The New Patented Medicines (Notice of Compliance) Regulations and Certificate of Supplementary Protection Regulations

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The Comprehensive Economic and Trade Agreement (CETA) was signed by Canada and the European Union (EU) on October 30, 2016. The following day, the Canadian Government introduced legislation to amend Canadian laws for the purpose of bringing consistency between Canadian and European Union intellectual property laws and regulations.[1] Bill C-30 changes the intellectual property landscape for the pharmaceutical and biologics industries by modifying the Patented Medicines (Notice of Compliance) Regulations (the PM(NOC) Regulations) and enacting the Certificate of Supplementary Protection Regulations (the CSP Regulations) which came into force on September 21, 2017. We had previously reported on Bill C-30; this bulletin examines the new Regulations created under Bill C-30.

The Patented Medicines (Notice of Compliance) Regulations

The Old Regulations

The old PM(NOC) Regulations provided a scheme whereby the innovator who had filed a new drug submission could submit to the Minister of Health a patent list in relation to the submission for addition to the Patent Register. This provided a "patent linkage" mechanism.

A subsequent manufacturer who wished to market a similar version of the drug in Canada could file a submission in which it directly or indirectly compared its drug to the drug of the innovator, whether by way of an abbreviated new drug submission in the case of a conventional generic drug or a new drug submission in the case of a biosimilar. If there was such a comparison and patents were listed on the Register, the subsequent manufacturer was required to address these patents in the following way: it could either agree to wait for the expiry of the listed patents before receiving its Notice of Compliance or it could make an allegation of non-infringement or invalidity to justify the issuance of a Notice of Compliance. Within 45 days following service of the Notice of Allegation, the innovator could institute proceedings before the Federal Court of Canada to prohibit the Minister of Health from issuing a Notice of Compliance to the manufacturer which would allow the sale of the subsequent version of the drug in Canada until the expiry of the listed patents. As soon as the proceedings were instituted, and until they were discontinued or dismissed, the subsequent manufacturer was prevented from entering into the market. The proceedings had to be completed within 24 months of their initiation.

Under the old Regulations, the issuance of the Notice of Compliance rendered moot any appeal by the innovator, since the Minister could no longer be prevented from issuing a Notice of Compliance. The only recourse left to the innovator was to initiate an infringement action under the Patent Act, leading to dual litigation over the same patent. Findings under the old Regulations regarding patent infringement or validity were not binding in a later action under the Patent Act, which could lead to inconsistent results.

The New Regulations

The Notice of Allegation

As before, a subsequent manufacturer will have to send a Notice of Allegation if it files a submission for a Notice of Compliance and the submission directly or indirectly compares the drug or makes reference to another drug in respect of which a patent list has been submitted. However, the Notice of Allegation will have to address all claims in the patent, even those that were irrelevant in the context of proceedings under the old Regulations, such as process claims. This will undoubtedly assist litigation concerning biological products, which are often defined by their processes.

The Action

As before, the innovator will have 45 days to commence proceedings under the Regulations. However, the proceedings will no longer be summary in nature, but will be full actions with documentary production and discovery. The decision to bring or not to bring an action under the new Regulations may have serious consequences for the innovator. Indeed, if the innovator decides not to bring an action under the Regulations with respect to some or all the patents addressed in the Notice of Allegation, it may be estopped from taking further action with respect to these patents in the future, unless it is able to show that it did not have a reasonable basis for bringing an action under the Regulations at the relevant time. The old Regulations did not contain such a disposition.

If an action under the new Regulations is taken, the Minister of Health will not be able to issue a Notice of Compliance to the subsequent manufacturer until the proceedings are discontinued or dismissed or a period of 24-month has expired, whichever comes first. However, the innovator will have the possibility of renouncing this 24-month period, thereby allowing the Minister to issue a Notice of Compliance as soon as the submission of the subsequent manufacturer is approved. This will allow the innovator to avoid any liability for damages, which are expanded under the new Regulations to include permanent loss of market share, but in return, the innovator must accept competition in the marketplace until reaching final judgment.

