order 57 rule 9A(4)(*b*) of the Rules of Court permits a party to apply in the course of the hearing for leave to introduce a new point not taken in the court below if it is stated clearly in its case. The principles governing the granting of leave to raise new points on appeal are not controversial and were discussed in our recent decision in *JWR* at [28] (citing *Abhilash s/o Kunchian Krishnan v Yeo Hock Huat and another* [2019] 1 SLR 873 ("*Abhilash*") at [39]–[41]):

> (a) Whether a party is granted leave to introduce on appeal new points not taken in the court below will be the subject of careful consideration in each case, having due regard to factors including (i) the nature of the parties' arguments below; (ii) whether the court had considered and provided any findings and reasoning in relation to the new point; (iii) whether further submissions, evidence or findings would have been necessitated had the new points been raised below; and (iv) any prejudice that might result to the counterparty in the appeal if leave were to be granted (*Grace Electrical Engineering Pte Ltd v Te Deum Engineering Pte Ltd* [2018] 1 SLR 76 ("*Grace Electrical*") at [38]).
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> (b) There is strictly speaking no legal impediment to an appellant raising new points of law on appeal even if they were not specifically pleaded provided that the existing pleadings were sufficiently wide to

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36 RC paras 84–86.

permit the new points to be raised. Further, the mere fact that the new point sought to be raised contradicts the case as pleaded below would not invariably lead to the denial of leave (*Abhilash* at [40], citing *Grace Electrical* at [36]).

(c) A different balance will be struck where the new argument to be raised on appeal would involve issues of fact, where it is almost inevitable that the failure to raise the point at trial had resulted in relevant evidence not being fully ventilated (*JWR* at [29]).

29 As explained earlier, Zyfas's only submission before the Judge was that reg 24(1)(*a*)(ii) required a false or misleading statement or material omission in a declaration to have been made knowingly or intentionally. At the hearing before us, counsel for Zyfas, Mr Wong Siew Hong ("Mr Wong"), explained that he had focused on the mental element required for a "false or misleading" declaration as that was the case Millennium had advanced below. Even so, that could not explain why Zyfas conceded expressly that process patents had to be declared under reg 23(2)(*a*) or why it maintained its position when it became clear that the Judge was proceeding on the issue of material omission only.

30 We think Zyfas's change in position was highly unsatisfactory. In advancing the new argument on appeal, Zyfas was retracting from the agreed parameters of the case before the High Court. The issue before us would no longer be about the requisite mental state for a declaration under reg 24(1)(*a*)(ii) of the TPR but about the scope of reg 23(2)(*a*). As a result, the High Court's decision was rendered quite irrelevant in this appeal as its correctness was not being challenged at all. In fact, at the hearing before us, both Mr Wong and counsel for Millennium, Mr Suhaimi Bin Lazim, agreed that the Judge was correct in his interpretation of reg 24(1)(*a*)(ii). Ordinarily, if both parties agree

that the trial court's decision is unimpeachable, then that should be the end of the matter. However, Zyfas was effectively asking the Court of Appeal to rehear the entire case on a totally different basis, thereby converting what should have been an appeal into a second trial.

31 It was even more unsatisfactory that the so called "new argument" was not new at all but was obviously an issue that Zyfas's counsel had considered and then conceded. The new argument was therefore nothing more than a retraction of its concession on a legal issue. Such a retraction probably arose from a reworking and rethinking of the litigation strategy and Zyfas was essentially doing a 180-degree about-turn on appeal by arguing against the very issue that it had conceded before the Judge.

32 In the circumstances, Zyfas's conduct of its appeal fell within the scope of the criticisms made by this court in *JWR* at [32]. In reality, there was no appeal before us. We would not be considering whether the Judge was wrong or otherwise in reaching the conclusions stated in his judgment since, as mentioned above, both parties agreed that the Judge was correct in his decision on the issues placed before him. In *JWR,* we observed that such conduct would amount to an abuse of the appeal process (at [32]). Ordinarily therefore, we could, as we did in *JWR*, have disallowed the new argument and dismissed the appeal.

