

The background of the cover features a detailed illustration of a blood vessel. The vessel is shown in cross-section, with a red, textured outer wall and a dark red interior. Several bright red, biconcave disc-shaped red blood cells are visible within the vessel. The overall color palette is dominated by reds and oranges, with a soft, glowing effect around the cells and vessel walls.

iam

Life Sciences 2017

*Key issues for senior
life sciences executives*

Pharmaceutical patents in Canada: key issues for life sciences
companies

*Yoon Kang and Daphne Lainson
Smart & Biggar/Fetherstonhaugh*

Innovative businesses choose Smart & Biggar — the recognized leader in intellectual property

**Canada's Intellectual Property
Litigation Firm of the Year**
Benchmark Canada Awards 2017

**Canadian Specialty IP Firm
of the Year Award** *Managing
Intellectual Property's North
America Awards in 2016*

**Band 1 for Intellectual Property
Law in Canada** *Chambers & Partners
– The World's Leading Lawyers for
2016 edition*

**Top Tier for Intellectual
Property in Canada**
The Legal 500 Canada 2017

SMART & BIGGAR
FETHERSTONHAUGH

Barristers & Solicitors • Patent & Trademark Agents

OTTAWA / TORONTO / MONTREAL / VANCOUVER / CALGARY

UNPARALLELED IP

SMART-BIGGAR.CA

Pharmaceutical patents in Canada: key issues for life sciences companies

By Yoon Kang and Daphne Lainson, Smart & Biggar/Fetherstonhaugh

There are some key distinctions between the US and Canadian drug approval systems and patent laws. This can create very different and unexpected outcomes for pharmaceutical manufacturers.

Patent regulatory landscape for drugs and biologics

The Hatch-Waxman Act created an abbreviated regulatory approval pathway for generic drugs and a process to allow issues of patent infringement and validity to be determined before Food and Drug Administration (FDA) approval of the generic drug. This patent regulatory framework did not extend to biologic drugs. It was not until the passage of the Biologics Price Competition and Innovation Act in 2010 that an abbreviated pathway was created for FDA approval of biosimilars and a process was established to allow innovators to assert patent rights before biosimilar approval.

Canada introduced a regime in 1993 that links patent rights and generic drug approval. The regime enacted under the Patented Medicines (Notice of Compliance) Regulations has many parallels to that created by Hatch-Waxman. However, a number of areas fundamentally diverge, including the application of this regime to generic drugs and biosimilars alike.

There are also differences in regulatory exclusivity terms, as well as the absence of any form of patent term extensions in Canada to date.

These differences can create different loss of exclusivity outcomes in Canada and the United States. With this in mind, this chapter highlights the most significant differences between the patent regulatory regimes in Canada and the United States.

Patent linkage

Under the linkage regime created by Hatch-Waxman, innovators list patents in the Orange Book and unless the generic awaits expiry of all listed patents, it must certify that it does not infringe the listed patents or that the patents are invalid. This may then lead to an infringement action by the innovator while FDA approval of the generic drug is stayed.

There is no patent listing process under the Biologics Price Competition and Innovation Act, which established a complicated 'patent dance' for exchanging lists of relevant patents and waves of litigation to address issues of infringement and invalidity of the patents. While there is a Purple Book of licensed products, this list does not include patent information.

In Canada, innovators list patents pertaining to chemical or biologic drugs on a publicly available Patent Register and generic or biosimilar manufacturers must address those patents before marketing authorisation (ie, a notice of compliance) is granted by Health Canada. This can lead to a court proceeding by the innovator. However, the nature of the court proceeding, the length of time that the subsequent entrant's regulatory submission is stayed before the health authorities, listing requirements, the types of patent that may be engaged, innovator liabilities and subsequent entrant exclusivities diverge north and south of the border.

Nature of proceedings

Unlike in the United States, the filing of an abbreviated new drug submission (ANDS) by a generic or a new drug submission (NDS) by a biosimilar manufacturer is not an act of

“The requirements for patent listing in Canada differ from the Orange Book requirements, beyond the fact that biologics are encompassed, and include distinctions in the process, timing requirements and the types of patent that can be listed”

infringement. Moreover, court proceedings under the Patented Medicines (Notice of Compliance) Regulations are meant to decide whether a notice of compliance should issue for a generic or biosimilar drug – these proceedings do not decide validity and infringement. Rather, the proceedings are summary only, with allegations of non-infringement and invalidity being found justified or not justified. If the allegations are justified, a notice of compliance may be granted for the generic or biosimilar drug. Once the notice of compliance issues, there is no effective right of appeal for an innovator, because the question to be determined (should a notice of compliance be granted?) has been rendered moot; in contrast, the unsuccessful generic that has yet to receive a notice of compliance can appeal.

If the generic or biosimilar manufacturer is successful in litigation under the Patented Medicines (Notice of Compliance) Regulations and launches its product in Canada, the innovator can then commence a patent infringement suit relying on the patents that it asserted during the proceeding under the regulations and any other patents that may be infringed. Unlike a proceeding under the Patented Medicines (Notice of Compliance) Regulations, which is based on a written evidentiary record, an infringement action is a full trial with live witnesses and full discovery.

