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CANADA'S NEW 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 servedon 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**

Governing legislation	*Patent Act,* s. 55.2(4) *Patented Medicines (Notice of Compliance) Regulations*	*1984 Drug Price Competition and Patent Restoration Act* - "Hatch-Waxman Act"
Practice Notice	*Federal Court Guidelines*	
Drugs covered	Small molecules, biologics approved via new drug submission (NDS) or supplemental NDS.	Small molecules only (with minor exceptions, e.g., insulin/HGH). Biologics governed by *Biologics Price Competition and Innovation Act.*
Listing of patents	*Patent Register*	*Orange Book*
Eligible patents for listing must include:	At least one claim to approved medicinal ingredient, formulation, dosage form or use. 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. Filing deadlines must be met.
Earliest possible generic challenge	If data protection applies, 6 years after innovator's first approval (generic 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.

		
Earliest possible generic challenge *continued*	No new use or new formulation exclusivity. No orphan drug 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. Other exclusivities (orphan drug, pediatric) may apply.
Notification of certification to patentee	Notice of allegation (NOA).	Paragraph IV notice letter.
Patents that need to be addressed in generic notification of certification	Generic only required to address patents listed on the Patent Register as of its regulatory filing date.	Generic only required to address patents listed in Orange Book as of its regulatory filing date.
Deadline to serve notification of certification	None.	20 days from FDA acceptance letter.
Ability to assert all claims in any listed patent	Yes.	Yes.
Ability to assert (i) patents listed after generic filing or (ii) unlisted patents	Yes, once NOA is served.	Possible, but need agreement between the parties or court order.
Innovator can 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.	Innovator can assert all patents in Orange Book even after 45 days, but forfeits automatic 30-month stay of approval.
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).	Up to 30 months, can be shortened or extended by court.
Generic submission ready, not approved because of statutory stay	Patent hold.	Tentative approval.
Markman hearing	No, but early claim charts may be required.	Very common. Timing depends on individual judge.
Early documentary disclosure (pre-discovery/ pre-deposition)	Yes, for both generics and innovators (if generic makes request in NOA).	Discovery governed by district court local rules or schedule judge sets.
Depositions/ examinations for discovery	Inventors and one corporate representative per plaintiff.	Corporate and fact witness depositions (inventors, corporate representatives, experts).
Likely date for trial	Ending by 21-month mark.	Prior to expiration of 30-month stay.
Likely length for trial	Two weeks.	1 week or less.
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.

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Damages for losses flowing from delayed generic entry if patentee unsuccessful	Yes, under s. 8 *Patented Medicines (Notice of Compliance) Regulations*	Not under statute. Other remedies possible for egregious conduct.
Monetary remedies for infringement if generic launches	Damages or generic's profits, if Court grants right to elect profits. Portion of attorney costs likely.	Lost profits and/or reasonable royalty. Treble damages possible if infringement is wilful; portion of attorney fees possible.
Post-grant review by Patent Office	Re-examination, uncommon.	Inter partes review, common.
OTHER		
Patent term extension for regulatory delays	Certificates of Supplementary Protection, max two years.	Yes, max 5 years.