Pharmaceutical Case Study

Meeting the threshold for second therapeutic use patents: A global strategy

*"We relied on Eric and his team to draft and defend the subsequent applications to **withstand expected challenges and competitors** in each country"*

Assisting our clients (University of Bordeaux and University Medical Centre of Bordeaux's IP Management organisation SATT Aquitaine Science Transfer[1]) to give access worldwide to a new breakthrough treatment, while securing their intellectual property rights — a case study.

The role of the university in invention and patenting systems worldwide is increasingly more important. Research and innovation outside the private sector is essential to the worldwide innovation system. The private sector simply does not invest in research at the level needed to drive innovation growth. Universities are in a unique position to capture all the benefits of innovation – better understanding of a field of study leads to new areas of investigation, training individuals for private sector jobs and knowledge sharing. In order for universities and hospitals, such as the University of Bordeaux and University Medical Centre of Bordeaux, to move the sharing of their knowledge with companies so that their innovation results can be commercialised through licensing and/or spin-offs.

Overview: Breakthrough treatment discovery

The University and the University Medical Centre of Bordeaux are research and teaching structures with many research departments including a hospital in which our case study begins. Dr Christine Léauté-Labrèze, a Dermatologist, and her team[2] which discovered the use of Propranolol in the treatment of infantile hemangiomas. Hemangioma is a type of benign vascular tumor most commonly encountered in infancy and early childhood and appear as a red or blue raised lesion. Some require treatment due to a significant proliferation, which may be complicated by ulceration, deformation aesthetic deformation or worse impairment. The conventional treatments were nearly ineffective and of particular concern in children due to numerous secondary effects.

A newborn was brought to the University pediatric dermatology department for a significant hemangioma blocking the airways in the nose. A few days after the start of conventional treatment, the child developed a myocardiopathy associated with the conventional treatment and Propranolol was used to address the cardiac pathology. At this point, Dr Léauté-Labrèze's team observed that the hemangioma began to shrink the day after the first administration and ended up disappearing within a few weeks. This spectacular effect was confirmed in another hemangioma patient who was also resistant to conventional treatments.

Challenge: Global patent coverage

Dr Léauté-Labrèze's team, the University and Hospital knew that they needed to get the Propranolol treatment for hemangioma in the hands of the world. SATT Aquitaine Science Transfer looked to Eric Enderlin, Director of Chemistry and Life Sciences Department at Novagraaf to assist with developing their worldwide patenting strategy.

In working with SATT Aquitaine Science Transfer, and the Bordeaux University and Hospital teams, we determined that the best approach to quickly get the treatment released and maintain optimal protection was to file first a strong priority application at the EPO and then to contact the French pharmaceutical company Pierre Fabre[3]. That company was able to finance the research for the development of adapted formulations for the children and to obtain the corresponding marketing authorisations in the different countries (FDA[4], EMA[5] ...). Knowing that the University, Hospital and Pierre Fabre planned to obtain patent protection worldwide, Eric and his team drafted and defended the subsequent applications to withstand expected challenges and competitors in each country.

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Novagraaf worked closely with the University to develop a comprehensive global strategy to give worldwide access to a new breakthrough treatment, while securing their intellectual property rights – a case study.

Strategy Recommendation

PHASE 1 : DEVELOP A GAME PLAN

- On the basis of Novagraaf's expertise of how each country views 'second therapeutic use patents' and follow-on innovations, determine the best type of claims (composition, method or specific further medical use claims) for each country, and draft the patent text and claims accordingly.

PHASE 2: INITIAL FILING PREPARATION

- File a strong priority application to establish the effective filing date and eliminate would-be prior art;
- Use as early indicators of patentability the EPO search report, and reinforce the patent text and claims before extensions in the other countries (PCT and national extensions).

PHASE 3: GLOBAL COORDINATION

- Coordinate parallel patent granting procedures worldwide and harmonise patent protections, taking into account the legal specificities of the different countries were the patents have been filed.

PHASE 4: PROSECUTION AND ENFORCEMENT

- Defend the patents in opposition proceedings;
- Assist the client and the licensee in stopping detected infringements;
- Assist the client and the licensee in obtaining an extension of the term of the patent specific for the drugs.

Success!

To date, the patent is active in

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countries worldwide

and countless children are successfully being treated for hemangioma[6].

Contact us at customerservice@novagraaf.com or for additional advice on strategies in patent protection in the Life Sciences sector, please contact our team of experts below.

- **Eric Enderlin,** Director of Chemistry and Life Sciences
  e.enderlin@novagraaf.fr
- **Nadège Lagneau,** Patent Attorney
  n.lagneau@novagraaf.fr
- **Lise Pascual-Luciani,** Patent Attorney
  l.luciani@novagraaf.fr

[1] **SATT Aquitaine Science Transfer (French Technology Transfer Office),** https://www.ast-innovations.com/en/home
Contact: Jean-Luc Chagnaud, Head of Health Business Unit

[2] Léauté-Labrèze C, Dumas de la Roque E, Hubiche T, Boralevi F, Thambo JB, Taïeb A., Propranolol for severe hemangiomas of infancy, *New England Journal of Medicine*; 358(24):2649-51.

[3] **Pierre Fabre,** https://www.pierre-fabre.com/en/our-group
Contact: Pierick Rousseau, Global IP Director

[4] FDA: U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/

[5] EMA: EUROPEAN MEDICINES AGENCY, https://www.ema.europa.eu/en

[6] Christine Léauté-Labrèze received the prestigious Eugene Van Scott Award for Innovative Therapy of the Skin and gave the Phillip Frost Leadership Lecture at the American Academy of Dermatology for this invention.

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