No. 13-720

IN THE

# Supreme Court of the United States

STEPHEN KIMBLE, *et al.*,

*Petitioners,*

*v.*

MARVEL ENTERPRISES, INC.,

*Respondent.*

**ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT**

## BRIEF FOR MEMORIAL SLOAN KETTERING CANCER CENTER, ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI, THE RESEARCH FOUNDATION FOR THE STATE UNIVERSITY OF NEW YORK, THE ROCKEFELLER UNIVERSITY, THE ASSOCIATION OF AMERICAN UNIVERSITIES, THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, THE ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES, THE COUNCIL ON GOVERNMENTAL RELATIONS, AND THE AMERICAN COUNCIL ON EDUCATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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## INTERESTS OF *AMICI CURIAE*[1]

*Amici* are leading academic research institutions and not-for-profit associations that represent the interests of research universities, medical schools and their affiliates. The Memorial Sloan Kettering Cancer Center ("Sloan Kettering") is the world's oldest and largest private institution devoted to patient care, education, and research relating to cancer. Comprised of a basic research unit (the Sloan Kettering Institute for Cancer Research) and a patient-care unit (the Memorial Hospital for Cancer and Allied Diseases), Sloan Kettering is at the forefront of basic and clinical research into the diagnosis, treatment, and prevention of cancer. Icahn School of Medicine at Mount Sinai is a leader in medical and scientific training, biomedical research, and patient care. The School includes 14 multidisciplinary research institutes through which faculty and students engage in research designed to improve society's ability to predict, diagnose, treat, and prevent human disease. The Research Foundation for The State University of New York ("SUNY") is the largest, most comprehensive university-connected research foundation in the United States and is responsible for the evaluation, protection, licensing, and enforcement of intellectual property developed at SUNY's 64 diverse

1. *Amici* state that no counsel for a party authored this brief in whole or in part, and that no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *Amici* and their counsel made a monetary contribution intended to fund the preparation or submission of this brief. *Amici* state that the parties have been given notice of *Amici*'s intention to submit this brief and consented to its submission. The parties' written consents are being filed with this brief.

campuses. It was founded in 1951 and supports research in a vast range of disciplines including life sciences and medicine; engineering and nanotechnology; physical sciences and energy; social sciences; and computer and information sciences. The Rockefeller University ("Rockefeller") is a world-renowned center for research and graduate education in the biomedical sciences, chemistry, bioinformatics and physics. Founded in 1901 by John D. Rockefeller, The Rockefeller Institute for Medical Research (later renamed The Rockefeller University) was the country's first institution devoted exclusively to biomedical research. Throughout Rockefeller's history, 24 of its scientists have won Nobel Prizes, 21 have won Lasker Awards, and 20 have garnered the National Medal of Science, the highest science award given by the United States. Thirty-three Heads of Laboratory currently at the University are members of the National Academy of Sciences.

The Association of American Universities ("AAU") is an association of 62 leading public and private research universities in the United States and Canada. It was founded in 1900 to advance the international standing of U.S. research universities. The 60 AAU universities in the United States award more than one-half of all U.S. doctoral degrees and 55 percent of those in the sciences and engineering. The Association of American Medical Colleges ("AAMC") is a nonprofit educational association whose members include all 141 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and 90 academic and scientific societies. Founded in 1876, the AAMC supports the entire spectrum of education, research, and patient care activities conducted by its member

institutions. The Association of Public and Land-grant Universities ("APLU") is a research, policy, and advocacy organization representing 238 public research universities, land-grant institutions, state university systems, and affiliated organizations. Founded in 1887, APLU is North America's oldest higher education association with member institutions in all 50 U.S. states, the District of Columbia, four U.S. territories, Canada, and Mexico. Annually, APLU member campuses enroll 4.8 million undergraduates and 1.3 million graduate students, award 1.2 million degrees, employ 1.4 million faculty and staff, and conduct $41.4 billion in university-based research. The Council on Governmental Relations ("COGR") is an association of 189 U.S. research universities and their affiliated academic medical centers and research institutes that concerns itself with the impact of federal regulations, policies, and practices on the performance of research and other sponsored activities conducted at its member institutions. COGR has been continuously involved in the development of all major financial and administrative aspects of federally-funded research. The American Council on Education ("ACE") represents all higher education sectors. As the major coordinating body for the nation's higher education institutions, ACE provides leadership and a unifying voice on higher education issues in order to influence public policy through advocacy, research, and program initiatives. Founded in 1918, ACE has approximately 1,700 members that are reflective of the extraordinary breadth and contributions of degree-granting colleges and universities in the United States.