The determination as to infringement and invalidity made by the Court in the action under the Regulations will be final, so that a further action under the Patent Act will not be necessary.

The Counterclaim

The new Regulations provide that the subsequent manufacturer "may" bring a counterclaim for a declaration of invalidity. The use of "may" in the Regulations means that the subsequent manufacturer can raise the invalidity of the patent in its Notice of Allegation without bringing a counterclaim. However, the innovator would then, in its Statement of Claim, request that the Court declare the patent valid. This may put an end to multiple litigation.

There is no estoppel in the case of a counterclaim. Under the new Regulations, and contrary to the case of the action, a subsequent manufacturer who fails to attack the validity of the patents addressed in its Notice of Allegation is not estopped from challenging these patents in the future.

The Appeal

The new Regulations provide that the Minister shall not issue a Notice of Compliance before the expiry of the 24-month period unless the action is discontinued or dismissed. Hopefully, the proceedings – now full actions rather than summary proceedings – can be resolved within that time. If not, and a Notice of Compliance is issued, the subsequent manufacturer would be free to enter into the market, although at risk. The situation is similar if the action is dismissed within the 24-month period. The subsequent manufacturer would then be entitled to receive its Notice of Compliance, whether the appeal has been heard or not, and to enter into the market at risk.

Please note that the possibility of extending the 24-month period has been curtailed by the new Regulations. The parties can no longer consent in this regard. The period can only be extended by the Court if it finds that a party has not acted diligently in carrying out its obligations or has not

reasonably cooperated in expediting the action. It can therefore be questioned whether there is, in practice, an equivalent and effective right of appeal for innovators.

Early Documentary Disclosure with Pleadings

Finally, early disclosure of documents will be required. For example, the subsequent manufacturer will have to include with its Notice of Allegation the relevant extracts from its submission as well as all documents supporting its allegation of invalidity. In turn, the innovator will have to serve with its action, if requested in the Notice of Allegation, information pertaining to the inventor as well as any laboratory notebook, research report or other document that may be relevant to determine "whether a particular property, advantage or use asserted by the second person to be part of the invention was established as of the filing date of the patent application." It will be interesting to see how this last part is interpreted, particularly in light of the recent Supreme Court decision in AstraZeneca which eliminates the promise doctrine in Canada.

Certificate of Supplementary Protection Regulations

Before CETA, Canada was the only G7 country that did not compensate for time spent in research and obtaining marketing authorization. Bill C-30 introduces patent term restoration of up to two years. The scope of protection can be no broader than the scope of protection afforded by the patent set out in the Certificate of Supplementary Protection (CSP) and is subject to the same limitations and exceptions as the patent. The new regulations on CSPs are required to meet Canada's commitment under CETA.

Timing requirement

According to the new CSP Regulations, only new drug submissions filed within one year of any first international drug submission filed for the same drug in the European Union, the United States, Australia, Switzerland, and Japan will be eligible for a CSP. In order to provide companies an opportunity to adjust their international filings and factor the timely submission requirement, the CSP Regulations include a transitional period of one year in which the period for timely submission is lengthened to 24 months.

Exclusion of certain medicinal ingredients

Medicinal ingredients entitled to a CSP must be first approvals. Certain variations of medicinal ingredients, which are listed in the new CSP Regulations, are excluded from CSP eligibility. This is inappropriate as a variation can sometimes be equated to a new substance discovered after many years of research, which is patentable and consequently entitled to CSP protection. The exclusion of these variations adds a limitation which has the effect of unduly reducing the scope of CSP protection for medicinal ingredients.

Conclusion

Bill C-30 introduces significant changes to the existing regulatory scheme. There is no doubt that the new PM(NOC) and CSP Regulations will give rise to numerous challenges, particularly with respect to their interpretation. There will also be procedural questions which will need to be resolved by the Courts. Intellectual property strategies for pharmaceutical companies may have to be re-evaluated in light of these new developments.

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[1] Bill C-30, An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures.