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February 22, 2024

Pharma Patent Case Round-Up

If your 2024 has been too busy to keep up with caselaw, below we summarize and provide the key takeaways from pharmaceutical patent decisions that have been issued from the Federal Court and Federal Court of Appeal in the last two months.

Two NOAs Is Not Better than One: *Janssen v Apotex* (December 22, 2023)

Summary: Apotex filed two abbreviated new drug submissions (ANDSs) comparing their paliperidone product to Janssen's INVEGA SUSTENNA product. Apotex served a Notice of Allegation (NOA) only alleging non-infringement in respect of the listed patent (335 Patent). Following a summary trial, the Federal Court held that Apotex would infringe the 335 Patent and issued an injunction. Apotex appealed the infringement judgment, and also served a second NOA alleging invalidity only. Janssen commenced an action in response and brought a motion for summary judgment arguing that the second NOA was an abuse of process. The FC dismissed the motion and that decision was appealed.

Key Takeaway: The FCA allowed the appeal and held that the second NOA was an abuse of process. More broadly, absent special circumstances, it is an abuse of process for second persons under the *NOC Regulations* to serve more than one NOA relating to the same patent and drug product. The FCA said:

> [T]he Regulatory Impact Analysis Statement (RIAS) that accompanied the 2017 amendments to the *Regulations* (Canada Gazette, Part II, Vol. 151, Extra No. 1) makes it clear that a principal aim was to avoid multiple proceedings concerning patents on medicines, regardless of whether those proceedings are within or outside the *Regulations*. […]
>
> [T]he Federal Court should have considered whether a defendant in a normal patent infringement action under section 55 of the *Patent Act* that defends itself on the basis of non-infringement (without challenging the validity of the patent in suit) would, after losing on that defence, be allowed to commence a separate impeachment action

> concerning the same patent. In the absence of special circumstances […], such a subsequent action would, in my view, typically constitute an abuse of process. I see no reason why this same reasoning should not apply in the case of separate actions under the *Regulations*.

Induced Infringement in Flux?: *Apotex v Janssen/Pharmascience v Janssen*, 2024 FCA 9 / 2024 FCA 10 (January 12, 2024)

Summary: Apotex and PMS each filed ANDSs comparing their paliperidone product to Janssen's INVEGA SUSTENNA product. The NOAs served by Apotex and PMS alleged non-infringement of Janssen's listed patent (the 335 Patent). Apotex and PMS brought motions for summary trial seeking dismissal of Janssen's action on the basis that their products would not infringe the 335 Patent since they would not provide the 75 mg-eq. dose, which is an essential element of all of the claims. The Federal Court held that Apotex and PMS would induce infringement of the 335 Patent. Apotex and PMS appealed.

Key Takeaway (Apotex): The FCA dismissed the appeal and upheld the FC's decision. This decision is an important development in the law of induced infringement and could be read as lowering the bar on the second prong of the inducement test: the inducer influenced the third party to the point that the infringing act would not have occurred without the influence. Until now, the second prong has often been considered to be a "but for" test – but for the influence, the infringement would not have happened. In endorsing the FC's decision, although the FCA purported to apply the established inducement test from *Corlac Inc v Weatherford Canada Ltd*, in practice the FCA may have softened that requirement:

> I turn now to Apotex's more substantive argument that the Federal Court erred in concluding that the high threshold for the second prong of the test for inducing infringement was met in this case. The main weakness of this argument is that it depends on there being a requirement that prescribing practices of physicians be altered because of Apotex's activities. In fact, this is not necessary. What is required is that the ultimate act of direct infringement occur because of Apotex's activities. [emphasis in original]

Key Takeaway (PMS): The FCA dismissed the appeal and upheld the FC's decision. Unlike Apotex, PMS had sourced the product from Janssen. This decision develops the law relating to

implied licenses and their relevance to the first prong of the inducement test: whether there was direct infringement by a third party. Canada does not have a developed patent exhaustion doctrine, and implied license is the closest doctrine we have. Pharmascience argued the purchase of Janssen's 75 mg drug product in a single dose included an implied license to use that dose in combination with doses obtained from other sources, in the claimed dosing regimen (the dosing regimen claimed in the 335 Patent includes at least three different doses). In essence, while the FCA recognised that the sale of a patented article without restriction includes the right to use that article as the purchaser pleases, the sale of the 75 mg dose by itself was not considered the sale of the patented article since the patent covered the entire dosage regime. The FCA stated:

> [T]o grant an implied licence, the sale of the entire combination had to occur, or at least, as in *Slater Steel*, the parties' intended use of the component at the time of sale contemplated its use in the patented combination.

It May Be CGK but It Still Has to Be Disclosed: *Takeda v Apotex* (January 23, 2024)

Summary: This decision arises from a patent infringement action relating to a Takeda patent covering aspects of its DEXILANT capsules. The Federal Court held that the patent was not infringed by Apotex's proposed generic dexlansoprazole capsules and, in any event, that the patent is invalid for inutility (lack of sound prediction) and insufficiency.

Key Takeaway: While very fact-specific, this decision sets a high bar for sufficiency of disclosure when the utility of a patent is based on predicted rather than demonstrated utility. In particular, the Court appears to hold that if aspects of the common general knowledge are being relied upon as the foundation for the prediction of utility, that reliance has to be disclosed in the patent.

No Bright Line Rules for Methods of Medical Treatment: *Pharmascience v Janssen* (February 1, 2024)

Summary: This is a third case in this blog relating to Janssen's INVEGA SUSTENNA product. This decision relates to PMS's allegation of invalidity of the 335 Patent on the basis that the claims comprise unpatentable subject matter, namely methods of medical treatment. The 335 Patent teaches a regimen to achieve an optimum plasma concentration-time profile. PMS argued that the dosage range for the maintenance dose claimed

indicates that no particular dose will work for every patient, and that selection of the appropriate dose for a specific patient will require skill and judgment from the prescriber. The Federal Court rejected the argument and held that the 335 Patent discloses patentable subject matter. PMS appealed.

Key Takeaway: The FCA dismissed the appeal. In doing so, it appears to have rejected the approach to methods of medical treatment in a line of cases at the Federal Court level. As noted by the FCA, “the jurisprudence at the Federal Court level has developed an approach whereby a claim [to the administration of a drug] may be found to be either patentable subject matter or an unpatentable method of medical treatment based on whether it defines a fixed dosage (or interval of administration) or a range of dosages (or intervals).” The FCA rejected this bright line rule and held that it would go too far to say that any drug regimen that requires a physician to monitor a patient is unpatentable. It also stated that while a fixed dosage and schedule may be a good indication that no skill and judgment would be required, evidence may indicate otherwise. The Court summarized its view as follows:

> To summarize, whether or not a patent claim to a dosing regimen relates to a method of medical treatment cannot be based exclusively on whether its dosing and schedule is fixed or not. The proper inquiry remains whether use of the invention (i.e., how to use it, not whether to use it) requires the exercise of skill and judgment, and the burden remains on the party challenging the patent. It is difficult to provide more detailed guidance than this for parties involved in future litigation and courts faced with allegations of invalidity of patent claims due to unpatentable subject matter, namely methods of medical treatment. Such allegations will generally turn on the particulars of the case and the evidence on the record.

This is a win for patentees as the Court recognized that a prohibition on any drug regimen requiring physician monitoring “would cast too wide a net, potentially encompassing almost any drug.” Having said that, the guidance from the FCA (cases will turn on their facts) is somewhat vague and will likely lead to less certainty for all parties.