Although *Amici* and their members do not undertake research principally for use in commercial applications,

patentable inventions often result from their research. The goals of *Amici* are to assure the utilization of such inventions for the common good and to grant licenses to encourage their development. Royalties received from such licenses are a vital source of revenue supporting the research of *Amici* or their members.

*Amici* seek to bring to the Court's attention the significant, negative impact that this Court's decision in *Brulotte v. Thys Co.,* 379 U.S. 29 (1964), has on the licensing of scientific and technological breakthroughs, by which promising research is transformed into commercial and industrial products that benefit the public. By making royalty payments that extend beyond the life of a patent *per se* illegal, *Brulotte* prohibits an important financial arrangement the unavailability of which may deter or delay the commercialization of vital scientific research.

## NATURE OF THE CASE AND STATEMENT OF FACTS

This matter involves an appeal from a judgment of the United States Court of Appeals for the Ninth Circuit holding that a "hybrid" licensing agreement between Petitioner Kimble and Respondent's predecessor—one that conveyed both patent and non-patent rights—was unenforceable beyond the expiration date of the patent under *Brulotte v. Thys Co.,* 379 U.S. 29 (1964). Under a settlement agreement resolving a patent and breach of contract litigation, Marvel agreed to purchase a patent Kimble obtained on a toy that allowed users to mimic Spiderman's web-spinning abilities by shooting foam from their hands using a can strapped to the waist or wrist. In exchange for the patent, Marvel agreed to pay (i) a

lump sum payable upon execution of the settlement, and (ii) 3% of net product sales (as defined in the settlement agreement). The agreement had no expiration date on Marvel's obligation to pay the 3% of product sales. The patent was to expire in 2010. Under the settlement agreement, Kimble also transferred to Marvel certain non-patent intellectual property rights, and the parties agreed to end their pending litigation, in which Kimble had won a jury verdict and both sides had pending appeals.

After the settlement, disputes arose relating to the calculation of royalties due Kimble. Kimble sued in Arizona state court for breach of contract; Marvel removed to federal court and counterclaimed, relying on *Brulotte,* seeking a declaration that it did not have to pay the royalties under the settlement agreement after the expiration of the patent in 2010. The district court granted summary judgment for Marvel, finding that the settlement agreement was a "hybrid" agreement that conveyed both patent and non-patent rights, and that the rights were not separable as Kimble had contended, because the agreement did not distinguish between the royalties for each group. The district court thus concluded that under *Brulotte,* the royalties could not extend beyond the patent's expiration date.

The Ninth Circuit affirmed, explaining that it was required to apply *Brulotte* although the decision is "frequently criticized," "counterintuitive and its rationale arguably unconvincing." Pet. App. 2. The court explained that it was "joining our sister circuits" in holding that *Brulotte* renders unenforceable beyond the patent expiration date "hybrid" licensing agreements "encompassing inseparable patent and non-patent rights,"

"unless the agreement provides a discounted rate for the non-patent rights or some other clear indication that the royalty at issue was in no way subject to patent leverage." Pet. App. 3. Agreeing with the district court that the parties' settlement agreement was such a hybrid agreement and provided for only one royalty, the Ninth Circuit affirmed. The Ninth Circuit observed that although "patent leverage in this case was vastly overshadowed by what were likely non-patent rights," it was "bound to follow *Brulotte* and [could not] deny that it applies here." Pet. App. 25-26.

