Intellia Therapeutics' Statement on Recent U.S. Patent and Trademark Office Actions Relating to Key CRISPR/Cas9 Genome Editing Technology

June 26, 2019

- *New patent interference proceeding initiated by the United States Patent and Trademark Office (USPTO) will determine if the University of California, University of Vienna and Emmanuelle Charpentier (UC Group) were first to invent the use of CRISPR/Cas9 in eukaryotic cells, which could result in up to 10 additional CRISPR/Cas9 technology patents being issued to the UC Group*
- *As of today, the USPTO has awarded to the UC Group six U.S. patents and allowed six additional patent applications encompassing CRISPR/Cas9 genome editing technology in any environment. None of these 12 U.S. patents will be involved in the interference proceeding.*

On June 24, 2019, the United States Patent and Trademark Office's (USPTO) Patent Trial and Appeal Board (PTAB) declared an interference between the University of California, University of Vienna and Emmanuelle Charpentier (collectively "UC Group") and the Broad Institute, Harvard University and the Massachusetts Institute of Technology (collectively "Broad"). This interference could result in the UC Group being awarded up to 10 additional patents covering the use of CRISPR/Cas9 in eukaryotic cells (e.g., plant and animal cells), and the Broad losing up to 13 patents and one patent application claiming this subject matter.

Current Interference

In this interference, the PTAB is expected to determine which research team first invented the use of the technology in eukaryotic cells: the UC Group researchers, who filed their initial patent application in May 2012 and published the seminal paper describing the CRISPR/Cas9 technology and its uses in June 2012; or the Broad researchers, who filed their first patent application approximately six months later in December 2012. The interference proceeding is necessary because the USPTO has concluded that 10 of the UC Group's patent applications should be granted as patents, but the Broad already holds patents covering those inventions. Because the UC Group filed its patent applications more than six months before the Broad, the agency will determine whether it improperly issued the patents to the Broad. If the PTAB determines that the UC Group invented first, then the USPTO could issue the UC Group's patent applications, while invalidating up to 13 patents currently issued to the Broad.

Previous Interference

This is the second interference declared by the PTAB involving these parties' respective CRISPR/Cas9 patent families. In the previous interference, the PTAB considered whether the UC Group's patent applications covering the use of the CRISPR/Cas9 technology in any non-cellular or cellular setting could be issued as patents in view of the Broad holding patents that covered the use of the technology specifically in eukaryotic cells. Even though eukaryotic cells are a subset of the cells covered by the UC Group's patent applications, the PTAB concluded that the use of the CRISPR/Cas9 technology in eukaryotic cells was a separate invention from the use in any setting. Accordingly, the PTAB terminated the interference without making any determination as to which research team first invented the use of the technology specifically in eukaryotic cells (a decision upheld by the U.S. Court of Appeals for the Federal Circuit).

UC Group's U.S. CRISPR/Cas9 Patents

As expected following the Federal Circuit's decision, the USPTO concluded that the UC Group was entitled to patents covering the technology's use in any non-cellular and cellular setting. Accordingly, since late 2018, it has issued to the UC Group six CRISPR/Cas9 patents, and allowed an additional six CRISPR/Cas9 applications that could issue as patents by August 2019. These patents cover, among other inventions, the use of the CRISPR/Cas9 technology in any non-cellular or cellular setting, the use of generic, dual- and single-guide RNAs in genome editing, single guide RNA compositions, and other guide RNA structures. Importantly, none of these patents are involved in the second interference declared this week.

