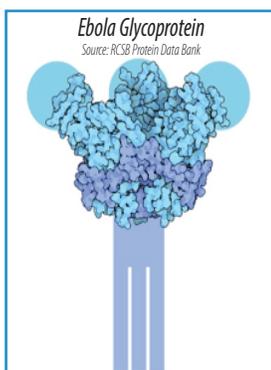


AN IP MANAGER'S STORY

Case Study: Ebola vaccine produced in plants

Plant-based vaccine production has become a viable alternative to other manufacturing methods, as it often involves fewer purification steps, is less expensive than traditional production, and yields ambient temperature-stable molecules [1]. This is particularly important for less developed regions of the world, such as Africa, where viruses like Ebola have devastated populations [2]. Because they have such high potential for providing low-cost immediate production, plant-produced vaccines hold immense promise to help the areas that need them the most [3]. Recent studies have demonstrated the feasibility of expressing an Ebola Immune Complex (EIC), coupling the Ebola glycoprotein GP1 to a humanized monoclonal antibody in tobacco plants [4]. Preliminary clinical trials for virus protection are showing promise in animal model systems [5].



In-house R&D genome sequencing of one Ebola strain identified a potential epitope protein that could be coupled with an immunoglobulin and expressed in plants, for purification and usage as a vaccine. In addition to working with both in-house and outside counsel, the IP search team worked with research scientists, licensing managers, and business leaders to enable decision making that supported the vision of the company. The group needed to ensure that not only did the scientists have the freedom to operate for research and development, but that the business had the ability to capture value when products got launched.

The IP search team included registered patent agents as well as individuals with expertise in bioinformatics sequence analysis, working together to provide best-in-class intellectual property information support for the groups that made the decisions to drive the business.

With so many different types of sequence search platforms on the market, it was difficult to be certain that search results encompassed all of the right types of documents from the geographies that were critical for the business, with complete accuracy. The cost of subscribing to several different platforms would have been expensive, so finding the right resources that provide the right answers was critical.

The IP search team worked closely with the R&D group to keep on top of the highest priority methods and compositions, to create reports for attorney evaluation and business leader decision making. As the business division supports products related to viral vaccine development and sale, it was important to know the IP landscape around EIC protein production in plants, which could represent a new value opportunity for the company.

Evaluation of Freedom to Operate (FTO)

The attorneys who rendered opinions needed precise, complete information. GenomeQuest offered comprehensive coverage of manually-curated sequences from every important patent authority. The GQ-Pat Gold+ collection included ST.25 listings and manually curated sequences from the US, EPO, WIPO, JP, KR. The GQ-Pat Platinum collection included non-ST.25 listings as well as extended legal status, normalized patent assignee, unique family sequence IDs for US, EPO, WIPO, JP, KR, AT, AU, BE, CA, CH, DE, ES, FR, GB, LU, NL, NO, TW, and in-country documents for CN, BR, IN, RU.

Identification of patentable opportunities

Evaluating sequence match parameters and claim language was straightforward with GenomeQuest, and specific documents that the team flagged as potentially impacting IP decisions were easily shared and accessed. Once a determination of FTO was completed, an assessment of novel aspects of research activity was made. Although the EIC sequence itself had been disclosed in the prior art at 100 percent identity over the entire query length, several components of the plant-based manufacturing process were identified that were determined to be patentable over the composition disclosure.

1. Hefferon K. "Plant-derived pharmaceuticals for the developing world". *Biotechnology Journal Special Issue: Plant Biotechnology*, Volume 8, Issue 10, pages 1193–1202, October 2013.
2. Feldmann H and Geisbert TW. "Ebola haemorrhagic fever". *The Lancet*, Volume 377, Issue 9768, 5–11 March 2011, Pages 849–862.
3. Cohen J. "Ebola vaccine: Little and late". *Science* 19 September 2014. Vol. 345 no. 6203 pp. 1441-1442
4. Phoolcharoen W, Bhoo SH, Lai H, Ma J, Arntzen CJ, Chen Q, Mason HS. "Expression of an immunogenic Ebola immune complex in *Nicotiana benthamiana*". *Plant Biotechnology Journal*. Volume 9, Issue 7, pages 807–816, September 2011.
5. Olinger Jr GG et al., "Delayed treatment of Ebola virus infection with plant-derived monoclonal antibodies provides protection in rhesus macaques". *PNAS* October 30, 2012 vol. 109 no. 44 pp. 18030-18035.