## SUMMARY OF THE ARGUMENT

The Ninth Circuit articulated compelling reasons for overruling *Brulotte*. In *Brulotte*, the Court reasoned that payment of patent royalties after the patent expires unlawfully "extends the patent" beyond the fixed term provided by law, but "'[t]hat is not true.'" After a patent expires, it remains the case that "'anyone can make the patented process or product without being guilty of patent infringement,'" and the "'patent can no longer be used to exclude'" anyone from making the patented product. *Kimble v. Marvel Enterprises, Inc.*, 727 F.3d 856, 866 (9th Cir. 2013), Pet. App. 24 (quoting *Scheiber v. Dolby Labs., Inc.*, 293 F.3d 1014, 1018 (7th Cir. 2002) (Posner, J.)). Merely extending the period over which royalties are paid does not change that, and "[e]xpiration thus accomplishes what it is supposed to accomplish." *Kimble*, 727 F.3d at 866, Pet. App. 24. The *Brulotte* rule is therefore "counterintuitive" and does not "reflect commercial reality or basic economics." *Id.* at 857, 866 n.7, Pet. App. 2, 25. The continued adherence to a *per se* rule that rests on an economically and conceptually incorrect understanding

of the post-expiration payment stream does not serve the policies underlying the patent laws, the interests of the contracting parties, or society as a whole. In his dissent in *Brulotte*, Justice Harlan recognized that as a matter of "economic substance" there is no meaningful distinction between a yearly minimum royalty payment during the patent term and royalty payments extending beyond the term based on the licensee's use of the patented product, and that the latter arrangement consequently involved "no misuse of patent leverage." *Brulotte*, 379 U.S. at 35-36 (Harlan, J., dissenting). Permitting payment of patent royalties that accrue after the patent expires therefore is not inconsistent with constitutional or patent law.

Important economic considerations support freely negotiated agreements that provide for post-expiration royalties. Although the total royalty payment reflects the value of the license during the patent term, payment of royalties based on post-expiration use facilitates the sharing of market risk between licensor and licensee. Thus, post-patent royalties may reflect, for the parties, an economically beneficial arrangement that is not indicative of an improper exercise of "monopoly influences." *Brulotte*, 379 U.S. at 33. As explained below by reference to the types of licenses granted by *Amici* or their members, there are substantial, socially beneficial, and pro-competitive reasons to accommodate such needs.

Since an agreement extending royalty payments into the post-expiration period does not extend the term of a patent, overruling *Brulotte* will not allow patent holders to extend a patent monopoly. If a particular licensing agreement has anti-competitive terms, the Federal Trade Commission or U.S. Department of Justice can police any

anti-competitive effects through enforcement actions in which the licensing agreement is assessed under standard antitrust analysis.

## ARGUMENT

## THE COURT SHOULD OVERRULE *BRULOTTE'S PER SE* PROHIBITION AGAINST LICENSE AGREEMENTS THAT PROVIDE FOR PAYMENT OF PATENT ROYALTIES ACCRUING AFTER THE PATENT HAS EXPIRED

### A. Allowing Licensees To Make Royalty Payments Based On Post-Expiration Activity Promotes The Transformation Of Scientific Research Into Potentially Life-Changing Therapies And Inventions That Benefit The Public

The type of licensing engaged in by *Amici* or their members shows not only why the *per se* rule of *Brulotte* is outmoded, but how this inflexible rule interferes with transactions that are beneficial to the licensor, the licensee, and the general public. For example, several *Amici* conduct basic research in fields such as cellular biology and immunology. As part of this research, new chemical and biological compounds are identified and characterized for their effect on different types of cells or cellular responses. Some of these compounds may become useful as human therapeutics for the treatment of serious diseases. Research universities represented by other *Amici* conduct basic research that leads to technological innovations in engineering, computer science, agriculture, telecommunications, and many other areas.

Academic research institutions file patent applications to protect their scientific breakthroughs. However, the expertise, experience, and resources needed to undertake commercial development of their discoveries generally are outside the capacity and mission of these institutions. An academic research laboratory that files for a patent for a new compound, for example, typically expects to grant a license on its discovery to a company with the financial resources and business expertise to undertake the development, regulatory approval process, and marketing that is necessary to transform its scientific discoveries into drugs that treat disease. Research universities also do not typically undertake the work necessary to commercialize the inventions and discoveries of their faculty.

### 1. The Commercialization Of Basic Research Is Vital To The Public's Well Being

Universities and related nonprofit research institutions conduct over half of the basic research in the United States, and approximately 60% of university research is federally funded. Since passage of the Bayh-Dole Act of 1980, universities have increasingly licensed the fruits of their research to the private sector for commercialization. This university technology transfer process provides a rich return on public and private funding for basic research, in the form of countless innovative products and processes that benefit the public, create jobs, and contribute to U.S. economic competitiveness and technological leadership internationally.

