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Reach Through Royalties as a Workaround for Patent Exhaustion

by PATRICK HAGAN

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Abstract

Reach through royalties (RTRs) allow companies that license patented research tools to profit from inventions created by others using these tools. Support for RTRs is split; some disfavor them for their potential anti-commons effects, while others believe RTRs provide important services, such as research tool valuation. This piece argues that RTRs should be allowed, outlining their current use in the United States and the financial implications for both tool licensors and researchers.

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by PATRICK HAGAN*

I. Introduction

In the high stakes worlds of pharmaceuticals and integrated circuits, an inventor of a new product that catches on stands to profit handsomely. As with any endeavor that creates a large amount of revenue, there is usually no shortage of claimants to some of the credit for the invention, and thus some of the money. This article discusses reach through royalties (“RTRs”), a method by which inventors of patented “research tools” can exercise some claim over the proceeds of these later inventions, and argues that this method should be enforceable under patent law. Although research tools can be defined very broadly, my analysis is concerned with patented methods and products used in the process of inventing additional patented products, such as a pharmaceutical.

II. Reach Through Royalties

A. Definition

“‘Reach-through licensing’ is licensing of technology/intellectual property, typically patent rights, with royalties based on a percentage of sales, where the licensed technology/intellectual property, such as basic research, is not incorporated into the end product.”¹ Sometimes the definition is confused with other types of license terms; one reference to an agreement in which the licensee was required to grant the licensor “the first rights to negotiate a license for any new inventions or discoveries arising from [the] use of the Kit” was called

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1. Thomas J. Kowalski, *Reach-through licensing: A US Perspective*, 6 J. OF COM. BIOTECH. 349 (2000) available at http://pharmalicensing.com/public/articles/view/963567614_396edffe132c5.

a “reach-through” agreement[.]”² In fact, this type of agreement is called a “grantback.”³ Later in the same article, however, the author refers to “royalties on commercial products that may not appear for a decade or more after the tool was actually used and then never be used again in the actual making of the product.”⁴ This accurately describes an RTR.

Another similar but distinguishable licensing scheme was that adopted in 1982 for the “Cohen-Boyer” patent by patentees Stanford University and the University of California.⁵ The licensing provisions were similar to those of an RTR in that the royalty amounts depended on future sales; however, royalties were computed on the actual use of the patented method in the manufacturing of a new product, not just use during the discovery phase.⁶ As such, the royalty computation did not “reach through” the patented product to another product.

Like the Cohen-Boyer license, most biotech RTRs involve only a license to the research tool itself.⁷ The focus of this article is on a rarer breed: the sales of patented products, whose use is also subject to a license enforceable through an infringement suit. In light of the doctrine of patent exhaustion, such a situation may seem impossible. However, there is at least one accepted situation in which such a license term is effectively enforceable under patent law, and I argue that RTRs should be another.

B. Legal Considerations

As a threshold matter, it should be noted that RTRs in general should not be prohibited as *per se* patent misuse or an antitrust

2. Naomi Freundlich, *Will Increasingly Aggressive Licensing Terms on Research Tool Patents Hurt Basic Research?*, SIGNALS, June 4, 1998, <http://www.signalismag.com/signalismag.nsf/0/B931DE6BB4A15AE788256618005B6335>.

3. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N. ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY §5.6 (Apr. 6, 1995), available at <http://www.justice.gov/atr/public/guidelines/0558.pdf> (“A grantback is an arrangement under which a licensee agrees to extend to the licensor of intellectual property the right to use the licensee’s improvements to the licensed technology”).

4. Freundlich, *supra* note 2.

5. Margaret Young, *The Legacy of Cohen-Boyer*, SIGNALS, June 11, 1998, <http://www.signalismag.com/signalismag.nsf/0/B7367C099E624AFE8825662000609D01>.

6. *Id.* The question still arises, as with RTRs, as to whether violation of these licensing terms could have subjected licensees to infringement suits or merely breach of contract suits.

7. Email from David Highet, Vice President and Chief Intellectual Property Counsel, Becton, Dickinson and Company (on file with author).

violation,⁸ and that an RTR is not necessarily an impermissible expansion beyond the scope of the patent.⁹ Licensors can, at the very least, enforce RTR provisions through breach of contract suits.¹⁰

The doctrine of patent exhaustion is the primary limit on “use restrictions” on a patented product that has been sold. A brief examination of the current state of the doctrine in patent law will show exactly how much of a limit it is. The Supreme Court’s recent decision in *Quanta v. LG Electronics*¹¹ announced a renewed emphasis on the power of the doctrine, which holds that a patentee loses all of his patent enforcement rights over a particular copy of his patented product when he sells that copy. Stated in positive terms, a patented product can be freely used by its buyer in any way he sees fit.

In *Quanta*, the patentee argued that the license restricted buyers who had acquired the patented product from a licensee from using the product without separately licensing for this right directly with the patentee. The Court disagreed, holding that once the product was sold, the patentee lost all authority (at least under patent law) to restrict the use of the product. The Court reiterated the rule from the 1942 case *United States v. Unis Lens Co.*: “Exhaustion is triggered only by a sale authorized by the patent holder.”¹² The two key words in the rule are “authorized” and “sale.” The significance of “sale” will be discussed below. For now, it is enough to know that an “authorized” sale is one that follows any restrictions the patent holder places on the sale. Any sale that does not is “unauthorized,” and subjects the buyer of the product (and the licensee, if any, who sold the product) to patent infringement liability if he or she uses it.¹³ This restriction can be seen as an incomplete transfer to the licensee of the bundle of rights granted by the Patent Act, specifically, the right to sell.¹⁴ The *Quanta* Court implicitly upheld the validity of this type of restriction, as stated earlier in *General Talking Pictures Corp. v.*

8. Alfred Server, *Reach-Through Rights and the Patentability, Enforcement, and Licensing of Patents on Drug Discovery Tools*, 1 HASTINGS SCI. & TECH. L.J. 21, 65 (2009).

9. *Id.* at 102. Server also notes that *Brulotte* involved a sale which was apparently “unrestricted,” and which should have triggered the exhaustion doctrine. The Court did not address the issue. *See id.* at 94 n.203.

10. *See id.* at 62.

11. 128 S. Ct. 2109 (2008).

12. 316 U.S. 241 (1942).

13. *Id.*

14. 35 U.S.C. § 271(a) (2006).

