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Patent term erosion and the availability of new medicines in Canada 2000-2022

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ATTRIBUTION
This legacy paper is corporately authored and edited based on proprietary template models and methods that are intended to facilitate regular updates. The design and content are a cumulative reflection of the diverse contributions collectively attributable to the CHPI affiliated researchers who may have variously participated in updating each edition. Data sources, methods and editorial presentation may evolve from previous editions.

EDITION
This is the first edition of this paper to be published as a CHPI research series. It builds on the concepts and methods from the original paper: Skinner BJ (2016). How long do new patented medicines have market exclusivity in Canada's public drug plans? *Canadian Health Policy*, August 16, 2016.

VERSION
This is the CHPI authorized version. Early working versions circulated during peer review or posted to the CHPI members preview section at canadianhealthpolicy.com are incomplete drafts under embargo.

DISCLAIMER
This study uses data from IQVIA Inc. The analysis, conclusions and opinions expressed in this paper do not necessarily reflect the views of the data supplier.

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ABSTRACT

This study estimated how long new drugs are covered under federal and provincial public drug insurance plans while protected by an active patent. New drugs (or medicines) were defined as patented drug products designated as new active substances and authorized for marketing in Canada between 1 January 2000, and 15 April 2022. Results showed that for the new medicines that were eventually covered under public insurance plans, the number of years of public reimbursement eligibility while under an active patent averaged 6.7 years, implying the loss of 13.3 years of commercially viable time under patent protection. The erosion of patent protected time under public insurance coverage has significantly reduced the economic value of a pharmaceutical patent in Canada and has likely created disincentives for pharmaceutical companies to prioritize the introduction of new medicines in Canada. The impact of patent term erosion on the availability of new medicines has potentially significant implications for population health in Canada. Feasible policy remedies include regulatory harmonization, expedited insurance coverage, and full patent term restoration.

HIGHLIGHTS

- A total of 576 drug products were identified as new active substances, which were patented, and were authorized for marketing between 1 January 2000 and 15 April 2022.
- Of the 576 new active substances identified, 149 (26%) were listed on at least one federal-provincial formulary as of 15 April 2022.
- For the 149 new medicines covered under public insurance plans, the number of years of public reimbursement eligibility while under an active patent averaged 6.7 years.
- The trend over the study period showed a decline in the average patent term remaining after first listing on a public drug formulary, falling from 6.8 years for the new medicines authorized for marketing in 2000 to a projected 6.4 years for new medicines authorized for marketing in 2021.
- The inverse numbers representing the loss of commercially viable market exclusivity indicate that patent term erosion averaged 13.3 years across the 149 new active substances listed.

INTRODUCTION

Patented medicines are novel pharmaceuticals protected by legally recognized intellectual property rights (IPR), which prohibit competitors from making, using or selling the same drug molecule. Patents are registered at the national level and patent laws are national in scope. In Canada, the nominal period of patent protection for pharmaceuticals is 20 years. The actual period of legal protection spans from the day the patent is granted to a maximum of 20 years after the day on which the patent application was filed. Due to the administrative delay between the filing for a patent and the granting of the patent, the actual period of protection is less than 20 years.

The countdown to patent expiry begins when the patent application is filed. Pharmaceutical patents are generally filed at the end of the scientific discovery process as soon as initial evidence of a drug's potential usefulness has been demonstrated. Typically, they are filed in all major markets through the World Intellectual Property Office (WIPO), which administers the Patent Cooperation Treaty (PCT). By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in all of the countries which are signatories to the treaty. Canada joined the treaty in 1990.

