

# THE IMPACT OF TIMING PATENTS WE ASK A PATENT AGENT FROM ROBIC...



Prior to bringing a biopharmaceutical composition to market, many years and significant financial resources go into research, clinical trials and regulatory approval. As such, when a promising composition is identified, it becomes imperative to protect it in order to prevent others from copying and commercializing it. A patent is one means of protection. **But when is the best time to file a patent application?**

To illustrate this idea, let's take the example of BioRespire, a hypothetical SME specialized in biotechnologies. Researchers from BioRespire have identified a compound that acts upon a key molecular pathway in a pulmonary disease, and the in vitro data are conclusive. Researchers see commercial potential and want to publish their results. Catherine, the director of BioRespire, was advised to protect the compound through a patent application. However, the question arises: **WHEN should she file this application?** We often hear "as early as possible," but in practice, resources are limited, and choices must be made. **What should Catherine know to make an informed decision?**

## DID YOU KNOW?



**News:** Since September 21, 2017, as part of the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), it is possible to extend the term of a pharmaceutical patent in Canada beyond 20 years from the filing date of the patent application, up to a maximum of two years.

**Learn more (+)...**



**GABRIELLE MOISAN, LAWYER AND PATENT AGENT, PARTNER AT ROBIC:**  
**WHEN SHOULD A PATENT APPLICATION BE FILED?**



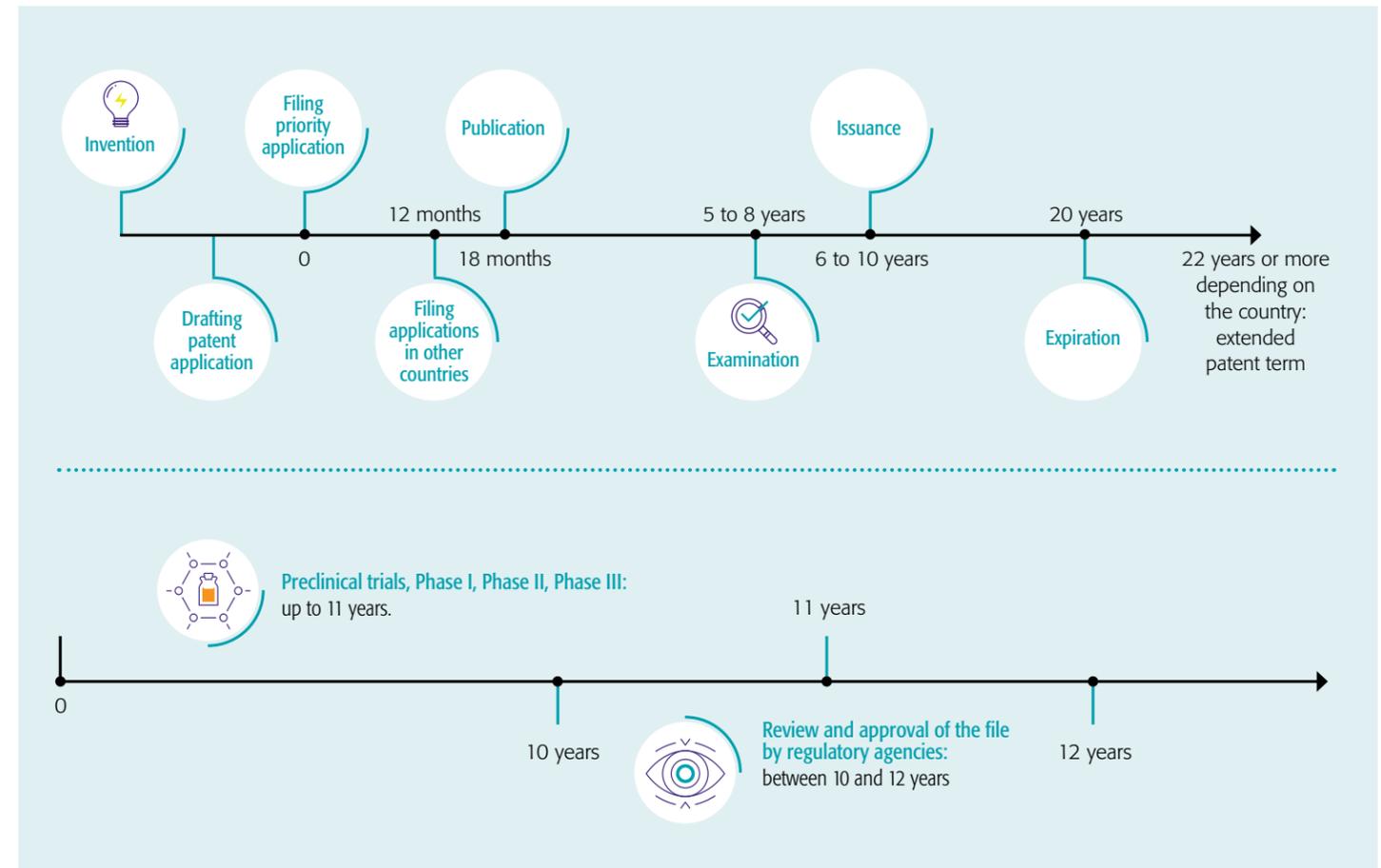
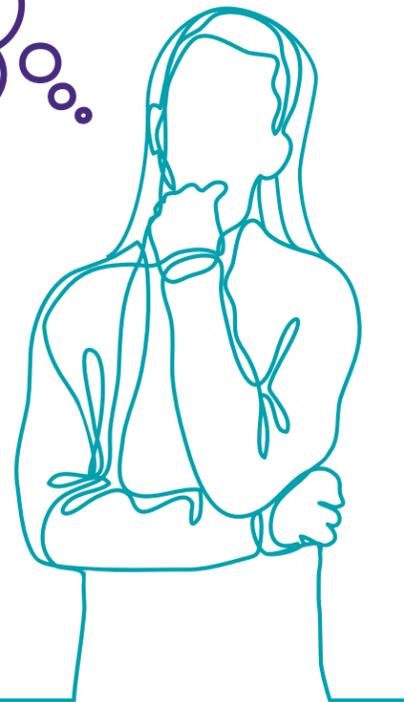
**BioRespire will have to consider several factors before deciding when to file a patent application. +**