The CAT scan, MRI, FluMist and many other commonly used vaccines, GPS, bar codes, Doppler radar, web browsers, and the Internet are some of the best-

known university innovations. A few examples of the diverse fruits of university research are:

- Taxol, the best-selling cancer drug in history, was developed out of research by a professor at Florida State University and has been used by more than 2 million women worldwide to fight ovarian and breast cancer.

- Zostovax, a vaccine for shingles developed out of research by faculty at the University of Colorado, promises to reduce shingles-related doctor visits in the United States each year by some 300,000 and hospitalizations by 100,000, yielding a savings of as much as $100 million spent on shingles-related care in the United States annually.

- Neupogen, a drug developed out of research at Memorial Sloan Kettering Cancer Center, has become the standard of care for cancer patients receiving chemotherapy or bone marrow transplants, and has been used by more than one million people around the world as treatment for immunosuppression caused by chemotherapy.

- Indego, a powered exoskeleton that enables people with severe spinal cord injuries to stand, walk, sit and climb stairs, was developed out of research by a team of engineers at Vanderbilt University. Its light weight, compact size, and modular design promise users an unprecedented degree of independence.

- FreezePruf, antifreeze for plants, was developed out of research by a biologist at the University of

> Alabama. FreezePruf helps commercial growers avoid crop damage due to freezes, resulting in tremendous economic benefits not only to the growers, but also to customers buying their produce at the supermarket.

Research institutions and their licensees generally structure their agreements using a combination of payment terms, including: (i) a lump-sum license issuance fee; (ii) milestone payments to be paid upon the occurrence of events during development, *e.g.*, the start or finish of different phases of clinical trials; (iii) annual fees for the use of technology; and (iv) running royalties for a fixed period of time based on commercial sales of a resulting product. Due to the difficulty and uncertainty of bringing a pharmaceutical product to market, licensees generally prefer to delay payments for as long as possible and to pay based on commercial sales of the approved drug. Research institutions, lacking their own resources to underwrite these processes, typically agree to delay receipt of royalties as licensees progress toward commercialization that can support the royalty payments.

Thus, although any one of the foregoing financial arrangements might have the same economic value, they are *not* equal to most prospective licensees from a business perspective, particularly in the world of pharmaceuticals. For example, a smaller firm may devote nearly all of its available funds to the development of a single promising drug that is a make-or-break opportunity for the company, leaving few resources to make payments up front. By contrast, a large pharmaceutical company with more varied expertise and greater resources may be better positioned to make payments while pursuing

development; but even large companies are unwilling to make substantial up-front license payments for what they view as high-risk projects. In both of these situations—which reflect the typical concerns of companies that engage in pharmaceutical-related licensing with institutions such as *Amici* or their members—the licensee may strongly prefer to defer a large portion of license payments from the development phase (generally within the life of the patent), in favor of royalties on eventual sales that may begin toward the end of the patent term and extend for years thereafter.

Allowing licensees to defer accrual of payments maximizes the potential for scientific research to be translated into life-saving drugs because it allows companies that are attempting to commercialize research the flexibility to enter into arrangements that are financially manageable for them. A blend of payment terms, for example, might accommodate the licensee's need to conserve its current financial resources and to shift some of the risk to the licensor. This may allow firms to enter the market that would otherwise be excluded and maximize the chances for successful commercialization. Under these circumstances, it is beneficial to the public for parties to be able to agree that royalties will be paid for an agreed-upon term starting with the first commercial sale, even if the royalty term extends beyond the expiration of the licensed patent.

### 2. The *Brulotte* Rule Constrains A Substantial Amount Of Economic Activity

The issue presented by this case has a substantial impact on the way in which academic research institutions

and licensees will structure new license agreements and perform under existing agreements. *Amici* respectfully submit that there is no sound basis to preclude one kind of contractual arrangement that gives licensing parties the flexibility to enter into agreements that will maximize the likelihood that scientific research will be commercialized and provide public benefit.

The issue presented is also of substantial importance to the public at large. Patent licensing by academic research institutions, such as *Amici* or their members, plays an important role in the nation's economy. According to a recent survey by the Association of University Technology Managers ("AUTM"), running royalties of survey respondents (comprising 193 U.S. universities, hospitals, and research institutions) increased by 30% in fiscal year 2012 over 2011, to $1.9 billion. *See* AUTM, *AUTM Licensing Activity Survey: FY 2012* 14 (2013). The total number of active license agreements reported by survey respondents now exceeds 40,000, and there are nearly 10,000 products on the market that originated in academic research laboratories. *See id.* at 14, 32.