Clinical testing of the safety and effectiveness of new drugs starts soon after discovery, and it consumes a considerable portion of the remaining patent term. A 2016 estimate found that the time between the start of clinical testing for a novel drug molecule (often a global process), and submission of a new drug application for marketing authorization in the United States (often the first market to receive a new drug application) was 6.7 years. **[1]**

In Canada, the delay associated with new drug launches further erodes the patent term. A recent CHPI analysis of new active substances authorized for marketing between 2016 and 2021, found that on average, new drug applications were submitted to the regulator in Canada 1.9 years after the application for the same drug was submitted to the regulator in Europe or the United States. **[2]**

Subsequently, patent terms are further eroded by the time spent in the regulatory process for marketing authorization. CHPI researchers estimated that between 2016 and 2021 the time lapse from the date that a new drug application was submitted in Canada to the date that Health Canada authorized marketing, averaged nearly one year. **[2]**

New drugs authorized for marketing in Canada are subsequently subject to additional processes including price regulation (Patented Medicine Prices Review Board, PMPRB), health technology assessment (HTA) (Canadian Agency for Drugs and Technology in Health, CADTH; Quebec Institut national d'excellence en santé et en services sociaux, INESSS), insurance coverage negotiation (pan-Canadian Pharmaceutical Alliance, PCPA), and formulary listing agreements (federal-provincial drug plans). These processes further erode pharmaceutical patent terms. CHPI researchers estimated that the time lapse between marketing authorization and the listing of a new drug on the formulary of a public drug plan averaged almost two years in Canada from 2016 to 2021. **[2]**

Time consumed by new drug launch delays, and slow regulatory, and insurance coverage processes, represents a real reduction of the commercially viable period of patent protection, which starts when a new medicine becomes eligible for insurance coverage and ends with patent expiry. The erosion of patent terms is therefore a lost opportunity for potential income incurred by pharmaceutical patent holders, which could affect economic incentives influencing decisions about supplying the Canadian market with new medicines. **[3]**

This study estimated how long new drugs are covered under federal and provincial public drug insurance plans while protected by an active patent. Remedial policy options are discussed.

METHOD

A comprehensive list of all patented drug products in Canada was obtained from Health Canada's patent register database extracts. **[4]** The database is updated daily and contains the patent filing date, granting date, and expiry date (actual or projected) for all medicines patented between 1 January 2000, and the researcher's access date which was 15 April 2022. Marketing authorization dates for all drugs approved by Health Canada over the same time frame were obtained from Health Canada's notice of compliance (NOC) database, which is updated daily. **[5]** Canadian formulary listing dates for the 11 federal (Non-Insured Health Benefit, NIHB) and provincial publicly funded drug plans were separately available from IQVIA Inc. **[6]** The data were supplemented and cross-referenced by accessing the publicly available formulary lists from the federal and provincial drug plans and cancer care agencies.

The three data sets (patent, marketing authorization, and formulary listing) were matched and merged using the common brand or trade name, medicinal ingredient, manufacturer, drug identification number (DIN), and administrative drug identifiers. When multiple patents for the same product DIN appeared in the patent register, the patent number associated with the latest expiry date was selected. Veterinary drugs, vaccines products, radiopharmaceuticals, and non-prescription drugs were excluded from the analysis. Health Canada's NOC database identifies new active substances (NAS) separately from other classes of new drug applications (e.g., new drug submissions [NDS], abbreviated new drug submissions [ANDS], supplementary and administrative). The clean data sets were merged to include only patented drug products, designated as new active substances and authorized for marketing between 1 January 2000, and 15 April 2022.

The estimate of patent term erosion focused on the experience of new medicines under public drug plans and excluded experience under private drug plans. For each of the drugs with at least one public formulary listing, CHPI calculated the number of days between the average of the earliest public formulary listing dates across the jurisdictions reporting data, and the latest patent expiry date recorded in the patent registry. The calculation excluded drugs which were not yet listed on a public formulary. The result is an estimate of the average maximum period of exclusivity under public insurance coverage, stated as a fractional remainder of the 20-year patent term (patent expiry date minus formulary date). Stated as the inverse fraction (formulary date minus patent filing date), the calculation represents the erosion of the economic value of the 20-year patent term.

RESULTS

EXHIBIT 1 summarizes the statistical output of the analysis. A total of 576 drug products were identified as new active substances, which were patented, and were authorized for marketing during the timeframe from 1 January 2000 to 15 April 2022; 170 were comprised of biologics, and 406 were comprised of chemical molecules. Of the 576 new active substances identified, 149 (26%) were listed on at least one federal-provincial formulary by the end of the study period; 28 were biologics, and 121 were chemical molecules.

