California Western Law Review

Volume 59 | Issue 1 Article 6

2022

Existing Patent Laws Promote Competition and Lower Drug Prices, But Is This Appropriate for COVID-19 mRNA Vaccines?

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EXISTING PATENT LAWS PROMOTE COMPETITION AND LOWER DRUG PRICES, BUT IS THIS APPROPRIATE FOR COVID-19 MRNA VACCINES?

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INTRODUCTION

In 2004, Mylan Pharmaceuticals substantially raised the price of its life-saving product, EpiPen, from $100 to $600.[1] At that time, EpiPen had yearly sales over $1 billion and enjoyed close to a 90% market share in the United States.[2] This severe price hike was compounded by three important considerations. First, EpiPens (also referred to as "pens") are used by people who have severe allergies, who carry the pens with them for use in life-threatening situations.[3] Second, people who carry EpiPens must carry two pens with them at any given time because if they use one pen and do not receive emergency care within fifteen minutes, they will need to administer a second dose.[4] Third, EpiPens have a short shelf life: most dispensed EpiPen prescriptions expire within one year.[5] Even if a person receives a pen that has an expiration date of *more* than twelve months, if left unused during the shelf life, the pen will still need to be replaced.[6] Combined, these circumstances give the appearance that the pharmaceutical industry is willing to exploit consumers' EpiPen dependency to generate large profits.[7] In doing so, they place the brunt of the impact of their profit gains on consumers.[8]

As a brand name drug, EpiPen enjoys a period of patent protection in the market place, prohibiting generic alternatives of the product from entering the market.[9] However, once a brand name drug loses its exclusivity period in the market, generic pharmaceutical manufactur-

1. Micah Vitale, Note, *The Rise in Prescription Drug Prices: The Conspiracy Against the Cure*, 20 QUINNIPIAC HEALTH L.J. 75, 78 (2017).

2. *Id.*

3. Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES: SCI. (Aug. 22, 2006), https://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/?sh=5bed46fb280c.

4. *Id.*

5. *Id.*

6. *Id.*

7. Vitale, *supra* note 1, at 79.

8. *Id.*

9. Ezekiel Emanuel, *Don't Only Blame Mylan for $600 EpiPens*, FORTUNE INSIDERS (Sept. 8, 2016), https://insiders.fortune.com/dont-only-blame-mylan-for-600-epipens-6ad0065373e0 (noting Mylan's four EpiPen patents are protected for a period of exclusivity in the marketplace until the year 2025).

ers can enter the marketplace and compete with the brand name drug, offering a cheaper version of the same drug.[10] When multiple generic alternatives enter the market, it promotes competition and drives down drug prices, which in turn benefits consumers.[11]

The pharmaceutical sector has been recognized as "the most profitable industry" in the nation for more than thirty years.[12] Many pharmaceutical firms realize enormous profits from their brand-name, blockbuster drugs.[13] Because prescription drug prices are not government regulated, pharmaceutical firms may sell their drugs at any price they choose.[14] Although many believe brand-name drug companies justify the cost of their drug by their need to recover costs of research and development, this is not exactly the case.[15] In fact, in the

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10. *See generally* James Borchardt, Note, *Merck v. Integra: Sec. 271(e)(1) and the Common Law Research Exemption*, 32 J. CORP. L. 943, 946 (2007) (citing Intermedics, Inc., v. Ventrix, Inc., 775 F. Supp. 1269, 1277 (N.D. Cal. 1991)); Michael Sertic, Note, *Muddying the Waters: How the Supreme Court's Decision in Merck v. Integra Fails to Resolve Problems of Judicial Interpretation of 35 U.S.C. Sec. 271(e)(1), the 'Safe Harbor' Provision of the Hatch-Waxman Act*, 17 HEALTH MATRIX J.L. MED. 377, 384 (2007); Katherine A. Helm, Note, *Outsourcing the Fire of Genius: The Effects of Patent Infringement Jurisprudence on Pharmaceutical Drug Development*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 153, 175 (2006).

11. Vitale, *supra* note 1, at 79 (citing Ananya Mandal, *Drug Patents and Generic Pharmaceutical Drugs*, NEWS MED., http://www.news-medical.net/health/Drug-Patents-and-Generics.aspx (last updated Sept. 8, 2014)); *see also Generic Competition and Drug Prices*, FDA: CTR. FOR DRUG EVALUATION & RSCH., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last updated Nov. 28, 2017).

12. Vitale, *supra* note 1, at 88–89 (citing PUB. CITIZEN, CONGRESS WATCH, PHARMACUETICALS RANK AS MOST PROFITABLE INDUSTRY, AGAIN 1 (2002), http://www.citizen.org/sites/default/files/fortune500_2002report.pdf).

13. *Id.* at 76 (citing Marc-André Gagnon, *Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health*, 41 J.L. MED & ETHICS 571, 573–74 (2013)).

14. Vitale, *supra* note 1, at 77–78 (citing Hagop Kantarjian et al., *High Cancer Drug Prices in the United States: Reasons and Proposed Solutions*, 10 J. ONCOLOGY PRAC. 208, 209 (2014)).

15. *See* Emily M. Wessels, Note, *Changing Course to Navigate the Patent Safe Harbour Post-Momenta*, 98 MINN. L. REV. 1565, 1572 (2014); Nisarg A. Patel, *Fee-for-Value in the Pharmaceutical Industry: A Policy Framework Applying Data Science to Negotiate Drug Prices*, 4 J.L. & BIOSCIENCES 205, 206 (2017) ("[B]ecause of [a] lack of price transparency and the inability for many payers to negotiate,

United States' free market system, brand name drug companies "price [their] drugs at as high a price as the market will allow."[16] With costs ranging from the hundreds of millions to billions of dollars to bring a drug to market, pharmaceutical companies naturally seek patent protection for their inventions.[17] However, brand-name drug companies earn profits far exceeding the costs of innovation, and realize increased corporate profitability.[18] Admittedly, pharmaceutical companies reside within the for-profit industry, and it is not a crime to make substantial profits.[19] Recognizing that, where will society draw the line on drug makers' profits at the expense of their health and welfare?

The framers of the Constitution recognized the importance of protecting technological advancements in the sciences for limited periods to incentivize innovators to pursue new discoveries.[20] The patent system allows patent holders (hereinafter patentees) the right to exclude others from making, using, and selling their inventions.[21] This allows

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pharmaceutical manufacturers can charge whatever they please, setting exorbitant prices that defy normal market forces[.]").

16. Vitale, *supra* note 1, at 89–90 (citing Vaishali V. Shah, *Prescription Drugs in America: The Pain of Pricing Has an Unpromising Cure*, 2006 U. ILL. L. REV. 859, 866 (2006)).

17. *See* Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How To Achieve the Dual Objectives Of The Hatch-Waxman Act While Resolving Antitrust Issues In Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 482–83 (2008) (citing Henry H. Gu, Note, *The Hatch-Waxman Act and the Declaratory Judgment Action: Constitutional and Practical Implications*, 57 RUTGERS L. REV. 771, 798 (2005)); PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2006, 2 (Mar. 2006), http://plg-group.com/wp-content/uploads/2014/03/Pharmaceutical-Profile-2006-Phrma.pdf; *Post-approval R&D Raises Total Drug Development Costs to $897 Million*, TUFTS CTR. STUDY DRUG DEV. IMPACT REP., 3, (May–June 2003), https://tufts.app.box.com/s/ksmp2rdtulp6uedujnx1trgi62labuwl/file/481674410998.

18. *See* Wessels, *supra* note 15, at 1584–85 (citing Adi Gillat, *Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry*, 58 FOOD & DRUG L.J. 711, 715–16 (2003)); Alexandra E. Blasi, *An Ethical Dilemma: Patents & Profits v. Access & Affordability*, 33 J. LEGAL MED. 115, 120 (2012).

19. Blasi, *supra* note 18, at 120.

20. U.S. CONST. art. I, § 8, cl. 8 ("To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.").

21. 35 U.S.C. § 154(a)(1); *see* Michael A. Greene, Note, *All Your Base Are Belong to Us: Towards an Appropriate Usage and Definition of the "Entire Market*

patentees to reap the significant financial benefits of monopolizing the market, and these benefits function as an incentive for their contributions.[22] Patent laws provide patentees the exclusive right to exclude others for a term of twenty years.[23] Therefore, long patent terms can realize large profits, enticing competition from other drug makers that are allured by patentees' financial gains in their prospective market area.[24]

Case law from both the Supreme Court and the Federal Circuit show that existing patent laws permit generic pharmaceutical companies to make strategic decisions to engage in infringing behavior.[25] Existing patent laws surrounding remedies for infringement allow pharmaceutical companies to adopt an "act first, ask for forgiveness later" approach to employ infringing activities as a business model. In many ways, this approach benefits society by providing generic alternatives at lower costs for consumers. However, in specialized areas of pharmaceutical innovation, such as mRNA COVID-19 vaccine production, this Comment will demonstrate how legitimized infringement can harm society in times when we are the most vulnerable.

Part I of this Comment discusses patent laws that impact infringement within the pharmaceutical industry. Part II looks at the methods used to determine damages for patent infringement suits. It will also demonstrate how varying judicial decisions create unpredictable outcomes in infringement litigation suits. Part III then considers how the lack of guidance from the courts allow pharmaceutical companies to implement deliberate patent infringement into their business models. Part IV weighs the benefits and drawbacks of deliberate patent infringement in the pharmaceutical industry. This Comment will conclude by arguing that, although deliberate patent infringement generally benefits society by decreasing costs and increasing drug

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Value" Rule in Reasonable Royalties Calculations, 53 B.C. L. REV. 233, 235–36 (2012) (citing U.S. CONST. art. I, § 8, cl. 8).

22. *Id.*

23. 35 U.S.C. § 154(a)(2).

24. *See* Bloomberg News, *Ruling Upholds Eli Lilly's Patent on Drug*, N.Y. TIMES (Dec. 27, 2006), https://www.nytimes.com/2006/12/27/business/27zyprexa.html (discussing two drug companies with proposed alternatives to Eli Lilly's Zyprexa that had asked a judge to invalidate Eli Lilly's patent on Zyprexa, which had brought in $4.2 billion in 2005; however, the Federal Circuit upheld the patent on Zyprexa).

