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CANADA'S LINKAGE LITIGATION SCHEME: A COMPARISON TO HATCH-WAXMAN

The September 21, 2017 amendments to the *Patented Medicines (Notice of Compliance) Regulations* (see our article here) introduced a new scheme for pharmaceutical patent linkage litigation in Canada for generic challenges served on and after this date. That scheme is now much closer to the US Hatch-Waxman scheme, but with remaining key differences, as shown in the chart below. A special thank you to Brian Coggio of Fish & Richardson for contributing the Hatch-Waxman details. **— Nancy P. Pei**

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Governing legislation	*Patent Act*, s. 55.2(4) *Patented Medicines (Notice of Compliance) Regulations*	*Drug Price Competition and Patent Term Restoration Act of 1984*, as supplemented – "Hatch-Waxman Act"
Litigation Practice Notice	Case and Trial Management Guidelines for Complex Proceedings and Proceedings under the *PM(NOC) Regulations* Timetable Checklist for proceedings under the *PM(NOC) Regulations*	N/A
Drugs covered	Small molecules and biologics.	Small molecules only. Biologics governed by *Biologics Price Competition and Innovation Act of 2009*.
Listing of patents	*Patent Register*	*Orange Book*
Eligible patents for listing must include:	At least one claim for approved medicinal ingredient, formulation, dosage form or use New Drug Submission (NDS). At least one claim for approved changed formulation, dosage form or use (Supplemental NDS). Filing deadlines must be met.	At least one claim to active ingredient, drug product (formulation and composition), or method of use covering the approved drug. At least one claim for approved changed formulation, dosage form or use (Supplemental NDS). Filing deadlines must be met.

Innovator marketing requirement	Yes (s. 3(3), s. 5(1)), s. 5(2)).	N/A
Earliest possible generic challenge	If data protection applies, 6 years after innovator's first approval (generic or biosimilar submission cannot be approved until 8 years after first approval or 8.5 years with pediatric extension).	If new chemical entity ("NCE"), generic cannot file for approval for 5 years after NCE approval. However, if generic challenges any Orange Book patent, it can file after 4 years.
	No new use or new formulation exclusivity.	Where original FDA approval is for a new use or formulation, the generic cannot be approved for 3 years after initial FDA approval, but generic's filing is not restricted as with NCE.
	No orphan drug exclusivity.	Other exclusivities (orphan drug, pediatric) may apply.
Regulatory exclusivity incentive for generic to challenge early	None.	Yes, 180-day exclusivity to the first generic applicant to challenge the patent(s) in the Orange Book.
Notice of generic regulatory filings	Yes: GSUR list records pending generic submissions accepted into review by Health Canada. SUR list records pending biosimilar submissions accepted into review by Health Canada.	Nothing beyond notification of certification.
Notification of Certification to patentee	Notice of allegation (NOA).	Paragraph IV notice letter.
Patents that need to be addressed in generic notification	Generic / biosimilar sponsor only required to address patents listed on the Patent Register as of its regulatory filing date.	Generic required to address all patents listed in Orange Book but only patents listed as of its regulatory filing date give rise to automatic 30-month stay of approval.

		
Deadline to serve notification of certification	None.	20 days from FDA acceptance letter.
Deadline to commence action	45 days from notification (s. 6(1) action). Only NOC holder must receive NOA, but must forward NOA to patent owner.	45 days from notification. Both NDA holder and patent owner must receive notice.
Ability to assert all claims in any listed patent	Yes.	Yes.
Court	Federal Court of Canada.	District Court (often, Delaware, New Jersey).
Statutory stay of generic approval	Up to 24 months, can be shortened or extended by Court (cannot extend on consent). Can be renounced when the action is brought, in which case s. 8 damages N/A.	Up to 30 months, can be shortened or extended by Court. No corresponding provisions.
Generic submission ready, not approved because of statutory stay	Patent (IP) hold (confidential).	Tentative approval (public).
Ability to assert **i. patents listed after generic filing or** **ii. unlisted patents**	Yes, in a separate patent infringement action (s. 8.2), once NOA is served.	Possible under appropriate circumstances.
Ability to assert patents addressed in a generic notification outside an action brought within 45 days	No, unless no reasonable basis for bringing action within 45-day period (s. 6.01).	Innovator can assert all patents in Orange Book even after 45 days, but forfeits automatic 30-month stay of approval.

Combining multiple proceedings	Yes, but only s. 6(1) actions relating to same submission (s. 6.02).	Yes, can combine different generic defendants in a single Hatch Waxman action relating to the same reference product; can also include unlisted patents in a Hatch Waxman action.
Early documentary disclosure (pre-discovery / pre-deposition)	Yes, for both generics (with NOA) and innovators (if generic makes request in NOA).	Discovery governed by district court local rules or schedule judge sets.
Examinations for discovery /depositions	Inventors and one corporate representative per plaintiff.	Expert and fact witness depositions (inventors, corporate representatives).
Markman hearing	No, but early claim charts may be required.	Very common. Timing depends on individual judge.
Likely date for trial	Ending by 21-month mark.	Prior to expiration of 30-month stay.
Likely length for trial	Ten days.	Typically 5 days or less, depending on the venue.
Jury trial	No.	No, unless generic launches product.
Burden of proof	Plaintiff bears burden of proving infringement (balance of probabilities); defendant bears burden of proving invalidity (balance of probabilities).	Plaintiff bears burden of proving infringement (preponderance of the evidence); defendant bears burden of proving invalidity (clear and convincing evidence).
Appeal as of right	Yes, for decision on merits, to Federal Court of Appeal. Further appeal to Supreme Court of Canada requires leave.	Yes, to Court of Appeals of the Federal Circuit (CAFC). En banc review requires leave. Petition to Supreme Court requires leave.

Damages for losses flowing from delayed generic entry if patentee unsuccessful	Yes, under s. 8 *Patented Medicines (Notice of Compliance) Regulations* N/A if statutory stay is renounced when the action is brought.	Not under statute. Other remedies possible for egregious conduct.
Monetary remedies for infringement if generic launches	Damages (lost profits and/or reasonable royalty) or generic's profits, if Court grants patentee right to elect profits. Portion of attorney costs likely.	Lost profits and/or reasonable royalty. Treble damages possible if infringement is willful; portion of attorney fees possible.
	OTHER	
Post-grant review by Patent Office	Re-examination, uncommon.	*Inter partes* review, common.
Supplementary patent protection / patent term extension for regulatory delays	Certificates of Supplementary Protection (CSP), max two years.	Patent term extension, max 5 years.
Patent term adjustment for Patent Office delays	Yes, Regulations came into force on January 1, 2025. Only patents filed on or after December 1, 2020 and issuing after December 1, 2025 may qualify. CSP term will run concurrently with PTA term.	Yes, see 35 USC §154(b).