Filing Requirements and DEADLINES as per *Patented Medicines Regulations* (amended March 2008)

The PMPRB is an economic regulatory body whose mandate is to ensure that prices of patented drug products sold in Canada are not excessive, thereby protecting consumer interests and contributing to Canadian healthcare.

Pursuant to the statutory scheme put in place by Parliament, a patentee is required to comply with various reporting requirements which fall into three categories: medicine and patentee identification information, prices and sales information, and revenues and scientific research and experimental development expenditures (R&D).

In this regard, the *Patent Act* and *Patented Medicines Regulations* (the Regulations) clearly set out the reporting obligations of patentees, the time frame within which patentees are to submit their information to the PMPRB and the penalties for failure to do so.

For those patentees who need to be reminded of the necessity to report in a timely manner or for those who may soon be selling a patented medicine in Canada and thus subject to the jurisdiction of the PMPRB, we thought it would be useful to provide a summary of the main statutory reporting requirements. They are fully described in the *Patent Act*, the Regulations, the Compliance and Enforcement Policy Guidelines and the Patentees Guide to Reporting.

Patentee & Medicine Information				
Information	Timing	*Patent Act*	Regulations	Form
Identity of medicine, patentee and patent(s)	Earliest of: **Seven (7) days** after the date the first Notice of Compliance issued **Seven (7) days** after the date the medicine is first offered for sale in Canada	80(1)(a) 80(2)(a)	3(1) 3(2) 3(3)	1
Updating information on identity of medicine/patentee	**Within thirty (30) days** after any modification of information		3(4)	1

Price and Sales Data				
Information	Timing	*Patent Act*	Regulations	Form
Price & sales data for the medicine sold	When a drug is first offered for sale in Canada, **no later than thirty (30) days after** the first day of sales	80(1)(b) 80(2)(b)	4(1)(e) 4(2) & (3)	2
Publicly available ex-factory price for the medicine sold to each class of customers	On or before **July 30** (January 1 to June 30 reporting period) On or before **January 30** (July 1 to December 31 reporting period)		4(1)(f)	
Publicly available ex-factory price sold to each class of customer in Germany, France, Italy, Sweden, Switzerland, United Kingdom and United States			4(1)(g)	

Revenue and R&D Expenditures				
Information	Timing	*Patent Act*	Regulations	Form
Revenues from sales and expenditures on R&D	**On or before March 1** of each year	88(1) 88(2)	5, 6	3

Notwithstanding that the above reporting requirements are very clear, some patentees have fallen into a “failure to file” situation by refusing and/or failing to: (i) report the identity of a patented medicine, (ii) submit a Form 1, Form 2 and/or Form 3 within the required time frame, (iii) submit a duly completed Form 1, Form 2, and/or Form 3, or (iv) update the Form 1 following any modification of the information contained therein.