Cell therapy licensing: a web for the unwary in *Kimble v. Marvel Entertainment*?

“...*Kimble v. Marvel Entertainment*.”

First draft submitted: 5 November 2015; **Accepted for publication:** 2 December 2015;
Published online: 12 February 2016

Keywords: patents • technology licensing

Recent Supreme Court of the US decisions on gene and diagnostics methods patents have highlighted judicial concerns over the balance struck by patent law between innovators and public access to new technologies [1–3]. In June 2015, the Court added to this trend in *Kimble v. Marvel Entertainment*. Replete with fanciful references to its Spider-Man subject matter, the decision upheld the *Brulotte* rule that prohibits a patent holder from charging royalties for the use of an invention past the expiry date of the patent. While the decision stabilizes expectations among the knowledgeable, it presents a trap for the unwary and foreign researchers. It may also encourage greater secrecy in fields of biotechnology that have long research and development timelines and that may be less reliant on patent protection. Here, we discuss its implications for licensing in cell therapy research and development.

Set by Congress, US patent law now provides inventors with 20 years of exclusivity from the first filing of their patent application. Extensions are available for pharmaceuticals kept off the market due to regulatory delays. When the patent expires, the invention enters the public domain. The question addressed by the Court was whether commercial parties can contractually agree to extend patent exclusivity periods via royalty payments after the patent has expired. The Court said no. In the 1964 case of *Brulotte v. Thys Co.*, the patent owner sold a hop picking machine that integrated seven patents. Instead of leaving

things there, the owner imposed both restrictions on use and annual royalty payments of unlimited duration. The Court held that the Thys Corporation had extended its exclusivity beyond the statutory period, thereby breaching the fundamental bargain struck by patent law that enables anyone, including the licensee, to use the invention once its patents have expired. Accordingly, the Court said that the license was unlawful and thus unenforceable.

Fast forward from 1964 to 2015: the Court was asked to overturn *Brulotte* because it represented poor economics. Limiting good faith licensing in the absence of a misuse of market power leads to more complex licensing agreements and greater reliance of advanced legal expertise with no economic benefit. The Court was willing to entertain this argument but put it aside, essentially because it found that as the Rule has been relied upon for 50 years, there was little empirical evidence that it actually caused harm. While the arcane Rule, specific to US law and patents – most other countries do not have an equivalent – was strongly contested by research institutions and technology licensing organizations, the US Government, which is both licensor and licensee of patented inventions, vigorously disputed that *Brulotte* had “caused any ‘significant real-world economic harm’” (cited in *Kimble*). The majority of the Court, quoting *Burnet v. Coronado Oil & Gas Co.*, decided that it is “more important that the applicable rule of law be settled than that it

Tania Bubela

Author for correspondence:
School of Public Health, Edmonton
Clinic Health Academy,
11405 87 Avenue, Edmonton,
AB, T6G 1C9, Canada
tbubela@ualberta.ca

E Richard Gold

Faculty of Law, McGill University,
3664 Peel Street, Montreal, QC,
H3A 1Y9, Canada

be settled right,” especially when the legal precedent interpreted a statute – the US Patent Act. The decision was greeted with relief by some patent experts who felt the Court had rendered enough change in patent law in other areas. In our view, the flexibility in the Rule appropriately allocates rewards between early and late-stage innovators, because the latter often incur greater costs and bear the risks of commercialization and market access. Nevertheless two problems arise from this ruling.

First, as occurred in *Kimble*, parties may not be aware of the Rule and thus enter in good faith into agreements that turn out to be invalid. Mr Kimble’s expired patents covered Marvel’s “Web Blaster” toy that enables would-be spider-men to shoot foam web strands from their wrists. Royalty obligations with no set time limit were part of a settlement agreement after a patent infringement suit, and, as the patents expired, an enterprising lawyer for Marvel uncovered the *Brulotte* rule to obvious effect. While the decision in *Kimble* did much to publicize this rule in the US, many parties still have little knowledge of the minutiae of US patent law – think of small cell therapy firms or foreign universities. These actors may unwarily enter into an agreement with a more sophisticated partner whose counsel presumably knows about the Rule.

The second problem, however, is more pervasive. The Court’s decision may precipitate a shift away from patent protection – and the disclosure that this entails – toward greater reliance on secrecy. As the Court left untouched royalties on data and on trade secrets covering unpatented research, clinical materials and methods, holders of these unpatented materials and data can potentially charge royalties indefinitely, without restriction from *Brulotte*. Even though the Court clarified certain aspects of the *Brulotte* Rule (see Table 1), it upheld so-called hybrid licenses that cover both patents and trade secret as long as royalties decreased once the patent expired. Because of the potential complexity of these ‘step-down’ licenses, parties still risk litigation and uncertainty over exactly what the hybrid license must say. This has been the experience of Massachusetts Biologic Laboratories in its litigation with MedImmune over sales of anti-RSV products RespiGam and Synagis. Massachusetts Biologic Laboratories claimed before the Court that its licensee had dragged it before the courts – to its great expense and continual uncertainty – on the basis of *Brulotte* despite the fact that there had been no patent at the time the license was signed and that the licensee had actually written the agreement.

