BLG EXPERTISE

Healthcare Intellectual Property Protection and Commercialization

SUMMARY

Proprietary advances are often discovered in the quest to assist patients through treatment innovation or research.

We help identify and protect intellectual property, file patent and trademark applications and assist with the process of commercialization – moving a technology or discovery from the lab to the market to bring about many social and economic benefits, whether through internal development programs or licensing, or sale to a third party having the necessary resources to bring it to market.

Our clients include teaching hospitals, researchers, technology transfer/industry liaison offices of hospitals and universities, research institutes and foundations, not-for-profit Network Centre of Excellence entities, multinational drug and medical device companies, and smaller and emerging biotech and other life sciences companies.

At the outset, we can help you assess whether a new technology or healthcare product is best protected by patent or other measures more suited to your business goals. And, of course, we draft, file and prosecute patent applications in all areas of health research, including products, methods and systems that improve the prevention, detection, diagnosis, treatment and management of various health conditions, illnesses and diseases. The team responsible holds advanced degrees in fields such as bioinformatics, pharmacology, chemistry, bio-organic chemistry, analytical chemistry, applied chemistry, molecular and cellular physiology, biophysics, molecular biology and genetics, to name just a few so we are well experienced in the areas of health and medical research.

Once the new technology or healthcare product is protected, we can assist with the development and commercialization process, including the conduct of preclinical and clinical studies, the preparation and negotiation of research collaboration agreements, license, sale and distribution agreements, product launches, and compliance with Health Canada and other regulatory requirements.

PUBLICATIONS

- *Life Sciences and Chemical Patent Practice in Canada: A Practical Guide*, 3rd Edition, Borden Ladner Gervais LLP, 2011, (Editors: G. Boocock, PhD, and K. Marsman, PhD).
- *Innovation to Commercialization: A Guide to Protecting Your Intellectual Property*, (Contributing Authors:C. Collard, D. Conn, PhD, A. Loh, K. Marsman, PhD, G. Zimmerman, E. Pisko, and G. Boocock, PhD).
- *Canadian Food and Drug Legislation & Commentary*, 2008, 2012, LexisNexis, (Contributing Authors: S. Acharya Van Horn, E. Chan, C. Collard, J. Graham, A. Loh, C. Saunders).
- *BLG Intellectual Property Weekly Abstracts Bulletin*

REPRESENTATIVE WORK

- Manage patent portfolios for therapeutic and nutritional technologies generated at a major research-based Toronto hospital. We work with the hospital's technology transfer

officers to assess patentability, draft and file patent applications and assess freedom-to-operate based on competing technologies.

- Drafted and prosecuted patent applications relating to cardiovascular diagnostic and therapeutic technologies for a well-known Canadian heart institute.
- Assisted a provincial cancer agency in drafting and prosecuting patent applications worldwide relating to cancer diagnosis and treatment.
- Assisted a federal Network of Centres for Excellence for research into prion diseases by developing educational material and workshops on intellectual property for its members.
- Developed a new contract model for use in a Canada-wide research study evaluating the performance of several novel prognostic tests in patients, which study involved a non-for-profit funding entity, a health authority as the coordinating site, a clinical researcher as the lead investigator, a biobank, six hospital sites (for collection of biological specimens), seven laboratory sites (for performance of the lab tests), a subcontractor study coordinator (to administer the hospital/clinical component) and a subcontractor project manager (to administer the lab test component), with no limits on the number of hospitals or laboratories that wish to participate in the study, whether at the outset or during the course of the study.
- Assisted a university in structuring, preparing and negotiating a clinical trial agreement for the conduct of a seven-year global clinical trial, using third party implantable devices and screening systems (some of which have market approvals in some countries but not in other countries) and a subcontracted remote data collection and management services.
- Structured an intellectual property ownership and exploitation rights agreement between a biotechnology company and several research institutions and researchers, including the negotiation and preparation of an IP tool kit of template agreements covering confidentiality and non-disclosure obligations, biological materials transfer, intellectual property option and licensing arrangements, research collaborations, and the provision of laboratory or other life sciences services that are consistent with each institution's IP policies.
- Assisted a university and teaching hospital in implementing the Canadian portion of an investigator-designed international clinical trial by subcontracting the recruitment of 1,000 research subjects to more than 20 teaching hospitals in Canada and resolving multi-jurisdictional issues.
- Assisted the Canadian blood and marrow transplant group in negotiating and preparing (i) a master clinical research contract with a U.S. entity (governed by 16 institutions in North America) to perform the Canadian portion of international blood and marrow studies funded by the U.S. National Institutes of Health, and (ii) master subcontracts with seven teaching hospitals in Canada.
- Sample International (PCT) health-related patent applications drafted by our patent team include:
    - WO/2012/122649 - RECOMBINANT ORF VIRUS
    - WO/2012/113064 - METHOD OF DIAGNOSING PRIMARY MEDIASTINAL B-CELL LYMPHOMA OR CLASSICAL HODGKIN LYMPHOMA BY DETECTING FUNCTIONAL MUTATION AT CIITA LOCUS
    - WO/2011/070440 - ONCOLYTIC RHABDOVIRUS
    - WO/2011/022838 - POLYHYDROXYLATED BILE ACIDS FOR TREATMENT OF BILIARY DISORDERS