25. *See* discussion *infra* Parts III, IV.

treatment availability, in the context of specialized pharmaceutical products like mRNA COVID-19 vaccines, infringing activities ultimately do more harm than good.

I. CURRENT PATENT LAWS THAT IMPACT THE PHARMACEUTICAL REALM

A strong patent system is fundamental to promoting scientific and technological advances across industries such as pharmaceutical research, drug development, biotechnology, and medical technology.[26] Patent protection fosters growth among investors, manufacturers, shippers, and suppliers, creates jobs, and stimulates the economy.[27] Brand-name drug makers have harnessed their scientific discoveries and turned their blockbuster drugs into revenues reaching into the billions.[28] Furthermore, patenting these discoveries and intangible assets create a great amount of value for pharmaceutical companies and their investors.[29] Overall, society as a whole benefits when drug companies patent their products. Not only do patents provide a blueprint of how to recreate a product, they lead to more drug discoveries and innovation.[30]

In spite of these benefits, there remains unsolved tension between the patent system's dual purposes: (1) incentivizing innovation, and (2) compensating those who distribute that information in the public domain.[31] There is high entrepreneurial value in rewarding patentees for their discoveries: inventors can realize profits for their inventions and can use resources to develop new technologies and bring them to market.[32] There is also high societal value in public disclosure of pa-

26. Helm, *supra* note 10, at 157.

27. *Id.* at 158.

28. *See id.* at 157; Patel, *supra* note 15, at 206 ("From 2009 to 2015, 30 medicines with sales of $1 billion or more per year underwent price increases of over double the rate of inflation as measured by the consumer price index, even when estimated discounts negotiated by health insurers and pharmacy benefit managers were taken into account.").

29. Helm, *supra* note 10, at 157 (citing Lesley Craig & Lindsay Moore, *Intangible Assets, Intellectual Capital or Property? It Does Make a Difference*, FRONT RANGE TECH BIZ (Feb. 3, 2002), http://www.klminc.com/articles/frt_feb02.html).

30. *See id.* at 160.

31. *Id.*

32. *See* Helm, *supra* note 10, at 160–61.

tented technologies that allows other inventors to build on the prior art and foster development.[33] While the dual benefits of the patent system can help society in the short term by lowering drug prices, these benefits are greatest among small molecule or chemically derived drugs. By contrast, for highly specialized pharmaceutical products, like mRNA COVID-19 vaccines, third party pharmaceutical firms that attempt to replicate these vaccines hinder our long-term progress by impeding vaccine production and distribution.

This section discusses some of the current patent laws that act within the dual purposes of the patent system. Subsection A discusses the Hatch-Waxman Act and highlights how existing patent laws encourage patent infringement among pharmaceutical companies. Subsection B details the compulsory licensing provisions in the United States Code ("U.S.C.") and takes a brief look at a time where compulsory licensing was contemplated in the Nation's history. Subsection C then discuss the Defense Production Act and how it has been utilized in response to the Coronavirus pandemic. Both compulsory licensing laws and the Defense Production Act have been contemplated in the wake of the ongoing Coronavirus pandemic.[34] These laws permit the Nation's leaders to react and respond in times of urgent need.[35] Understanding how these laws have and may be used in the future is important in understanding how dangerous they can be when employed in very specialized fields of innovation such as mRNA vaccines.

A. Hatch-Waxman Act of 1984 and the Common Law Research Exemption

Before the enactment of the Hatch-Waxman Act of 1984, there were virtually no generic drugs competing with brand name drugs in the marketplace.[36] Even after a brand name drug's patent expired, the brand name medication retained a market monopoly for years.[37] Due

33. *Id.* at 160.

34. Keith McWha, *Compulsory Licensing and March-in Rights in COVID-19 Vaccine Production*, LAW.COM: N.J. L.J. (Sept. 29, 2021, 11:00 AM), https://www.law.com/njlawjournal/2021/09/29/compulsory-licensing-and-march-in-rights-in-covid-19-vaccine-production/?slreturn=20211128172916.

35. *See* discussion *infra* Part II.B–C.

36. Liu, *supra* note 17, at 455.

37. *Id.*

to the high costs associated with engineering drugs and the long Food and Drug Administration (FDA) approval process, generic drug companies did not seek approval to market brand name alternatives.[38]

For over two centuries, courts have recognized a judicially created research exemption from patent infringement.[39] In its simplest terms, the research exemption provides that using a patented invention is not an act of infringement if the use is only for the purpose of experimentation for research purposes.[40] This early common law research exemption allowed patented inventions to be used under certain circumstances, without the patentee's consent, so long as the use of the invention did not garner an accused infringer any profits.[41] Therefore, the use of a patented invention was not permitted in situations where such use would further the user's legitimate business.[42] The existing patent law and research exemptions to patent infringement endeavored to find a middle ground.[43] In allowing researchers to use patented inventions in their research without threat of legal action for patent infringement, scientists were granted the opportunity to further progress by building off of another's patented technology.[44] This arm of the patent system is what helped society, in general, advance.

The benefits of common law research exemptions from patent infringement liability and the strong economic considerations in providing greater access and affordability to pharmaceutical consumers were clear. Accordingly, Congress enacted the Hatch-Waxman Act of 1984.[45] Section 271(e)(1) of the Act lays out the congressional grant of the "safe harbor" research exemption:

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38. *Id.*

39. Borchardt, *supra* note 10, at 944 (discussing the origin of the common law research exemption from patent infringement).

40. *Id.*

41. *Id.*

42. *Id.*

43. Helm, *supra* note 10, at 165 (citing 35 U.S.C. § 271(e)(1)).

44. Borchardt, *supra* note 10, at 948 (citing Rebecca Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–46 (1989)).

45. *See generally id.*; *see also* Liu, *supra* note 17, at 443 (citing *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98–417, 98 Stat. 1585 (1984)).

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .[46]

Through this Act, Congress sought to benefit the public. The Act enabled generic drug companies to capitalize on the research and development of patent protected brand name drugs and bring their own generic alternatives to market as soon as the patent term expired.[47]

Under the Hatch-Waxman Act, generic drug companies are permitted to use the patented drug's specification as a reference to generate the data required to submit to the FDA for regulatory approval without the threat of liability for patent infringement.[48] This includes permitting a generic drug maker to use the brand name drug company's original safety and efficacy data in their new drug application (NDA), thus saving them years of time researching and wading through the regulatory process.[49] Included in this abbreviated approval process, generic drug makers must prove their generic drug is bioequivalent to the brand name drug.[50] Bioequivalency is proven by showing, among other requirements, that the generic drug will deliver

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46. 35 U.S.C. § 271(e)(1).

47. *See* Borchardt, *supra* note 10, at 946.

48. *See* Liu, *supra* note 17, at 443 (citing FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY II, 3–5 (2002) [hereinafter *FTC Study*], https://www.ftc.gov/os/2002/07/genericdrugstudy.pdf); Borchardt, *supra* note 10, at 946 (citing Eli Lilly & Co., v. Medtronic, Inc., 496 U.S. 661, 671 (1990)).

49. Liu, *supra* note 17, at 443 (citing *FTC Study*); *see also* Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B, 297, 298 (2013) (discussing how generic drug manufacturers were subjected to a costly and lengthy approval under the Food, Drug, and Cosmetic Act (FD&C Act), the predecessor to the Hatch-Waxman Act).

50. Generic manufacturers must show the generic is bioequivalent for the brand name it intends to substitute. This includes a showing that the generic performs equivalently to the brand name, the production process meets the same requirements for "identity, strength, purity, and quality" "under the FDA's good manufacturing practice regulations." *See* U.S. FOOD & DRUG ADMIN., MANUAL OF POLICIES AND PROCEDURES: FILING REVIEW OF ABBREVIATED NEW DRUG APPLICATIONS (2017); s*ee also* Sertic, *supra* note 10, at 385–86.

the same active ingredients to the recipient's bloodstream over the same amount of time and in the same concentration as the brand name drug.[51]

To be granted approval and enter the market as soon as the brand name patent expires, the generic drug company must file an Abbreviated New Drug Application (ANDA) with the FDA before the brand name drug's patent expires.[52] In addition to filing an ANDA, the generic drug company must file a certification based on one of four grounds for each patent claiming the brand name drug.[53] Under what is commonly known as "paragraph IV certification," the generic drug manufacturer asserts the patent claiming the brand name drug is invalid or, alternatively, that the manufacture, use, or sale of the generic drug will not infringe the brand name, patented drug.[54] The application of an ANDA utilizing certification under paragraph IV of the Hatch-Waxman Act typically results in patent infringement litigation[55] because in submitting this application, the generic drug company seeks FDA approval to market a drug before the brand name drug's patent expires.[56] Under paragraph IV certification, the generic drug maker asserts that their alternative drug product should be permitted to enter the market in view of the patented drug.[57] Brand name drug companies then have a forty-five day window to file a complaint against the generic drug maker for infringement.[58] When infringe-

51. Sertic, *supra* note 10, at 385–86

52. *See* Liu, *supra* note 17, at 448 (citing 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.53(f) (2004); 21 U.S.C. § 355(j)(2)(A)(vii)) (The Hatch-Waxman Act provides four separate certifications: "(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new [generic] drug" seeking approval.); Sertic, *supra* note 10, at 386.

53. Liu, *supra* note 17, at 448–49.

54. *Id.*

55. *Id.* (citing 35 U.S.C. § 271(e)(2)(2003); Jacob S. Wharton, *"Orange Book" Listing of Patents Under the Hatch-Waxman Act*, 47 ST. LOUIS U. L.J. 1027, 1033–34 (2003)).

