HATCH-WAXMANIZING COPYRIGHT Michal Shur-Ofry*

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ABSTRACT

This article introduces a novel proposal for counter balancing "copyright overspills". In the background of the discussion is the common reality of users succumbing to right-holders attempts to license uses which are most likely fair uses, or completely free of copyright protection. These practices have attracted considerable attention in recent literature. Most scholarly proposals in this context emphasize the need to clarify the contours of the fair use doctrine, and to remove doctrinal ambiguities. Yet, these initiatives are probably insufficient for overcoming users riskaversion, due to an inherent structural imbalance within copyright law. While the law is designed around the prevailing narrative of providing an incentive for innovation, it is quite oblivious to providing an incentive to challenge copyright overspills. The article argues, then, that users should be provided with an actual incentive to challenge undue attempts to broaden copyright's scope.

The proposal is inspired by the unique system of incentives created under the "Hatch-Waxman Act" in order to increase challenging of pharmaceutical patents by generic pharmaceutical companies. These incentives have led to a significant rise in the number of patent challenges in the pharmaceutical field. In the spirit of the Hatch Waxman regime, the article advocate the introduction of an incentive to challenge into copyright law, so as to offset copyright overspills. It then proposes to develop an affirmative copyright misuse doctrine, which would entitle successful challengers of copyright overspills to statutory damages. Beyond the doctrinal proposals, the article's more fundamental conclusion is that, in order to achieve the desired access-incentive equilibrium, copyright law should be concerned not merely with providing an optimal degree of incentive to innovate but also with providing users with an adequate incentive to challenge.

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I - INTRODUCTION

Recent copyright scholarship correctly identifies that copyright protection produces a chilling effect on legitimate and permitted uses¹. The principal causes for this phenomenon are the unpredictability of the fair use principle, coupled with general risk aversion on part of users. The combination of the two discourages users from challenging right-owners payment requirements and encourages them to seek licenses even for permitted and fair uses². This practice, which was termed "the clearance

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¹ See, most notably, James Gibson, Risk Aversion and Rights Accretion in Intellectual Property Law. 116 YALE L. J. 882 (2007); Jennifer Rothman, The Questionable Use of Custom in Intellectual Property. 93 VIRGINIA L. REV. 1899 (2007) [Rothman: Custom]; Thomas F. Cotter, Fair Use And Copyright Overenforcement, 93 IOWA L. REV. 1271 (2008).

² Gibson, *supra* note 1; Rothman: Custom, *supra* note 1 at 1911.

culture"³, leads to the *de facto* broadening of copyright law beyond its *de-jure* limits, and to the corresponding shrinking of the public domain. Numerous proposals have been made for dealing with this phenomenon, most of which aim to increase the clarity and certainty in the application of copyright's exceptions, particularly the fair use doctrine⁴.

This article shares the above concerns but proposes a different conceptual approach for addressing them. This approach is inspired by an area of intellectual property in which intellectual property rights are constantly being challenged by prospective users, to the benefit of the public domain and the public in general. This is the field of pharmaceuticals, governed by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the "Hatch Waxman" Act⁵. The Act contains a complex set of provisions, among them the provisions commonly known as "Paragraph IV"⁶. The latter creates a detailed intellectual property challenging mechanism, by granting a 180 days generic exclusivity to the first generic company which files a generic drug for approval and successfully challenges the patents protecting the innovator's ("brand-name") drug. This substantial incentive has led to the development of a vibrant patent-challenging litigation on the pharmaceutical field, which can result in narrowing patent overspills through striking out weak patents or through earlier entry of generic substitutes to the market, to the benefit the public.⁷

Without being oblivious to the difficulties entailed in the implementation of the Hatch Waxman Act, nor to proposals for various amendments in the Act on part of many scholars, I believe this regime carries an important conceptual lesson for copyright law: copyright's prevailing narrative should not be concerned merely with providing an incentive for innovation. In order to counter-balance copyright overspill

³Rothman:Custom, *ibid*; Jennifer Rothman, *Best Intentions: Reconsidering Best Practices Statements in the Context of Fair Use and Copyright Law*, 75 J. COPYRIGHT SOC'Y, 371 (2010) [Rothman: Best Intentions].

