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Amended *PM(NOC) Regulations*: Third Anniversary Update.

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September 21, 2020 marked the third anniversary of the coming into force of the amended *Patented Medicines (Notice of Compliance) Regulations* (*Regulations*), which heralded significant changes to the litigation landscape for pharmaceutical companies in Canada, including an end to dual litigation.

This article provides an update as of the third anniversary of the amendments (see our first and second anniversary updates). Over the last year, significantly more actions under the *Regulations* were commenced compared to the prior year, the first decisions on the merits issued, and inescapably, COVID-19 had an effect on actions under the *Regulations*.

Status of actions under the amended Regulations

To date, there have been approximately 140 actions commenced under the amended *Regulations*. Around 65 actions have been discontinued/dismissed on consent and decisions have been rendered in four actions.

From September 21, 2019 to September 21, 2020, approximately 49 sets[1] of actions (57 total) were started, representing an increase from last year (49 vs 35), continuing the upward trend in the number of actions commenced since the amended *Regulations* came into force.

The following is a list of actions pursuant to section 6 of the *Regulations* in respect of which at least one action is pending (although some of the actions may be stayed or adjourned pending an appeal in another proceeding):

Small-molecule pharmaceuticals:

- abiraterone acetate (Janssen's ZYTIGA)
    - Generics: Apotex; Pharmascience; Dr. Reddy's Laboratories; JAMP
- adapalene and benzoyl peroxide (TACTUPUMP FORTE)
    - Generic: Taro
- afatinib dimaleate (Boehringer Ingelheim's GIOTRIF)
    - Generic: Teva
- apixaban (Bristol-Myers Squibb's ELIQUIS)

    - Generics: Pharmascience; Sandoz; JAMP
- darifenacin hydrobromide (Searchlight Pharma's ENABLEX)
    - Generic: JAMP
- dolutegravir (Viiv's TIVICAY)
    - Generic: Sandoz
- doxycycline (Galderma's APPRILON)
    - Generic: Sandoz
- efinaconazole (Bausch Health's JUBLIA)
    - Generic: Taro
- glatiramer acetate (Teva's COPAXONE)
    - Generic: Pharmascience
- lisdexamfetamine (Shire's VYVANSE)
    - Generic: Apotex
- lurasidone hydrochloride (Sunovion's LATUDA)
    - Generics: Pharmascience; Taro; JAMP
- macitentan (Janssen's OPSUMIT)
    - Generics: Sandoz; Apotex; JAMP
- mirabegron (Astellas Pharma's MYRBETRIQ)
    - Generic: Sandoz
- naloxone hydrochloride (Opiant's NARCAN Nasal Spray)
    - Generic: Teva
- paliperidone palmitate (Janssen's INVEGA SUSTENNA)
    - Generic: Pharmascience
- perampanel (Eisai's FYCOMPA)
    - Generic: Taro
- pirfenidone (Hoffmann-La Roche's ESBRIET)
    - Generics: Sandoz; Teva; JAMP
- pomalidomide (Celgene's POMALYST)
    - Generics: Natco; Dr. Reddy's Laboratories
- rivaroxaban (Bayer's XARELTO)
    - Generics: Apotex; Taro; Dr. Reddy's Laboratories; Pharmascience; JAMP; Mint

- saxagliptin (AstraZeneca's ONGLYZA)
    - Generic: Sandoz
- silodosin (Allergan's RAPAFLO)
    - Generic: Sandoz; Pharmascience
- sitagliptin (Merck Sharp & Dohme's JANUVIA)
    - Generic: Sandoz; Pharmascience; Apotex; JAMP
- sitagliptin and metformin hydrochloride (Merck Sharp & Dohme's JANUMET and JANUMET XR)
    - Generic: Apotex
- sodium risedronate (Allergan's ACTONEL DR)
    - Generic: Apotex
- sunitinib malate (Pfizer's SUTENT)
    - Generic: Sandoz; JAMP

Biologics (see latest update on biosimilars here):

- filgrastim (Amgen's NEUPOGEN)
    - Biosimilar sponsor: Sandoz
- pegfilgrastim (Amgen's NEULASTA)
    - Biosimilar sponsors: Pfizer; Purdue

In addition, 7 actions have been started under section 8.2 of the *Regulations*, which permits a first person/patentee to bring an infringement action regarding a patent not addressed in a Notice of Allegation (NOA) (*e.g.*, not listed on the Patent Register) once served with a NOA:

- 1 action relating to liraglutide (Novo Nordisk's VICTOZA) (discontinued)
- 1 action relating to efinaconazole (Bausch's JUBLIA)
- 4 actions relating to sitagliptin (Merck's JANUVIA) and
- 1 action relating to sitagliptin/metformin (Merck's JANUMET)

Lastly, Pfizer has commenced the first action under amended section 8, seeking damages following Amgen's unsuccessful action relating to filgrastim (see discussion of the decision on the merits below).