In 2013, U.S. universities were issued more than 5,200 patents, and research performed at universities led to the formation of 818 new start-up companies. These start-up companies provide economic benefits to the nation, but they are especially important to the regions and states in which research universities are located; more than three-quarters of these new start-up companies had their primary place of business in the licensing institution's home state. A recent Biotechnology Industry Organization (BIO) study estimates of the total number of additional jobs created from university-licensed products ranged from about 7000 jobs in 1996 to 23,000 in 2010.

Congress has recognized the benefits of encouraging the grant of patent licenses by universities to small businesses, having expressed "the policy and objective of the Congress to use the patent system . . . to promote collaboration between commercial concerns and nonprofit organizations, including universities; [and] to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise . . . ." 35 U.S.C. § 200 (Bayh-Dole Act). *Brulotte* restricts universities and small businesses (as well as large companies) from entering into contractual arrangements that maximize the potential benefits of the universities' technological advancements.

*Amici* respectfully submit that *Brulotte*'s blanket prohibition against payment of post-expiration patent royalties should be overruled in favor of a traditional rule of reason analysis under the antitrust laws. *See* Point D, *infra*. As the type of licensing engaged in by academic research institutions demonstrates, payment of royalties based on post-expiration activities may reflect terms that make an agreement attractive and economically viable and are in the best interests of the contracting parties and consequently of the public. Facts such as these represent the antithesis of an improper exercise of market power by the patentee.

### B. Neither The Patent Statutes Nor Their Underlying Policies Justify A *Per Se* Ban On Post-Expiration Royalties

Patent law is designed to "promote the Progress of Science and useful Arts" by securing to inventors, for limited times, the exclusive right to their discoveries. U.S.

CONST., Art. I, § 8, cl. 8. Although Congress has imposed limitations on patent rights, *Brulotte* does not serve to implement them. Indeed, *Brulotte* was not based on an interpretation of the patent provisions of the Constitution or patent statutes, but rather upon the judgment that post-expiration royalties necessarily violate the policy and purpose behind the limitation upon the patent term. *See* 379 U.S. at 31-32. The *Brulotte* assumption was that post-expiration royalties amounted to a leveraged use of the patent to assert "monopoly power in the post-expiration period when, as we have seen, the patent entered the public domain." *Id.* at 33; *see also id.* at 32-33 (payment of royalties after patent has expired would result in "the free market visualized for the post-expiration period . . . [being] subject to monopoly influences that have no proper place there").[2] *Brulotte* is mistaken on this central point.

Post-expiration royalties do *not* extend a patent owner's exclusive rights beyond the term of the patent. A patent grants to the owner "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States." 35 U.S.C.

2. It has been recognized that use of the term "monopoly" to refer to the exclusive rights conferred by a patent is not strictly correct. *See, e.g., In re Kaplan*, 789 F.2d 1574, 1578 n.3 (Fed. Cir. 1986) ("'[M]onopoly' is used in different senses in patent and antitrust law, hence its ambiguity. Because of its antitrust connotations and association with illegality in connection therewith, it often evokes negative reactions inappropriate to a dispassionate analysis of patent law problems."); 35 U.S.C. § 154(a)(1) (2014) (providing that patents grant the right to exclude other from taking certain actions); Howard Markey, "Why Not the Statute?," 65 J. PAT. OFF. SOC'Y 331, 331-33 (1983) (advocating use of statutory language).

§ 154(a)(1) (2014). This grant of exclusive rights is for a limited term. *See* 35 U.S.C. §§ 154(a)(2), 154(c)(1) (2014); *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896) ("It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist . . . .").