⁴See, e.g. Gibson, *supra* note 1, at pp. 935-47 and the references in Part I-B *infra*, notes 17-21.

⁵ The current version is codified at 21 U.S.C. § 355 (2006). Previous codification was scattered in sections of 15, 21, 35 and 42 U.S.C. The differences between the versions are immaterial for our purposes here.

⁶ 21 U.S.C. § 355 (j)(5)(B)(iv).

⁷ A detailed discussion of the Hatch Waxman scheme appears in Part III *infra*.

externalities and maintain the desired incentive-access equilibrium, copyright law should also provide users with an adequate incentive to challenge.

The article, then, proceeds as follows: Part II describes the need for an "incentive to challenge" in copyright law. Building on existing literature discussing copyright's expansion beyond its statutory scope, it argues that many current proposals to remedy this phenomenon are likely to be insufficient for overcoming users' risk aversion. The analysis further demonstrates that in order to counterbalance copyright overspills, the law should provide users with an affirmative incentive to challenge. Part III briefly describes the incentive-to-challenge regime in the field of pharmaceutical patents, as established under the Hatch Waxman Act, and continues to explore its conceptual significance for copyright law. Part IV explores manners in which an incentive-to-challenge regime can be incorporated in copyright doctrine, particularly the development of an affirmative copyright misuse doctrine and the introduction of a statutory damages remedy for copyright misuse. Concluding remarks follow.

II - THE NEED FOR AN "INCENTIVE TO CHALLENGE" IN COPYRIGHT LAW

A. Copyright's Overspill Externalities

This article was sparked by a personal experience. I was about to publish an academic book entitled "Popularity and Networks in Copyright Law"⁸, and was discussing the exciting issue of the front cover with a colleague. He proposed that the cover will present several famous cartoon characters, as these popular works are, after all, the subject of the book. "I don't have the budget for licensing these images", I told him. "It's probably fair use", he observed, "you don't actually need a license". "You're right", I replied. "Still, I cannot risk being sued by the Studios". The idea was thus abandoned.

This anecdote is merely a small example of copyright's chilling effect. As *James Gibson* recently observed, copyright markets are

⁸ MICHAL SHUR-OFRY, POPULARITY AND NETWORKS IN COPYRIGHT LAW (Harry and Michael Sacher Institute for Legislative Research and Comparative Law, Faculty of Law, Hebrew University of Jerusalem and Nevo Publishing, 2011, in Hebrew).

characterized by a "license-don't-litigate" policy, namely a tendency to license each and every use of underlying works, even when there is a strong fair-use case or other defenses against infringement⁹. Several prominent factors can explain this overly conservative policy. The first is the doctrinal ambiguities in the law itself, particularly in the fair-use doctrine. These ambiguities make the *ex ante* prediction of the prospects of a fair-use argument largely uncertain, which in turn directs users towards seeking a clearance¹⁰. A second, related, factor is users' risk aversion: as highlighted by James Gibson and Thomas Cotter, the risks of being sued, which entail litigation costs and may also have insurance implications, often outweigh the perceived advantage of a free use¹¹. Furthermore, while right-holders often have a clear incentive to enforce copyright protection in an overly expansive manner, the costs of individual licenses to uses which are *de jure* permitted uses may be relatively modest, and the overall damage resulting from over-expansive copyright is often dispersed over a large number of users. Each user therefore lacks a clear incentive to object to such overspill¹². Thus, some users may well decide to abandon a requested use, despite its actual legality, as illustrated by the famous example of director John Else. Else attempted to use a very short segment from "the Simpsons" in the background of a documentary film. He neglected the idea after being requested to pay thousands of dollars by the right holders, and despite receiving legal advice that his use was in fact a fair use¹³. In other instances where the requested fee is relatively modest, seeking a clearance would be the rational choice, even for repeat sophisticated players from the media industries who may be acquainted with the intricacies of copyright's defenses. The result is that copyright

⁹ Gibson, *supra* note 1, at 891.

