Pharmaceutical intellectual property laws need reform

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Canada's pharmaceutical intellectual property laws need major reform to encourage and protect innovation in developing new drugs, states an analysis in *CMAJ* (*Canadian Medical Association Journal*).

The federal government supports drug innovation in several ways, including funding of basic research, and tax breaks for companies that conduct drug R&D in Canada. Patents, however, are the most significant and valuable form of support. Patents provide developers of new pharmaceuticals with exclusive rights to market drugs without competition from generic manufacturers. However, there are problems with the current approach.

"We argue that the system is broken," writes Dr. Paul Grootendorst, Leslie Dan Faculty of Pharmacy, University of Toronto, with coauthors. "The adjudication of patent validity (and hence the period of market exclusivity) is determined by extraordinarily costly and time-consuming litigation between generic and brand (i.e., innovator) drug companies."

They state the reasons for the dysfunction stem from complex rules and regulations that lead to legal ambiguity. The regulations also provide brand name and generic companies with the tools needed to contest the period of market exclusivity; brand firms use the regulations to delay generic entry while generic firms attempt to do the opposite. The outcome of this contest is an extraordinary amount of litigation between brand name and generic companies that has strained the federal courts and resulted in hundreds of millions of dollars in legal fees, costs that are

passed on to drug plans and consumers.

The authors suggest that reform of the legal and regulatory framework for market exclusivity is needed. This could include replacing current regulations with a standard guaranteed fixed period for market exclusivity (perhaps 10 years); this would reduce litigation and improve investment certainty to brand firms. A second option would be to abolish the Patented Medicines (Notice of Compliance) regulations, which govern the introduction of generic versions of brand drugs still under patent, and to rely instead on the Patent Act.

"Other countries are facing the same challenges as Canada; none, however, have attempted fundamental reform of its laws on pharmaceutical intellectual property," conclude the authors. "It is time for Canada to show leadership."

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