Assessment of white-space opportunities

In addition to FTO and patentability assessments, the business leaders were interested in understanding where future research opportunities could be developed. Claim language and patent histories were pulled for the relevant hits, that fully map the prior art to understand which areas could be exploited for unencumbered potential inventions. It was important to fully enable a portfolio strategy that would support all outcomes of the research: product development, value capture, company positioning.

Monitoring third party activity

Not only was GenomeQuest useful for the standard patent-related IP questions, it was a significant tool for competitive intelligence. Sorting and grouping of results were easy, facilitating trend identification. In addition to assignee intelligence, global trends were easily mapped with snapshots of filing statistics. It was of importance to learn that the earliest granted IP on the EIC composition was in the United States. From the EIC search results, potential collaboration and licensing opportunities were identified, an analysis that was streamlined with the option of normalized patent assignee names.

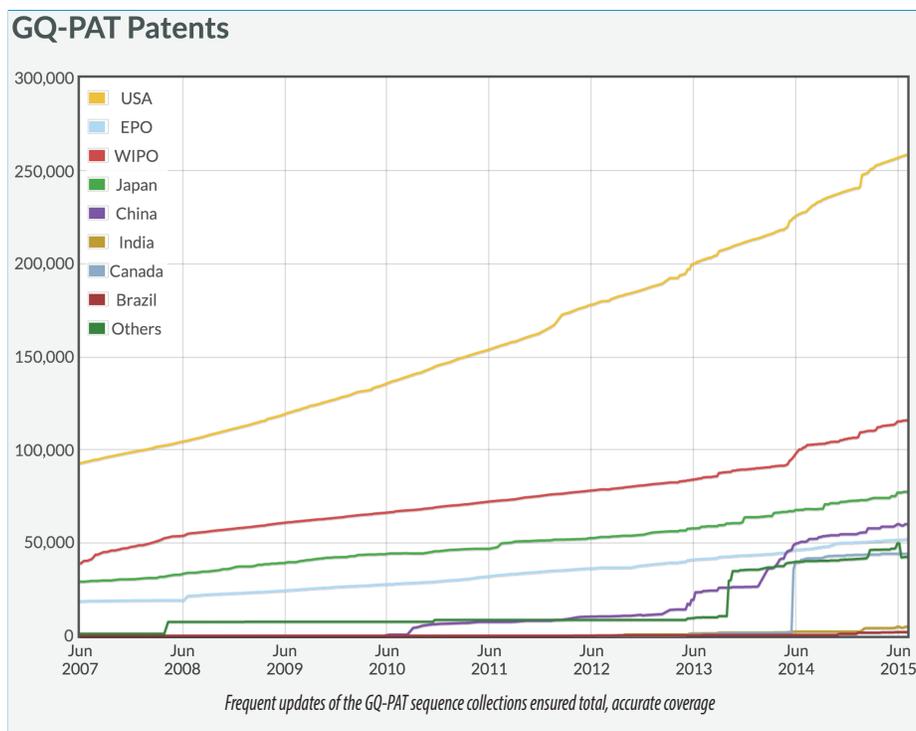
GenomeQuest streamlined resources and facilitated decision making

In addition to critical features such as global patent document coverage, curated sequence collection content, streamlined analysis tools, and flexible reporting functions, easy project and file sharing between individuals made project management easier. With the ability to set unique permissions, different groups had access to just the right information to facilitate work.

Maintaining an in-house GenomeQuest subscription was critical, so that the patent team kept pace with R&D and the attorneys. There was no delay between concept and search, and decision tracking was simplified if an outside opinion became necessary.

- Comprehensive patent authority coverage
- Unparalleled content accuracy with manually-curated sequences
- Fully customizable query searches and results reporting
- Complete suite of analysis tools within a single platform
- Seamless sharing of results with other GQ users

GenomeQuest was the only sequence search platform that provided the most complete, accurate results with the most flexible analysis options. The unique combination of critical features helped the searchers, patent managers, attorneys, and business teams make the best decisions.



For more information on how GenomeQuest can help:
<https://www.genomequest.com/contact>

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