

Principles for guiding Commercialization of research utilizing seminal IP (e.g. genomics) derived at the BC Cancer Agency

BCCA is a public institution with the mission to reduce the incidence of cancer; to reduce the mortality rate of people with cancer; and to improve the quality of life of people living with cancer. This mission will be furthered by the application of new knowledge and technology to improve the health and outcomes of patients with cancer. The principles enunciated here are meant to ensure broad access to seminal findings including those drawing from genomics-based research for the socioeconomic benefit of British Columbia and Canada. Ethical, responsible commercialization of intellectual property (IP) arising from research is a key objective in pursuing this mission. A set of principles needs to be embraced to ensure that this commercialization takes place with due consideration for the expectations of taxpayers, donors and the public in general to receive the full benefits of research they have funded for the public good.

Statement of Principles:

- IP generated from BCCA research must be developed / commercialized for the maximum public good.
- Patents will be obtained on IP wherever strategically advisable, based on potential utility for patients.
- Non-exclusive and exclusive license strategies will be employed as appropriate to avoid the blocking of product development, to maximize competition, and/or to maximize likelihood of successful product development. In general, platform technology (such as gene targets, genetic signatures, basic research tools etc) will be licensed non-exclusively.
- Institutions both public and private must be made aware of BCCA's principles prior to embarking on joint projects, sponsored research *etc.* and agree any resulting IP shall be managed in accordance with BCCA's guidelines where BCCA is the lead institution.

D) Role of public and private sector organizations:

Public institutions do not have the finances or the mandate to develop products to the final market stage. As such, BCCA through its Technology Development Office (TDO) will wherever possible seek industry partners/collaborations early in the development of a technology to ensure appropriate development and protection of the resultant intellectual property. Ultimately, the development of useful products must be completed by private sector investment, which is driven by a desire for profit. The public however has a right to expect that its institutions will adopt principles that will harness those market forces to maximize the development of beneficial products. This requires the use of strategies that embody social and indirect economic benefits rather than only dollar return as the

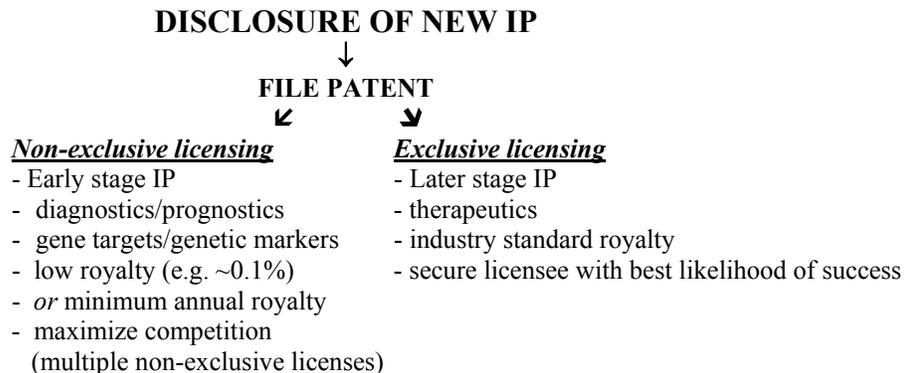
yardstick by which success is measured. The type of commercialization strategy appropriate to undertake with the private sector will be determined by the stage of product development and nature of the technology (*i.e.* broad based application or narrow application).

II) Role of BCCA:

- To assist the researchers at BCCA in obtaining patents to strategically maximize the potential utility of the IP under development.
- To impress upon all BCCA staff the principles (with respect to patenting and licensing strategies) embodied in this document.
- To retain ownership of all IP arising (as per the policy of BCCA) and to manage that IP in accordance with the principles established herein. Cooperation of public institutions (Industrial Liaison Offices or equivalent), private institutions (biotech companies and Pharma) and individual researchers will be essential.
- To enable / ensure the unfettered ability of staff to publish research findings – BCCA must always retain its right to publish even in Sponsored Research Agreements.

Patenting / Licensing framework:

The patent system can be harnessed to drive development of intellectual property of different types and at different stages as follows:



Non-exclusive licensing, in which license to IP may be granted to more than one entity, is appropriate for any *early stage IP* (that which is likely to be the basis for the subsequent development of separately patentable IP). This would include all gene targets and genetic markers as a matter of principle, since it is impossible to foresee the possible future developments for which they may be critical. Inclusive are all diagnostic / prognostic / predictive possibilities that stem from such patentable discoveries. Making the patented IP available to as many entities as possible for as low a cost as possible, while developing the potential of creating a profit-generating product, fosters competition and will maximize the likelihood of success. It also prevents any one entity from blocking development of useful products through the exercise of an exclusive license over such seminal or core IP that may prove to be of key value in more than one area. (e.g. This is the strategy that has been employed by BCCA in pursuing in the SARS genome patent.)

Exclusive licensing, in which the right to particular IP is granted to one entity only, is appropriate for IP that will require significant dollar investment (e.g. small molecule or biologic being developed as a lead therapeutic) and is itself subject of the final commercial product (*late stage IP*). A licensee with a good potential for successful development of such IP can reasonably expect to be granted an exclusive license in exchange for the risk of a high investment, while a higher percentage return to the institution (in accordance with industry standards for the type of IP) is appropriate. The security of the exclusive license for this type of IP provides essential incentive for industry in the development of the desired products. Exclusive licenses are often crafted to a specific “field of use”.

Categories such as “Early Stage” and “Late Stage” may not be obvious, and are intended to serve as guidelines only. The tests to apply in determining whether exclusive or non-exclusive licensing is appropriate are: (a) the likelihood that the IP represents a *core patent* (early stage) from which separately patentable subject-matter / IP will result; (b) the level of investment that will be required to bring the IP to its final stage of development. The overriding principle must always be to maximize the public benefit, in accordance with the mandates of BCCA.

Re-iteration of principles:

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- **Patents will be obtained on IP wherever strategically advisable, based on potential utility for patients.**
- **Non-exclusive and exclusive license strategies will be employed as appropriate to avoid the blocking of product development, to maximize competition, and/or to maximize likelihood of successful product development.**
- **Institutions both public and private must be made aware of BCCA’s guidelines prior to embarking on joint projects, sponsored research etc. and agree any resulting IP being managed in accordance BCCA’s guidelines.**