The New United States-Mexico-Canada Agreement – Positive for Patent Protection

October 2, 2018

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On October 1, 2018, a draft of the renegotiated North America Free Trade Agreement was published under the new title of United States-Mexico-Canada Agreement (USMCA) (hereinafter the "Agreement"). Article 20 of the Agreement relates to intellectual property matters including trademarks, copyright, patents and industrial designs. Many aspects of Canadian patent practice will be unaffected by the provisions of the Agreement as our current practice complies with the various provisions. Issues such as patentable subject matter, grace periods for prior disclosure, data protection for agricultural chemical products and non-biologic pharmaceutical products, and patent term adjustment for regulatory delays (i.e. Certificate of Supplementary Protection) will likely not change. Two major areas of positive change for patentees in Canada have been negotiated: patent term adjustment due to patent office delays and extended data protection for biologics.

Article 20.F.9 stipulates that a Party shall provide patent term adjustment to compensate for unreasonable delays in the issuance of a patent attributable to the granting authority (i.e. the Patent Office). Unreasonable delay is defined to include when the issuance of a patent occurs more than five years after the filing date, or more than three years after a request for examination, whichever is later. This is especially meaningful in the life sciences, where patent examination routinely takes more than three years before final disposition. Delays attributable to the Patent Office may include delays during the examination period and the administrative processing of the application at the initial or the granting stage. Delays attributable to the patentee such as reinstatement or extensions of time are not included in the adjustment. However, this new patent term adjustment provision is not likely to come into effect immediately. This section must be fully implemented within 4.5 years of the date of entry into force of the Agreement. Furthermore, it will only affect applications filed on or after the date of entry into force, or two years after the signing of the Agreement, whichever is later. Thus, currently pending applications are unlikely to benefit from the new regime.

For patent holders seeking regulatory approval with Health Canada for biologics, Article 20.F.14 extends the data protection period for a new pharmaceutical product containing a biologic from eight years to ten years. Paragraph 2 of Article 20.F.14 provides a minimum definition of biologics to include biotechnological products that are or contain a virus, therapeutic serum, toxin, antitoxin, vaccine, blood component or derivative, allergenic product, protein or analogous products. Paragraph 2 also states that such protection should be afforded to at least products for use in human beings. It remains to be seen whether Canada will continue to provide data protection for innovator "biologics" for non-human veterinary use as this is not a requirement under the Agreement. Unfortunately, like for patent term adjustment, this increase in data protection does not need to be fully implemented until 5 years after the date of entry into force of this Agreement.

An interesting note concerning US patent practice worth mentioning is the provision relating to publication of a patent application under Article 20.F.9, where "each party shall endeavour to publish unpublished pending applications" after 18 months from the filing date. Because the agreement language uses the phrase "shall endeavour" in contrast to merely "shall", it does not necessarily provide for an absolute publication requirement. However, it does suggest that the current US practice that allows a request for non-publication of patent applications until grant may be at risk.

Overall, these changes should be considered a win for future patent applicants and inventors in general. We look forward to the specific legislative changes that will follow in Canada, at which point a more detailed analysis will be necessary.