Decisions on the Merits

The last decision under the pre-amended *Regulations*

On November 28, 2019, a decision issued in *Janssen Inc v Apotex Inc*, ending the last of the ongoing applications for prohibition orders under the pre-amended *Regulations*. Justice Phelan granted Janssen a prohibition Order regarding Apotex's version of ZYTIGA (see article here). As seen in the list above, there are a number of pending actions relating to abiraterone under the current *Regulations*. Apotex has appealed (A-437-19). There is also another appeal pending from a prohibition Order regarding Apotex's version of VYVANSE (see article here).

Amended Regulations

By the third anniversary, three decisions on the merits had issued in four actions under the *Regulations*, all of which have been appealed:

- *Amgen Inc v Pfizer Canada ULC*, 2020 FC 522 (filgrastim, Pfizer's NEUPOGEN): the claims relating to granulocyte colony-stimulating factor made using recombinant genetic technology were found to be obvious (see article here). Amgen has appealed (A-122-20). As mentioned above, Pfizer has brought an action seeking section 8 damages due to the alleged delay in the issuance of its NOC pending the disposition of the action.
- *Janssen Inc v Teva Canada Ltd*, 2020 FC 593 (paliperidone palmitate, Janssen's INVEGA SUSTENNA): the validity of the patent for dosing regimens of paliperidone palmitate depot formulations was upheld, and certain claims were found infringed (see article here). Teva has appealed, and Janssen has cross-appealed (A-131-20).
- *Biogen Canada Inc v Taro Pharmaceuticals Inc and Pharmascience Inc*, 2020 FC 621 (fampridine, Biogen's FAMPYRA): claims for the use of fampridine sustained release formulations for improving walking speed were found obvious, and certain claims were found anticipated (see article here). Biogen has appealed (A-145-20; A-146-20).

Procedural Matters

Procedural decisions

As reported previously, the Federal Court had ordered that validity issues common to four separate actions be heard in a concurrent trial. Apotex and Teva were granted leave to appeal, and the Federal Court of Appeal overturned the Federal Court's decision. As reported here, the Court of Appeal held that the decision was inconsistent with the prohibition against joinder of actions under section 6.02 of the *Regulations*. In obiter, the Court of Appeal also stated that the *Regulations* do not require the Federal Court to render a judgment within 24 months, which is a "goal" rather than an obligation.

Notwithstanding this comment from the Court of Appeal, the three decisions on the merits discussed above were rendered approximately two months after the last day of trial, and in advance of the expiry of the stay.

In *AstraZeneca v Sandoz* (saxagliptin), the Federal Court held that an action under the *Regulations* scheduled for trial after patent expiry would not be rendered moot by the patent's expiry (see decision reported here).

Other

Effect of COVID-19: due to COVID-19, the third year brought many disruptions to the timely hearing of actions under the *Regulations*. As tracked here, the Federal Court had suspended its regular functions from March 17 to June 15 or June 29, 2020, depending on the province. Some trials of actions under the *Regulations* were adjourned and rescheduled, though interlocutory steps continued with the Federal Court providing continued case management throughout the suspension period. In at least one proceeding, the 24 month stay was extended. The Federal Court has also embraced virtual hearings, and at least two trials on the merits have been heard using the Zoom platform. The Federal Court has published many materials relating to such hearings, including consolidated practice directions, and attendance at virtual hearings.

Health Canada's Statistical Report: Health Canada has issued the Statistical Report 2019/2020 for the Patented Medicines (Notice of Compliance) Regulations, Data Protection and Certificates of Supplementary Protection, which reflects its fiscal year April 1, 2020 to March 31, 2020. Some highlights include:

- The fiscal year saw the fewest additions to the Patent Register (556) in the last five years (from a high of 794 in fiscal year 2016/2017).
- Consistent with the increased number of proceedings compared to prior year, in the 2019/2020 fiscal year, there were 153 submissions for which Form Vs were filed, compared to 96 the year before (though 153 is lower than the 200 in 2015/2016 year), and 78 NOAs in 2019/2020 compared to 67 in 2018/2019.

Should you have any questions, please do not hesitate to contact a member of the Pharmaceutical Litigation group.

References

1. Actions between the same parties in respect of the same innovator reference drug are considered one “set”. The statistics are provided as of the three-year anniversary, September 21, 2020.

The preceding is intended as a timely update on Canadian intellectual property and technology law. The content is informational only and does not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly.

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