Measured from the average of the earliest federal-provincial formulary listing dates to the latest patent expiry dates, the number of years of public reimbursement eligibility while under an active patent averaged 6.7 years across the 149 new active substances listed. The corresponding figures for biologics were 6.4 years, and 6.7 years for chemical molecules. The inverse numbers representing the erosion of commercially viable patent term are also shown. Patent term erosion averaged 13.3 years across the 149 new active substances listed, ranging from 20 years to 1.3 years. The corresponding figures for biologics were 13.6 years, and 13.3 years for chemical molecules.

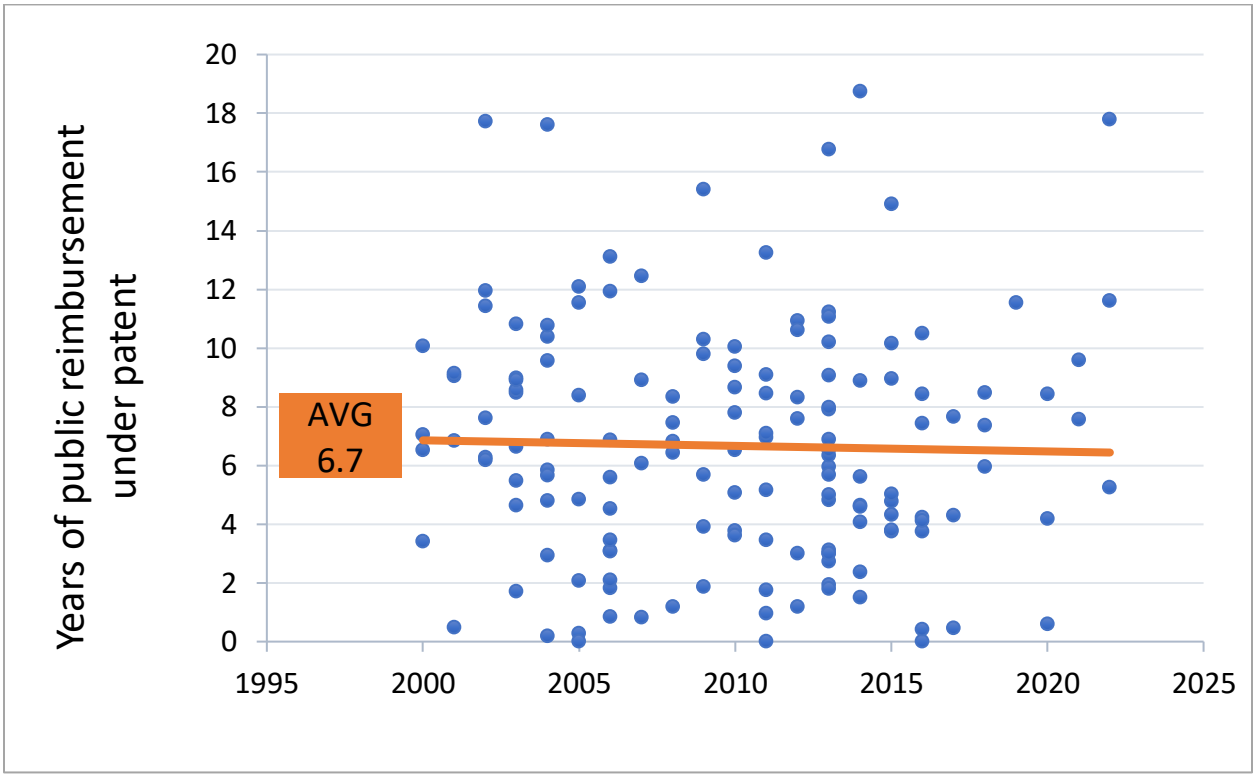
Exhibit 1. Statistical summary.

