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CETA and Intellectual Property: The debate over pharmaceutical patents

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Background

When it comes to intellectual property protection for patented drugs, Canada is often unfairly depicted as a laggard as compared to other developed countries (Pharmaceutical Research and Manufacturers of America 2013). In the on-going negotiations over the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union (EU), this preconception explains the European demands for Canada to increase its patent protection for brand-name drugs. At over $900 per person on average per year, Canada already spends more per capita on pharmaceuticals than any other country in the world except the United States (US) (Canadian Institute for Health Information 2013). When comparing with countries overseas, Canada represented 2.6% of the global market sales for prescription drugs in 2011, while the United Kingdom, with a population almost twice as large as in Canada, represented only 2.5% of the global

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market (Patented Medicines Price Review Board 2012). According to OECD Health Data 2013, Canada also had one of the highest growth rates for drug costs per capita among all OECD countries between 2000 and 2010 (OECD frequently requested data 2013). The second largest driver for this high growth, after volume effects, was mix effects, i.e. substituting newer, more expensive drugs in exchange for older, less expensive ones (Canadian Institute for Health Information 2012). While using more expensive drugs is justifiable when the drug is therapeutically superior, it is noteworthy that overall, fewer than 1 in 10 new drugs offer any significant therapeutic advantages (Prescrire Editorial Staff 2012).

EU demands for Canadian patented drugs in the CETA negotiation

The EU is demanding that the CETA include three provisions affecting Canadian intellectual property rights (IPRs) for patented drugs: patent term restoration, an increase in data protection, and a right to appeal under the Notice of Compliance (NOC) regulations. No demand on the table would affect the European intellectual property regime for patented drugs.

Patent Term Restoration

Under the terms of the World Trade Organization's Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, patents on pharmaceuticals (and all other goods) last for 20 years following the initial patent filing. In the CETA negotiations, European countries are requiring Canada to add years to the patent to make up for time lost due to regulatory approval regardless of who is responsible for the delay, even if it is the pharmaceutical company or patentee. This compensation will add up to 5 years (plus 6 months if pediatric studies have been carried out) on top of the existing 20-year term of monopoly patent protection (Grootendorst and Hollis 2011). According to Rx&D, the association representing Canadian brand-name drug companies, "Canada remains the only developed nation that provides no form of compensation to innovative pharmaceutical companies for regulatory approval delays" (Rx&D 2012).

The rationale supporting patent term-restoration is that, without such a change,

Canada has an incentive to slow down the approval process. A slower approval process means that the drug has less monopoly time on the market before generics appear. A study sponsored by Rx&D and produced by the firm Norton Rose (Kierans, Wall and Daley 2011) claims that Canadian drug approval times are 152 days slower than those in the EU, 433 versus 281 days. This study has been heavily criticized, due in large part to the study's use of incomplete data (Hollis and Grootendorst 2012), as the report only compares approval times for 22 drugs. When a much larger sample is used, between 2001 and 2010 the median approval time at the European Medicines Agency (EMA) was 366 days (interquartile range, 310 to 447) and 393 days (interquartile range, 310 to 603) at Health Canada for a difference of 27 days instead of 152. When drugs approved by both the EMA and Health Canada are compared, that difference drops to just 10 days, and if we compare only the time of the first review of the drug (instead of total review time, which includes the delays for which drug companies are responsible) Health Canada is in fact 14 days faster than the EMA (Downing et al. 2012). The claim that the Canadian regulatory process for the approval of patented drugs is slower than in Europe is thus simply unsubstantiated.

Data Protection

The "data" in the term refers to the clinical data about the drug's safety and efficacy that brand-name companies generate through the clinical trials conducted in order to get their drugs approved. Typically generic companies rely on this data when they submit their applications to get their products approved. Both the North American Free Trade Agreement (NAFTA) and the TRIPS agreement specify that data should be protected for 5 years, although even that 5-year period is subject to interpretation. Article 39.3 in TRIPS only requires countries to protect against "unfair commercial use" of marketing approval data and it gives countries considerable discretion to define "unfair" in the context of their own national laws and culture (Correa 2002). In 2006, Canada already extended data protection to 8 years of market exclusivity with an extra 6 months if companies have studied a drug in a pediatric population. CETA might extend data protection even further to 10 years if Canada meets the EU's demands.

The EU is demanding improved data protection not just for new chemical entities,

i.e., drugs that have never been sold in Canada before, but also for any pharmaceutical products (Grootendorst and Hollis 2011). Given current patent arrangements, even minor changes to existing medications could benefit from 10 years of data protection. The net effect would be to ultimately offer financial incentives for companies to engage in minor molecular manipulation that offers no new therapeutic advances, instead of focusing on new molecular entities that normally represent breakthrough innovation.