¹⁰ Gibson, *ibid*; Cotter, *supra* note 1, at 1284 (highlighting the inherent uncertainty of the fair use doctrine). *See also* Rothman: Custom, , *supra* note 1 at 1910-11 (criticizing the ambiguity in the application of "fair use" by courts).

¹¹ Gibson, *ibid*, at 893-4, Cotter, *ibid*, at 1284-88.

¹²*Cf.* Alexander Peukert, *A European Public Domain Supervisor*, INT'L REV. OF INTELLECTUAL PROPERTY AND COMPETITION LAW (forthcoming 2011), available at SSRN: <u>http://ssrn.com/abstract=1711745</u> (highlighting the asymmetry between users and owners incentives); Cotter, *supra* note 1, at 1274 (making a similar observation).

¹³ For a detailed account of this affair *see* NEIL W. NETANEL, COPYRIGHT'S PARADOX: PROPERTY IN EXPRESSION AND FREEDOM OF EXPRESSION, 15-17 (2008); James Boyle, *Staking Claims in Cyberspace (an interview)*, 89(6) DUKE MAGAZINE (ON-LINE)(2003), <u>http://www.dukemagazine.duke.edu/dukemag/issues/091003/index.html</u>.

protection overspills to actually cover uses beyond the scope of the rights granted under the Copyright Act.

Moreover, scholars correctly indicate, that this "clearance culture" further influences the fair use doctrine in a circular manner, since courts often consider non-conformity with industry practices as a factor weighing against fair use¹⁴. This circular feedback, then, results in further shrinking of the public domain.

Copyright overspills are further enhanced by additional market circumstances and right owners' practices. Thus, for example, Joseph Liu has recently highlighted the tendency of copyright intermediaries to disable or prohibit certain uses by end-users, which may be clearly permitted, for fear of incurring liability due to their enablement¹⁵. Likewise, Jason Mazzone discussed the problematic practice of unfounded allegations as to the subsistence of copyright in certain copyright-free contents – such as court cases, legislative materials, or materials in which copyright has long expired - and the conditioning of their use upon unjustified conditions¹⁶.

B. Overcoming Overspills and the Balance of Incentives

Against this background, copyright scholarship is currently engaged in a thriving discussion of possible solutions to the over expansion phenomenon. A series of proposals have been put forward in this context. Most of them aim at increasing the clarity as to the applicability of fair use and additional copyright standards, in hope that greater certainty will encourage users to object to copyright overspills¹⁷. Part of this attempt is

¹⁴ Gibson, *supra* note 1, at 897 (describing the "doctrinal feedback" of overly conservative licensing practices); Rothman : Custom, , *supra* note 1 at 1902 (highlighting that courts consider non conformity with practices as a basis for rejecting fair use).

¹⁵ Joseph Liu, *Toward a Defense of Fair Use Enablement, or How U.S. Copyright Law is Hurting My Daughter* 75 J. COPYRIGHT SOC'Y 101 (2010) (analyzing this tendency and further proposing a defense of "fair-use enablement" to intermediaries).

¹⁶ Jason Mazzone, *Copyfraud* 81 NYU L. REV. 1026 (2006) (describing varieties of such practices, which he terms "copyfrauds").*See also* Cory Tadlock, *Copyright Misuses, Fair Use and Abuse: How Sports and Media Companies are Overreaching Their Copyright Protections,* 7 THE JOHN MARSHALL REV. OF INT.PROP. L. 621 (2008) (describing the practices of overly broad 'copyright warnings' employed by entities in the sports and media industry).