*Western Elec. Co.*¹⁵ In *General Talking Pictures*, a patentee and a licensee had agreed to a restriction on which third party buyers the licensee could sell to. A sale by the licensee to a prohibited third party would literally infringe the patent. This provided one answer to the ultimate question of what types of restrictions could result in infringement liability for buyers and/or licensees. Unfortunately, *Quanta* Court merely held that the facts involved were not similar to those in *General Talking Pictures*, and offered little, even in dicta, in the way of general affirmative guidance on other restrictions.

Perhaps more relevant to the RTR situation is that of “single use only” restriction on the buyer, which was dealt with in *Mallinckrodt v. Medipart*,¹⁶ an earlier Federal Circuit decision. The Federal Circuit concluded the restriction was valid, calling it “an express[] condition[]” of the sale.¹⁷ The *Quanta* Court did not offer any specific guidance on this restriction, either, which is unfortunate, as it appears that the patentee in *Quanta* “took full advantage” of the *Mallinckrodt* holding in crafting its license.¹⁸ Some have argued that, at the time it was decided, *Mallinckrodt* was already a departure from established Supreme Court precedent and that in light of *Quanta*, it can be considered dead law.¹⁹ One thing is certain, however: the facts in *Mallinckrodt* approximate those in *Quanta* much more closely than those in *General Talking Pictures*. However, even assuming *Mallinckrodt* is no longer good law,²⁰ RTRs aren’t “use” restrictions on products that have been sold, and thus can’t be held to fail to prevent exhaustion on that ground, either.

The *Quanta* Court did cite, along with *Univis*, several examples of restrictions that *have not* allowed protection from patent exhaustion;²¹ however, there are no examples in Justice Thomas’ four-paragraph history of the doctrine of patent exhaustion (two of which are devoted to *Univis*) of restrictions that *were* allowed.²² This author

15. 305 U.S. 124, 127 (1938).

16. 976 F.2d 700 (Fed. Cir. 1992).

17. LG Electronics. v. Bizcom Electronics, 453 F.3d 1364, 1369–70 (Fed. Cir. 2006).

18. See Harold C. Wegner, *Post-Quanta, Post-Sale Patentee Controls*, 7 J. MARSHALL REV. INTELL. PROP. L. 682, 690 (2008).

19. Thomas G. Hungar, *Observations Regarding the Supreme Court’s Decision in Quanta Computer, Inc. v. Lg Electronics, Inc.*, 49 IDEA 517, 529 (2008–09).

20. *Id.* at 530.

21. *Quanta v. LG Electronics*, 128 S. Ct. at 2116. (*discussing* *Bauer & Cie v. O’Donnell*, 229 U.S. 1, 14–17 (1913)); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 518 (1917).

22. 316 U.S. 241, 241 (1942).

is not aware even of dicta in any Supreme Court case that hints at what sorts of restrictions may *theoretically* be allowed to insulate a patent from exhaustion.

One possibility is that the *General Talking Pictures* restriction could be manipulated to transform an authorized sale into an unauthorized sale the moment that the buyer violated the use restriction. The idea is that a patentee could insert into the license a contractual “condition precedent” that the product would only be used by the buyer in the permitted fashion. Although the Court has never directly addressed the question, at least one commentator does not think this is possible.²³

As may be gleaned from the above discussion, *Quanta* is notable for what it *didn't* say. In addition to shedding very little light on the issue of restrictions on sales of patented products, the Court did not offer any affirmative pronouncements on the mere contractual enforceability of use restrictions, stating that the patentee was not “necessarily” precluded from pursuing contractual remedies.²⁴ One concern is whether such a provision would amount to patent misuse.²⁵

C. RTRs as a Workaround to Patent Exhaustion

Recall the postponement of the discussion, above, of “sale” in the rule of *Univis*, as well as the wording of *Mallinckrodt*. How else could “use” restrictions be characterized to comply with current law? Hungar points out that “it seems reasonable to predict that some patent holders may attempt to avoid the impact of *Quanta* by restructuring sales transactions as licenses, leases, consignments or bailments in which title does not pass to the consumer.”²⁶ In such a case, a license may be structured to contemplate an eventual sale. Such sales of real property can be subject to a condition precedent.²⁷ An RTR can be considered a condition precedent of a sale, with the licensee promising to pay money in the future in exchange for eventually acquiring title to the product. The patentee promises to allow use of the product prior to the sale in exchange for the user’s promise to buy, which necessarily requires compliance with the condition precedent. Without such a promise, the user could simply decide that he or she does not want title, thereby refusing to pay the

23. Hungar, *supra* note 19, at 540.

24. 128 S. Ct. at 2122 n.7. The patentee did not claim breach of contract.

25. Server, *supra* note 8; Hungar, *supra* note 19.

26. Hungar, *supra* note 19, at 533 n.83.

27. *Id.* at 532 (citing early 20th century cases).

RTR even though a sale is contemplated in the license. If the user breaks this promise, even if he or she is no longer using the product, this constitutes infringement in addition to breach of a contract.

This arrangement is slightly different from a use restriction, dismissed above, which attempts to retroactively transform an authorized sale into an unauthorized one. In the proposed arrangement, the sale does not take place until the future royalties, the true price for title to the product, are paid. If the licensee refuses to pay the money, he or she never gets title to the product. While this may be a moot issue by the time such a refusal is made, the user can be held liable for infringement as a mere licensee. Although this could be seen as “retroactively” changing the nature of the *use* of the product, it is no different than any other contract in which duties of performance by one party are not due simultaneously with or prior to the other party’s performance.

An RTR effectively turns royalties into a delayed payment plan for use of a patented product, an idea that has some historical precedent. In *Brulotte v. Thys*, a license that required royalty payments based on use of a product after the patent’s expiration was held to be patent misuse;²⁸ the dissent characterized the license arrangement as a mere delayed payment plan, which the purchaser used to “amortize the machine’s fixed cost.”²⁹ Judge Posner discussed this idea approvingly in a recent case as well.³⁰ A later case, *Zenith Radio Corp. v. Hazeltine Research*, distinguished the *collection* of royalties from their *accrual*, “recognizing . . . that the payment of this royalty could be postponed beyond [the expiration of the patent].”³¹ Coincidentally, the district court in *Bayer v. Housey*,³² as of early 2009 the only existing federal decision involving an RTR, suggested that the RTR at issue could be seen as such a delayed payment plan, although neither of the parties submitted evidence showing whether royalties actually *accrued* after patent expiration.³³

Thus, RTRs on patented products are not really royalties at all: they are just a way to compute the final sales price of the product. Parties have wide latitude to negotiate for royalties, as long as they

28. *Brulotte v. Thys Co.*, 379 U.S. 29 (1964).