- WO/2011/140655 - PHENOLIC COMPOSITIONS DERIVED FROM APPLE SKIN AND USES THEREOF
- WO/2010/040204 - DETECTION OF GRANULOSA-CELL TUMORS
- WO/2010/130036 - STABLE FUNCTIONAL BEVERAGE COMPOSITIONS AND PROCESSES FOR MAKING SAME
- WO/2009/065229 - BIODIESEL PRODUCTION USING ULTRA LOW CATALYST CONCENTRATIONS IN A MEMBRANE REACTOR
- WO/2009/111881 - BIOMARKERS FOR DIAGNOSIS OF DIFFERENTIATED THYROID CANCER
- WO/2009/065230 - METHODS FOR DETECTING LUNG CANCER AND MONITORING TREATMENT RESPONSE
- WO/2008/092228 - METHOD OF DRYING BIOLOGICAL MATERIAL
- WO/2008/000089 - METHOD OF DETECTING PREECLAMPSIA

- Assisted a federal Network of Centres for Excellence for research into prion diseases with its corporate governance (including the preparation of its bylaws) and delivery of educational material and workshops on intellectual property to its members (including the preparation of an intellectual property primer booklet with chapters on patents and the Canadian and PCT patent systems, commercialization agreements, and Health Canada's drugs and medical devices regulations).
- Advised on the establishment of a federally funded pan-Canadian knowledge network of experts with experience in the treatment of certain severely debilitating injuries. The group's mandate was to translate breakthrough research findings into best practices for the improvement of functional outcomes and quality of life, by developing an electronic registry and identifying and implementing the best practices through several centres of excellence across Canada.
- Developed a guidance document for a university and its affiliated teaching hospitals that set out the regulatory process and requirements for the implementation of investigator-sponsored clinical research studies, including the completion and submission of Clinical Trial Applications to Health Canada.
- Assisted a university and affiliated teaching hospital in rectifying critical errors made by their clinical researchers in their Clinical Trial Applications to Health Canada.
- Advised research institutions on clinical trial informed consent forms, and on the collection, use and disclosure of personal health information of research subjects and patients.
- Assisted research institutions in advising their clinicians on Health Canada's Special Access Program.
- Developed conflicts of interest policy for a research institution with respect to professional and outside activities of its staff.
- Advised a U.S. healthcare company on regulatory strategies relating to product classification, advertising and labeling to permit earlier commercialization of the substance and delivery system combination in Canada.

RANKINGS & RECOGNITIONS

The Healthcare Law Group or its members are recognized in:

- The 2018 edition of *The Best Lawyers in Canada*®.
- The 2017 edition of *Intellectual Asset Management's Patent 1000 — The World's Leading Patent Practitioners.*
- The 2017 edition of *Managing Intellectual Property*'s *IP Stars.*
- The 2017 edition of the *Canadian Legal Lexpert® Directory*.
- The 2017 edition of the *World Trademark Review 1000*.
- The 2015 edition of *LMG Life Sciences*.