Once a patent has expired, the party that owned the patent has no legal basis to enjoin or otherwise restrain others from practicing the invention. *See, e.g., Kimble*, 727 F.3d at 866, Pet. App. 24. Thus, payment terms in a licensing agreement reflect the parties' assessment of the fair value of the use of the patent or the right to practice the invention on an exclusive basis *during* the patent term. As *Brulotte* itself recognized, the patent owner is entitled to be paid whatever amount the licensee is willing to pay. *See* 379 U.S. at 33 ("A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly."). An agreement to license a patent for consideration that includes royalties to be paid after the patent has expired does not extend the term of exclusive rights enjoyed by the patent owner, but instead is "a risk-shifting credit arrangement between patentee and licensee." *Scheiber*, 293 F.3d at 1017. As the Ninth Circuit stated, "'[t]he duration of the patent fixes the limit of the patentee's power to extract royalties; it is a detail whether he extracts them at a higher rate over a shorter period of time or a lower rate over a longer period of time.'" *Kimble*, 727 F.3d at 866 (quoting *Scheiber*, 293 F.3d at 1017), Pet. App. 24.

### C. Post-Expiration Royalties Can Provide Substantial Pro-Competitive Benefits And Further The Goals Of The Patent System

There are substantial pro-competitive business justifications for post-expiration royalties. During the initial stages of developing a new product based on new technology, both the product development and the marketing costs (as well as the uncertainty as to the value of the invention) are at their highest. *See* Note, An Economic Analysis of Royalty Terms in Patent Licenses, 67 MINN. L. REV. 1198, 1230 (1983) (hereafter "Economic Analysis") ("[U]ncertainty arises because it is difficult to predict the size of the market, how rapidly the market will grow, and the amount potential buyers will be willing to pay."). Thus, post-expiration royalties allow a licensee to delay the payment of license fees until it is in a better position to pay, opening the door to a potentially larger universe of prospective licensees.

Flexible royalty provisions also permit the parties to balance and allocate risk. When the predominant consideration for a license is fixed payments not based on sales—such as up-front payments and periodic license maintenance fees—the licensee bears the risk of product failure because its license payments are not tied to the successful commercialization of the invention. A royalty-based payment system, by contrast, allows the licensor and licensee to share this risk. Providing for a lower royalty rate, typically in exchange for a longer royalty term (that may include post-expiration), further reduces the risk to the licensee. In his dissent in *Brulotte*, Justice Harlan recognized this possible motivation for structuring a licensing agreement in this way. *See* 379

U.S. at 37-38 (Harlan, J., dissenting) ("If the farmer has no fixed estimate of his use requirements he may have good business reasons entirely unconnected with 'patent leverage' for wanting payments tied to use, and may indeed be willing to pay more in the long run to obtain such an arrangement."). As one commentator noted, the productive gains accruing to small licensees from risk-reducing royalty terms tend to promote competition in the marketplace because such terms allow them to compete with large firms that have greater resources to devote to development and can better shelter themselves from risk. *See* Economic Analysis, 67 MINN. L. REV. at 1233.

Given the nature of their missions, *Amici* or their members frequently grant licenses for early-stage technology that has not been fully developed and that is, as yet, of unknown or speculative commercial value. In such cases, their licensees face a particular risk that no viable product or process will be developed during the patent term. This risk is particularly acute with respect to pharmaceutical innovations, where development costs and failure rates are very high and many years of development, clinical trials, and regulatory review are required before a product reaches the commercial market—if it ever does. In these circumstances, the institution has no economic or market power to coerce monopolistic license terms, and the prospective licensee has strong business reasons for preferring to defer royalty payments or pay them at a lower rate over a longer period of time. The goal of the patent system is served by allowing such parties to negotiate freely the license terms that make sense to them in order to maximize the development of desirable (even life-saving) products and processes. The *per se* rule of *Brulotte* disserves this goal and serves no comparable goal of its own.

### D. Use Of Post-Expiration Royalties For Anti-Competitive Purposes Can Be Policed By Application Of Antitrust Principles

Without the *Brulotte* rule, the task of policing anti-competitive licensing agreements would be where it belongs: with the federal antitrust laws. Agreements that have been shaped to yield true monopolistic effects and provide for payment of post-expiration royalties would still be proscribed by the antitrust laws under a rule of reason analysis, consistent with the approach of this Court, the enforcement agencies, and the lower courts. *See Federal Trade Commission v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013) ("[T]his Court has "indicated that patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly' . . . that is conferred by a patent."); U.S. Department of Justice & U.S. Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property § 2.0 (1995) (hereafter Antitrust Guidelines) ("[F]or the purpose of antitrust analysis, the Agencies regard intellectual property as being essentially comparable to any other form of property."); *Virginia Panel Corp. v. Mac Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997) (applying antitrust-based rule of reason analysis where practice alleged to constitute patent misuse is "neither *per se* misuse" under the case law nor "specifically excluded" by statute from being considered misuse); *USM Corp. v. SPS Techs.*, 694 F.2d 505, 512 (7th Cir. 1982) ("Our law is not rich in alternative concepts of monopolistic abuse; and it is rather late in the day to try to develop one without in the process subjecting the rights of patent holders to debilitating uncertainty."). Indeed, the principles for evaluating license agreements under the rule of reason are well-defined. *See* Antitrust Guidelines § 4.