29. *Id.* at 36 (Harlan, J., dissenting).

30. *Scheiber v. Dolby Labs.*, 293 F.3d 1014, 1020 (7th Cir. 2002).

31. 395 U.S. 100, 136 (1969).

32. *Bayer AG v. Housey Pharm., Inc.*, 228 F. Supp. 2d 467, 472–73 (D. Del. 2002).

33. *Id.* at 473.

are not “exorbitant or oppressive” or “discriminatory.”³⁴ So why shouldn’t parties have that same freedom to negotiate a final sales price? Of course, “the effectiveness of such schemes will likely depend on the extent to which the substance of the transaction is consistent with its form. There is precedent for judicial reexamination of such transactions to determine whether they are, in substance, sales and should thus be treated accordingly.”³⁵ In fact, Justice Thomas performed this analysis in *Quanta* when he responded to LGE’s argument that the licensing agreement was a restriction on the “right to sell”: “LGE overlooks important aspects of the structure of the Intel-LGE transaction. Nothing in the License Agreement restricts Intel’s right to sell its microprocessors and chipsets”³⁶ Just because Intel gave notice to its customers of its inability to sublicense the method patents did not mean that the license agreement actually restricted Intel’s sales.

This author is not aware of any cases involving RTRs and exhaustion as of December 2009 (probably because most RTRs do not involve patented product sales³⁷). Indeed, as already stated, only one case involving the validity of RTRs in any context has made it into a federal courtroom.³⁸ Only time will tell how these arguments will fare.

III. Why RTRs Should Not Be Allowed to Run Afoul of Exhaustion

Policy will be a key component of the arguments on both sides of an RTR validity dispute, either under patent or contract law. Aside from legislation explicitly declaring RTRs unenforceable after a sale of a patented product, policy may be the only consideration at this point in time that could effectively put an end to RTRs.

Arguing for RTRs necessarily involves arguing for the value of tools in general. As patentability is strong evidence that tools are valued, it is not possible to have a full discussion of the policies surrounding RTRs without mentioning the policy supporting the patentability of research tools in the first place. Research tools are

34. See THOMAS J. PARKER, PATENT LICENSING TRANSACTIONS §§ 301, 304 (Matthew Bender & Company, Inc. 2009).

35. Hungar, *supra* note 19, at 533 n.83.

36. *Quanta v. LG Electronics*, 128 S. Ct. at 2121.

37. Highet, *supra* note 7.

38. *Server*, *supra* note 8, at 90 (discussing *Bayer v. Housey*, 228 F. Supp. 2d 467(D. Del. 2002), *aff'd*, 340 F.3d 1367 (Fed. Cir. 2003)).

unquestionably patentable.³⁹ However, the policy underlying the caselaw is unclear, and tool patents are not explicitly favored or disfavored by governmental policy pronouncements.

As noted above, most RTR licenses are “use” licenses for method patents.⁴⁰ Unsurprisingly, many statements of current policy and law are implicitly written with method patents in mind.⁴¹ One such method patent is an “assay” tool, which is a method of targeting a component of a living cell that acts as a switch in controlling a disease process. More research will be directed to learn what other molecules can control that switch, and one of those molecules may eventually become a pharmaceutical. These assays can be patented, but they are not “sold” as discrete physical products. Instead, the patentee effectively licenses the ability to do additional research on the particular cell component identified, through the practice of the targeting method at issue. For example, although the National Institutes of Health (“NIH”) guidelines name other research tools which *can* be sold as discrete physical products, thus triggering patent exhaustion (e.g., “cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs . . . , clones and cloning tools (such as “PCR”), . . . laboratory equipment and machines . . .”) the guidelines do not mention exhaustion as a doctrine that would moot any questions of licensing.⁴² RTRs on product sales are likely subject to the same policy restrictions from both the NIH and the Food and Drug Administration (FDA).

A. Current Policy

Although the legal landscape tends to answer the question of what an actor must or can do, the policies of other significant players help determine what an actor *will* do. One of the most influential players in research tool patent licensing is the NIH. Current NIH policy guidelines for recipients of NIH research funds, largely a product of former NIH Director Harold Varmus’s stance on the issue with respect to DuPont’s Cre-lox genetic engineering system,⁴³ frown

39. Server, *supra* note 8, at 30.

40. Hight, *supra* note 7.

41. Server, *supra* note 8, at 25–121.

42. Server, *supra* note 8, at 25 n.10 (citing NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS 3 (1998), available at <http://www.nih.gov/news/researchtools/index.htm>).

43. Freundlich, *supra* note 2. (The “Cre-lox patent” was U.S. patent 4,959,317, which expired Sept. 25, 2007. The Canadian version expired Dec. 24, 2008.)

on RTRs.⁴⁴ Although these guidelines have no legal authority, they are extremely influential on universities and biotech companies that depend on NIH grants. A patentee using an RTR for a patent developed with NIH money may find him or herself unable to secure further NIH grants. Consequently, a good deal of biotech research will most likely not be licensed through RTRs.⁴⁵ Whether a government agency besides the United States Patent and Trademark Office should be able to influence patent issues directly is another question, but the fact of this influence is inescapable.

Overall, however, “the NIH has left considerable discretion to Recipients in determining how to achieve the principle of ensuring appropriate distribution of NIH-funded tools,” and suggests that “Recipients should engage in such interactions on an infrequent, case-by-case, and highly controlled and monitored basis.”⁴⁶

The FDA’s policy on RTRs is less clear: “The goal of critical path research [research moving a laboratory idea to a commercial drug] is to develop new, publicly available scientific and technical tools . . . that make the development process itself more efficient and effective Such tools will make it easier to identify earlier in the process those products that do not hold promise, thus reducing time and resource investments, and facilitating the process for development of medical products that hold the most promise for patients.”⁴⁷ The key issue is whether an RTR is incompatible with “public availability.”