The summary nature of a proceeding under the Patented Medicines (Notice of Compliance) Regulations may give rise to very different results in Canada and the United States. However, this potential for two proceedings on the same patent, between the same parties and involving the same drug, will likely soon come to an end. Canada and the European Union signed a trade agreement in 2016 – the Comprehensive Economic and Trade Agreement (CETA) – which includes a provision requiring that all litigants be afforded equivalent and effective rights of appeal. The Canadian government has announced that this provision “gives scope for Canada to end the practice of dual litigation”.

Length of stay

Health Canada approval of generic drugs and biosimilars is stayed for up to 24 months from the date that the innovator commences proceedings under the Patented Medicines (Notice of Compliance) Regulations, in contrast to the 30-month stay on the FDA under Hatch-Waxman measured from a generic’s notice of an abbreviated new drug application (ANDA) filing and the absence of a stay under the Biologics Price Competition and Innovation Act.

There is no 20-day or other deadline in Canada, such as in the United States, by which a generic or biosimilar manufacturer must notify the innovator of its regulatory filing. However, once a notice of allegation that addresses the listed patents is served on an innovator and, as is the case under Hatch-Waxman, once notice is given, the innovator has only 45 days to commence a proceeding.

Consequently, commencement of litigation under the Patented Medicines (Notice of Compliance) Regulations may be delayed for many months compared to the progress of ANDA litigation in the United States. Moreover, the difference in the availability and length of the stays may also affect the timing of generic and biosimilar entry in Canada compared to the United States. It is not yet known what effect CETA ratification will have on the length of the statutory stay.

Damages to generic

If a generic is successful in a proceeding under the Patented Medicines (Notice of Compliance) Regulations, it may be entitled to damages from the innovator. These ‘Section 8’ damages are intended to compensate the generic for any delay to its approval because the innovator commenced a proceeding resulting in the ‘patent hold’. There is no corresponding system in the United States and it is not known whether CETA ratification will affect the current availability of Section 8 damages.

The magnitude of these damages under the current regulations can be significant and may

affect decisions to commence Patented Medicines (Notice of Compliance) Regulations proceedings in Canada.

Generic/biosimilar exclusivity

In the United States, the first generic that certifies that the patents listed on the Orange Book are invalid, unenforceable and/or not infringed may receive a 180-day period during which no other generic product will be authorised by the FDA. There is no corresponding exclusivity period under the Biologics Price Competition and Innovation Act for biosimilars (with the exception of ‘interchangeable biosimilars’, for which the act provides a period of protection for the first interchangeable biosimilars).

There is no generic or biosimilar exclusivity in Canada. This can be another factor affecting the timing of generic/biosimilar challenges in Canada.

The Canadian government has not indicated whether ratification of CETA will lead to a period of generic or biosimilar exclusivity.

Patent listing

The requirements for patent listing in Canada differ from the Orange Book requirements, beyond the fact that biologics are encompassed, and include distinctions in the process, timing requirements and the types of patent that can be listed. The listing requirements may change if CETA is ratified, but there are presently no specific details on what may be varied, if anything.

In order for a patent to be eligible for listing in Canada, the patent must have a Canadian (Patent Cooperation Treaty (PCT)) filing date that precedes the filing date of the related NDS or supplemental NDS. If the Canadian (PCT) filing date is after filing of the NDS or supplemental NDS, the patent is not eligible for listing. The priority filing date is irrelevant. This requirement has resulted in a number of patents being ineligible for listing in Canada, where the US equivalent is listed on the Orange Book.

The innovator is not obliged to list a patent in Canada, unlike in the United States, or submit forms post-approval. While Canada and the United States similarly require submission of patent listing forms with the new drug application (NDA) or NDS/supplemental NDS, or within 30 days of grant if the patent issues after the submission is filed, late listing is not possible in Canada. If a listing deadline is missed for any reason, the patent list will not be accepted. This too can result in differences between patents that

can be asserted under the linkage laws in both jurisdictions.

In contrast to the FDA process – which does not involve a substantive review of listing forms – the Office of Patented Medicines and Liaison (OPML) at Health Canada will assess whether a patent meets the requirements for listing. If the OPML finally rejects the listing, the innovator can have this decision judicially reviewed.

Both Canada and the United States permit listing patents relating to the drug (active ingredient/medicinal ingredient), a composition thereof or its use. However, Canada strictly applies a product-specificity approach, which includes no consideration as to whether the patent may be infringed by a non-licensed user, as in the United States.

In Canada, the patent must claim the medicinal ingredient, formulation, dosage form and/or use that has been approved from a NDS. If the patent is being listed for the first time in relation to a supplemental NDS, it must claim the very change in use, formulation or dosage form that is approved from the supplemental NDS. This ‘matching’ is not required where a patent is being carried forward to a later supplemental NDS.

It is possible that an innovator product falls within the scope of subject matter claimed, but does not satisfy the product-specificity requirements of the Patented Medicines (Notice of Compliance) Regulations. This may result in different patents being eligible for Orange Book listing from those that are eligible for listing in Canada.