¹⁷ See Gibson, supra note 1, at 934-42 (admitting, though, that this solution is far from simple); *cf.* Gideon Parchomovsy and Kevin A. Goldman, *Fair Use Harbors* 93 Virginia

reflected in the establishment of "fair-use-best-practices" in various fields, that strive to represent the understandings and practices of different industries as to permitted uses¹⁸. Others further suggest expanding educational measures, such as law clinics, aimed at educating and encouraging the public to exercise its fair use rights¹⁹, while a recent European proposal calls for the establishment of a "public domain supervisor", that will represent the interest of the public in public and political fora, that are frequently influenced more by stakeholders than by users²⁰.

A critical analysis of these proposals is beyond the scope of this essay. Briefly, however, "fair use best practices" have been criticized for being phrased without the involvement of stakeholders, and for being more of a wishful thinking than an actual representation of the law.²¹ On the other hand, the related idea to establish fair use "safe harbors" in regulation may deny the fair use doctrine of its inherent flexibility, and may also prove a two-ended sword, since the permitted uses set out as minimums in such regulation may quickly be interpreted as maximums by courts²².

L. Rev. 1483 (2007) (advocating the introduction of "harbors" that define minimum levels of uses as "fair").

¹⁸ See e.g., Rothman: Best Intentions, *supra* note 3 (describing the spreading phenomenon of fair use practices); Niva Elkin-Koren, Orit Fischman Afori, Ronit Haramati-Alpern and Amira Dotan, Fair Use Best Practices for Higher Education Institutions: The Israeli J. COPYRIGHT SOC'Y Experience. (forthcoming) available at SSRN: http://ssrn.com/abstract=1648408 (describing an initiative to establish "fair use best practices" for Israeli academic institutions). For a specific example of a practice which was established by several organizations see, e.g. "Fair Use Principles for User-Generated Content", available at http://www.eff.org/files/UGC Fair Use Best Practices 0.pdf. But see Rothman's criticism of these practices - note 21 infra and accompanying text.

¹⁹ Rothman: Best Intentions, *supra* note 3, at 386.

²⁰ Peukert, *supra* note 12. *See also* Jason Mazzone, *Administering Fair Use*, 51 WILLIAM AND MARY L. REV. 395 (2009) (proposing the establishment of a public agency to regulate and administer fair use). Other ideas raised in this context are the establishment of a public domain registry to minimize "copyfrauds" and the formation of a "fair use enablement" defense for intermediaries that facilitate fair use by third parties – *see*, respectively, Mazzone, *supra* note 16 at 1090-91; Liu, *supra* note 15 at 119-22.

²¹ See, e.g., Rothman: Best Intentions, *supra* note 3, at 376.

²² Gibson, *supra* note 1, at 881-82; *cf.* Pachomovsky and Goldman, *supra* note 17, at 1524-1528 (acknowledging these objections but estimating that the concerns are exaggerated).

However, the concern I wish to highlight here is of a more general nature. The measures proposed in recent scholarly discussion, even if presumably desirable and even if implemented in their entirety – may be insufficient to significantly decrease users' risk aversion and their lack of incentive to challenge stakeholders' demands²³. A simple economic calculation indicates that in many instances, paying a modest clearance fee to stakeholders may be the rational choice, even for sophisticated, welladvised users who are repeat players in the media industries. Consider the following (hypothetical) example: a newspaper wishes to quote several lines out of Martin Luther King's "I have a Dream" speech. Now imagine, that the estate of Luther King requires a fee of 400 dollars for this use²⁴. The newspaper receives legal advice that the quote is probably a "fair use", and the consent of the right holders is therefore unnecessary. Yet, from an ex-ante perspective, it must also take into account the potential costs of challenging the stakeholders position. These include the low chances that the fair use argument will eventually be rejected, and the newspaper will have to pay a substantial amount of statutory damages for copyright infringement²⁵. Often, these also include the costs of litigation [Lc] and the possible increase in the costs of insurance [Ic], resulting from the mere filing of the suit²⁶. Thus, when the *ex post* statutory damages may amount to 150,000 dollars for willful infringement or to 30,000 dollars for a "regular" one, and the ex ante clearance fee is relatively modest (400 dollars in our example), the rational and risk averse user is likely to pay the

 $^{^{23}}$ For a similar observation *see* Cotter, *supra* note 1, at 1312-18 (noting that "tinkering" with fair use may be an ineffective means for overcoming the problem of over-enforcement).