Right of Appeal

In 1993, the Canadian government introduced the Notice of Compliance (NOC is the term Health Canada uses for marketing approval) linkage regulations. The regulations meant that Health Canada was prevented from issuing an authorization for market entry for a generic until all of the relevant patents on the brand name product had been proven to have expired. As a result, when the generic company submits its application to get a product approved, the company must also send a Notice of Allegation (NOA) to the patent holder claiming that no patents are being infringed. The patent holder then has 45 days during which to initiate an application in the Federal Court of Canada to seek an order to prohibit Health Canada from issuing a NOC to the generic manufacturer for a period of 24 (originally 30) months. At that point, the matter may proceed to a court hearing. The stay expires either at the end of the 24 months, when the patent expires or when the court case is decided, whichever comes first (Faunce and Lexchin 2007).

The argument put forward by the patented drug industry has been that if the generic company loses the court case, they have a right of appeal under the summary proceeding of NOC linkage regulation (Pharmaceutical Research and Manufacturers of America 2013). However, if the generic manufacturer wins the court case and is allowed to market its product, the brand-name drug companies do not have an effective right of appeal under the NOC linkage regulation because of the summary nature of the proceeding. As a result, "the patentee is then left with no alternative but to start another proceeding (an action for patent infringement) once the generic enters the market" (Pharmaceutical Research and Manufacturers of America 2013).

If the EU's demands are met, CETA would provide that when the patent linkage mechanism is used, patent holders and the manufacturers of generic medicines would be

treated in a fair and equitable way, including their respective rights of appeal. An effective right of appeal for patent holders would mean that generic medicines could not enter the market during the time of the appeal, extending *de facto* market exclusivity for patent holders. In practice, under CETA there could be a further delay of 6-18 months before generics appear while the appeal makes its way through the court system (Grootendorst and Hollis 2011). Since the EU does not use patent linkage and CETA would not require it to do so, this provision only applies to Canada. In fact, the European Commission prohibits EU member states from introducing patent linkage provisions because they delay the entry of generics; Italy was even reprimanded in 2012 for trying to introduce such a system and was asked to eliminate it (European Commission 2012). It is thus a bit ironic that under CETA negotiations, rather than Canada eliminating its patent linkage system, it is pressured into providing a right of appeal that would create further delays for the entry of generics.

Financial Implications of CETA

Although it is impossible to be sure what the final financial implications of CETA will be once its IPR provisions fully come into effect, Grootendorst and Hollis (2011) have used a sample of 15 drugs to provide an estimate of the consequences. They believe that, if all the EU's demands are met, CETA will delay the entry of generics by 3.46 years on average leading to an additional total drug cost of $2.8 billion per year for Canadians. This additional cost would be shared among provincial governments (32.3% of total drug expenditures), the federal government (1.8% of total drug expenditures), private insurers (29.8% of total drug expenditures) and patients (32.9% of total drug expenditures is paid out-of-pocket, including over-the-counter drugs) (Canadian Institute for Health Information 2013). Internal documents from the federal government estimated that the additional costs for patented drugs could be up to $2 billion, but the methodology used to arrive at this estimate is not known (Canadian Press 2012). Following the demands of some provinces, there is a possibility that the federal government may be willing to mollify provincial concerns about drug cost increases by offering to compensate the provinces for any additional costs related to the CETA. If this proves to be the case, it will result simply in a transfer of costs: instead of Canadian taxpayers

paying additional costs at the provincial level, they will be paying it at the federal level.

Conclusion

Countries within the EU are home to large multinational pharmaceutical companies and, in pushing for changes to IPRs in Canada, the EU is trying to strengthen those companies. A better economic outlook for the European-based pharmaceutical industry translates into significantly increased drug costs for Canadians. Any promised benefits to Canada in terms of more R&D are very likely to prove to be illusory. Since Canada has not shown any intention to impose new conditions to pharmaceutical companies in order to increase national R&D investment, there is no reason why increasing Canadian sales for patented drugs by foreign companies would generate R&D spin-offs in the Canadian pharmaceutical sector. Some might contend that increasing earnings for foreign drug companies remains a good thing because they will be able to spend more on R&D in order to discover new therapeutics, from which Canadians will benefit. This claim forgets that the global pharmaceutical sector was characterized in the last 15 years by both record earnings and an innovation crisis (Gagnon 2009). Canadians already pay more on average for patented drugs than Europeans, and costs are increasing at a faster rate in Canada. It is likely that the CETA will include clauses that significantly contribute to further increasing the cost of drugs in Canada, without any significant benefits for Canadians.

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