56. *Id.*

57. *Id.*

58. Liu, *supra* note 17, at 448–49 (21 U.S.C.A. § 355(j)(5)(B)(iii); Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1342 (Fed. Cir. 2007)).

ment litigation arises, the generic drug maker can challenge the validity of the brand name drug's patent and attempt to determine rights regarding infringement claims.[59]

Under the Hatch-Waxman Act, the first generic drug company to file an ANDA—proving either invalidity or non-infringement—is awarded a 180-day period of exclusivity.[60] This bars other generic drug manufacturers from selling within that timeframe, and awards the first filer a chance to gain a large share of profits in the brand name drug's market.[61] The Hatch-Waxman Act paved the way for generic drug manufacturers to capitalize on the success that brand name drug manufacturers cultivated, and ushered in a new era of generic alternatives.[62] The Act ultimately benefits society by decreasing costs and increasing drug accessibility through encouraged competition among generic drug manufacturers once a brand name drug's patent term expires.[63]

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59. *Id.*

60. Liu, *supra* note 17, at 449–50 (citing 21 U.S.C. § 355(j)(5)(B)(iv); Reid F. Herlihy, Note, *The Federal Circuit's Interpretation of the Hatch-Waxman Act: Allowing Generics to Induce Infringement*, 15 FED. CIR. B.J. 119, 136 (2005); Sarah M. Yoho, *Note, Reformation of the Hatch-Waxman Act, an Unnecessary Resolution*, 27 NOVA L. REV. 527, 534–35 (2002); *Teva Pharms. USA, Inc.*, 482 F.3d at 1342).

61. *Id.*

62. The Hatch-Waxman Act required that the FDA publish what is known as the "Orange Book," which lists approved brand name drugs and their therapeutic equivalents, or generics. The Orange Book aided prescribers to substitute brand name drugs for generic alternatives. It also included patent exclusivity information for brand name drug patents in force. This provided an opportunity for generic drug companies to observe the market and select brand name, blockbuster drugs to manufacture generic alternatives. Generic drug companies knew getting approved as the first generic alternative meant they would attract relatively high prices and capture a majority of the generic market share while generics that entered the market later would realize lower profits. Although an ANDA filing was a gamble in terms of the possibility of being adjudged an infringer and ordered to pay damages, it was a huge incentive for generic drug makers to enjoy a market duopoly with the brand name drug and realize enormous profits. Prior to the passage of the Hatch-Waxman Act, generic alternatives represented 13% of marketplace; by 2012, generics represented 84% of all dispensed prescription drugs. *See* Liu, *supra* note 17, at 450; Boehm, *supra* note 49, at 298–99.

63. As generic drug manufacturers do not incur the high costs brand name drug companies expend in lengthy clinical trials and safety studies required to generate the necessary data for FDA approval, generic drugs can be offered at much cheaper alternatives to brand name drugs. *See* Liu, *supra* note 17, at 447; *see also*

In 2005, patent infringement litigation centered around the common law research exemption and the statutory research exemption when *Merck KGaA v. Integra Lifesciences I, Ltd.* reached the Supreme Court.[64] Integra owned five patents for short peptides known as RGD peptides.[65] The company sued drug maker, Merck, and Dr. Cheresh, who were researching the anti-angiogenic properties of various RGD peptides.[66] Together, their goal was to reach FDA application for a new drug candidate.[67] The Court considered whether use of patented inventions in preclinical research where results of the research are not included in an FDA application are nonetheless exempted from infringement by 35 U.S.C. § 271(e)(1).[68] The Court held the infringement exemption extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the Food, Drug, and Cosmetics Act, applying a broad view of the research exemption.[69] Moreover, so long as there is a reasonable basis for believing that research experiments will produce relevant information for investigational new drug applications (INDs) or NDAs, use of patented compounds in preclinical studies is exempt from infringement.[70] Thus, the Hatch-Waxman Act paved the way for small molecule, chemically derived, generic pharmaceuticals to enter the market.[71] It also provided the statutory exemption for using patented inventions in research.

Borchardt, *supra* note 10, at 946 ("According to the legislative history, the Act containing § 271(e)(1) was intended to benefit the public by increasing access to and lowering costs of generic drugs while limiting the disincentive effects of these measures[.]").

64. *See, e.g.*, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 200 (2005) (acknowledging the district court concluded that Merck's "pre-1995 actions . . . were protected by the common-law research exemption").

65. Borchardt, *supra* note 10, at 948–49 (citing Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 862 (Fed. Cir. 2003), *vacated and remanded*, 545 U.S. 193 (2005)).

66. *Merck KGaA*, 545 U.S. at 198–200.

67. *Id.*

68. *Id.* at 195.

69. *Id.* at 202.

70. *Id.* at 208.

71. *See Differences between Biologics and Small Molecules*, UCL THERAPUTIC INNOVATION NETWORKS, https://www.ucl.ac.uk/therapeutic-innovation-networks/differences-between-biologics-and-small-molecules (last visited Jan. 3, 2022) (de-

B. Compulsory Licensing

The Constitution provides that private property shall not "be taken for public use, without just compensation."[72] This provision recognizes the important public good that can come from fairly compensating for patented inventions, while balancing the burdens placed on inventors seeking to build on prior art. Congress recognized that bebecause valuable inventions serve such a high public good, the need to carve out an exception for the use of the invention without authorization may be justified. Thus, Congress delineated the action and remedy for patentees when the government uses their patented invention without authorization.[73]

When a patented invention is used or manufactured by or for the United States without a license, the reasonable and entire compensation for use of the patented invention is the patentee's remedy.[74] The United States may use the compulsory licensing power to take privately owned patented inventions to serve the public.[75] However, this power is only used under extreme conditions, such as when the patented invention meets vital public health needs, in national emergency, or when there are strong societal interests in accessibility to the invention.[76] Yet, the United States has declined to invoke its power to grant compulsory licenses in the past.[77]

Under the compulsory license provisions, the government can force a brand name drug maker to grant a license to a generic manufacturer to produce a drug for the United States.[78] Alternatively, the

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scribing how most drugs on the market are small molecule compounds that are produced by chemical synthesis).

72. U.S. CONST. amend. V, § 5.

73. *See* 28 U.S.C. § 1498(a).

74. *Id.*

75. JOHN R. THOMAS, CONG. RSCH. SERV., R43266, COMPULSORY LICENSING OF PATENTED INVENTIONS 1, 3–8 (2014) (citing Katharine W. Sands., *Prescription Drugs: India Values Their Compulsory Licensing Provision – Should the United States Follow in India's Footsteps?*, 29 HOUSTON L. J. 191 (2006)).

76. *Id.* at 9.

77. *Id.* at 6.

78. Lauren Keller, *Ciprofloxacin and Compulsory Licensing of Pharmaceutical Patents (2002 Third Year Paper)*, DIGIT. ACCESS TO SCHOLARSHIP AT HARV. 2 (Apr. 23, 2002), https://dash.harvard.edu/bitstream/handle/1/8852122/Keller.pdf?sequence=1&isAllowed=y; 28 U.S.C. § 1498(a).

government can use its power under the compulsory license provisions to force a brand name drug maker to produce more of a drug than it originally desired.[79] This may cause a drug maker to make more of a drug at a less profitable rate and can force a drug maker to buy more raw materials and supplies, or use its manufacturing capacity past the point of profitability, causing the company to lose money.[80]

In 2001, the government threatened to use its power under the compulsory licensing provisions on Bayer Pharmaceuticals to stockpile a patent-protected medication, Cipro (ciprofloxacin), in response to the Anthrax biological terrorism threat.[81] Fears of potential shortages put pressure on lawmakers to use the provision to contract with generic manufacturers to produce ciprofloxacin to increase supplies of the drug.[82] Although ciprofloxacin is not the only drug to treat Anthrax, it is a first line drug of choice to treat the virus.[83] Government officials eventually reached an agreement with Bayer and decided against a compulsory license of the drug.[84] The agreement provided that Bayer would produce several hundred million tablets of Cipro for the United States at a rate of seventy-five to ninety-five cents per tablet.[85] At that time, the retail price of Cipro was $5.32 per tablet,[86] equating to a roughly eighty-six percent discount per unit that Bayer had to absorb.

C. Defense Production Act

The Defense Production Act is an authority used to support homeland security, under the direction of the President.[87] Pursuant to presidential authorization, the Defense Production Act expedites and ex-

79. *See id.* at 3.

80. *See id.*

81. *Id.* at 2.

82. *Id.*

83. *Antibiotics to Prevent Anthrax After Exposure, Anthrax*, CDC, https://www.cdc.gov/anthrax/prevention/antibiotics/index.html (last reviewed Nov. 20, 2020).

84. Keller, *supra* note 78, at 3.

85. *Id.*

86. *Id.*

87. *Defense Production Act*, FEMA, https://www.fema.gov/disaster/defense-production-act (last updated Nov. 19, 2021).

pands supplies of materials and services from the industry sector to promote national defense.[88] On March 2, 2021, President Biden triggered the Defense Production Act to expand production of Johnson & Johnson's COVID-19 vaccine using Merck's prescription drug manufacturing facilities.[89] The Executive Order directed "immediate actions to secure supplies necessary for responding to the pandemic, so that those supplies are available, and remain available, to the Federal Government . . . as well as to America's health care workers, health systems, and patients."[90] The move came after Johnson & Johnson (J&J) experienced difficulties producing its vaccine during the COVID-19 pandemic.[91]

In response, the United States Department of Health and Human Services collaborated with Merck to adapt Merck's facilities to allow "rapid large-scale manufacturing of vaccines" to boost the J&J vaccine supply.[92] In addition to allowing J&J to use its facilities, Merck also used some of its facilities to produce the J&J vaccine itself.[93] Although the Order facilitated increased production of J&J's patented vaccine by permitting Merck to manufacture it,[94] that result did not come without its drawbacks.

In March 2021, a third-party firm, Emergent BioSolutions, announced it would begin manufacturing J&J's COVID-19 vaccine at its Baltimore, Maryland, facilities.[95] Emergent produced drug substance for J&J as part of the vaccine supply chain.[96] The drug substance—

88. *Id.*

89. *Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines*, U.S. DEP'T. OF HEALTH & HUMAN SERVS.: NEWS (Mar. 2, 2021), https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html [hereinafter *Historic Manufacturing Collaboration*].

