

Covid collaborators

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Karen Sebaski examines how companies can avoid or prepare for patent disputes when teaming up to accelerate vaccine developments



Without a doubt, the race to develop safe and effective vaccines to combat the novel Covid-19 virus is an unprecedented, global effort. At present, more than 165 vaccines are in development worldwide,²⁷ of which are in human trials.¹ And although the aspirational timeline for a Covid-19 vaccine is 12-to-18 months, the typical timeline to develop an average vaccine candidate is just over 10 years.²

Just one of the hallmarks of current efforts is a trend toward major collaborations. Sanofi and GlaxoSmithKline, for example, have teamed up to accelerate the development of “an adjuvanted vaccine for Covid-19 using innovative technology from both companies.”³ Such collaborations are wise, particularly given that, as a general matter, “empirical studies have suggested that some of the highest value research is coming from teams that cross-disciplinary, organisational, and national boundaries, providing support for the view that diversity in collaboration can yield innovation gains.”⁴

Under US law, patent rights initially vest in each inventor, which are those individuals who have contributed “in some significant manner to the conception of the invention.”⁵ Typically, however, as a condition of their employment, employees of pharmaceutical companies, like most other institutions, will agree by contract to assign to their employer any patent rights to inventions made in the ordinary course of their employment. As a result, collaboration among two or more entities may result in jointly-owned patents that, by default, give each entity an independent right to “make, use, offer to sell, or sell the patented invention within the US, or import the patented invention into the US, without the consent of and without accounting to the other owners.”⁶ Thus, although all co-owners generally must voluntarily join in any litigation to enforce a patent against an accused infringer,⁷ absent an agreement to the contrary, each patent owner independently may license the patent and is not required to account to its co-owners for any royalty revenues. Each owner also has complete freedom to assign their respective patent rights without the consent of or prior notification to their co-owner(s). Notably, foreign law on joint IP ownership varies significantly, further complicating collaborations among multi-national corporations.⁸

At first blush, the positive aspects of such freedoms can appear enticing. For instance, under the default rules, a co-owner can determine how best to license or assign their rights to a US patent without any hold-up risk and may succeed in “avoiding extra

administrative burden, such as an acquisition of consent, which can be very time-consuming. Patent prosecution also may become more expensive and time-consuming. In light of such pitfalls and uncertainties, even in the context of a detailed agreement, joint ownership can have a significant impact on efforts to monetize IP assets.

As our leading innovators race to develop effective vaccines for the novel coronavirus, the urgencies of our new reality have the potential to disrupt ordinary best practices for such collaborations, including:

- Written agreements that define each collaborator's ownership and usage of all intellectual property that relates to the collaboration. If the parties prefer to jointly own any fruits of their collaboration, then such agreements should specify whether prosecution and exploitation activities of patents and other intellectual property will be truly joint, or whether one co-owner will take the lead, outlining all rights and responsibilities in detail;
- In the event that collaborators are unable to negotiate intellectual property ownership from the outset, interim agreements are an important tool to preserve each party's respective interests;
- To reduce the risk of future disputes, documentation is critical, including how collaborators may use previously-owned IP; as the collaboration progresses, each party's specific inventive contributions and development activities; and any receipt and usage of federal funds, which may trigger responsibilities under the Bayh-Dole Act; and
- Detailed reporting and notification procedures, including with respect to each party's patent prosecution efforts and regulatory approvals that relate to the fruits of the collaboration, as well as any required royalty payments, either to one another or to a third-party, on a worldwide basis.

In these unprecedented times, collaborators will be well served by avoiding any temptation to short-circuit best practices as they look to develop effective vaccines and take innovative solutions to market.

Footnotes

1. Coronavirus vaccine tracker, The New York Times, available at <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> (last visited 3 Aug 2020).
2. Pronker ES, Weenen TC, Commandeur H, Claassen EHJM, Osterhaus ADME (2013) Risk in vaccine research and development quantified, available at <https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0057755&type=printable>.
3. Press Release, Sanofi and GSK to join forces in unprecedented vaccine collaboration to fight Covid-19, 14 Apr 2020, available at <https://www.sanofi.com/en/media-room/press-releases/2020/2020-04-14-13-00-00>
4. L Vertinsky, Boundary-spanning collaboration and the limits of joint inventorship doctrine, 55 Hous. L Rev 401, 410 (2017).
5. Falana v Kent State University, 669 F.3d 1349, 1357 (Fed Cir 2012).
6. 35 USC section 262.
7. See Ethicon v US Surgical Corp, 135 F.3d 1456, 1468 (Fed Cir 1998),
8. R Millien, The default law of joint IP ownership, IP Watchdog, available at <https://www.ipwatchdog.com/2016/02/18/the-default-law-of-joint-ip-ownership/id=66154/>. Unlike the US, in France, for example, joint patent owners may not license a patent absent the consent of their co-owners. Also, with prior notice, an owner may enforce their patent rights against an accused infringer without joining their co-owners.

Author

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