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The Ongoing Patent Battle Over CRISPR/Cas-9

Shifra Ben-Jacob
Cardozo Journal of Conflict Resolution, sbenjaco@law.cardozo.yu.edu

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CRISPR/Cas 9 is a bacterial defense system for editing genomes that has been coined one of the most monumental biotechnologies since the discovery of the polymerase chain reaction (PCR).[1] Since 2012, two research teams, one out of the University of California, Berkeley, and the other from both the Broad Institute and the Massachusetts Institute of Technology, have been battling an ongoing patent war. The US Patent and Trademark Office (USPTO) is left to decide who can claim the technology as their own.[2]

Before 2013, the USPTO awarded patents based on who first invented the technology. Now, they grant patents to those who file their applications first.[3] This change in procedure effectuated a long patent battle between the two research teams. Over the last decade, the USPTO ruled in favor of the Broad Institute, stating there was no interference between both patents, claiming that "eukaryotic CRISPR and other uses of the genome editor were separate inventions."[4] In February of 2022, the USPTO named the Broad Institute as the first inventor of the CRISPR-Cas/9 technology, but the battle did not end there.[5] UC Berkeley was the first to file in 2012, before the Patent procedural laws were changed and, therefore, believe they should be granted the patent.[6] In April 2022, UC Berkeley appealed the USPTO decision.[7]

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[1] Heidi Ledford, *Bitter Fight Over CRISPR Patent Heats Up: Unusual Battle Among Academic Institutions Holds Key to Gene-editing Tool's Future Use*, 529 NATURE PUBL'N GRP. 1, 1–2 (2016).

[2] *Id.*

[3] Heidi Ledford, *Major CRISPR Patent Decision Won't End Tangled* Dispute, NATURE (Mar. 9, 2022), https://www.nature.com/articles/d41586-022-00629-y [https://perma.cc/VKB3-TQFJ].

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Id.*

It is evident, based on this decade-long dispute, that patent litigation has not been able to resolve this matter efficiently. Additionally, due to the 2013 change in procedural laws in deciding who is granted patents, both sides have a legal stake in the matter. If the law cannot effectively or correctly solve this technological dispute, an alternative dispute resolution method, such as negotiation, might be more successful in handling such a delicate matter.

The issue of whether a negotiation tactic might be better suited to handle the ongoing CRISPR dispute should be strongly considered because the implication of ongoing litigation hinders the use of this ground-breaking technology. Scientists and universities interested in experimenting and using the CRISPR technology must now take out licenses to do so.[8] Specific companies who use UC Berkeley's patent portfolio must now reexamine their rights if the USPTO finds that UC Berkeley does not hold the rights to CRISPR utilization in plant and animal cells.[9] Furthermore, patents can limit the ability to share CRISPR widely across research institutions, which makes this patent dispute critical to the future of this technology.[10]

The issue first arose after UC Berkeley's broad patent application for the use of CRISPR-Cas9 in any living cell became null and void after the Broad Institute issued a more narrow patent on the use of CRISPR-Cas9 in eukaryotic cells (i.e., animal and plant cells).[11] Thus, the Broad Institute has priority in the use of the CRISPR-Cas9 technique in animal and plant cells "where arguably the greatest potential benefits of the technique lie."[12] Arti Rai, an

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[8] *4 Lessons Learned from the CRISPR Patent* Battle, IP.COM, https://ip.com/blog/4-lessons-learned-from-the-crispr-patent-battle/ [https://perma.cc/WE4G-72JE] (last visited Aug. 28, 2022).

[9] *Id.*

[10] *For Journalists: Statements and Background on the CRISPR Patent Process*, BROAD COMMUNICATIONS (Feb. 28, 2022), *https://www.broadinstitute.org/crispr/journalists-statement-and-background-crispr-patent-process* [https://perma.cc/X72Q-K3UE]

[11] Vincent Grandpré & Felicia Lozon, *Making Sense of the Battle for the CRISPR-Cas9 Patent Rights*, OSLER (Mar. 15, 2021) https://www.osler.com/en/resources/critical-situations/2021/making-sense-of-the-battle-for-the-crispr-cas9-patent-rights [https://perma.cc/64UD-N4XE]

[12] *Id.*

internationally recognized expert in IP law at Duke University, claims that it is unusual for academic research institutions to battle intensely over a patent and more often come to mutual agreements to share rights to the invention.[13] The ongoing dispute is most likely a reflection of the immeasurable revenue-generating potential of this groundbreaking technology.[14]

Using negotiation to find a resolution to this patent battle could generate wide-use and access to CRISPR technology in an already highly collaborative field, involving contributions from scientists around the world.[15] Licensing revenue and royalties, however, have become much more crucial for academic institutions. The institutions that are granted patents over CRISPR technology are securing profits in a technology that may be worth almost six billion dollars by 2025.[16] Therefore, it is understandable why negotiation might not seem appealing to these research teams.[17]

Such patent disputes between scientific communities are costly, high-stakes, high-profile, and damper future scientific collaboration.[18] The goal of a negotiation is to come to a settled agreement between both parties. Neither research team has been granted all CRISPR rights. While this cannot hinder basic research, any therapeutic or commercial opportunities to use this technology must cease until the legal battle is resolved.[19] Both institutions should negotiate an agreement in which there is a one-stop shop to license the potential IP rights, where both universities are given recognition and reap the benefits.[20] Negotiation requires putting egos and

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[13] Ledford, *supra* note 1.
[14] Grandpré, *supra* note 11.
[15] *See supra* note 10.
[16] *Id.*
[17] *Id.*
[18] Jacob Sherkow, *Patent protection for CRISPR: an ELSI review*, 4 J. of L. & the Biosciences, 565–576 (2017).
[19] Grandpré, *supra* note 14.
[20] *Id.*

animosity aside. It allows for a solution. Without a solution, the dispute over this vital technology may go unresolved, leaving some of the most foundational questions in agriculture and medicine unanswered.