90. Exec. Order No. 14,001, 86 Fed. Reg. 7,219 (Jan. 26, 2021).

91. *Historic Manufacturing Collaboration*, *supra* note 89.

92. *Id.*

93. *Id.*

94. *Id.*

95. *Emergent BioSolutions Statement on Johnson & Johnson's Collaboration with Merck*, EMERGENT BIOSOLUTIONS (Mar. 3, 2021), https://www.emergentbiosolutions.com/story/emergent-biosolutions-statement-johnson-johnsons-collaboration-merck.

96. *Id.*

which is the active pharmaceutical ingredient of the vaccine—was produced at Emergent's facility. It was then shipped to others in the supply chain for filling and finishing in preparation of distributing the vaccine.[97]

Workers at Emergent's Baltimore facilities mixed up ingredients meant for AstraZeneca's COVID-19 vaccine with the J&J COVID-19 vaccine; however, the ingredients were not interchangeable.[98] The error contaminated fifteen million doses of the J&J vaccine, and halted the facility's production of both vaccines while the FDA investigated.[99] Quality control verifications of the vaccine indicated that a batch of drug substance failed to meet quality standards.[100] Although none of the doses made at Emergent's facilities had been authorized for use in the United States, the impact of the mix up was felt worldwide.[101] Millions of doses had been shipped across the globe, and regulatory agencies in the recipient countries had to ensure their doses were safe for use.[102]

The Emergent BioSolutions vaccine mixup illustrates the complexity of vaccine production and the expertise required to produce mRNA vaccines.[103] In an already strapped COVID-19 vaccine production scheme, where raw materials and mRNA vaccine manufacturing know-how strains vaccine production,[104] the error wasted valuable

97. *Id.*

98. Sharon LaFraniere & Noah Weiland, *Johnson & Johnson's Vaccine is Delayed by a U.S. Factory Mixup*, N.Y. TIMES: THE CORONAVIRUS PANDEMIC (Mar. 31, 2021), https://www.nytimes.com/2021/03/31/world/johnson-and-johnson-vaccine-mixup.html.

99. *Id.*

100. Jen Christensen, *Quality Issue at Baltimore Vaccine Plant Delays Some of Johnson & Johnson's Vaccine*, CNN (Mar. 31, 2021, 10:19 PM), https://www.cnn.com/2021/03/31/health/johnson—johnson-vaccine-manufacturing-problem/index.html.

101. Chris Hamby et al., *Baltimore Vaccine Plant's Troubles Ripple Across 3 Continents*, N.Y. TIMES: THE CORONAVIRUS PANDEMIC (May 6, 2021), https://www.nytimes.com/2021/05/06/world/baltimore-vaccine-countries.html.

102. *Id.*

103. *See* Amy Maxmen, *The Fight to Manufacture COVID Vaccines in Lower-Income Countries*, NATURE, Sept. 23, 2021, at 455–57.

104. Raisa Santos & Elaine Ruth Fletcher, *Moderna Makes Milestone Pledge To "Not Enforce Our Patents" On COVID-19 Vaccine Technologies During Pandemic & Issue Open Licenses Afterward*, HEALTH POL'Y WATCH (Aug. 10, 2020), https://healthpolicy-watch.news/77521-2/.

resources. This shows that even experienced drug makers may lack the knowledge and experience required to make COVID-19 vaccines.[105] In fact, Pfizer CEO Albert Bourla says it could take "years" for many companies to attain the knowledge and capabilities needed to produce mRNA COVID-19 vaccines.[106]

Although, in theory, authorizing another manufacturer to make COVID-19 vaccines could help reach populations other countries could not reach,[107] it may not actually alleviate the production issues surrounding vaccine manufacturing. Allowing pharmaceutical companies that lack the manufacturing capacity or expertise to produce COVID-19 vaccines to insert themselves in the vaccine production space can interrupt the supply chain and cause raw material shortages and delays.[108] In fields such as specialized mRNA COVID-19 vaccines, using the Defense Production Act to put vital supplies in the hand of those less able can prove counter-productive, even deadly.[109]

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105. *See generally* Maxmen, *supra* note 103, at 456–57.

106. *Id.*

107. Claire Klobucista, *A Guide to Global COVID-19 Vaccine Efforts,* COUNCIL ON FOREIGN RELS., https://www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts (last updated July 19, 2022, 2:35 PM).

108. Maxmen, *supra* note 103, at 457.

109. "Individuals fully vaccinated" is defined as receiving two doses of Pfizer's mRNA vaccine, twenty-one days apart, and seven days after the second dose. A "COVID-19 infection" is defined as positive COVID-19 PCR test from any sample and in any clinical setting. It is estimated that there have been more than 187 million confirmed cases of COVID-19 worldwide and more than 4 million deaths due to COVID-19. The Pfizer mRNA COVID-19 vaccine confers protection against COVID-19 infection in fully vaccinated individuals at a rate of 91.1% (95% Confidence Interval ("CI") 89.0 to 93.2). This represents an efficacy of 86 to 100% in populations across the globe with diverse characteristics and risk factors for COVID-19. Both statistics include individuals with no evidence of prior COVID-19 infection. The vaccine effectiveness was 96.7% (95% CI 80.3 to 99.9) against severe disease, including death. Even despite a gradual decline in vaccine efficacy (vaccine efficacy declined to 83.7% from 4 months after the second dose to the study period cut-off (95% CI 74.7 to 89.9)), Pfizer's mRNA COVID-19 vaccine remained effective against infection with COVID-19 variants. *See* Stephen J. Thomas, et al., *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months*, 385 NEW ENG. J. MED. 1761–73 (2021).

The Johnson & Johnson COVID-19 vaccine was 66.1% (adjusted 95% CI 59.0 to 73.4) effective in preventing COVID-19 infection in individuals who received the vaccine and had no evidence of a previous COVID-19 infection. The Johnson & Johnson COVID-19 vaccine was 85.4% (adjusted CI 54.2 to 96.9) effective against

The safest, most effective way to scale up vaccine production, according to Bourla, "is to do it in-house," concentrating raw materials, supplies, and products at the source, where competent, quality controlled vaccines can be made.[110] Thus, in the area of specialized mRNA COVID-19 vaccines, patent infringement will not benefit society, but rather, will hamper the process of getting critical vaccines to patients across the globe and harm society's interests in the long term.

Although the Defense Production Act can help support homeland security by mobilizing resources in critical times of need, it is a powerful tool that can have unexpected and unintended consequences.

II. DETERMINING DAMAGES IN PATENT INFRINGEMENT LITIGATION

Existing patent laws permit pharmaceutical companies to adopt the "act now, ask for forgiveness later" approach to business decisions regarding infringing activities. This is shown in several examples of the court's handling of the following methods used to determine damages and remedies for patent infringement. Subsection A discusses methods used to determine reasonable royalties in patent infringement suits. Subsection B then discusses the principle of apportionment, used in multi-component products in patent infringement cases. Subsection C reviews enhanced damages and demonstrates how the Supreme Court grants discretion to district courts in awarding enhanced damages under existing patent laws. Finally, subsection D discusses the grant of discretion to district courts in the decision to award injunctions in infringement suits.

Each of the methods discussed in this section reference different factors used for determining damages. These discrepancies lead to

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severe-critical COVID-19 infection, including death, in individuals who were tested 28 days after receiving Johnson & Johnson's single dose COVID-19 vaccine. *See* Jerald Sadoff et al., *Safety and Efficacy of Single Dose Ad26.COV2.S Vaccine against Covid-19*, 384 NEW ENG. J. MED. 2187–2201 (2021).

When pharmaceutical companies attempt to make generic versions of mRNA COVID-19 vaccines, the chance of producing compromised vaccine doses may be higher than if the brand name vaccine maker produced them. Like the Emergent BioSolutions example, where contaminated vaccine products ruined 15 million doses of Johnson & Johnson's vaccine, issues with vaccine production in third party pharmaceutical firms may very well lead to death in individuals who are unable to receive the life-saving vaccine. *See* Christensen, *supra* note 100.

110. Maxmen, *supra* note 103, at 457.

unpredictable results. When coupled with discretionary judicial decision making, these methods for determining patent infringement remedies have resulted in pharmaceutical companies' adoption of an "act now, ask for forgiveness later" approach to infringing activities. The courts' wide discretion to grant remedies in patent infringement suits have evolved into an implicit permission for pharmaceutical companies to employ infringement activities as business decisions. Admittedly, generic pharmaceutical companies' patent infringement activities serve society's interests in the short term, by providing lower cost, generic alternatives to brand-name drugs. However, patent infringement in highly technical areas of the pharmaceutical sector, like mRNA COVID-19 vaccines, will ultimately harm society in the long term.

A. Reasonable Royalty

Section 284 of the Patent Act provides for monetary damages and a reasonable royalty to compensate patentees for an infringer's use of a patented product.[111] The statute requires a damages award notwithstanding a jury's determination of damages.[112] Compensation may be determined by proving "lost profits, a reasonable royalty, or a combination" of both methods.[113]

To obtain damages for lost profits owing to the infringement, a patentee must show: (1) market demand for their patented product; (2) absence of acceptable, non-infringing alternatives to satisfy market demand; (3) the patentee's manufacturing and marketing ability to capitalize on the demand; and (4) the profits the patentee would have gained but for the infringing product's availability in the market.[114] Patentees who fail to meet all prongs of the test are entitled to recover only a reasonable royalty.[115] A reasonable royalty is the amount a person desiring to manufacture and sell a patented product would be

111. 35 U.S.C. § 284.

112. *Id.*

113. Brian J. Love, *The Misuse of Reasonable Royalty Damages as a Patent Infringement Deterrent*, 74 MO. L. REV. 909, 912 (2009) (citing Minco, Inc. v. Combustion Eng'g, Inc., 95 F.3d 1109, 1119 (Fed. Cir. 1996)).

114. *See* Panduit Corp. v. Stahlin Bros. Fibre Works, 575 F.2d 1152, 1156 (6th Cir. 1978); Love, *supra* note 113, at 913.