Some policy embedded in the Patent Act itself appears to favor “limit[ing] the reward that may be gained by early stage inventors:” “rules requiring a specific use for an invention and limiting the

44. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (Dec. 23, 1999).

45. Donald R. Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q. J. 267, 292 (2002) (“Based upon an informal survey of university, biotech, and pharmaceutical company clients, . . . the industry trend is moving away from reach-through royalties for research tools that do not form an integral component of a drug product. . . . [L]arge pharmaceutical companies. . . have [also] adopted strict policies against entering into drug discovery or other research tool licenses that contain reach-through royalty provisions”). Whether any of these examples are due to the NIH guidelines is unclear.

46. *Supra* note 44; *See also* Server, *supra* note 8, and Kowalski, *supra* note 1 (supporting the proposition that there is no absolute prohibition on RTRs for NIH funded tool inventions).

47. U.S. DEP’T OF HEALTH & HUM. SERV., FOOD AND DRUG ADMIN., CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS 8 (2004), available at http://www.nipte.org/docs/Critical_Path.pdf.

protection to that use, other rules relating to the scope of a patent, rules on blocking patents, and the reverse doctrine of equivalents.”⁴⁸

A comparison to the policy justifications underlying *General Talking Pictures* and *Quanta* is also informative. If a restriction on the “right to sell” is accepted as a valid restriction on a sale, then why are restrictions on use unacceptable? The answer to this question requires distinguishing the parties in a sale transaction. The Supreme Court recognized long ago that “licensees ‘stand[] on different ground’ from purchasers in authorized sales.”⁴⁹ The licensees never own the product, but merely pass it on to the ultimate purchaser.

However, as seen in *General Talking Pictures*, even a buyer can be liable for infringement if he or she uses a product purchased in knowing violation of the licensing agreement between the seller and the patentee. Is this not effectively a “use” restriction? It can be a *complete* use restriction, as well, if the buyer is not supposed to be able to obtain the product from the licensee at all. In this light, an RTR, which allows a buyer to use the product at will, *as long as* he or she later remits a portion of the sales of his own product, is less of a use restriction on a buyer than the sales restriction could be. This alternative interpretation of the effect of sales restriction highlights that the primary concern of the Court might not be a restriction on “use” *per se*. So what exactly is the policy force at work in *Quanta*?

On the surface, *Quanta* is purely legal analysis, based on long-established principles. However, it may also signify a very simple policy preference by the Court when managing commercial transactions that implicate patent law: certainty. In this context, the certainty desired is the clear insulation of a buyer and a licensee/seller from post-sale infringement liability. The Court discusses the knowledge of the licensee and the buyer at the time of sale:⁵⁰ if both parties subjectively understand the sale to be authorized when it takes place, the sale is forever considered authorized, even if it is subsequently determined to violate a licensing restriction. Conversely, to be liable for infringement, the parties must be aware at the time of sale that they are violators. This sale is forever *unauthorized*, and cannot be converted into an authorized sale later.

48. Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 445 n.206 (describing how time, scope, and other aspects of the patent system strike a balance between the rights of original developers and subsequent improvers (citing Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989 at 991–93, and 1000–13 (1997))).

49. Hungar, *supra* note 19, at 535 n.93.

50. *Id.* at 541.

This policy preference for certainty should not affect RTRs. Although they exist to exploit the uncertainty of the worth of research tools, RTRs do not leave the buyer uncertain as to future infringement liability. Assuming RTRs are enforceable in patent law as conditions on sales, the buyer will be aware that his own future behavior is the only determinant of infringement liability. A violation of the RTR provision will subject him or her to the same infringement liability he or she would have for violating any other type of royalty provision of a licensing agreement where no sale has taken place. This contrasts with the potential liability if a *Quanta*-type license were enforceable at patent law. Such a license “would effectively transform licensees into insurers of their customers’ good conduct,”⁵¹ over which the licensees have no control. The buyer could also unwittingly acquire products in violation of the licensing agreement and still be liable for infringement.

Reiterating the opinions of those who believe *Mallinckrodt* to be dead law,⁵² one scholar speculates that “the *Quanta* Court’s treatment of [patent exhaustion] case history suggests it may limit the ability of patentees to limit the transfer of rights” with a use restriction like that in *Mallinckrodt*.⁵³ Even assuming that RTRs are not *Mallinckrodt*-type use restrictions, a case invalidating RTRs on policy grounds would seemingly have to deal with facts involving an actual RTR. RTRs are different enough to make policy analogies from other types of licensing strategies difficult.

Another recent case with possible policy implications for RTRs is the unanimous decision of *Merck v. Integra*.⁵⁴ The holding of this case appears to allow drug manufacturers free use of patented research tools in the process of researching new drug candidates, using the “reasonably related to the development and submission [of an application for a new drug]” language from 35 USC §271(e)(1) as a defense to infringement. At least one commentator believes *Merck* did not destroy the enforceability of research tools in all situations, but that it definitely provides for broad protection of researchers relatively early in the development pipeline.⁵⁵ This suggests the Court

51. Hungar, *supra* note 19, at 540.

52. *Id.* at 530.

53. James W. Beard, *The Limits of Licensing*, 12 UCLA J.L. & TECH., 1 at 43 (Fall 2008).

54. 545 U.S. 193 (2005).

55. Server, *supra* note 8, at 49, 51 (pointing out that research tool patents, to avoid §271(e)(1) coverage, would probably need to be used in “[b]asic scientific research on a

might look askance at tool manufacturers trying to extract royalties from these researchers under circumstances other than the most basic research, even if those researchers are commercial, in-house employees of a for-profit pharmaceutical company.⁵⁶ This may be read as the Court's pursuit of a policy supporting early stage researchers; on the other hand, research tools can be considered the very earliest stage of research, so perhaps a more precise definition of the policy would be support of researchers whose goal is a marketable drug. If this is indeed the policy, RTRs may be in trouble, as they are aimed squarely at those researchers.

