

A settling CAR-T development



[Jacob Plieth](#)

Since CAR-T mania took off last year there has been one overriding fear keeping the bulls awake at night: the threat of crippling expensive litigation. So yesterday's news that two key players, Juno and Novartis, were settling out of court should be greeted with sighs of relief.

The relatively benign terms of the deal bode well for future potential claims of patent infringement. And – given the long academic history of T-cell therapeutic development on the one hand and the huge market potential on the other – there could be plenty of these in store.

The Juno settlement related to technology the group had licensed from St Jude Children's Hospital, which had given rise to the '645 patent – the basis for Juno CAR-T constructs that use the 4-1BB co-stimulatory domain. At the heart of this dispute was the pioneering work done by one of today's most prominent CAR-T researchers, the University of Pennsylvania's Dr Carl June.

Dr June had licensed biological material from St Jude, and his work formed the basis of a deal between Penn and Novartis. But material transfer agreements between St Jude and Dr June suggest that he was limited to using the material up to phase I, and precluded transfer to third parties – implying that Dr June/Penn were not allowed to license the technology on to Novartis.

The case was to have come to trial this month, but has now been settled, with Novartis paying Juno \$12.5m plus future milestones and “mid-single digit” royalties, thus ensuring that development of the groups' respective CAR-T projects, the most advanced in this burgeoning field, can continue.

Risk off

Why is this so important? Firstly because it removes an important uncertainty for Juno, whose 2015 cash burn guidance of \$125-150m specifically excluded legal costs; it had spent \$8.7m on litigation last year, but there were fears that this might rise sharply.

But an arguably even more important read-across concerns numerous other disputes that might be brewing between several other CAR-T players. While the size of the future milestones to Juno is not known, and 4.5% is not exactly an irrelevant payaway, the settlement suggests that unclear IP positions can be ironed out in a way that does not pose a crippling burden on either party.

Smart investors will for instance have been keeping an eye on a CD22 CAR-T therapy with which some CD19-negative relapsing patients had been treated in trials run by Novartis and Kite Pharma; the CD22 CAR-T project is actually owned by Juno, under a deal struck last December with Opus Bio.

Then there is the recent purchase by Coronado Biosciences of rights to City of Hope CAR-T technology that appears to target CD123 and to incorporate an EGFR-based suicide switch ([Coronado's latest opportunistic move: CAR-T therapy, March 19, 2015](#)). City of Hope had earlier licensed technology, including EGFR-based ablation, to ZetaRx, a group later acquired by Juno.

Meanwhile, January saw the founding of a UK CAR-T player, Autolus, based on the work of Dr Martin Pule, who was formerly with Baylor University. Baylor's work, including a suicide switch mediated by caspase activation, forms the basis of technology on which Bellicum Pharmaceuticals is now working.

Of course, not every one of these cases might result in an IP overlap, and there is no suggestion that any that do will result in litigation. Moreover, past legal settlements are no guide as to future ones, and the world of biopharma litigation is full of surprises.

But it is not inconceivable that cross-licensing arrangements will soon become the order of the day in CAR-T, and that is not a bad thing.

EP Vantage has published a broad overview of the current opportunities and risks in the CAR-T space. A free copy of the report is [available by download](#).

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