How Changes to NAFTA May Affect Drug Development & Patent Term


Recently on September 30th, 2018, a pending trade agreement was informally agreed upon known as the United States-Mexico-Canada Agreement (USMCA). Once implemented in the second half of 2019, this legislation will replace the North American Free Trade Agreement (NAFTA). NAFTA, which went into effect on January 1, 1994, was significant because it was the first trade agreement to implement intellectual property (IP) provisions.

The key changes to IP that will affect drug makers and drug developers involves uniform standards of regulatory data protection (RDP), as well as amendments to patent term restoration. Currently, for drug manufactures to obtain approval by a governmental agency such as the FDA, manufactures must show evidence of safety and efficacy of the compound. When the compound is a generic drug and/or a biosimilar, safety and efficacy data from brand name drugs may be used. Protection of this data, known as RDP is generally kept confidential for a certain term of years. RDP precludes others from using data for a same or similar product for a specific period of time without consent of the original party. RDP is frequently relied upon, because often trials with the brand compound can be difficult to perform and the brand name product needed to perform such trials is often still protected by a patent.

The USMCA looks to streamline protection of RDP in all three countries so that any one country is not at a disadvantage. Under NAFTA, chemical pharmaceutical products such as small molecules, were given RDP protection for five years. Biological pharmaceutical products were not addressed in NAFTA, because they were not widely developed at the time when NAFTA was negotiated and implemented in the early 1990’s. Currently, the U.S maintains the five year protection window set out in NAFTA for chemical pharmaceutical products, and provides twelve years of RDP protection for biological pharmaceutical products. Canada provides eight years of RDP protection for both chemical pharmaceutical products and biological pharmaceutical products. Mexico currently provides five years of RDP only for chemical pharmaceutical products.
The USMCA creates uniformity of RDP protection in all three member countries, by providing for five year RDP protection for chemical pharmaceutical products and ten years of protection for biological pharmaceutical products. These time periods will run from the date of first marketing approval of a novel product in a relevant country. It is to be noted, that the ten year RDP for biologics is shorter than the twelve years of protection in the U.S. but longer than the eight and zero years of protection in both Canada and Mexico, respectively. In addition, the USMCA provides avenues for the U.S. to enforce longer RDP time periods in both Canada and Mexico. Furthermore, Canada and Mexico will be granted a transition period of five years to fully implement these new provisions.

The second major change to IP rights by this new trade agreement includes adjustments to patent terms for unreasonable delays caused by a patent office. Currently patent terms in the U.S., Canada, and Mexico last for 20 years from earliest filing date. Legislation in the USMCA will allow inventors to benefit from an adjusted patent term when there has been an “unreasonable” delay by the patent office, defined as a minimum of 5 years from the date of application filing, or 3 years after the request for an examination, whichever is later. This is especially important for biological pharmaceutical products because the technology involved can take several years for a patent to be fully prosecuted and eventually granted.

Looking ahead, the USMCA is expected to be implemented in the second half of 2019. Both Canada and Mexico will be given a five-year grace period to fully comply with some of these IP regulations. Once ratified and implemented by each country, the USMCA will be reviewed by all three countries after six years. For now, we must wait and see how these provisions will be enacted and implemented, including other industries that may be affected by USMCA including the dairy industry, as the USMCA has proposed new labeling and naming of cheese exports leaving the U.S. For now we can hold onto asiago, but maybe not for too long!