²⁴ Although the example is hypothetical it does not seem completely farfetched: *Cf.* KEMBREW MCLEOD, FREEDOM OF EXPRESSION (R), OVERZEALOUS COPYRIGHT BOZOS AND OTHER ENEMIES OF CREATIVITY, 33 (2005) (the author describes how he was requested to pay over \$200 to the copyright holders for quoting four sentences from the Luther King speech, and further detailing how "USA Today", which in 1993 reprinted the speech in its entirety to mark its 30^{th} . anniversary, was sued by the Estate of Martin Luther King).

²⁵ 17 U.S.C. § 504(c)(2) (2006) (Providing that willful copyright infringement may entitle the copyright owner to statutory damages in a maximum amount of 150,000 dollars). Under sub-section (1) of this provision the amount of statutory damages in the absence of willful infringement can reach 30,000 dollars. *See*, in this context, Pamela Samuelson and Tara Wheatland, *Statutory Damages in Copyright Law*, 51 WILLIAM AND MARY L. REV. 439, 441 (2009) (noting that the "willfulness" requirement was interpreted quite broadly by courts).

²⁶ See note 11 supra and accompanying text.

fee rather than challenge the stakeholders demand, even when the prospects of its fair-use argument are as high as 80%²⁷. Another rational alternative would be to avoid using the content in question altogether, assuming that such use is not critical for the user's project²⁸. This option may be particularly attractive for incidental non-industry users, whose familiarity with the subtleties of permitted uses may be more limited²⁹.

This analysis reveals an inherent structural imbalance within copyright law. Indeed, it is widely acknowledged that copyright law is not only about incentive to innovation, but seeks to achieve an (ever elusive) equilibrium between incentivizing innovation and additional values which necessitate access to copyrighted works³⁰. *De jure*, this balance is achieved through setting out limitations to the scope of copyright. Yet, as demonstrated above, the law's current structure results in the de facto expansion of copyright beyond their intended scope. In other words, while copyright law is designed around the prevailing narrative of providing an incentive to innovation, it is quite oblivious to providing an incentive to challenge copyright overspills. Decreasing the law's ambiguity may improve the situation in some cases, but would not significantly affect this imbalance in many other instances. As Thomas Cotter recently observed in the context of fair use, the doctrine "relies on individuals to champion the public interest...without providing them with sufficient incentive to do so^{"31}. Protecting the equilibrium envisaged by the legislator, then, requires the formation of an affirmative incentive-to-challenge regime under copyright law.

²⁷ Roughly, the calculation is: 400\$ [Clearance Fee] < 30,000 / 6,000[claim's estimated prospects of 20% X maximum statutory damages of 150,000 or 30,000, respectively] + Lc + Ic. True, this is a very rough illustration, as the amount of statutory damages awarded in a certain case may be lower than the maximum amount, and the *ex ante* prospects of a claim cannot be accurately evaluated. Yet, it does serve to demostrate the distorted "balance of incentives" under the present regime.

²⁸ Consider, again, the example of John Else, who renounced using a segment of "the Simpsons " as a background in his documentary – *see* note 13 *supra* and accompanying text.

²⁹ Joseph Liu colorfully illustrates this point by describing his daughter's decision to refrain from drawing "famous" characters altogether – *see* Liu, *supra* note 15 at 104-5.

³⁰ The latter statement is of course oversimplified; indeed, copyright law can and does promote additional interests besides incentive, such as personality interests or Lockean values: *see, e.g.*, Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287 (1988).

³¹ Cotter, *supra* note 1, at 1274.