The differences in listable patents may therefore also result in a difference as to what patents can be asserted in each jurisdiction under the linkage laws.

Regulatory exclusivities

The United States provides for:

- a five-year regulatory exclusivity period for a new chemical entity, which may be reduced to four years if a generic certifies non-infringement/invalidity;
- a 12-year regulatory exclusivity period from first licensure of a reference biologic product; and
- a three-year period of exclusivity for non-biologic drugs based on new clinical investigations conducted or sponsored by the NDA applicant and essential for approval.

Each of these periods may be extended by a further six months if the paediatric extension applies.

Canada provides a six-year period for an innovative drug where a generic or biosimilar manufacturer cannot file its submission and a total period of eight years of market exclusivity, which can be extended by a further six months if the paediatric extension applies.

The availability of this exclusivity does not depend only on the drug being a new chemical (or biologic) entity and the limitations on what constitutes an 'innovative drug' can lead to divergent results in the United States and Canada. There is also no additional term in Canada based on new clinical data. Thus, new formulations, indications or combinations of two previously approved medicinal ingredients are given no additional data protection in Canada. Moreover, the United States has other exclusivities (eg,

orphan drug exclusivities) which have no parallel in Canada.

The differences in the US and Canadian regimes can lead to situations where an innovator is granted regulatory exclusivity in the United States, but not in Canada, or the terms may be significantly different. The regulatory exclusivity framework may therefore also contribute to a different loss of exclusivity result north and south of the border.

Patent term extensions

Unlike in the United States, Canada does not extend patent terms in order to address regulatory or patent office delays. However, under CETA Canada will provide up to a two-year patent term restoration. This will reduce the gap between



Yoon Kang

Partner

ykang@smart-biggarc.ca

Yoon Kang is a partner in the Toronto office, where she is responsible for leading the life sciences practice group. Her practice has focused on patent litigation and prosecution for over 20 years. She counsels global pharmaceutical innovators and research institutions on all aspects of patent rights, including in small molecules and biologics inventions, and plays a leading role in the firm's life sciences litigation practice. She has significant experience as the lead counsel, representing pharmaceutical clients before the Federal Court and Federal Court of Appeal in complex patent litigation, including under the Patented Medicines (Notice of Compliance) Regulations.



Daphne Lainson

Partner

dclainson@smart-biggarc.ca

Daphne Lainson specialises in securing patent protection for chemical, pharmaceutical and biotechnology-related inventions. She also provides advice to clients on pharmaceutical regulatory law. This includes providing strategic advice during patent prosecution and following patent grant for both pharmaceuticals and biologics. She is called on to advise innovative pharmaceutical and biopharmaceutical companies in matters relating to data protection, the Patented Medicines (Notice of Compliance) Regulations and the Patented Medicine Prices Review Board. She is a lawyer and a qualified patent and trademark agent, and holds an advanced degree in chemistry. She has been assisting clients with securing patent protection for their innovations for over 15 years.

patent exclusivities in Canada and the United States. However, differences in loss of exclusivity will remain, given the distinctions in how patent term restoration is calculated in each country and the maximum available terms.

In the United States, patents relating to a human drug product (chemical or biologic), a method of using the product or a method of manufacturing the product may be extended. The extension is based on the regulatory review period after patent grant and provides up to one half-day for each day spent in the pre-NDA testing period and one day for each day spent in the FDA review period. The term can be reduced for lack of due diligence before the FDA, is capped at five years and cannot result in a total patent term remaining from the product's approval date exceeding 14 years.

CETA includes provisions that will similarly extend the term of patents relating to products, processes and applications of a product, and is based on the European scheme that provides supplementary protection certificates. Bill C-30 (the CETA implementing legislation) includes a calculation based on the difference between the patent filing date and the marketing authorisation date, less five years and capped at two years. The term of the certificate of supplementary protection will similarly take effect at the end of the patent term and can be reduced based on unjustified delay by the sponsor before Health Canada, and may not be available if an innovator does not timely file its NDS after foreign regulatory filings.

Pricing

There is a feature of the Canadian patent regulatory landscape that has no parallel in the

United States. The Patented Medicine Prices Review Board (PMPRB) has jurisdiction over the price of patented medicines in order to address concerns regarding excessive pricing that could arise by virtue of a patent monopoly. The presence of the PMPRB can also alter the market for subsequent entrants.

Conclusion

The current patent regulatory landscapes can create significant differences in exclusivities in Canada and the United States. Under CETA, there should be greater harmony with the United States; but as with the current system, Canada draws on not only the United States to inform its legislative regime, but also Europe and other jurisdictions. There will therefore continue to be distinctions between the two countries; as such, companies should be aware of the differences in order to understand the exclusivity framework and when loss of exclusivity may result. *iam*

SMART & BIGGAR FETHERSTONHAUGH

Barristers & Solicitors • Patent & Trademark Agents

Smart & Biggar/Fetherstonhaugh

1100-150 York Street

Toronto ON M5H 3S5

Canada

Tel +1 416 593 5514

Fax +1 416 591 1690

Web www.smart-biggar.ca