In some types of cases, the antitrust laws impose a more stringent *per se* analysis. Under antitrust law, "[p]er se treatment is appropriate '[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.'" *State Oil v. Khan*, 522 U.S. 3, 10 (1997) (quoting *Arizona v. Maricopa County Medical Soc'y*, 457 U.S. 332, 344 (1982)); *see also Broadcast Music, Inc. v. CBS*, 441 U.S. 1, 9 (1979) ("[I]t is only after considerable experience with certain business relationships that courts classify them as *per se* violations ...."') (quoting *United States v. Topco Associates, Inc.*, 405 U.S. 596, 607-08 (1972)). *Brulotte* did not invoke judicial experience with post-expiration royalties or identify an evidentiary basis that would justify a *per se* prohibition.

More recently, the trend has been to look to economic realities, rather than *per se* rules, to identify anti-competitive conduct. In 1988, "Congress amended the Patent Code to eliminate th[e] presumption that [patent-equals-market-power] in the patent misuse context." *Illinois Tool Works Inc. v. Independent Ink Inc.*, 547 U.S. 28, 41 (2006). The amended statute provides that a tying arrangement in which licensing of a patented product is conditioned on the licensing or purchase of another product shall not constitute patent misuse "unless *in view of the circumstances,* the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned." 35 U.S.C. § 271(d)(5) (emphasis added); *see also Illinois Tool Works*, 547 U.S. at 41-42 (describing 1988 amendment of Patent Code).

In *Illinois Tool Works*, this Court extended Congress's de-linking of the patent-equals-market-power presumption to the antitrust context. The Court framed the question as "whether the presumption of market power in a patented product should survive as a matter of antitrust law despite its demise in patent law," and held that "the mere fact that a tying product is patented does not support such a presumption." *Id.* at 31. Rather, based on "the congressional judgment reflected in the 1988 amendment," "tying arrangements involving patented products . . . must be supported by proof of power in the relevant market rather than by a mere presumption thereof." *Illinois Tool Works*, 547 U.S. at 42-43. More recently, in *Federal Trade Commission v. Actavis*, this Court held that reverse payment settlements in patent litigation should be evaluated under a rule of reason standard, rather than considered presumptively unlawful as the FTC had urged. *See* 133 S. Ct. at 2237. In so doing, the Court reiterated that "abandonment of the 'rule of reason' in favor of presumptive rules (or a 'quick-look' approach) is appropriate only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.'" *Id.* (quoting *California Dental Assn. v. FTC*, 526 U.S. 756, 770 (1999)). That cannot be said of the kind of licensing agreements at issue here.

If *per se* treatment of post-expiration royalties is not required under the antitrust laws, it is equally inappropriate under the doctrine of patent misuse. From its inception, the goal of the misuse doctrine has been the same as that of the antitrust laws—promotion of competition. *See, e.g., Carbice Corp. v. American*

*Patents Dev. Corp.*, 283 U.S. 27, 33-34 (1931) (affirming dismissal of patent infringement suit and noting that the plaintiff's conduct was "analogous to the use of a patent as an instrument for restraining commerce which was condemned, under the Sherman Anti-Trust Law"). Thus, for example, there is "no offense to 'public policy' from a patent-based tying arrangement that antitrust law regards as competitively harmless or even as procompetitive." 10 Philip E. Areeda et al., Antitrust Law ¶ 1781d at 521 (3d ed. 2011); *see also* Roger B. Anderwelt, *Competition Policy and the Patent Misuse Doctrine*, 25 Pat. Trademark & Copyright J. 41, 42 (Nov. 11, 1982) (speaking as Chief of the Intellectual Property Section, Antitrust Division, U.S. Department of Justice) ("[W]e should reject improper *per se* misuse rules and prohibit conduct on economic grounds only when economic analysis demonstrates the conduct to be anticompetitive."). Indeed, the relationships between patent-owning research institutions like *Amici* or their members and their licensees illustrate the fallacy of *Brulotte*'s assumptions about market power: biomedical research institutions and medical schools do not themselves develop drugs; research universities do not create marketable products; and neither group has monopolistic leverage over the for-profit companies they rely on to transform their discoveries into commercially viable products.