B. Normative Policy

We now turn to more fundamental policy considerations, many of which suggest that RTRs have positive effects. RTRs can be used to fill in the gaps between protection of intellectual property and the economics of the biotech industry. Most importantly, RTRs solve the problem of valuation of basic research:⁵⁷ "It is the market-place—not the cost of patenting and developing the [research tool] that determines [its] value."⁵⁸ As a negative example, a research tool that no one wants to use has no value at all, no matter how much money was spent developing it; thus, a research tool that costs virtually nothing to create, but has a high value for research, should be worth a lot. Seen in an absolute sense, "but for the research tool, there would not have been the end product drug"⁵⁹ The head of SIBIA Neurosciences in 1998, Dr. William Comer, said the company "gives away" its research tools in exchange for later royalties if the recipient goes on to develop a commercially successful product.⁶⁰

A tool inventor "solve[s] problems the drug developer either could not afford or did not find profitable to solve, or did not timely

particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce..." (quoting *Merck* at 205-06)).

56. Unlike the NIH guidelines, Hatch-Waxman does not provide separate standards for non-profit vs. for-profit researchers.

57. Kowalski, *supra* note 1.

58. *Id.* ("If the basic research tool...cost at most only US\$2m to develop and patent (or less), a reach-through royalty of US\$25-300m still may not be excessive compensation.")

59. *Id.*

60. Freundlich, *supra* note 2. SIBIA was acquired by Merck in Nov 1999, and Comer's tenure as CEO apparently ended around that time, as well. SIBIA's current licensing practices are unknown.

solve first,”⁶¹ or didn’t solve as efficiently. Profitability is always a factor in a “go/no go” drug development decision.⁶² The efficiency of the tool could have a huge impact on this profitability factor. The tool can thus provide a “considerable competitive advantage” to its user.⁶³

RTRs probably increase the likelihood of a tool being used, as well, which benefits the licensee, the licensor, and the public. The small up front cost for licensees significantly reduces their risk exposure to the use of a particular tool, versus the risk the licensee would be taking if it initially paid “full price.”⁶⁴ Furthermore, even if a tool lowers the financial hurdle to create a new product, there is always the business risk that the licensee will be unable to convert a seemingly useful final product into a *profitable* final product. Unlike other products without licensing arrangements, RTRs effectively allow licensees to push some of this business risk onto the tool patentee.⁶⁵ Nothing encourages risk-taking like a reduction of risk, so allowing such risk sharing should encourage innovation by licensees. In fact, one analyst claims that biotech pharma has always insisted on anti-stacking language (see below) in licenses to “patent pending” research tools in order to shift the risk of patent blocking to the tool patentee. This risk is significant due to the U.S. Patent and Trademark Office’s long prosecution timeline for biotech products.⁶⁶

Additionally, the tool inventor benefits, at minimum, from the small income stream generated by the licensee’s initial use of the tool under an RTR arrangement. Ultimately, the public will receive the benefit of a drug that would not have existed otherwise (see above on tools being a large part of a decision to go ahead with drug development).

One real-world application of the ability of RTRs to measure the value of research is that courts have used them to calculate “reasonable royalty” damages in infringement cases,⁶⁷ although this author is not aware of any cases involving RTRs in the context of product sales. In explaining current court practice, one commentator cited cases involving the use of a patented product in the actual

61. *Id.*

62. *Id.*

63. Server, *supra* note 8, at 27.

64. Feldman, *supra* note 48, at 442.

65. *Id.*

66. *Id.*

67. Ware, *supra* note 45. *See also* Server, *supra* note 8, at 112.

production of the infringer's product, but not the development stage.⁶⁸ Thus, it is still unknown whether a court might consider an RTR in an infringement involving a sale of a patented product.

Comparing RTRs to another type of final value determination, the use of sales of one product to determine the value of another happens routinely for patented products used in subcomponents of larger products, such as automobiles. The only difference between auto parts contracts and RTRs is that in RTRs the "sales" do not involve products that actually practice or embody the patent, or were even manufactured using a patented product or method. The licensed product is used solely to develop the new product, after which it is never used again.

Of course, there are arguments that cut against RTRs. One of the most memorable analogies is to a typewriter manufacturer demanding royalties on an author's book.⁶⁹ Perhaps such an arrangement would be unfair in the case of the typewriter, but in many biotech examples, the distance between the patented product and the "author's" new product is much closer than a typewriter is to a bestselling novel. For example, a researcher using a DNA microarray to look for a bacterium possessing a certain gene really isn't doing anything more than using the patented tool: anyone who read the instruction manual could do it. However, not everyone who sits down at a typewriter is Shakespeare. Thus, it should be up to the parties to a private contract to speculate on how much more "inventiveness" would hypothetically be embodied in whatever "new" product is developed, and to determine how much financial value should be attached to this difference.

Opponents of RTRs give little weight to the argument that the potential financial reward of an invention is the main incentive for its development, a notion that is one of the basic tenets of the patent system. Research tools are a fantastic illustration of "why patents are within the term 'intellectual property.'"⁷⁰ They are ways of identifying and using (and thus valuing) the ideas of the mind in the same way a farmer demarcates and uses his fields.

What happens when there are no RTRs? In the initial stages of research, where the risk is high, big pharma chooses the "cheap

68. Ware, *supra* note 45, at 283.

69. *Of mice, men, SNPs, targets and other research tools*, SIGNALS, Apr. 8, 1998, <http://signalmag.com/signalmag.nsf/0/6CD9AC2C39DB5A31882565E0004DC318>.

70. Kowalski, *supra* note 1.

route” of secretly infringing a tool patent.⁷¹ If nothing ever comes of the research, the patentee will probably never know about the violation of its patent. If a new drug is eventually developed, and the tool patentee wins an infringement suit, a judge might not consider the final sales of the drug in determining a “reasonable royalty,” but instead may base the royalty on the market for the research tool *at the time of the initial research*,⁷² which might be a very low number in light of the product’s eventual sales. Instead of a licensed patent with an RTR provision that keeps licensee costs low in the research stage, we are left with situations like the Hatch-Waxman dispute in *Merck*. As one commentator points out, currently “it is the courts deciding which biotech tools are exempt, which infringers will be the benefactors of de facto compulsory licensing, and which biotech companies will stay in business. A better solution is needed.”⁷³ RTRs are that solution.

The most vocal proponents of RTRs seem to be those who stand to recover a windfall profit (tool patentees), while those who oppose RTRs are parties who may have to pay that profit out (pharmaceutical producers). However, as shown above, end-product producers do benefit from RTR schemes. This illustrates a broader problem: many parties on both sides view RTRs as a zero-sum game. This view entirely discounts the value of simply doing research at all, versus doing no research because the necessary tools are unavailable. When a final product is created, so is new value. Twenty percent of something is better than 100% of nothing.