**As there is a lot of active research in the field, Catherine believes that an application should be filed quickly.** She believes that it would be better to have a patent in their name with a closer expiration date than to risk the possibility of not being able to obtain a patent at all. She would like to understand, however, how long will it take for a patent to issue after an application has been filed? +



**Will BioRespire's competitors automatically have access to the patent application?**  
When is an application published? +



1. Is an invention protected for 20 years from the issue date of a patent?
2. Do patent applications have to be filed in all countries right from the start?
3. What can BioRespire do if it learns that a third party is copying their invention in Canada?

**+ ANSWERS**



**61%—growth in 10 years**

**of the number of patents originating in Canada granted annually in LSHT**

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**BioRespire will have to consider several factors**  
before deciding when to file a patent application.

- **The timing** of filing a patent application must be a part of the protection strategy considered by the applicant. If it is filed **too soon**, there may be insufficient results and/or inadequate funding to draft a proper patent application with the required support to obtain claims of sufficient scope to block third parties. If it is filed **too late**, there is a risk that the information will have already been disclosed by the inventors, the applicant, or by third parties and, as a result, the invention will no longer be "new."
- To be patented, an invention must be new and have not been publicly disclosed. Documents can only be cited as novelty-destroying if they are published before the filing date of a patent application. In the event that two parties file separate patent applications for the same invention, it is the first applicant to file who prevails, not the first to invent. If the researchers from BioRespire or another laboratory publish and/or otherwise disclose the structure of the composition prior to filing a patent application, the composition will no longer be "new."



- The filing date triggers the 20-year protection period of the patent. Theoretically, during the 20-year period, the owner of a granted patent has the exclusive right to make, construct, use or sell the patented invention.
- In the life sciences field, it is important to consider the impact of preclinical and clinical trials and the regulatory approval process on the effective duration of a patent. These steps will delay the commercialization of the product and, as a result, will shorten the effective duration of the patent's protection. It is therefore preferable to file as late as possible so that the patent term will start as late as possible, thereby allowing the 20-year protection period to cover as much of the commercialization period as possible.



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- After the patent application is filed, a review is conducted by the patent office in each country where the patent application was filed, in the form of examination reports to which the applicant responds with arguments and/or claim amendments. The deadlines, the number and the content of these examination reports vary from country to country, according to specific laws and practices of each country. In some countries, the examination is automatic, whereas in others it must be requested by paying an additional governmental fee. It is also possible to accelerate or slow down the examination process. On average, once examination has begun, it lasts between two and four years.
- The claims represent the extent of the protection conferred by the patent and define the scope of the exclusive privilege to make, construct, use or sell the invention. When filing an application, the applicant drafts claims with a broad scope to obtain the best available protection. "Negotiations" will subsequently take place between an examiner at the patent office and the applicant to delineate the scope of the claims, based on relevant prior art documents located by the examiner.
- There are mechanisms to obtain a patent faster, especially if the invention is already being used or if there is a risk of infringement by third parties. One mechanism allows relying on a patent already granted to the applicant in another country (PPH). The risk is that the protection obtained may be narrower.
- There are mechanisms **to delay the prosecution**, especially if the funding is not available or if the product to be claimed is not finalized.



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- A patent application is published 18 months after its earliest filing date.
- This means that if a search is conducted to locate patent applications in a particular field, there will be an 18-month "blackout" period during which applications may have been filed but will not have been published yet.
- This date is important in case researchers have new results that could be included as part of a second patent application, but would not want the first application to be cited as prior art: they must file the second application before the end of the 18-month period.

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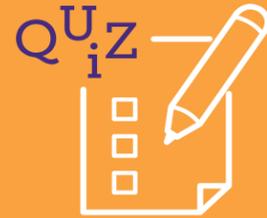
**News:** Since September 21, 2017, as part of the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), it is possible to extend the term of a pharmaceutical patent in Canada beyond 20 years from the filing date of the patent application, up to a maximum of two years. The patent owner or a manufacturer with authorization from the patent owner must apply for an additional certificate of protection from Health Canada within 120 days of market authorization or the grant of the patent and must pay a fee. The Canadian patent must relate to the same medicinal ingredient, or a combination of the same medicinal ingredients, contained in a human or veterinary drug for which an initial market authorization (i.e. notice of compliance) has been issued or will be issued in Canada after September 21, 2017.

[To learn more, click here](#)





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## ANSWERS

**1.** Is an invention protected for 20 years from the issue date of a patent?

**Yes.**

**NO.** An invention is protected for 20 years from the patent filing date. It is for this reason that the timing and the content of the patent application are very important.

**2.** Do patent applications have to be filed in all countries right from the start?

**Yes.**

**No.** It is possible to file an application in a first country to get a priority date, and then file in other countries separately or to file an international (PCT) application within the next year.

**3.** What can BioRespire do if it learns that a third party is copying invention in Canada?

- A patent which covers the copy must be obtained quickly in Canada.
- Once the patent is granted, a formal demand letter must be sent to the third party and a patent infringement lawsuit can be filed.