This case presents a compelling opportunity for the Court to reconsider *Brulotte* and hold that freely negotiated contracts allowing for payment of post-expiration royalties should be subject to conventional antitrust analysis under the rule of reason, instead of the inflexible prohibition of *Brulotte*. Applying well-developed antitrust principles to assess whether a

particular licensing agreement constitutes patent misuse will thus rest on modern economic understanding of post-expiration royalty payments rather than *Brulotte*'s outdated assumptions.

### E. The Ninth Circuit's Expansive Reading Of The *Brulotte* Rule To Invalidate Complex Licenses That Do Not Separately Account For The Value Of Patent Rights Further Constrains The Commercialization Of Important Academic Research

The Court of Appeals held—following its Circuit precedent—that licensee Marvel was not required to pay anything to the licensors after the patent expired because their settlement agreement did not provide for a separate and discounted rate for non-patent royalties paid after the licensed patent expired. 727 F.3d at 857, 864-65, Pet. App. 2, 20-21. Stated differently, because the contracting parties did not provide for a (likely artificial) division of value between the licensed patent and the non-patent elements of their transaction, *see id.*, the licensee was relieved of making *any* payments after the patent expired, since there was no "clear indication that the royalty was in no way subject to patent leverage." *Id.* at 865, Pet. App. 21. This was so even though the court conceded that "Kimble's primary leverage in negotiating the settlement was undoubtedly the jury verdict on the contract claim." Pet. App. 22.

The Ninth Circuit's expansive reading of *Brulotte* imposes another unjustified constraint on the types of licenses that *Amici* or their members often grant, which may involve the provision of, in addition to patent rights,

non-patent elements such as biological materials, scientific know-how, patient data, or trade secrets, to name a few. Similarly, some licenses include a license initiation fee for inchoate patent rights (where a patent application is pending but not yet granted). This kind of payment, which extends the payment term on the front end, also is outside the patent term. Pre-patent and post-patent term payments have distinct economic values to the licensing parties even if not separately broken down in the agreement. The mere fact that they are included in the licensing deal does not give the licensor any patent leverage.

The Ninth Circuit's interpretation of *Brulotte* requires institutions to assign separate, discounted values to the non-patent rights in complicated or "hybrid" transactions like these—which are very much the norm for institutions like *Amici* or their members—even though the discounted value may not reflect the true value of the non-patent rights, or the patent and non-patent rights may be intertwined. For example, it may be that the final form of a product that obtains FDA approval was not known at the time of the licensing agreement, because several candidates were included in the package of rights, materials, and (non-patent) know-how transferred. It is also not uncommon for therapies to have non-patent components as well as patent components. Finally, the licensor or licensee may create new intellectual property based on the licensed discovery, but under the lower court's interpretation of *Brulotte* the parties may not amend their arrangement to account for the deal's changing economics unless they ensure the strict separation of patent and non-patent rights and a discounted payment for the latter. Thus, while the contracting parties can and must agree on the basic

economic terms of their relationship, attempts to ascribe separate values to different elements in the bundle of rights would be clumsy at best and arbitrary at worst.

There is no public benefit in compelling sophisticated parties to complicated transactions—which by their nature have substantial risks of failure and economic rewards that will be realized (if at all) years in the future—to assign arbitrary values to the mix of rights being licensed, for the sole purpose of providing a "clear indication that the royalty was in no way subject to patent leverage," 727 F.3d at 865, Pet. App. 21, as apparently required under the Ninth Circuit's interpretation of *Brulotte*. If the logic of *Brulotte* compels such a rule, the constraint it places on socially beneficial transactions between sophisticated entities is another reason to overrule the case.

## CONCLUSION

For the reasons stated above, *Amici* respectfully urge the Court to reverse the judgment of the United States Court of Appeals for the Ninth Circuit.

Respectfully submitted,

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