115. *See generally* 35 U.S.C. § 284; *Panduit Corp.*, 575 F.2d at 1157.

willing to pay to produce and sell the patented item.[116] Under these subjective circumstances, courts construct hypothetical negotiations to arrive at a royalty amount that would have been agreeable to the involved parties prior to the initial act of infringement.[117]

In *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, the court established a fifteen-factor test to guide its analysis of the hypothetical negotiation; these factors are still being applied, some forty years later.[118] Among the factors are inquiries into items such as: comparable licenses, objective properties of hypothetical licenses, bargaining positions of the parties, licensing policy of the patentee, benefits of the patented product, market value of the product, impact on infringer's profits, expert testimony, and the economic impact on what the parties would have agreed upon before infringement began.[119] The *Georgia-Pacific* factors contain both reinforcing and contradicting effects, resulting in unpredictable royalty awards. Demand for carefully constructed testimony supported by the particular facts of the case is required for reasonable royalty analyses.[120] However, good advocacy and adequate evidentiary proof can tip the scales heavily in either direction.[121]

Other standards used to determine the royalty rate have since fallen out of favor. In *Uniloc USA, Inc. v. Microsoft Corp.*, the court abolished the "twenty-five percent rule" as an "abstract and largely

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116. *Panduit Corp.*, 575 F.2d at 1157–58 (quoting Goodyear Tire and Rubber Co. v. Overman Cushion Tire Co., 95 F.2d 978, 984 (6th Cir. 1937)).

117. Love, *supra* note 113, at 914. *See also* Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1121–22 (S.D.N.Y. 1970).

118. *See* Axel Schmitt-Nelson, Article, *The Unpredictability of Patent Litigation Damage Awards: Causes and Comparative Notes*, 3 AM. U. INTELL. PROP. BRIEF 53, 55 (2012); *Georgia-Pacific Corp.*, 318 F. Supp. at 1120.

119. *See* Schmitt-Nelson, *supra* note 118, at 55–56; *Georgia-Pacific Corp.*, 318 F. Supp. at 1120.

120. *See* Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1317 (Fed. Cir. 2011) (stating the expert testimony regarding the damages calculations "must carefully tie proof of damages to the claimed invention's footprint in the marketplace" under the *Georgia-Pacific* factors, which frame the reasonable royalty inquiry).

121. *See* Schmitt-Nelson, *supra* note 118, at 56–57; Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1335 (Fed. Cir. 2009) (recognizing some factors seem to offset each other and juries could have reasonably concluded otherwise regarding several factors).

theoretical construct."[122] This rule conferred to the patentee twenty-five percent of the value of the accused product.[123] The court reasoned "[the twenty-five percent rule] is a fundamentally flawed tool for determining a baseline royalty rate in a hypothetical negotiation," because "it fails to tie a reasonable royalty base to the facts of the case."[124] The court noted the patentee bears the burden of proving damages in infringement suits; to meet that burden, the patentee's proffered expert testimony regarding damages must sufficiently relate to the facts of the case.[125] Moreover, under the *Georgia-Pacific* factors, evidence "must be tied to the relevant facts and circumstances of the particular case at issue and the hypothetical negotiations that would have taken place in light of those facts and circumstances at the relevant time."[126]

The reasonable royalty standard held firm in *Integra Lifesciences I, Ltd. v. Merck KGaA* (the "Integra Action"). There, on remand from the Federal Circuit, the district court was ordered to calculate a reasonable royalty supported by the record.[127] The jury had initially awarded Integra $15 million in damages against Merck for infringement of its RGD peptides.[128] However, the Federal Circuit found insufficient evidence to support that amount.[129] In response, the district court considered a hypothetical negotiation between the parties and analyzed the record for evidence of "sound economic and factual predicates."[130] The record supported that as of August 1994, Telios (Integra) was amenable to a licensing agreement with Merck for $1.5

122. *Lucent Techs.*, Inc., 580 F.3d at 1317.

123. James Young Hurt, *Reasonable Royalty for Patent Infringement of Non-Direct Revenue Producing Products*, 56 IDEA 211, 234 (2016) (citing *Uniloc USA, Inc.*, 632 F.3d at 1318).

124. *Id.* (quoting *Uniloc USA, Inc.*, 632 F.3d at 1315).

125. *Id.*

126. *Uniloc USA, Inc.*, 632 F.3d at 1318.

127. Integra Lifesciences I, Ltd. v. Merck KGaA, No. 96CV1307-B, 2004 U.S. Dist. LEXIS 20725, at *4 (S.D. Cal. Sept. 7, 2004) *vacated and remanded*, 545 U.S 193 (2005), *rev'd*, 496 F.3d 1334 (Fed. Cir. 2007).

128. *Id.* at *10–11.

129. *Id.* at *11.

130. *Id.* at *13 (quoting Riles v. Shell Exploration & Prod. Co., 298 F.3d 1302, 1311 (Fed. Cir. 2002) (citations omitted)).

million per year.[131] After determining the infringement period was fifty-one months, the court calculated a reasonable royalty of $6.375 million[132] for Integra's RGD patents.[133] It would seem the nearly fifty-eight percent decrease in the damages award was likely far more reasonable to the party responsible for paying the sum—Merck.

B. Apportionment

A different method is applied when determining reasonable royalties for multi-component products. There, the "final royalty base and royalty rate must reflect only the value conferred by the infringing features of the product, and no more."[134] Put differently, the reasonable royalty is the measure of the "value of what was taken."[135] When both patented and unpatented features comprise a product, a determination of the value added by the patented features is paramount to calculating damages.[136] The jury must "apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features [using] reliable and tangible evidence."[137] Apportionment can be determined in a variety of ways. For example, "by careful selection of the royalty base to reflect the value added by the patented feature, where that differentiation is possible; by adjustment of the royalty rate so as to discount the value of the product's non-patented features; or by a combination thereof."[138] Ultimately, the indispensable requirement is that a reasonable royalty award be contemplated only "on the incremental value the patented invention adds to the end product."[139]

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131. *Id.* at *35.

132. *Id.*

133. Integra Lifesciences I, Ltd. v. Merck KGaA, No. 96CV1307-B, 2004 U.S. Dist. LEXIS 20725, at *35–38 (S.D. Cal. Sept. 7, 2004) *vacated and remanded*, 545 U.S 193 (2005), *rev'd*, 496 F.3d 1334 (Fed. Cir. 2007).

134. Ericsson, Inc. v. D-Link Sys., 773 F.3d 1201, 1226 (quoting VirnetX, Inc. v. Cisco Sys., Inc., 767 F.3d, 1308, 1326 (Fed. Cir. 2014)).

135. *Id.* (quoting Dowagiac Mfg. Co. v. Minn. Moline Plow Co., 235 U.S. 641, 648 (1915)).

136. *Id.*

137. *Id.* (quoting Garretson v. Clark, 111 U.S. 120, 121 (1884)).

138. *Id.*

139. *Id.*

The *Ericsson, Inc. v. D-Link Sys.* case exemplifies the principle of apportionment. In 2010, Ericsson brought suit against D-Link Systems for patent infringement of its WiFi technology used in electronics to wirelessly connect to the Internet.[140] The jury found that D-Link infringed Ericsson's patents and awarded Ericsson $10 million in damages.[141] D-Link appealed, arguing in part that Ericsson's damages theory violated the "entire market value rule," (EMVR).[142] The entire market value is the value of the whole product, inclusive of all components. The EMVR stands for the concept that damages can be based on the entire market value of a product only where the patented feature at issue is what drives market demand for the product as a *whole*.[143] Accordingly, if the patented feature is *not* the item driving the multi-component product's market value, relying only on the EMVR could mislead the jury.[144] Ultimately, the court required the jury to apportion the incremental benefit Ericsson's patented WiFi technology added to the value of D-Link System's multi-component products.[145] Unfortunately for Ericsson, the court vacated the original damages award after finding the lower court failed to properly instruct the jury on this apportionment principle.[146]

C. Enhanced Damages

In an effort to protect patented inventions, Congress provided for enhanced damages to deter bad-faith infringement via 35 U.S.C. § 284.[147] This patent damages statute makes clear "the court may increase the damages up to three times the amount found or as-

140. Ericsson, Inc. v. D-Link Sys., 773 F.3d 1201, 1207–13 (Fed. Cir. 2014).

141. *Id.* at 1207.

142. *Id.* at 1208.

143. *E.g.*, Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1318 (Fed. Cir. 2011) ("The entire market value rule allows a patentee to assess damages based on the entire market value of the accused product only where the patented feature creates the basis for customer demand or substantially creates the value of the component parts.").

144. *Ericsson, Inc.*, 773 F.3d at 1227.

145. *Id.* at 1226.

146. *Id.* at 1235.

147. Rachel Weiner Cohen et al., *Article: The Halo Effect: Willful Infringement and Enhanced Damages in Light of Halo*, 69 AM. U. L. REV. 1067, 1068 (2020) [hereinafter *Halo Effect*].

sessed."[148] However, courts have varied in their application of this provision.[149] Typically, a jury must first determine whether an alleged infringer has committed acts warranting increased damages.[150] Then the judge will decide whether and to what extent to enhance the damages awarded to the patentee.[151] Central to this determination "is the egregiousness of the defendant's conduct based on all the facts and circumstances."[152]

The Supreme Court recently considered enhanced damages in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*[153] In *Halo*, the Court considered whether the two-part test from *In re Segate*—used to determine when a district court could increase damages—adhered to § 284.[154] The Court rejected the *Segate* test as "unduly rigid," stating it "impermissibly encumbers" the district court's discretion to enhance damages.[155] The Court recognized § 284 permits courts to exercise discretion when awarding enhanced damages against those adjudged guilty of patent infringement.[156] However, the Court emphasized district courts should continue to rely on precedent established through the "sound legal principles" developed over nearly two centuries of interpretation and application of the Patent Act.[157]

The Court further acknowledged that patent law balances the desire to promote innovation through patent protection and the need to

148. 35 U.S.C. § 284.

149. *Halo Effect*, *supra* note 147, at 1071 (citing Seymour v. McCormick, 57 U.S. 480, 488–89 (1854)).