One could argue that the shift toward trade secrecy simply reflects the market reality that data and mar-

Table 1. How to avoid ensnarement in the web of the <i>Brulotte</i> rule.	
Licensing strategies allowed by the <i>Brulotte</i> rule	Reasoning and examples
1. Amortization of payments beyond the patent term is allowable if those deferred payments were incurred for use <i>during</i> the patent term (<i>Zenith Radio Corp. v. Hazeltine Research Inc</i> , 1969) [†]	Enables parties to reduce early outlays and spread financial risks over a longer time period, overcoming some of the concerns raised by research institutions and the biotechnology sector
2. The Rule only comes into effect when the last patent integrated into the invention expires (<i>Brulotte v. Thys Co.</i> , 1964) [†]	Provides extended protection for some early patents covered by an invention/platform that integrates multiple patents
3. Since the Rule only applies to royalties, it does not bar the sharing of risks and rewards of commercialization through joint ventures (<i>Kimble v. Marvel Entertainment</i> , 2015) [†]	Lower courts have found that joint ventures include joint research collaborations, so the Rule should not impact collaborative research agreements (<i>MedImmune v. Board of Trustees of the University of Massachusetts</i> , among others, 2013) [‡]
4. Post-expiration royalties are allowable for the non-patent elements of hybrid licenses that cover some combination of patented technologies, know-how, and trade secrets (<i>Kimble v. Marvel Entertainment</i> , 2015) [†]	For example, a license for both a patent and a trade secret could set a royalty rate during the patent period, which is then reduced to reflect that the license is for the trade secret alone once the patent expires. This kind of “step-down” licensing is common practice and allowable, indeed essential, with the <i>Brulotte</i> Rule intact
5. Royalty provisions in a license may survive the denial of a patent application (<i>Aronson v. Quick Point Pencil Co.</i> , 1979) [†]	Use step-down to account for a lower royalty rate if the patent application is denied
[†] Supreme Court of the USA. [‡] Court of Special Appeal of Maryland.	

ket exclusivity protections combined with reliance on know-how and trade secrets, high regulatory hurdles, and technical challenges ensure sufficient protection against competitors for innovators of cell therapies without the need of patents [4]. That is, regulatory uncertainty and low likelihood of success will prevent the entry of biosimilar products. While this may be true, innovators still have other reasons to seek patents – and thus disclose their inventions and submit their cell lines and materials to biobanks – such as to obtain financing. *Brulotte*, however, serves as an reason for innovators to avoid the patent system.

The serious issue facing cell therapies is the likely expiration of patents prior to market access due to lengthy development timelines. In the end, the Court flipped this issue of industry-specific periods of exclusivity back to Congress. It declined to interfere with the current terms through contractual provisions, indicating that Congress has had multiple opportunities to consider and overturn *Brulotte* but declined to do so. Indeed, the Court made it clear that since pharmaceuticals already benefit in the USA from up to 5-year patent term extensions to compensate for lengthy regulatory approval processes, any further

considerations for the biotechnology sector is in the hands of Congress, not the Courts. Of course, given the significant changes that the Court has brought to patent law without Congressional leadership, one wonders at the sincerity of these statements.

Financial & competing interests disclosure

Funding was provided by the Canadian Stem Cell Network through a Strategic Core Grant: Public Policy and ELSI Research in the Stem Cell Field: Enhancing Translational Stem Cell Research: Innovative Models for Multi-Sectoral Collaboration (PIs T Bubela, H Atkins, R Gold, C McCabe, J Piret) and a Genome Canada 2012 Large-Scale Applied Research Project Competition grant: PACEOMICS: Personalized, Accessible, Cost-Effective applications of 'Omics technologies (PIs C McCabe and T Bubela) funded by Genome Canada, Genome Alberta, the Canadian Institutes for Health Research (CIHR) and Alberta Innovates – Health Solutions. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

References

- 1 Davey S, Davey N, Gu Q *et al*. Interfacing of science, medicine and law: the stem cell patent controversy in the United States and the European Union. *Front. Cell Dev. Biol.* doi:10.3389/fcell.2015.00071 (2015) (Epub ahead of print).
- 2 Gold ER, Cook-Deegan R, Bubela T. *AMP v Myriad*: a surgical strike against blockbuster genetic diagnostic business models. *Sci. Transl. Med.* 5(192), 192ed9 (2013).
- 3 Matthews DJH, Cook-Deegan R, Bubela T. Patents and misplaced angst: lessons for translational stem cell research from genomics. *Cell Stem Cell* 12(8), 508–512 (2013).
- 4 Kafelas P. Innovator cell therapies present barriers to the entry of copy versions regardless of patent protection. *Cell Therapy Catapult* (March, 2014). <https://ct.catapult.org.uk/documents>