	Average n years	Count
New active substances patented and approved for marketing 2000 to Q1 2022	n/a	576
Biologics	n/a	170
Chemicals	n/a	406
COMMERCIALLY VIABLE PATENT TERM		
Formulary listing to patent expiry – New active substances	6.7	149
Formulary listing to patent expiry – Biologics	6.4	28
Formulary listing to patent expiry – Chemicals	6.7	121
EROSION OF COMMERCIALLY VIABLE PATENT TERM		
Patent filing to formulary listing – New active substances	13.3	149
Patent filing to formulary listing – Biologics	13.6	28
Patent filing to formulary listing – Chemicals	13.3	121

EXHIBIT 2 charts a scatter plot distribution of the number of years of public reimbursement while under an active patent associated with the 149 formulary listings of patented new active substances, plotted by year of marketing authorization from 2000 to 2022. The average period of exclusivity under insurance coverage in public drug plans was 6.7 years and ranged from a low of 0.0 years to a high of 18.7 years.

A trendline is displayed showing a decline in the average period of exclusivity under public insurance coverage over the study period, falling from 6.8 years for drugs authorized for marketing in 2000 to a projected 6.4 years for drugs authorized for marketing in 2021-Q1 2022.

EXHIBIT 2. Number of years from the average federal-provincial formulary listing date to patent expiry, 149 drugs listed on at least one federal-provincial formulary of 576 new active substances patented and authorized for marketing 1 JAN 2000 to 15 APR 2022.



POLICY IMPLICATIONS

The erosion of the commercially viable period of market exclusivity under public insurance coverage has significantly reduced the economic value of a pharmaceutical patent in Canada. This has likely created disincentives for pharmaceutical companies to prioritize the introduction of new medicines in Canada. Research has shown a correlation between the level of protection for pharmaceutical patents and company decisions about the geographical priority of markets when launching new drug products. **[3]**

The available evidence indicates that Canada is indeed a low priority market for new drug launches relative to Europe and the United States. A recent CHPI study of new drug launches found that between 2016 and 2021, pharmaceutical companies introduced 333 new drugs into the United States, 300 new drugs into Europe, and only 205 new drugs into Canada; and drug makers waited an average of almost 1.9 years after launching a new drug in Europe or the United States, to launch the same drug in Canada. The overall time lapse between the global launch date (first new drug application in any of the 3 markets) and the domestic insurance coverage date for

new medicines in a public drug plan, was on average 3.8 years longer in Canada than the corresponding time period in the United States (i.e., Medicare), and 3.6 years longer versus Germany. **[2]**

The data imply a significantly greater degree of patent term erosion occurs in Canada. The erosion of patent terms is one factor that potentially explains why fewer new drugs are launched in Canada than in Europe or the United States. The impact of patent term erosion on the availability of new medicines has potentially significant implications for population health in Canada. One literature review found 68 studies published in peer-reviewed academic journals affirming that greater use of innovative pharmaceuticals is empirically associated with improved patient and population health outcomes, reduced potential health system costs, and reduced societal costs like economic productivity losses from untreated or under-treated illness. **[7]** Turning these potential benefits into real health and economic gains requires new policy approaches to the pharmaceutical regulatory and reimbursement processes which are eroding patent terms and creating disincentives to supply the Canadian market with new medicines.

POLICY OPTIONS

Regulatory harmonization

Patent terms are eroded partially as a result of the time consumed by the regulatory process governing marketing authorization in Canada, which tends to begin after the completion of the process in Europe and the United States and takes longer to complete. Patent term erosion could be partially mitigated through regulatory harmonization under which, Health Canada would automatically and immediately recognize new drug approvals occurring first in either the European Medicines Agency (EMA) or the United States Food and Drug Administration (FDA). Health Canada could implement this policy unilaterally without requiring mutual recognition. Scientific standards for new drug applications are the same for Health Canada, the EMA and the FDA. CHPI researchers have estimated that during the years 2016 to 2021, regulatory harmonization could have reduced the patent term erosion occurring between the date that a new drug application was submitted, and the date that marketing authorization was granted by up to 1.7 years. **[2]**