150. *See* Liquid Dynamics Corp. v. Vaughan Co., No. 01 C 6934, 2005 U.S. Dist. LEXIS 6162, at *10 (N.D. Ill. Mar. 22, 2005) (denying Vaughan Co.'s motion *in limine* to exclude evidence of wilfullness at trial).

151. *Id.*

152. *Halo Effect*, *supra* note 147, at 1073 (quoting Read Corp. v. Portec, Inc., 970 F.2d 816, 826 (Fed. Cir. 1992)).

153. Halo Elecs., Inc. v. Pulse Elecs., Inc. (*Halo I*), 831 F.3d 1369, 1373 (Fed. Cir. 2016) *vacated*, 579 U.S. 93 (2016) ("The Supreme Court only addressed the issue of enhanced damages in granting certiorari to Halo[.]").

154. *Id.* at 1380–81 (citing In re Segate Tech., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007)).

155. *Id.* at 1381.

156. *Id.*

157. Halo Elecs., Inc. v. Pulse Elecs, Inc. (*Halo II*), 579 U.S. 93, 103 (2016) (quoting Martin v. Franklin Cap. Corp., 546 U.S. 132, 139 (2005) (citations omitted)).

permit the "imitation and refinement through imitation" required to advance a competitive marketplace.[158] The Court reasoned this balance is disrupted when courts award enhanced damages in "garden-variety" cases.[159] Still, "enhanced damages [need not] follow a finding of egregious misconduct."[160] Instead, courts should continue to weigh the particular facts of each case in its decisions on whether to order damages, and for how much.[161] In analyzing the facts at bar, courts need only apply a preponderance of the evidence standard to satisfy the evidentary burden under § 284.[162]

Justice Breyer's concurrence noted the Court's references to "willful misconduct" do not justify enhanced damages in situations where the evidence shows only that the infringer knew about the patent, without more.[163] Rather, Justice Breyer posited that enhanced damages are a disciplinary sanction imposed on those who engage in conduct that is either "deliberate" or "wanton."[164] Further, although "intentional or knowing" infringement may justify a court in handing down a punitive sanction, the Court uses the term *may*, not must.[165] Thus, it is the circumstances of the infringer's behavior that "transforms simple knowledge" into egregiousness, "and that makes all the difference."[166] Therefore, because the district court has discretionary power to enhance damages, appellate courts review decisions under the abuse of discretion standard.[167]

The *Halo* decision reinforced the district court's discretion to award enhanced damages; accordingly, district court judges have devised their own methods to address allegations of willful infringement throughout the litigation stages.[168] Some courts will settle allegations

158. *Id.* at 109.
159. *Id.*
160. *Id.* at 106.
161. *Id.*
162. *Id.* at 107.
163. *Halo II*, 579 U.S. 93, 110 (2016) (Breyer, J., concurring).
164. *Id.* at 111 (Breyer, J., concurring).
165. *Id.*
166. *Id.*
167. *Id.* at 114 (2016) (Breyer J. concurring) (quoting Highmark Inc. v. Allcare Health Mgmt. Sys., Inc. 572 U.S. 559, 560–61 (2014)).
168. *Halo Effect*, *supra* note 147, at 1069.

of willfulness early on through pre-trial motions to dismiss or motions for summary judgment.[169] Other courts will leave the determination of willfulness to the jury.[170] Still more, in cases finding willful infringement some courts refuse to enhance damages while others use their power to award triple damages to the plaintiff.[171]

D. Injunctive Relief

In accordance with the remedies provision of the Patent Act, Congress recognized that injunctions may be granted to prevent patent rights violations *when justice so requires*.[172] Congress thus granted the district courts discretion to award injunctions in infringement suits[173] "on terms the court deems reasonable . . . to prevent others from violating rights secured by patents.[174] The decision in *eBay Inc. v. MercExchange L.L.C.* reiterated this principle of patent law.

In *eBay*, the Supreme Court held that "well established principles of equity determined by the courts require a plaintiff seeking a permanent injunction to satisfy a four-factor test."[175] The patentee must show: (1) he has suffered irreparable harm, (2) money damages are inadequate to compensate for his injury, (3) an equitable remedy is justified, and (4) the public interest would not be harmed by a permanent injunction.[176] Again, the Court reiterated the district courts' discretion in determining whether to award a permanent injunction.[177] Precedent does not dictate that injunctions should automatically follow a finding of patent infringement; rather, district courts "may" grant injunctive relief in its discretion, on terms it may deem reasonable.[178] Put differently, *eBay* directs district courts to consider the four-pronged test, and other considerations it deems reasonable, when granting permanent injunctions to protect patent rights.

169. *Id.* (collecting cases).
170. *Id.*
171. *Id.* at 1069–70 (collecting cases).
172. *See* 35 U.S.C. § 283 (emphasis added).
173. *See id.*
174. *Id.*
175. eBay Inc v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).
176. *Id.*
177. *Id.*
178. *Id.* at 392–93.

III. THE IMPLIED "ACT NOW, ASK FOR FORGIVENESS LATER" APPROACH TO INFRINGING BEHAVIOR

The following section highlights examples of cases that resolved with limited remedies awarded and limited injunctions granted. These examples support the premise that existing patent laws permit pharmaceutical companies to adopt an "act now, ask for forgiveness later" approach to infringing activities. Subsection A considers how courts have interpreted existing patent laws, declining to exact enhanced damages in some cases, thus permitting pharmaceutical companies to adopt such a business model. Subsection B then reviews injunctions as a remedy for infringement, providing examples of situations in which courts have resolved to grant or deny injunctions.

Because district courts vary on whether to award enhanced damages and injunctions, pharmaceutical companies are left free to adopt an "act now, ask for forgiveness later" approach to patent infringement. The result? Legitimized patent infringement may occur when small-molecule generic drugs enter the market before their counterpart brand name drug patents expire. True, society benefits from the lower drug costs for consumers. This model, however, may be unworkable for mRNA COVID-19 vaccines.

A. Limited Remedies

The Federal Circuit in *Presidio Components, Inc. v. American Technical Ceramics Corp.*, relying on *Halo*'s holding, held that an enhanced damages award "does not necessarily flow from a willfulness finding."[179] Yet, the *Halo* Court did not propose a test to determine the behavior which warrants enhanced damages.[180] Rather, *Halo* required the courts' consideration of the totality of the circumstances to determine whether enhanced damages are "appropriate on a case-by-case basis."[181] In light of this guidance, courts have held "the continued sale of [an] infringing product without removing its infringing capability is merely typical infringement behavior that is not a proper

179. 875 F.3d 1369, 1382 (Fed. Cir. 2017); *Halo II*, 579 U.S. 93, 106 (2016) ("[N]one of this is to say that enhanced damages must follow a finding of egregious misconduct.").

180. *See id*.

181. *Halo Effect*, *supra* note 147, at 1091.

basis for awarding enhanced damages."[182] Thus, a "potential patent infringer may not be deterred whatsoever from committing *willful* infringement" if they perceive they may face enhanced damages even without a finding of willful infringement.[183] The Supreme Court's emphasis to exact triple damages only in "exceptional" cases of infringement cautions against enhanced damages awards, therefore indirectly supporting patent infringement as a viable business strategy.[184]

By way of a hypothetical, a pharmaceutical company could seek approval of a generic product to enter the market as an alternative to a successful brand name drug. If the pharmaceutical company is later found liable for patent infringement, it can then use a portion of its profits to pay out a limited damages award. Entering the market with an alternative to a block-buster drug could net billions of dollars in profits. Yet having to pay a mere portion of that revenue for engaging in infringing activities could be a rational, viable decision for the company. With profits in the hundreds of millions, paying damages, even triple damages, may be perceived as merely a cost of doing business.

The reality of the hypothetical was laid bare in *Integra Lifesciences I, Ltd. v. Merck KGaA*. There, the Federal Circuit Court ordered the lower court to re-calculate damages in conformity with the record.[185] Though it affirmed the previous ruling that Merck willfully infringed Telio's (Integra) RGD patents, the Federal Circuit did not find sufficient evidence to support the $15 million award.[186] Instead, it determined a reasonable royalty would have been $6.375 million.[187] Furthermore, the court found there was no factual basis in the record to increase or decrease the hypothetical royalty.[188] Therefore, alt-

182. *Id.* (quoting TecSec, Inc. v. Adobe Inc., No: 1-10-cv-115, 2019 WL 1233882, at *2 (E.D. Va. Mar. 14, 2019)).

183. Eric C. Wrzesinski, *Breaking the Law to Break into the Black: Patent Infringement as a Business Strategy*, 11 MARQ. INTELL. PROP. L. REV. 193, 200–01 (2007) (citing 35 U.S.C. § 285) (emphasis added).

184. *Id.* at 197–98.

185. Integra Lifesciences I, Ltd. v. Merck KGaA, No. 96CV1307-B, 2004 U.S. Dist. LEXIS 20725, at *3–4 (S.D. Cal. Sept. 7, 2004) *vacated and remanded*, 545 U.S 193 (2005), *rev'd*, 496 F.3d 1334 (Fed. Cir. 2007).

186. *Id.* at *11.

187. *Id.* at *35.

188. *Id.* at *36.

hough the jury found Merck guilty of *willful* infringement, the award announced by the district court not only *reduced* the awarded damages, it did *not* include any enhanced damages.[189] Litigation costs notwithstanding, Merck's approach to patent infringement made good business sense: the royalty they were ordered to pay was a mere fraction of their bottom line realized by infringing Integra's patent.

B. Limited Injunctions

Although courts have awarded injunctions in cases where a patentee satisfies the four-pronged test, courts have also declined to grant permanent injunctions in several different cases.[190] Courts have denied requests for injunctions in cases where the patentee has a history of granting licenses to others to use or manufacture the patented invention, and where the patented product was incorporated into a larger product.[191] Injunctions have also been denied in cases where the patentee failed to commercialize the patented invention to bring it to market.[192] Where the courts decline to grant injunctions, the infringer is permitted to continue using and making the patented invention and must pay the patentee a royalty for the duration of the patent term.[193]

In two separate, but related suits, a brand name drug maker sued two generic manufacturers for infringement of its patent on Biaxin XL (clarithromycin extended release), an antibiotic used to treat bacterial infections.[194] In *Abbott Labs. v. Andrx Pharms., Inc.*, Abbott sued Teva Pharmaceuticals after Teva filed an ANDA seeking to market a generic version of Abbott's Biaxin XL.[195] The court granted Abbott a preliminary injunction because it found that Abbott had established a likelihood of success on the merits, and that entry of a generic competitor would likely "crush the [extended-release clarithromycin] mar-

189. *Id.* at *37 (emphasis added).