Parties' IP Included and Excluded From Interference

Instead, this second interference proceeding involves 10 UC Group applications that were not involved in the first interference, all of which were prosecuted after the initial PTAB decision and which expressly cover the use of CRISPR/Cas9 technology in eukaryotic cells. For the Broad, almost all of its CRISPR/Cas9 patent estate relating to the initial application of the technology will be subject to the current interference, including all 12 of the patents and the one patent application that had been involved in the first interference. A new patent that issued to the Broad after the PTAB 2018 decision is also involved. The table below shows each parties' U.S. issued, allowed or allowable CRISPR/Cas9 patents resulting from the UC Group's May 2012 patent application family and the Broad's December 2012 patent application family:

ISSUED OR ALLOWED PATENTS **NOT INCLUDED** IN CURRENT INTERFERENCE	
BROAD	**UC GROUP**

8,889,418	10,000,772
9,822,372	10,113,167
	10,227,611
	10,266,850
	10,301,651
	10,308,961
	15/435,233
	15/925,544
	16/201,848
	16/201,836
	16/201,853
	16/201,855

ISSUED, OR ALLOWABLE PATENTS/APPLICATIONS **INCLUDED IN** CURRENT INTERFERENCE	
BROAD	**UC GROUP**
8,697,359	15/947,680
8,771,945	15/947,700
8,795,965	15/947,718
8,865,406	15/981,807
8,871,445	15/981,808
8,889,356	15/981,809
8,895,308	16/136,159
8,906,616	16/136,165
8,932,814	16/136,168
8,945,839	16/136,175
8,993,233	
8,999,641	
9,840,713	
14/704,551	

Interference Process and Timeline

The interference process generally takes approximately two years to complete from its declaration through a final decision by the PTAB and has two phases. During the first phase, also known as the motion phase, the PTAB may consider motions filed by the parties seeking to, among other things, terminate the interference or invalidate the other party's patents, add or exclude certain patent claims, redefine the invention count, and seek a different seniority designation. In this interference, for example, the parties could seek to change the PTAB's preliminary senior and junior party designations, which would impact the burden of proof in the second phase of the proceeding. In the second phase, known as the priority phase, the PTAB determines the ultimate issue as to which research team first invented and, therefore, is entitled to the patents covering the use of CRISPR/Cas9 in eukaryotic cells. That is, at the conclusion of the interference, the PTAB will determine whether the 10 patent applications covering the use of CRISPR/Cas9 in eukaryotic cells should be issued as patents to the UC Group. And, if that is the case, whether the Broad should lose its current patents that purport to cover the same invention.

Intellia's Rights to UC Group IP

As a sublicensee, Intellia has exclusive human therapeutics rights, with the exception of antibacterial and antifungal applications, to the University of California and University of Vienna's rights in the UC Group's CRISPR/Cas9 patents. Separately, Intellia has filed for patents covering its own CRISPR/Cas9 technological innovations, delivery applications and product candidates. None of Intellia's own patent applications are involved or impacted by the interference between the UC Group's and Broad's respective patents and patent applications.

Forward-Looking Statements

This statement contains "forward-looking statements" of Intellia within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding the intellectual property position and strategy of Intellia, its licensors or other parties from which it derives rights, including with respect to intellectual property regarding the CRISPR/Cas9 genome editing technology, or that of unrelated third parties; Intellia's ability to develop and commercialize CRISPR/Cas9-based therapeutic products to address severe and life-threatening diseases; Intellia's expectations around the potential implications of the interference and the timing of the United States Patent and Trademark Office's Patent Trial and Appeal Board's determination; and Intellia's scientific, business and financial plans and prospects. Any forward-looking statements in this statement are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks related to Intellia's ability to protect and maintain its position and rights regarding its intellectual property portfolio, risks related to the ability of Intellia's licensors and other parties from which it derives rights to protect and maintain their intellectual property position and rights, the risk that third parties own or control intellectual property necessary for Intellia to develop or commercialize its product candidates, and the risk that any one or more of Intellia's product candidates will not be successfully developed and commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Intellia's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Intellia's most recent annual report on Form 10-K filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Intellia's subsequent filings with the Securities and Exchange Commission. All information in this statement is as of the date of the release, and Intellia Therapeutics undertakes no duty to update this information unless required by law.