Expedited formulary listing

Patent terms are also eroded by delays to formulary listing under publicly funded drug insurance plans. Germany provides a real-world model for expediting insurance coverage of new medicines that would partially mitigate patent term erosion in Canada. The German system for pharmaceutical pricing and reimbursement in its public drug plans is based on structured negotiation instead of regulation and is designed to allow immediate interim insurance coverage following marketing authorization, with permanent insurance coverage pending the outcome of negotiations. **[8]** Under the German Medicines Market Reorganization Act (AMNOG) 2011, pharmaceutical manufacturers launching a new drug on the market, are free to set the price for a maximum of twelve months. Manufacturers must submit clinical evidence to the Federal Joint Committee (G-BA) that proves the additional benefit of the drug. If there is additional therapeutic benefit, the manufacturer negotiates the price at which the drug will be reimbursed by the

statutory health insurance funds. Price negotiations must reach agreement within six months. If no agreement can be reached, an arbitration board decides on the reimbursed price using European reference prices. There is an appeal process. Drugs lacking evidence of additional therapeutic benefit are reimbursed in the reference group price system.

Applying this model to Canada, the federal price regulations would be eliminated. New active substances would be listed on drug plan formularies immediately following market authorization. The initial formulary list price would be the manufacturer's suggested price and would be used as a benchmark for rebates negotiated with the pCPA or directly with the drug plans. Negotiations would be informed, but not determined, by publicly available international reference prices and the HTA process. When negotiations were complete, the difference between the manufacturer's suggested price and the negotiated price would be retrospectively applied to sales that occurred in the interim period. Negotiations would be time limited and if agreement could not be reached, would progress to arbitration. The formulary listing would expire if either party rejected the arbiter's price and revenues earned under the interim price would be rebated according to the arbiter's price. Manufacturers would have the option to request renegotiation in the future if new clinical or cost effectiveness data emerged, or any other circumstances changed the value proposition of the drug product. The pCPA would be obliged to accommodate a second round of negotiation. The proposed changes would expedite insured access to new drugs while leaving the bargaining leverage of the payer (formulary exclusion) and the seller (withholding product) ultimately intact. Researchers estimated that adopting this policy change would have reduced the associated patent term erosion in 2016 to 2021 by almost two years for publicly insured Canadians, equal to the current average time spent from Health Canada marketing authorization to formulary listing in a public drug plan. **[2]**

Patent term restoration

Europe and the United States both have patent term restoration (PTR) regimes that offer research-based pharmaceutical companies the potential to recover up to five years of patent time lost because of administrative delays in the regulatory process for marketing authorization. Canada's patent term restoration regime offers only two years of compensatory time extension.

Moreover, PTR applies only to delays occurring between the new drug application date and the marketing authorization date. PTR does not compensate for patent term erosion caused by subsequent governmental processes for price regulations, HTA, pCPA negotiations and federal-provincial public formulary listing agreements.

The time consumed by these consecutive processes is significant and most new medicines consequently experience substantial erosion of patent terms. Canada's PTR regime does not adequately compensate for the full extent of the loss of commercially viable time under market exclusivity caused by regulatory and reimbursement processes. Extending patent term restoration to compensate for a full recovery of all time lost from the filing of a new drug application to formulary listing would remove the intellectual property related disincentives to launching new drugs earlier in Canada.

CONCLUSION

This study estimated the average maximum period of exclusivity under public insurance coverage for new medicines, defined as patented drug products designated as new active substances and authorized for marketing in Canada between 1 January 2000, and 15 April 2022. Results showed that for the new medicines that were eventually covered under public insurance plans, the number of years of public reimbursement eligibility while under an active patent averaged 6.7 years, implying the loss of 13.3 years of commercially viable time under patent protection. The erosion of patent protected time under public insurance coverage has significantly reduced the economic value of a pharmaceutical patent in Canada and has likely created disincentives for pharmaceutical companies to prioritize the introduction of new medicines in Canada. The impact of patent term erosion on the availability of new medicines has potentially significant implications for population health in Canada. Feasible policy remedies include regulatory harmonization, expedited insurance coverage, and full patent term restoration.

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