Millennium Pharmaceuticals, Inc *v* Drug Houses of Australia Pte Ltd and another appeal [2019] SGCA 31

Case Number : Civil Appeals Nos 79 and 84 of 2018

Decision Date : 30 April 2019

Tribunal/Court : Court of Appeal

Coram : Andrew Phang Boon Leong JA; Tay Yong Kwang JA; Woo Bih Li J

Counsel Name(s) : Suhaimi bin Lazim, Chow Jian Hong and Yan Chongshuo (Mirandah Law LLP) for the appellant in Civil Appeals Nos 79 and 84 of 2018; Kang Choon Hwee Alban, Tan Lijun and Mok Ho Fai (Bird & Bird ATMD LLP) for the respondent in Civil Appeals Nos 79 and 84 of 2018.

Parties : Millennium Pharmaceuticals, Inc — Drug Houses of Australia Pte Ltd

Civil Procedure – Injunctions

Civil Procedure – Pleadings – Striking Out

Patents and Inventions – Infringement

[LawNet Editorial Note: This was an appeal from the decision of the High Court in [2018] SGHC 149.]

30 April 2019

Tay Yong Kwang JA (delivering the judgment of the court *ex tempore*):

1 In an application to strike out a statement of claim on the ground of no reasonable cause of action, it is established law that the statement of claim must be obviously unsustainable on the law or the facts or both.

2 In this case, we think it can be fairly implied that the Respondent did not declare the existence of the Appellant's two patents to the Health Sciences Authority ("HSA") despite the clear requirements in reg 23 of the Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) ("the TPR"). If it did, we do not see why it would not want to make this explicit when asked by the Appellant on this point. The declaration has to be made whenever there is a patent in force in respect of the therapeutic product and here, the Appellant's patents fell within this description and there was no allegation by the Respondent that it was unaware of these patents. In any case, it must have known about these patents because its affiliate, Teva, was involved in patent actions with the Appellant in Canada since 2012.

3 The Respondent avers that its product does not infringe the processes protected by the Appellant's patents and therefore the patents had no relevance to the product and there was no need to declare them to HSA. However, that is not a course of action which the Respondent can choose to take. It has to declare the patents and then state, among several possibilities, that the patents are invalid or will not be infringed by the doing of the act for which the registration of its product is sought. It is then for HSA to decide whether to invoke reg 23(5) of the TPR to require the Respondent to serve the requisite notice on the Appellant.

4 If such a notice was directed to be served, there would have been the 44-day moratorium in

reg 23(8) of the TPR followed by the 30-month moratorium in reg 23(9) of the TPR. Due to the Respondent's non-compliance with the regulations, it bypassed these moratoriums.

5 It is therefore not open to the Respondent to then argue that the Appellant could only proceed by the reg 23 TPR route when the Respondent was responsible for depriving the Appellant of that route by its non-compliance.

6 In any event, reg 24 of the TPR opens the way for a challenge to the registration of the Respondent's product if the Appellant manages to obtain a court order determining either of the matters spelt out in reg 24(1)(*a*)(i) or (ii). That appears from the statement of claim to be precisely what the Appellant is hoping to achieve.

7 In our opinion, reg 24(1)(*a*)(i) of the TPR is not necessarily about proving actual or past infringement of a patent. Instead, it envisages the situation where the Court (or the Registrar of Patents) considers an act authorised by the registration of the therapeutic product and determines whether that act amounts to infringement of a patent in the particular circumstances. As pleaded at paragraph (11) of the statement of claim, the acts in question are supply, manufacture, import and wholesale. The act may or may not have taken place. For instance, an applicant under this provision may argue before the Court that the person granted registration under the TPR is thereby permitted to import the product into Singapore but the act of importing the product would infringe its patent. The question that the Court has to answer is whether importing the registered product infringes a patent, irrespective of whether importation has already taken place or not.

8 At the very least, we think that such an interpretation of reg 24 may be fairly argued before the Court and is not a hopelessly untenable one. Even if actual infringement must be shown, it is also arguable that such infringement took place when the Respondent participated in the hospitals' public tender for the product by offering to dispose of the product, which the Appellant will have to prove was obtained directly by means of the patented process within the meaning of s 66 of the Patents Act (Cap 221, 2005 Rev Ed). This is something that can be particularised subsequently after discovery and/or interrogatories.

9 Where reg 24(1)(*a*)(ii) of the TPR is concerned, the High Court has held that the declaration sought by the Appellant should not be struck out and we agree. It is for the Appellant to prove at the trial that the declaration made to HSA is false or misleading in a material particular or has omitted to disclose a material matter. Based on what we have set out above regarding the registration scheme in reg 23, the Appellant's case cannot be said to be hopeless or obviously unsustainable.

10 If the Appellant succeeds in obtaining either of these determinations in reg 24(1) of the TPR from the Court, it may then apply to HSA to cancel the Respondent's registration. There can be no doubt that it is an "interested person" within the meaning of the regulation. We think the Respondent overstates its case when it submits that this opens the door to abuse by those who missed the deadlines in reg 23 of the TPR. That regulation concerns the registration process and provides for moratoriums against registration. A proprietor of a patent who misses any of the deadlines has to take the risk of the competitor flooding the market with generic products after registration because he has lost the opportunity to delay or even stop the registration process. There is no abuse in the proprietor now wanting to have the registration cancelled if he can obtain a determination on the specified matters.

11 Accordingly, we do not see why the statement of claim seeking these determinations should be seen as revealing no reasonable cause of action. We therefore allow Civil Appeal No 79 of 2018 and restore all the averments struck out by the High Court.

12 In respect of the application for an injunction, it follows from our discussions above that the Appellant does have a reasonable cause of action and consequently, there is a serious question to be tried. However, the Appellant has not shown credible evidence at this stage why damages would not be an adequate remedy. As held by the High Court, any damages suffered would be easily quantifiable as the hospitals are the customers of the therapeutic product here and they would maintain proper records of their purchases. Further, the tenders are from year to year. The Appellant has also not disclosed the terms of its licence agreement with Johnson & Johnson and there is no evidence on how the royalties are computed to justify a finding that such royalties would be affected adversely "in an uncertain and unquantifiable manner" as submitted by the Appellant.

13 The Appellant submits that it would lose its monopoly if the injunction is not granted to stop the Respondent from entering the Singapore market. However, this is a specialised anti-cancer drug used by a specialised clientele. If the Appellant succeeds in its action, its monopoly in Singapore is restored. Any lower price offered by its erstwhile competitors would only be a basis for the hospitals to try to negotiate with the Appellant or its licensee but the fact remains that the Appellant holds the monopoly for this product and the hospitals would probably need the product.

14 We therefore dismiss Civil Appeal No 84 of 2018 although we disagree with the High Court that there is no serious question to be tried.

15 Having considered the costs schedules filed by the parties, we award costs to the Appellant at $25,000 for these appeals. This amount includes disbursements and takes into account the issue on whether damages would be an adequate remedy, an issue which the Appellant did not succeed on.

16 For the hearing in the High Court, the costs order of $5,000 awarded to the Respondent for the striking out application is reversed so that the same amount is now payable to the Appellant. The costs order of $7,000 awarded to the Respondent for the application for an injunction is varied by reducing the amount payable to the Respondent to $3,500. This is to take into account the issue on whether there is a serious question to be tried which should have been decided in the Appellant's favour.

17 We make the usual consequential orders on security for costs.