33 In this case, however, there were some special features that persuaded us to exercise our discretion to allow Zyfas to make the "new argument" despite its concession in the High Court. First, the issue to be canvassed was a question of law which would impact the work of the HSA in implementing the TPR. It was also likely to affect many applicants seeking to register various therapeutic products in an industry that is growing increasingly important. Leaving the

scope of reg 23 unclear or seemingly arguable would not be conducive to good administration in such an important industry. It would also create uncertainty for the businesses dealing in therapeutic products.

34 Secondly, the new argument would not cause any prejudice to Millennium as it was given ample notice about it and was prepared to argue the issue before us. Its written submissions covered this legal point fully.

35 Third, if Zyfas had not made the concession in the High Court and had instead raised this argument in its submissions, we believe that the Judge would in all likelihood have considered himself bound by *Drug Houses of Australia* anyway (see GD at [13]). We note that in Zyfas's submissions in the High Court, it referred to the statement on this legal issue in *Drug Houses of Australia* as *obiter dicta* but accepted that it represented the law correctly.[37] If it truly believed that it was *obiter dicta*, then it should not have made the concession and should not have accepted that the Judge was bound by our earlier decision. Accordingly, based on the special circumstances in this case, we allowed the question of law to be argued on appeal despite the earlier concession by Zyfas.

36 Although the correctness of the Judge's decision was not disputed before us, we would like to express our agreement with his conclusions. We agree that reg 24(1)(*a*)(ii) of the TPR does not require that a false or misleading statement or an omission to disclose a material matter must be made knowingly or intentionally. However, if such knowledge or intention was found in any particular case, an offence under reg 25(*a*) or (*b*) would be disclosed and the

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37 (III) ROA 265, 270 (Zyfas's submissions in OS 1034 at paras 23, 43–44).

maker of the declaration would be subject to the criminal sanctions spelt out in that regulation.

The interpretation of reg 23(2)(a)

37 The sole issue in this appeal was therefore whether process patents were within the ambit of "a patent under the Patents Act… in force in respect of the therapeutic product". If so, the process patents must be declared pursuant to reg 23(2)(*a*) of the TPR. To answer this question, we first consider whether this issue was an integral part of the reasoning and decision in *Drug Houses of Australia*, which concerned two of the three process patents in this case and involved the same proprietor of the process patents.

38 Zyfas submitted that our reasoning on this issue was *obiter dicta* and, in any event, the earlier decision was wrong and was not binding on us in this appeal. We rejected the submission on *obiter dicta*. Our reasoning in *Drug Houses of Australia* was necessary to the decision that was made in that appeal. Although DHA in that case did not advance the argument specifically that process patents did not fall within the meaning of reg 23(2)(*a*), we held that Millennium's patents fell within the provision and had to be declared. If they did not, then Millennium would have no cause of action against DHA at all.

39 For completeness, we consider briefly the parties' arguments on the application of the purposive approach, which involves three steps (see *Tan Cheng Bock* at [37]–[53]):

> (a) First, ascertain the possible interpretations of the provision, having regard not just to the text of the provision but also to the context of that provision within the written law as a whole, aided by rules and canons of statutory construction where relevant.

(b) Second, ascertain the legislative purpose or object of the statute. In doing so, the court may draw from the text of the relevant legislative provision, the statutory context or extraneous material, though primacy should be accorded to the text of the provision and its statutory context.

(c) Third, compare the possible interpretations of the text against the purposes or objects of the statute.

40 Section 2 of the Patents Act states that "patent" means "a patent under this Act and includes a patent in force by virtue of section 117(3) [of the Patents Act]". A patent under the Patents Act includes process patents and the Act generally does not distinguish between product and process patents (see s 2, which refers to "patented process", and ss 14(2), 51(1), 66, 68). The plain text of reg 23(2)(*a*) therefore suggested that process patents were included in its scope.

