NEWS RELEASE

kymab

Kymab announces that the US Patent Trial and Appeal Board rejects a fifth request by Regeneron for invalidation of Kymab's US patents

USPTO upholds a fifth Kymab patent covering Human Antibodies and Platforms

Cambridge, UK, 3 June 2020: Kymab, a clinical-stage biopharmaceutical company developing fully human monoclonal antibody therapeutics, announces that Regeneron Pharmaceuticals Inc ("Regeneron") has been unsuccessful in its attempt to invalidate a fifth Kymab patent (US patent No. 10,165,763). The Kymab patent is part of a series (known as the "Bradley Patents") covering genetically modified mice with chimaeric human/mouse antibody genes used as platforms to produce human antibody therapeutics. Therapeutic antibodies produced using such mice are also covered. Equivalent patents have been granted by the European Patent Office and in other jurisdictions including Japan. Regeneron had filed oppositions against the Japanese Bradley patents, but the Japanese Bradley patents were upheld in unappealable decisions by the Japanese Patent Office.

In September 2019, Regeneron filed requests[1] at the US Patent Office's PTAB (Patent Trial & Appeal Board[2]) seeking Inter Partes Review (IPR) proceedings against 4 of the Bradley US patents. IPRs are trial proceedings conducted at the PTAB to review the patentability of one or more claims in a patent[3]. In January 2020, Regeneron filed a further request for the PTAB to instigate IPR proceedings on a 5th Kymab patent[4]. Regeneron relied on its own patent application (the "Murphy application", which is directed to mice containing "reverse chimeric" human/mouse antibody genes) as the main purported prior art reference and argued that Kymab's patented inventions should be found obvious in view of the Murphy application in combination with other prior art.

In April 2020 the PTAB issued decisions rejecting all 4 initial petitions filed by Regeneron, holding that Regeneron's arguments concerning the prior art were substantially the same as those the Examiner had already considered and Kymab successfully overcame during examination of the patents. The PTAB noted that "Petitioner has not demonstrated that the Examiner materially erred in considering the prior art and arguments". Regeneron has not sought to request a re-hearing. This month, the PTAB issued a further decision rejecting Regeneron's request for an IPR on the 5th patent.

These PTAB judgments follow an August 2019 decision from the Australian Patent Office (IP Australia) rejecting on all grounds an opposition by Regeneron against Kymab's patent AU2011266843. In this opposition, Regeneron relied upon its own earlier Murphy patent application (WO2002/066630) as an alleged prior art reference. IP Australia found, however, that the Murphy Application does not provide sufficient information to put the "reverse chimeric" concept into practice, and therefore does not provide an "enabling disclosure" as required for the purposes of

assessing novelty or inventive step. Thus, IP Australia disregarded Regeneron's Murphy application, finding instead for Kymab on novelty and inventive step for chimeric antibody technology as detailed in AU2011266843. Regeneron appealed to the Australian Federal Court, but in May 2020 Regeneron agreed to discontinue its appeal and Kymab's Australian patent is now upheld.

A US counterpart of the Murphy Application (US patent No. 8,502,018) has been litigated by third parties where the patent was found by the US District Court to be invalid for indefiniteness (that finding was upheld by the Court of Appeal for the Federal Circuit, CAFC). The District Court also held that the claims of the Regeneron Murphy patent were unenforceable and the CAFC upheld this decision as well, adding that this outcome was "because of Regeneron's inequitable conduct during prosecution". The US Supreme Court denied a *certiorari* hearing to Regeneron in its appeal of the Federal Circuit's decision. Regeneron's US Murphy patent thus remains invalid and unenforceable.

In litigation against Kymab in the United Kingdom based on the Murphy patents (EP (UK) patents 1360287 and 2264163), the High Court found that they were not enabled and could not be practised at their earliest filing date, although this decision was overturned by the Court of Appeal. Kymab appealed this decision on the test for enablement; this appeal was heard by the UK Supreme Court in February 2020 and a decision is pending.

References:

1. IPR2019-01577 (U.S. Patent No. 9,505,827); IPR2019-01578 (U.S. Patent No. 9,434,782); IPR2019-01579 (U.S. Patent No. 9,447,177) & IPR2019-01580 (U.S. Patent No. 10,064,398).

2. The PTAB is an adjudicative body within the U.S. Patent and Trademark Office (USPTO), consisting of statutory members and administrative patent judges. The statutory members include the Director of the USPTO, the Deputy Director of the USPTO and the Commissioner for Patents. In addition to the statutory members, the PTAB includes a number of administrative patent judges (APJs) who are appointed by the US Secretary of Commerce in consultation with the Director of the USPTO. Administrative patent judges are required by statute to be "persons of competent legal knowledge and scientific ability." Thus, every APJ must have a technical background, in addition to a law degree, and experience in the legal field. Many APJs also have had distinguished engineering or scientific careers in addition to their extensive legal experience.

3. Inter Partes Review (IPR) is a trial proceeding conducted at the PTAB to review the patentability of one or more claims in a patent. The IPR process begins with a third party filing a petition setting out why an IPR should be instituted, including one or more arguments alleging the lack of novelty or obviousness of the claimed invention. An IPR may be instituted upon a showing, in the PTAB's judgment, that there is a reasonable likelihood that the petitioner would prevail with respect to at least one claim challenged. If the PTAB does not make such a finding that the petition would likely prevail in a full IPR proceeding, the PTAB may dismiss the petition and the IPR is not instituted. A party may request rehearing of the Board's decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was addressed. From 2013 to date, year-on-year more IPRs have been instituted than denied (Ref: USPTO statistics).

4. IPR2020-00389 (U.S. Patent No. 10,165,763).

###ENDS###

NOTES TO EDITORS

About Kymab

Kymab is a clinical-stage biopharmaceutical company developing a deep pipeline of novel antibody-based therapies in a broad range of indications. The Company generates its product candidates using its proprietary, integrated platforms collectively called IntelliSelect®. Kymab's platforms have been designed to maximize the diversity of human antibodies produced in response to immunization with antigens. Selecting from a broad diversity of fully human antibodies allows for the identification of antibodies with optimal drug-like properties.

For more information on Kymab please see http://www.kymab.com.

Forward-looking statements

This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of our control, that could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany

the forward-looking statements. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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