190. THOMAS, *supra* note 75, at 8.

191. *Id.* (citing Ronald J. Schultz & Patrick M. Arenz, *Non-Practicing Entities and Permanent Injunctions Post-eBay*, 12 SEDONA CONF. J. 203, 204 (2011)).

192. *Id.*

193. THOMAS, *supra* note 75, at 8 (citing ActiveVideo Networks, Inc. v. Verizon Comms., Inc., 694 F.3d 1312 (Fed. Cir. 2012)).

194. Abbott Labs. v. Sandoz, Inc., 500 F. Supp. 2d 807, 815 (N.D. Ill. 2007).

195. Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1332–33 (Fed. Cir. 2006).

ket."[196] On appeal, the Federal Circuit found the prior art of a related patent, known as the "'190" patent, owned by Abbott *did* teach of the desirability of making a compound leading to the features claimed in the patent at issue, the "'718 patent."[197] Stated differently, the prior art of Abbott's '190 patent could lead a person with ordinary skill in the art to reasonably expect success in making the extended-release clarithromycin.[198] Based on that prior art, Teva had raised a substantial question of invalidity of claims 2 and 4 of Abbott's '718 patent.[199] Teva also raised substantial questions regarding the validity of several claims of Abbott's patents regarding the improved gastrointestinal side effects from extended-release clarithromycin formulations.[200] Thus, the court found Abbott did *not* establish a likelihood of success

196. *Id.* at 1332–34.

197. *Id.* at 1340–42.

198. *Id.*

199. The prior art included the '190 patent, owned by Abbott, which disclosed a composition of clarithromycin in an alginate polymer capable of being administered only once a day so that it is bioequivalent of the twice daily immediate release formulation. "Thus, the '190 patent discloses an extended release formulation of clarithromycin wherein the polymer used is alginate as opposed to the polymers like HPMC in the '718 patent." Teva argued the '190 patent disclosed a clarithromycin combined with alginate that had essentially the pharmacokinetic parameters required in claim 4 of the '718 patent. Abbott's own claim limitations "in claim 4 of the '718 patent state that the '190 patent does not disclose the claimed polymers of the '718 patent." However, Pfizer's '422 publication discloses controlled-release formulations using azithromycin with HPMC. Thus, Teva argued, "based on the '422 publication, a person of ordinary skill in the art would replace the alginate of the '190 patent with HPMC because the '422 publication disclosed using HPMC with azithromycin, a compound related to clarithromycin." *See id.*

200. These two claims recite an improvement of a side effect for claim 6 of the '718 patent and GI side effects for claim 2 of the '616 patent. "The district court found that 'GI side effects of clarithromycin were known to be dependent on the drug concentration in the blood.'" Abbott contended that "an extended release formulation would reduce maximum blood plasma concentration of the drug." Because "the [] reduction in GI side effects" from extended-release clarithromycin "cannot be said to be unexpected." "Teva raised a substantial invalidity question as to claim 2 of the '616 patent." Teva's argument regarding taste perversion of claim 6 of the '718 patent pointed to a single study Abbott conducted on taste perversion suggesting taste perversion is dose-dependent sufficiently raised a substantial question as to the claim of the '718 patent. *See id.* at 1345–47.

on the merits of their claims,[201] and vacated the preliminary injunction ruling by the lower court.[202]

However, in a separate case regarding Abbott's extended-release clarithromycin patents, the Federal Circuit upheld a lower court's grant of a preliminary injunction.[203] In *Abbott Labs. v. Sandoz, Inc.*, Abbott sued Sandoz in response to Sandoz filing an ANDA for its generic version of extended-release clarithromycin.[204] The Federal Circuit decided there was no reversible error in the lower court's ruling on anticipation and obviousness, and that Abbott was likely to prevail on the merits.[205] Furthermore, Sandoz was unlikely to succeed in establishing inequitable conduct on the '718 and a related '616 patent on either of the two bases Sandoz advanced.[206] Sandoz had argued that Abbott made a material misrepresentation in a submission to the Patent and Trade Office (PTO) because an inventor failed to analyze statistical significance in clarithromycin concentrations of extended-release and immediate-release formulations.[207] Sandoz also argued that Abbott intended to deceive the PTO because Abbott failed to dis-

201. Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1345–47 (Fed. Cir. 2006).

202. *Id.* at 1348.

203. Abbott Labs. v. Sandoz, Inc., 500 F. Supp. 2d 807, 846 (N.D. Ill. 2007).

204. *Id.* at 815.

205. Sandoz argued Abbott's '718 patent was anticipated by the '571 publication because clarithromycin, an erythromycin derivative, are inherent in the extended-release formulations of the '571 publication. Because the '571 publication does not describe the product of the '718 claim and does not state the pharmacokinetic properties disclosed in the '718 claim, the district "court concluded Sandoz would not likely succeed in establishing anticipation by this reference." Sandoz argued Abbott's patents at issue were invalid in light of prior art for obviousness because in view of prior art from the '571 publication, the PCT application and the '190 patent "no more than routine experimentation was needed to find a controlled release formulation that would meet the pharmacokinetic requirements stated in the '718 claims." Sandoz also argued that the PCT Application teaches that controlled release azithromycin reduces GI side effects and the '190 patent shows azithromycin and clarithromycin can be interchanged using alginate salts. However, relying on expert testimony, the district court held the extended-release properties in the '718 patent were dissimilar and unpredictable from data in the PCT Application to be insufficient to render the '718 patent obvious. *See id.* at 838–41.

206. *Id.* at 817.

207. *Id.* at 817–18.

close the results of clinical trials on taste perversion.[208] The court reasoned that neither the statistical significance nor the results of the taste perversion trials were material to the patentability of the claims.[209] Based on the record, Abbott showed a reasonable likelihood of proving infringement.[210] Moreover, the court held the equitable factors considered for preliminary injunctions weighed in Abbott's favor and upheld the lower court's ruling.[211] The court reasoned that the public interest is best served by enforcing patents which have a substantial likelihood of being valid and enforceable.[212] Unfortunately for Abbott, only Sandoz's infringement, not Teva's, sufficed to justify an injunction against further infringement of Abbott's '718 patent.

IV. SOCIETAL BENEFITS & DRAWBACKS TO INFRINGEMENT

There are several recognized benefits to pharmaceutical drug companies choosing to engage in infringing activities. Robust patent protection encourages innovation, and aids in the advancement of society. Moreover, the research exemption to patent infringement promotes the production and sale of generic drugs, which in turn provides consumers a wider variety of generic alternatives, and lowers drug costs. However, there are also many drawbacks to patent infringement in the pharmaceutical realm. For example, pharmaceutical companies faced with less-robust patent protection may no longer be incentivized to innovate. This, in turn, negatively impacts society by leading to less advancements and less innovation. As the world continues to cope with the coronavirus pandemic, many pharmaceutical companies have expressed desire to imitate the success of mRNA COVID-19 vaccines. However, in the highly specialized area of mRNA vaccines, patent infringement will not only hinder society's progress, it may cost people their lives. Thus, this is one area of the

208. *Id.* at 818–19.

209. Abbott Labs. v. Sandoz, Inc., 500 F. Supp. 2d 807, 826 (N.D. Ill. 2007).

210. *Id.* at 842.

211. *Id.* at 842–45 (A party seeking injunction must show (1) a likelihood of success on the merits, (2) irreparable harm without granting the injunction, (3) balance of hardships in favor of the moving party, and (4) impact of the injunction on the public interest).

212. *Id.* at 845–46.

pharmaceutical realm where patent infringement activities will harm society.

Subsection A discusses the benefits flowing from the Hatch-Waxman Act and shows how more drug competition leads to lower costs for consumers. Legitimized patent infringement, sanctioned by patent laws, as in the Hatch-Waxman Act, facilitates pharmaceutical companies' "act now, ask for forgiveness later" approach to infringing activities. Again, those activities benefit society in the short term, lowering costs and increasing competition in the market. Subsection B considers negative incentives to innovate and harmful effects of patent infringement in specialized pharmaceutical areas.

A. Wider Access to Drug Treatments Translates into Decreased Costs for Consumers

The Hatch-Waxman Act was designed with the goal of lowering prices on pharmaceutical products by increasing competition and bringing generic alternatives to the market sooner.[213] Legislators recognized that pharmaceutical patent infringement meant more competition and cost-effective alternatives to the brand name drugs available to the public.[214]

In fact, legitimized infringement was sanctioned by patent laws.[215] Congress's grant of research exemptions and encouragement of generic drug development in the Hatch-Waxman Act show how drug development accomplished by imitating patented products is valued in our

213. Sertic, *supra* note 10, at 384.

214. Generic drug manufacturers do not incur the high costs that brand name drug companies expend in lengthy clinical trials and safety studies that are required for FDA approval; therefore, generic drugs can be offered as much cheaper alternatives to brand name drugs. *See id.*; Liu, *supra* note 17, at 447; *see also* Eric E. Williams, *Article: Patent Reform: The Pharmaceutical Industry Prescription For Post-Grant Opposition And Remedies*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 354, 374 (2008) ("By foregoing the expense of research and development, a generic drug company can sell its copy of medication at a fraction of the cost charged by an innovator drug company.").