C. Opposition

The massive reward garnered by RTRs is only possible through a government-enforced monopoly. The tradeoff is the exclusion of those who don’t agree to the conditions of practicing the patent (e.g., an RTR). Other costs are also borne by society.⁷⁴ Because RTRs make so much sense from the parties’ perspectives, the theorized danger is that they will be agreed to very frequently, thus forcing costs onto those not party to the transaction.⁷⁵ The licensor’s choice is

71. *Id.*

72. See discussion of Ware’s biotech reasonable royalty factors, *supra* note 45, at 280.

73. Ruth E. Freeburg, *No Safe Harbor and No Experimental Use: Is It Time for Compulsory Licensing of Biotech Tools?* 53 BUFFALO L. REV. 351, 385 (Winter 2005).

74. Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1818–20 (1984) (cited in Feldman, *supra* note 48, at 443 n.200).

75. There is some irony in the fact that the other main argument against RTRs is that no licensees will agree to them, or perhaps even be able to agree to them. See discussion of the “stacking” problem below.

likely between zero licensing revenue and a huge payoff, and the licensee's choice is between no product (which also represents zero revenue) and a huge payoff, minus a (probably) small percentage.⁷⁶ Neither party is likely to take the "assured zero revenue" route, no matter how risky the other option is, making the law the only obstacle to the transaction. With this in mind, depending on the types of costs society must pay for RTRs, perhaps some limits should be placed on their use.

The main policy opposition to RTRs seems to center around their alleged "anticommons" effect.⁷⁷ Opposition to these arguments has also been laid out along doctrinal grounds.⁷⁸ The main point is that RTRs make it too hard (i.e., costly and slow, with high transaction costs) for downstream inventors to license upstream tool patents. The ultimate effect is that "the accrual of too many royalty slices diminishes potential profit to the point that the company shouldering the early research and development costs may decide the drug is not worth the cost of development."⁷⁹ This concept is commonly referred to as "royalty stacking." As an illustration, Ware lays out 15 different research tools that a hypothetical researcher (here, in the proteomics field) would need to use to develop a product; this means the researcher could potentially be required to license 15 separate tools before beginning work.⁸⁰

The backstop on too much stacking is that licensors are "keenly aware that some royalty on an end product is better than no royalty where there is no end product."⁸¹ Thus, a stacking problem will tend to be self-resolving; a licensor that initially insists on a large percentage of final sales will have to lower its rates if it wants any license revenue at all. As one biotech executive opined in the late 1990s, "there will have to be equilibrium. It may get to the point where everyone starts saying 'we won't sign these darn things.'"⁸²

76. Feldman, *supra* note 48, at 447.

77. Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

78. Heather Hamme Ramirez, *Defending the Privatization of Research Tools: An Examination of the 'Tragedy of the Anticommons' in Biotechnology Research and Development*, 53 EMORY L.J. 359, 362 (2004).

79. Freundlich, *supra* note 2.

80. Ware, *supra* note 45, at 269-70.

81. Kowalski, *supra* note 1.

82. Freundlich, *supra* note 2 (quoting Millennium Pharmaceuticals' Chief Business Officer Steven Holtzman).

An examination of evidence of the lack of stacking problems observed in real life RTRs, as well as “anti-stacking” compensatory measures, also suggests the anticommons effect is not as pronounced as some fear. A good initial example is the Cohen-Boyer patent. Though not a true RTR, its license shared the “percentage of the pie” method of computation that theoretically creates a stacking problem. The license did not seem to slow down use and the ensuing development of the biotech industry, which it is credited with creating, when compared to what could have happened if it was exclusively licensed, or licensed only for huge upfront fees. This is the practical licensing choice that companies have: potential for no money now vs. some money later. At the time the patent expired, there were 380 licensees.⁸³

A back-of-the-envelope calculation from an attorney in the field might be instructive for those concerned about “overrewarding” a tool inventor. Payback won’t typically commence until approximately the tenth year of the patent term of the research tool at the earliest, entitling the toolmaker to at most ten years of royalty payments before encountering the *Brulotte* limit. The developer of the ultimate product will therefore have ten or more years of royalty free yet still patented sales, which could be extended even further through “evergreening.” For example, “the drug developer might realise a US\$1bn per year market for 15 years or US\$15bn . . . and have an outlay of reach-through royalties of only [at most] US\$100-300m (at 1-3 per cent [reach-through] royalty),” amounting to at most a two percent royalty over the lifetime of the drug patent.⁸⁴

Of course, the numbers might not work out so favorably in specific instances. One example is Millenium Pharmaceuticals, which served as the “identifier” of drug candidates. After this identification, Millenium passed the compound on for development by another company; in the event the compound ever became a commercial product, Millenium would receive an RTR of 5-15%.⁸⁵ During the identification phase, Millenium routinely assembled approximately five research tools. Many of the tools were offered by universities, and an executive of the company claimed the tool RTRs were usually 1/2% to 3% of total sales of an end product. Apparently, Millenium had to reimburse the tool patentee for the full percentage, even though it only received 5-15% of total sales. Thus, Millennium could

83. Young, *supra* note 5.

84. Kowalski, *supra* note 1.

85. Freundlich, *supra* note 2.

have ended up with an effective royalty stack of 25-50% on its revenue.⁸⁶

The example of the Cre-lox patent shows the realistic choice that patentees have to make when determining the amount of its licensing fee: namely, between charging a large up-front fee or collecting royalties later (bearing the risk that later royalties will never materialize).⁸⁷ The Cre-lox patentee originally planned to charge \$10,000 per institution for use of the technology. In the words of a company executive, “that went over like a lead balloon . . . Universities were not willing – or perhaps unable – to make that kind of commitment to a still basic-stage research tool. They wanted the chance to play with it in the lab for a while and learn more about its possibilities.”⁸⁸ According to the executive, the patentee then offered an RTR, and in response, “plenty” of organizations agreed to the license.⁸⁹ Reportedly, at least 150 organizations have agreed to DuPont’s terms, “most of them universities and other non-profit research centers,” including Stanford, Harvard, and the Howard Hughes Medical Institute; in 1998 DuPont said it executed five new academic licenses per month.⁹⁰ Reflecting self-interest, the limiting factor on runaway RTRs, as well as the basic motivation of inventors, he further stated, “We’re not out there to strangle [licensees] We just want compensation.”