41 However, Mr Wong argued that the word "patent" in the TPR must be qualified by the words "in respect of the therapeutic product". He then pointed to the definition of "therapeutic product" in the HPA. The First Schedule of the HPA states that "therapeutic product" means any substance that has as a constituent any of the following active ingredients, one of which is "any chemical". Mr Wong highlighted that bortezomib is a chemical and therefore the relevant patent in this case must be one in respect of that chemical. Since Millennium's patents were in the process of manufacturing the active ingredient bortezomib and not in bortezomib as a product, he submitted that the process patents here were not relevant under the TPR and therefore did not need to be declared in an application for registration.

42 In answer to our question during discussions, Mr Wong accepted that it was logically possible for the bortezomib in Myborte to have been manufactured using the processes in Millennium's process patents although Zyfas's position was that its therapeutic product did not use those processes to make bortezomib. In our opinion, this meant that the process patents here were "in respect of the therapeutic product" because the active ingredient in that product could have been made using the patented processes. The proper procedure for Zyfas's application for registration was therefore to declare the existence of the process patents under reg 23(2)(*a*) and then go on to declare further under reg 23(3)(*b*)(ii) that it was not the proprietor of the patents but the patents would not be infringed by the doing of the act for which the registration of the therapeutic product is sought, if Zyfas genuinely believed that there was no infringement. It would then be up to the HSA to decide whether to require Zyfas to serve the requisite notice under reg 23(5) on the proprietor. We came to this same conclusion in *Drug Houses of Australia* at [3].

43 The fact that the provisions of the TPR and Form 1 used the word "product" did not mean that the word was intended to restrict "patents" to only product patents. After all, "product" is part of the term "therapeutic product" which in turn is a "health product" as stated in the First Schedule of the HPA.

44 We agree with the Judge that the purpose of reg 23 was to fulfil Singapore's obligations under the USSFTA through the patent linkage scheme (GD at [13]). Mr Wong argued that the exclusion of process patents from the US patent linkage scheme was relevant because our scheme was modelled on it. However, Mr Wong also accepted that it could not be inferred that Parliament intended to copy the US patent linkage scheme.

45 The USSFTA does not refer to process or product patents. Local legislation is to be interpreted as far as possible to be consonant with Singapore's treaty obligations and not in derogation thereof. However, if the clear words of the legislation indicate that Singapore has done more than what its treaty obligations require, we think that there is nothing objectionable about giving effect to the clear intent.

46 Under the patent linkage scheme, after declaration of the patent, HSA can then direct the applicant to notify the proprietors of the patent about any application for registration of a therapeutic product, pursuant to reg 23(5). The proprietor then has the opportunity to object to registration during a 44-day moratorium imposed by reg 23(8) during which it can seek an injunction or a declaration that the patent will be infringed. Regulation 23(9) then provides for a 30-month moratorium for the court to reach a decision and during which the HSA will not register the product. This ensures that while the issue is before the courts, generic products will not flood the market to the prejudice of proprietors (see also *Drug Houses of Australia* at [10]).

47 Mr Wong argued that the Broad Interpretation made it onerous for applicants seeking registration of therapeutic products as they would have to declare process patents as well and then wait 30 months after the relevant notice was given before the therapeutic products could be registered. However, he accepted that such applicants could choose to shorten the 30-month wait by being proactive and taking out an action for a declaration of non-infringement if they wanted to.

48 We think that the Broad Interpretation would be consonant with the legislative purpose of reg 23 as it was intended to give notice and protection to proprietors of relevant patents, whether they are product or process patents. We

see no reason why product patents should be accorded more protection than process patents since a therapeutic product could infringe one or the other.

Conclusion

49 For the above reasons, we dismissed Zyfas's appeal. We awarded costs in favour of Millennium fixed at $40,000 (inclusive of disbursements) and made the usual consequential orders relating to the security for costs of this appeal.

Andrew Phang Boon Leong	Tay Yong Kwang	Woo Bih Li
Judge of Appeal	Judge of Appeal	Judge

Wong Siew Hong and Kuek Kai Liang (Eldan Law LLP) for the appellant;
Suhaimi Bin Lazim and Yan Chongshuo (Mirandah Law LLP) for the respondent.