215. *See supra* Part II.A. *See generally* Borchardt, *supra* note 10, at 945 ("This common law research exemption allowed for certain uses of patented inventions without the consent of the patentee as long as the use did not 'divert to the accused infringer a portion of the profits.'").

society.[216] Under the provisions of the Hatch-Waxman Act, a generic drug company can use a patent protected drug's published specification to develop its generic alternative, then try to sell its product in the market.[217] If litigation arises regarding the infringing activity, the generic drug company can attempt to have the drug's issued patent invalidated, permitting the drug company to sell its version in the market.[218] Legislators also recognized that society benefits when generic drugs enter the market.[219] As a patent term is set to expire, the more generic drug companies that are poised to deliver their own cheaper alternatives increases competition and drives costs down.[220]

Borrowing the research and development of brand-name drug makers leads to substantial savings for the generic drug companies. In 2002, pharmaceutical companies invested, on average, $800 million to bring a drug from development to the market.[221] Under the provisions of the Hatch-Waxman Act, the cost to reverse engineer a generic medication and receive FDA approval for it is a mere one or two million dollars.[222] Generic manufacturers also enjoy the success of their brand-name counterparts by reaping the benefits of the prior marketing groundwork and recognized therapeutic benefits of the brand name drug.[223] The cost savings opportunity presented by the Hatch-Waxman Act, along with the marketing success of brand name drugs, provide ample incentives for generic drug companies to invalidate brand name drug patents to permit early entry of their generic versions in the market.

In this current state of patent laws, the lure of market shares of a successful brand-name drug product[224] entices pharmaceutical companies to adopt an "act now, ask for forgiveness later" approach to pa-

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216. *See supra* Part II.A.

217. *See* Williams, *supra* note 216, at 373; Liu, *supra* note 17, at 447–48.

218. *See* Williams, *supra* note 216, at 374 (citing 21 U.S.C. § 355).

219. *See id.*

220. *See* Helm, *supra* note 10, at 174 (citing Samuel M. Kais, Comment, *A Survey of 35 U.S.C. § 271(e)(1) as Interpreted by the Courts: The Infringement Exemption Created by the 1984 Patent Term Restoration Act*, 13 SANTA CLARA COMPUT. & HIGH TECH. L.J. 575, 576 (1997)).

221. Blasi, *supra* note 18, at 120–21.

222. *Id.* at 123–24.

223. *Id.* at 124.

224. Wessels, *supra* note 15, at 1584 (citing Gillat, *supra* note 18, at 715–16).

tent infringement. Under the Hatch-Waxman Act, generic pharmaceutical companies are practically invited to engage in infringing activities, and their actions are seemingly protected under the reading of current patent laws.[225] Once the pharmaceutical company files an ANDA, the act of infringement may be realized and challenged.[226] But at that point, the generic pharmaceutical company can make a business decision to press on in its quest to have the brand-name drug's patent invalidated, ushering an unfettered entry into the market.[227] As the first ANDA filer, the company may realize a partial monopoly in the market, for a limited time, as the first and only generic alternative to the brand name drug upon a successful challenge.[228] Either way, the pharmaceutical company is gambling with a reasonable chance of winning. As legislators saw the benefit of wider access to generic drugs when generic manufacturers are able to enter the market upon patent term expiration, pharmaceutical companies also recognized the benefit of engaging in this sanctioned activity under pain of potential infringement litigation. Ultimately, existing patent laws permit pharmaceutical companies to take this risk and may even implicitly encourage it.

B. Decreased Incentives for Innovation and Progress

A major drawback to pharmaceutical patent infringement is its impact on negative incentives to advance pharmacological innovation. Pharmaceutical companies enjoy patent protection for their blockbuster drugs, and claim to recoup the costs of developing the drug during the patent term.[229] In turn, this incentive for market monopolization encourages new drug development and innovation.[230]

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225. *See* Blasi, *supra* note 18, at 122.

226. Wessels, *supra* note 15, at 1575 (citing 35 U.S.C. § 271(e)(1)).

227. *See, e.g.*, Blasi, *supra* note 18, at 122; Liu, *supra* note 17, at 449–50 (citing 21 U.S.C. § 355(j)(5)(B)(iv); Herlihy, *supra* note 60, at 136; Yoho, *supra* note 60, at 534–35; Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1342 (Fed. Cir. 2007)).

228. Blasi, *supra* note 18, at 122 (noting the first ANDA filer that receives a judgment of invalidity or non-infringement of the patent is awarded a 180-day exclusivity period).

229. *See* Helm, *supra* note 10, at 160–61.

230. *Id.*

Pharmaceutical companies are intricately important to the advancement of our society[231] because their work transcends the healthcare field into commerce and ultimately the national economy.[232] Thus, it can be argued that pharmaceutical companies that choose to infringe drug patents ultimately harm society, generally.

If pharmaceutical companies are not given sufficient patent protection, they will have less motivation to innovate. Brand name drugs cost upwards of hundreds of millions of dollars over the course of bringing a candidate drug from the research and development stage, through FDA approval, to the market. Because of this lengthy and costly process, there would be far less incentive to innovate and pioneer new drug therapies if drug patents were not adequately protected. This would lead to less innovation across the pharmaceutical industry, as drug companies would be less inclined to spend money to develop new drugs. Without the protections patents offer pharmaceutical firms, it is unlikely that advanced COVID-19 mRNA vaccines would have been developed. Ultimately, insufficient patent protection would lead to less drug discovery, less innovative disease treatments, and would negatively impact the advancement of society.

Furthermore, considering the current global pandemic and the progress of society, there are strong public policy reasons to justify willful patent infringement. Countries across the globe are scrambling to obtain vaccine doses for their populations.[233] After the "Omicron" coronavirus variant was detected in the U.S. in early December 2021, shortly after being identified in Botswana and South Africa just weeks prior,[234] it is apparent that no one is safe until everyone is safe.[235] The interconnectedness of the global economy means that even if areas far

231. *Id.* at 155.

232. *Id.*

233. *See* Stephanie Baker & Vernon Silver, *Pfizer Fights to Control Secret of $36 Billion Covid Vaccine Recipe*, BLOOMBERG (Nov. 14, 2021), https://www.bloomberg.com/graphics/2021-pfizer-secret-to-whats-in-the-covid-vaccine/.

234. Carl Zimmer & Andrew Jacobs, *Omicron: What We Know About the New Coronavirus Variant*, N.Y. TIMES (Jan. 3, 2022), https://www.nytimes.com/article/omicron-coronavirus-variant.html.

235. *See* Tedros Adhanom & Ursula von der Leyen, *A Global Pandemic Requires a World Effort To End It – None of Us Will Be Safe Until Everyone is Safe*, WORLD HEALTH ORG. (Sept. 30, 2020), https://www.who.int/news-room/commentaries/detail/a-global-pandemic-requires-a-world-effort-to-end-it-none-of-us-will-be-safe-until-everyone-is-safe.

across the globe are being impacted by COVID-19, the result will be production delays, losses of economic activity, and friction among channels of commerce: the repercussions will be felt worldwide.[236] Moderna, maker of one of the mRNA COVID-19 vaccines, pledged not to enforce its patents related to COVID-19 for the duration of the pandemic.[237] However, as seen in the example of the Emergent BioSolutions vaccine production mishap, errors can cause huge production delays and even loss of human life. In the context of highly specialized mRNA COVID-19 vaccines, where technical skill and know-how is required to produce the vaccines,[238] willful patent infringement among pharmaceutical manufacturers could severely impact global efforts to address the pandemic.

CONCLUSION

Although the U.S. patent system generally protects patents, statutory grants for research exemptions and case law encourage an "act now, ask for forgiveness later" approach to infringing activities. This approach is made possible through the unpredictable outcomes of remedies awarded in patent infringement suits. As shown, the reasonable royalties and apportionment systems are subject to vast judicial discretion. By limiting awards through damages and injunctions, judges ultimately incentivize willful infringement.

Pharmaceutical companies' pro-infringement business model typically benefits consumers by ushering in competition in the small molecule pharmaceutical drug market, which translates into lower drug costs. Therefore, there are major advantages to patent infringement in the pharmaceutical industry when considering the economic impact of

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236. *See* Fareed Zakaria, *Opinion: The Pandemic Will Not End Unless Every Country Gets The Vaccine*, WASH. POST (Jan. 28, 2021, 6:49 EST), https://www.washingtonpost.com/opinions/global-opinions/the-pandemic-will-not-end-unless-every-country-gets-the-vaccine/2021/01/28/e57f739a-61a7-11eb-afbe-9a11a127d146_story.html (highlighting an International Chamber of Commerce study detailing the "lopsided vaccination of the world will cause global economic losses of $1.5 trillion to $9.2 trillion").

237. *See* Baker & Silver, *supra* note 233.

238. Kevin Breuninger, *Pfizer CEO Opposes U.S. Call To Waive Covid Vaccine Patents, Cites Manufacturing and Safety Issues*, CNBC (May 7, 2021, 3:55 PM), https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html.

generic drug availability in the marketplace. However, when the patented product is something as intricate as mRNA COVID-19 vaccines, patent infringement can harm society by shunting important materials and supplies away from vaccine producers, ultimately causing delays and wasting valuable resources.[239] In critical times, such as a global pandemic, a pervasive infringement approach to pharmaceutical activities can be both harmful and deadly. Compromising the quality of vaccines, including contaminating its component substrates, will delay effective prevention efforts and prolong the efforts aimed at combating COVID-19.[240] Ultimately, in specialized areas of the pharmaceutical industry sector, infringing activities will hinder our progress as a society.

Where should we draw the line on patent infringement and brand-name drug makers' profits in the context of the health and welfare of society? At least for highly specialized pharmaceutical products, like mRNA COVID-19 vaccines, society is better served by discouraging infringing behaviors among third party pharmaceutical firms. Keeping the limited supply of raw materials concentrated in the hands of mRNA COVID-19 vaccine patentees will help to ensure quality vaccine products are maintained. Discouraging mRNA COVID-19 vaccine production by generic pharmaceutical manufacturers should be pursued for the time being. The lack of mRNA vaccine production know-how and production manufacturing capabilities, coupled with supply chain issues, can lead to significant safety issues. Producing these advanced vaccines in-house will assure the highest quality. The result will enable vaccine makers to reach populations in need, aiding our society as a whole.

239. *Id.*

240. *See* Breuninger, *supra* note 238.

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