An example from the semiconductor industry shows that patentees still have to make a choice about the size of their RTRs if they decide to use this method instead of an up-front fee. When the standard setting organization for 3G wireless technology in Europe polled its members for royalty rate proposals on “essential” patents involved in the technology, the cumulative royalty rate was initially estimated to be 30% of the total price of a 3G phone,⁹¹ which would have drastically reduced the profitability (and with it the widespread use) of cell phones. However, tool patentees eventually realized that the lower they price their tools (in terms of percentage of ultimate

86. *Id.*

87. Feldman, *supra* note 48, at 447.

88. Naomi Freundlich, *Cre-lox controversy divides institutions, prompts NIH panel*, SIGNALS, June 12, 1998, <http://signalsmag.com/signalsmag.nsf/0/A91504E7700ED9B0882566210046C958> (quoting Robert Gruetzmacher, senior licensing business manager at DuPont Central Research).

89. *Id.*

90. *Id.*

91. Mark A. Lemley and Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2026 (2007).

sales), the more money they stand to gain later on. In order to determine an appropriate percentage, a tool owner may require an end-product developer to provide a basic plan for how they plan to use each tool, but many businesses do this when asking suppliers for better deals. The leverage for a lower rate can take many different forms, from future business deals directed to the supplier, to an opportunity to test the supplier's product in the real world, to free promotion for the supplier.

How much can a patentee charge through an RTR before the licensing scheme becomes unviable economically for potential licensees? An experienced attorney in the field offered hypothetical rates of 0.5 to 3% for a workable licensing regime.⁹² These were also the rates in the Cohen-Boyer licensing terms.⁹³ An analysis of SmithKline-Beecham's RTR exposure in the late 1990s showed that the company was probably paying around 21% of its sales to tool licensors.⁹⁴ The Cre-lox RTR was capped at 25% of royalties,⁹⁵ and the patentee managed to extensively license the tool. Are any of these examples unreasonable? It is difficult to say for sure, but all three real-life cases were certainly not examples of failures to license.

Whether it is really a problem or not, there are contractual solutions to stacking. Kowalski offers the option of variability: the percentage of the royalty could change over the course of the licensing period, based on the total RTRs paid to all licensors, or "a sliding scale royalty rate, i.e. a royalty rate that increases over the life of the patent or the license such that the royalty rate is lower when the product is initially introduced and higher . . . after the product has attained a market."⁹⁶ Variations in the percentage to be paid could be a 50% reduction in the event the licensee must pay more than a certain total RTR amount to all licensors, for example, a figure such

92. Kowalski, *supra* note 1.

93. Joan Hamilton, *Stanford's DNA patent 'enforcer' Grolle closes the \$200M book on Cohen-Boyer*, SIGNALS, Nov. 25, 1997, <http://www.signalsmag.com/signalsmag.nsf/657b06742b5748e888256570005cba01/2d348d68e91004988825655b000b4862?OpenDocument&Highlight=0,cohen-boyer>.

94. *Is the alliance deck becoming "anti-stacked" against innovators?* SIGNALS, May 29, 1998, <http://www.signalsmag.com/signalsmag.nsf/0/FFD2CF3F7F7EA56F8825661200697CE3>. (Although the sample calculation at the bottom of the chart does not clearly represent one particular product, the 21% is offered as an example of the "minimum" percentage SmithKline could expect to pay.)

95. Freundlich, *supra* note 88.

96. Kowalski, *supra* note 1.

as 3%.⁹⁷ Real-life evidence for this exists, as well: “In an analysis done by ReCap of university/biotech license agreements, about 80% have anti-stacking language for the benefit of the biotech company, and most of this language is of the ‘fully creditable to floor’ variety. That means the university’s take goes from, for example, 5% of net sales down to a floor rate of 2.5% if the biotech player has to pay third parties in excess of 2.5% in royalties as well.”⁹⁸

A variation on the sliding scale is a modified “milestone” payment RTR. Royalties would be paid in lump sums based on a percentage of sales at certain sales points (e.g., at \$1 million and \$5 million in total sales). The percentage could rise from an initially nominal amount, thus allowing a healthy market for the product to develop before toolmakers start taking their cut. This doesn’t always work, however. “There is anti-stacking language in most of [a major pharmaceutical company’s] agreements, yet in [some] disease areas . . . it’s conceivable the potential royalty exposure to net sales of a given product could exceed 20%.”⁹⁹

This example, along with Ware’s hypothetical above,¹⁰⁰ pale in comparison to the potential stacking problem in the semiconductor industry: an Intel lawyer told one commentator that Intel CPUs are covered by 5,000 patents.¹⁰¹ The broad cross-licensing agreement is a solution to this problem. Although mainly used to lower the risk of unintentional infringement, a broad portfolio license could also have the effect of eliminating the stacking problem. The broad license itself could, of course, contain an RTR provision, but it would be impossible to calculate. The primary utility of the cross-license is to save companies from spending immense amounts of time investigating other inventors’ patents. Figuring the actual royalty amount for a portfolio RTR would involve establishing whether or not a patent was actually used, which would require the very research the broad license was used to avoid. Perhaps in the future, biotech companies will execute broad cross-licensing agreements similar to those found in the integrated circuit industry.

97. Kowalski, *supra* note 1.

98. *Supra* note 95.

99. *Id.*

100. Ware, *supra* note 45, at 269–70.

101. Mark A. Lemley, *Ten Things To Do About Patent Holdup Of Standards (And One Not To)*, 48 B.C. L. REV. 149, 151 (2007).

Defensive patenting is another possible anticommons danger of allowing exponential rewards for early-stage patentees.¹⁰² Another comparison to the semiconductor industry illustrates this problem and how RTRs could be a solution instead of a cause. In semiconductors, the business strategy of “defensive patenting” is the norm;¹⁰³ companies file as many patents as possible in a given area in order to lower the future risk of infringement by their products.¹⁰⁴ In order to keep transaction costs low, companies agree to broad, royalty-free cross-licenses of their entire patent portfolios.

What if those cross-licenses came with RTRs? Instead of an RTR on a single research tool, by which a tool inventor could be “over-rewarded” if a downstream researcher uses that tool to invent a blockbuster product, the downstream researcher would have access to every tool the inventor owns in exchange for his RTR obligation on any products the researcher creates. Surely a percentage of profits in exchange for the entire productive output of a licensor is a fair trade. Defensive patenting does seem to be occurring in biotech. As one law professor stated, “Everybody is filing as many patents as possible so they have a bargaining chip against being held up by someone else.”¹⁰⁵ Perhaps RTRs would be an acceptable solution.

