

Intellectual Property Framework – June 2020

Context

This framework suggests an approach to the protection and management of the National Research Council of Canada's (NRC) intellectual property (IP) related to the NRC's pandemic response.

Scope

This framework applies to foreground IP developed by the NRC in the context of internal research or jointly-owned IP developed in collaboration with clients, upon the agreement of the co-owners. It would not apply to our collaborators nor to recipients of G's & C's funding. This framework is intended to complement NRC's existing practices and the IP protection and commercialisation strategy of each invention will be determined on a case-by-case basis.

Background

- The Government of Canada has announced initiatives aimed at protecting the Canadian economy, and the health and safety of all Canadians during the current global outbreak of the novel coronavirus (COVID-19).
- The Prime Minister has announced support for researchers, including those at the NRC, to conduct scientific work to protect the health and safety of Canadians and support international efforts to fight this pandemic. The NRC has been granted funding for a new Pandemic Response Challenge Program, composed of teams of government, academic and private sector partners to address a range of medium-term needs of the Public Health Agency of Canada and Health Canada. These include personal protective equipment, sanitization products, diagnostic and testing products, therapeutics, and disease tracking technology.
- Further, the NRC has received \$15M of funding to upgrade its Human Health Therapeutics facility in Montréal to develop, test and scale-up promising vaccine candidates to be ready for industrial production.
- Through the COVID-19 Challenges Procurement Program, NRC Industrial Research Assistance Program (IRAP) will post challenges seeking near-to-market solutions from small and medium-sized businesses that need financial support to refine and sell their product or solution to meet a COVID-19 related need. IRAP will fund promising projects, or bring promising solutions for procurement into Innovative Solutions Canada.

Considerations

- The NRC has the capacity to help Canada and stakeholders within this context. The potential benefits to Canada of NRC's pandemic response research are multifaceted:
 - Current priority is health and safety of Canadians.
 - IP also represents potential economic benefit to Canada, both during and following the pandemic.
- It is a priority to avoid any actions that would impede research or otherwise slow the dissemination of information; therefore, there are likely to be short timelines between disclosure of inventions and information to the IP Team and publication.
- Third party IP should be identified, assessed, and mitigated quickly. This could include:
 - Negotiating licences or cross-licenses; or

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- Seeking compulsory license under section 19 of the *Patent Act*.
- IP continues to be an asset which is an important tool in the economy.

Options

1. Protect IP relating to the pandemic response expeditiously and offer open licenses.
 - Fast-track disclosure of inventions and filing of patent applications as appropriate.
 - Inventors remain obligated to disclose any inventions by submitting a completed Form 1 as required under the *Public Servants Invention Act* (PSIA); however, with respect to inventions with the potential to be related to pandemic response, flexibility in the content of Form 1 disclosures required at first instance. A more detailed Form 1 should be submitted as soon as possible following the initial disclosure, no later than 10 months following the filing of a provisional application.
 - VP Research approval will be sought for the following IP strategy for inventions related to the pandemic response:
 - Upon the recommendation of the IP Advisor in conjunction with the relevant Business Advisor, the Director of Business Services will be responsible for approvals for US provisional patent filings and for the associated costs (US provisional application fees (US\$280.00) and, where appropriate, the costs for filing through an outside patent agent).
 - For clarity, no IP Approval (IPA) or formal presentation to an IP Committee (IPC), nor approval of the VP Research would be required in order to file a provisional application for a pandemic-response related invention only.
 - If appropriate in the discretion of the IP Advisor, limited prior art searching may be conducted in-house, both to expedite and as patent applications filed during this pandemic will not yet be laid open to the public.
 - US provisional applications to retain rights for up to 12 months.
 - Once provisional application is filed, researchers will be encouraged to publish and disseminate the invention.
 - Following any provisional filing, the IPC and VP Research will be notified by email within 5 business days and the file will be added to the agenda to be discussed at next IPC meeting.
 - Consideration should be given to the possibility of mobilising the IP through open, royalty-free licences to IP (including provisional patent applications, trade secrets or other relevant forms of IP) where appropriate, taking into account factors including but not limited to background IP, existing and future IP commercialisation strategy and agreements, industry practice, and requirements for NRC support.
 - If deemed appropriate, open licenses could be offered through the most expeditious and appropriate process, including through the NRC's express licensing mechanism. Terms could include any or all of: requirement for recognition, geographic requirements for certain uses (e.g. Canadian production and/or distribution), limited fields of use, limited time (e.g. duration of global

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pandemic as defined by WHO); automatic termination where a licensee employs unethical pricing practices with respect to products containing the licensed IP.

- Where a license to background IP is required to enable the practice of the arising IP for the purpose of pandemic response, the availability and terms of any such license, including royalties, will be determined on a case-by-case basis, with consideration given the goal of openly disseminating IP in support of the pandemic response while also taking into account factors including the NRC's existing and future commercialization strategies and any required support.
- Continued assessment of patent strategy, need and appropriateness of patent protection (considering commercialization potential and public good) will be conducted ahead of any further filing or prosecution deadlines. NPBS considerations:
 - Facilitated by active collaboration of the relevant IP Advisor.
 - Consideration would have to be made in the patent costs budget.
 - Licensing terms would have to be carefully drafted to ensure open license under certain terms to protect the NRC's and Canada's interests.
- Pros:
 - Increase the likelihood of having freedom to operate to scientists, researchers and manufacturers that they have the right to use the IP for research, manufacture, and sales in the context of the pandemic response.
 - IP rights would be available as a tool for cross licensing to get access to 3rd party IP, to protect against bad actors.
 - Retain potential to commercialise IP at a later stage to support Canadian businesses, generate profit, and/or ensure affordability and access for Canadians over the long term.
- Risks:
 - In a dynamic research environment and with short timelines available for searching, higher risk that provisional applications are filed for inventions which will prove not to be novel or non-obvious.
 - The potential costs for filing is difficult to project given uncertainty with respect to the number of potential filings; however, this can be mitigated by minimising costs by filing most US provisional patent applications in-house.

2. Publication only

- Researchers would be encouraged to publish openly, without seeking IP protection. PSIA Form 1 disclosures will be made at the earliest opportunity following publication.
- Pros:
 - Information and materials rapidly available to researchers worldwide.
 - Publication would help to preserve NRC and Canadian's ability to use IP through these defensive publications thereby preventing others from patenting the same invention.
 - Cost effective.
 - NRC recognition and contribution through prompt publication/information sharing with the scientific community.
- Risks:

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- Would not provide a tool for cross licensing to get access to third party IP, or for addressing bad actors.
- Limited potential for licensing outside of pandemic response.
- May limit NRC's ability to patent future inventions.

3. Status Quo

- All inventions to be disclosed and decisions made using existing procedures.
- Pros:
 - Stronger due diligence and stewardship of funds for patenting costs.
- Risks:
 - May result in delays or barriers to quickly mobilizing inventions.
 - NRC may be viewed as failing to meet a moral obligation to quickly mobilize and contribute to the resolution of this pandemic.

Recommendations

- Option 1: Fast track disclosure, provisional patent filing (where appropriate) and simultaneous publication, and giving consideration to limited open licensing where appropriate for pandemic-response related inventions.
- Exceptionally, Option 2 could be considered on a case-by-case basis in circumstances such as compliance with industry norms.
- Non-Disclosure Agreements (NDAs) and Material Transfer Agreements (MTAs) should continue to be used to transfer all materials.
- Maintain status quo IP processes for non-pandemic response related inventions. This will develop a pipeline of patents that may be licensable to Canadian businesses to the benefit of the economy following the pandemic.
- Develop communications products to inform research community of fast-track process for the assessment of disclosures and potential filing of provisional patent applications, as well as continuity of other IP-related policies and practices at the NRC. This should include link to the IP Advisor contact information, as well as that of the Contract Coordinators for assistance with NDSs and MTAs.