Adherents to the anticommons effect could take solace in the fact that there is a natural termination of any problem when a patent expires. This is ensured by *Brulotte v. Thys* and should assuage any fears of RTRs persisting indefinitely.¹⁰⁶ At the same time, this limit should not deter licensors; it is unlikely that a licensee would intentionally wait to sell its product until the patent expired (except perhaps towards the end of the patent life).

Some of the loudest complaints about stacking come from proponents of public service. As noted above, the NIH adopted a policy disfavoring RTRs in 1998. The main policy argument seemed to be that the difficulty and expense of obtaining research tools burdened by an RTR made RTRs a poor choice for research tools developed with public money. In the case of low-cost public-interest work, one government scientist pointed out their “trouble getting

102. Feldman, *supra* note 48, at 446.

103. Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CAL. L. REV. 1889, 1949 (2002).

104. *Id.*

105. Freundlich, *supra* note 2.

106. Feldman, *supra* note 48, at 444.

companies interested in developing TB or malaria drugs You add stacking royalties onto that and who gets hurt is the public.”¹⁰⁷

Interestingly, the NIH guidelines state that when transferring “an NIH-funded research tool to a for-profit entity that intends to use the tool for its own internal purposes, recipients [of NIH grant money] are entitled to capture the value of their invention.”¹⁰⁸ Perhaps NIH only meant to protect purely academic research from the supposed anticommons effect of RTRs; Dr. Varmus’ initial motivation for convening the panel, after all, was his refusal to agree, on behalf of the NIH, to license a DuPont patent on DuPont’s reach-through terms (which over 150 other entities, many of them academic labs, had already agreed to).¹⁰⁹

There is some inherent contradiction in the NIH guidelines that lends support to this theory. At one point, the guidelines state that “[r]oyalties on the sale of a final product that does not embody the tool, or other reach-through rights directed to a final product that does not embody the tool discourage use of tools and are not appropriate in these circumstances.”¹¹⁰ However, the guidelines later state that “[r]oyalties on the sale of final products are more appropriate to situations where a for-profit entity seeks to commercialize the tool, e.g., by developing a marketable product or service, or incorporating the tool into a marketable product or service.” There seems to be an outright prohibition of RTRs that is later partially withdrawn if the licensee is a “for-profit entity.”

Whatever the ultimate policy thrust of the licensing guidelines, the Cre-lox licensing agreement between NIH and DuPont can be used for “public interest” research on tuberculosis or vaccines that are not profitable enough for a for-profit pharma to pursue.¹¹¹ The RTR provision was essentially dropped in exchange for NIH’s agreement to transfer the technology only to non-profit entities. This is precisely the situation in *General Talking Pictures*.

Some who protest RTRs are motivated not by a concern for the public (as seems to be the case with the NIH and the FDA), but by

107. Freundlich, *supra* note 88 (quoting Mark Rohrbaugh, the then-director (1998) of the Office of Technology Development at the National Institute of Allergy and Infectious Diseases).

108. Kowalski, *supra* note 1 (citing 64 Fed. Reg. 72,091 (Dec. 23, 1999)).

109. Freundlich, *supra* note 2.

110. 64 Fed. Reg. 72,091 (Dec. 23, 1999).

111. *NIH and DuPont hammer out Cre-lox agreement*, SIGNALS, Aug. 20, 1998, <http://www.signalsmag.com/signalsmag.nsf/0/D74AC16AC20D99C1882566670012D6B7>.

their own desire for financial reward. Large pharmaceutical companies don't like RTRs, for the obvious reason that they stand to lose significant amounts of revenue to licensing fees.¹¹² One attorney's personal experience is that "larger, for-profit companies have [initially] offered miniscule lump sum execution fees that would barely cover the patent prosecution costs for patent protection for basic research, only to agree eventually to proper annual payments and royalties based on a percentage of sales of end product – reach-through licensing – illustrating that reach-through licensing is indeed a necessary reality to 'capture the value of...invention.'"¹¹³ Ironically, however, biotech pharma has always insisted on anti-stacking language in licenses to "patent pending" research tools for a different reason: to shift the risk of patent blocking to the patentee, a justification already mentioned above.¹¹⁴

Bridging academia and private industry, one university professor, who would seemingly represent the "academic community" regarding RTRs, but is also the founder of a company that commercialized a biotech invention, said "I'd rather pay (a company) up front, and then that's it, rather than take this and if anything comes of it, then have to pay 20% later."¹¹⁵ This statement represents a contradiction: on one hand, he'd presumably agree to an RTR on his own product. On the other, as evidenced by his words, he doesn't want to pay another patentee an RTR. Many formerly purely academic researchers are now in the same position thanks to the Bayh-Dole Act, which has effectively condensed the policy dispute in many cases.

Despite academic opposition to RTRs, universities themselves use them. One biotech executive said that "we often find ourselves walking away from licensing in tissue samples or other tools because the university . . . is insisting that if we ever develop a drug using the tool we have to pay a royalty,"¹¹⁶ which he claims usually runs from 1/2% to 3%.

IV. Conclusion

On balance, RTRs incentivize early-stage biotech inventors by providing them with the tools they need at a reasonable up-front cost.

112. *Supra* note 95.

113. Kowalski, *supra* note 1.

114. *Id.*

115. Freundlich, *supra* note 2 (quoting Professor Gerald Rubin of U.C. Berkeley).

116. *Id.* (quoting Millennium Pharmaceuticals' Chief Business Officer Steven Holtzman).

As with any general strategy, RTRs might not always fulfill their promise in specific situations. Overall, however, they fit well with current legal concepts, the US patent system, and our capitalist economy. They also support the national interest in encouraging further development of biotech.

It seems likely that RTRs will eventually be tested in court and perhaps some of the arguments discussed here will be used. As human knowledge expands and the production pipeline for biotech medicines grows longer and more complex, increased numbers of inventors will have their hands in the pie. The amount of money available at the end of the pipeline depends on many factors, but assuming the power of these medicines grows ever greater (“cure for cancer in 5 easy pills!”), there will be money, and claimants to it will soon follow.