Interestingly, a look beyond the contours of copyright law reveals that such a mechanism has already been introduced in another area of intellectual property. I am referring to the field of pharmaceutical generic litigation under the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act"³². Before taking a closer look at the incentive-to-challenge regime under the Hatch Waxman Act, a caveat is in order. Indeed, the Act regulates a different subject-matter than the copyright subject-matter, and its provisions cannot be "copypasted" into copyright law in a verbatim manner for numerous reasons which are discussed below³³. Yet, despite these caveats the incentive-to-challenge regime under the Hatch Waxman Act is an important example that can inspire the establishment of a market-based incentive-to-challenge mechanism within copyright law. The following Part turns to take a closer look at this scheme.

III - INCENTIVE TO CHALLENGE : THE HATCH - WAXMAN REGIME

The Hatch-Waxman Act introduced a complex web of provisions concerning both patent law and drug-approval processes by the Food and Drug Administration (FDA). A complete review of these terms is beyond the scope of this essay³⁴. Rather, for our purposes it is sufficient to describe the unique incentive-to-challenge system the Act created.

The legislation was motivated, at least in part, by the notion that innovative ("brand-name") drug companies sometimes succeed in registering weak and low-quality patents, whose validity can be questionable³⁵. Once registered, these patents extend the *de facto* protection granted to certain drugs, and may block the market entry of generic

³² Supra, note 5.

³³ Part IV Infra, notes 57-60 and accompanying text.

³⁴ For a more comprehensive review of the Act's provisions *see, e.g.,* Michael Carrier, *Unsettling Drug Patent Settlements: A Framework For Presumptive Illegality,* 108 MICHIGAN L. REV. 37 (2009); Alfred Engelberg, *Special Patent Provisions for Pharmaceuticals: Have they Outlived Their Usefulness?* 39 IDEA 389 (1999); Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals* (2010), available at SSRN: http://ssrn.com/abstract=1675947, at pp. 6-14.

³⁵ C. Scott Hemphill and Bhaven N. Sampart, *When Do Generics Challenge Drug Patents* (2010), available at SSRN: <u>http://ssrn.com/abstract=1640512</u>, at p. 4.

competitors for many years beyond the life of the initial patent that often protects the novel active ingredient in the drug³⁶.

Indeed, patents are open to challenge even after their registration, and invalidity arguments can be raised by defendants during infringement litigation. Yet, in the arena of pharmaceutical patents, too, risk-aversion often prevailed. The inherent *ex-ante* uncertainty of litigation outcomes³⁷ combined with the substantial litigation costs in this field that can easily reach millions of dollars³⁸, hindered the challenging of patents that protect "brand name" pharmaceuticals. Other players' ability to immediately take advantage of holdings of invalidity obtained by a generic company added an additional burden to such challenging³⁹. Much like in copyright law, then, "patent overspills" prevailed: patents which did not actually reflect non-obvious advancement over prior art were under-challenged, to the detriment of the public and the public domain⁴⁰.

Against this background, the Hatch Waxman Act introduced a sophisticated set of provisions designed to increase generic manufacturers' incentive to challenge, with the ultimate purpose of targeting the high prices of pharmaceuticals. First, it introduced a process of an Abbreviated New Drug Application (ANDA), which enables the FDA to approve generic versions of innovative pharmaceutical drugs on the basis of demonstrating bioequivalence to an already approved drug⁴¹. When the

³⁶ Hemphill & Sampart, *supra* note 35 at 6.

³⁷ See Mark Lemley and Carl Shapiro, *Probabilistic Patents*, J. ECO. PERS. 75 (2005) (analyzing patents in terms of a right to *attempt* to exclude alleged infringers and emphasizing that litigation outcomes are uncertain from an *ex ante* perspective).

³⁸ Hemphill & Sampart, *supra* note 35 at 9; Dolin, *supra* note 34 at 14; Matthew Higgins and Stuart Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scale*, 326 SCIENCE 370(2009)

³⁹ Joseph Farrell and Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help* 19 BERKELEY TECH. L. J. 1 (2004) at 9-10 (analyzing the "public goods" problem which hinders challenging of patents in general); Hemphill & Sampart, *supra* note 35 at 9.

⁴⁰ See Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101 (2006) (referring mainly to patents whose subject matter is not covered by the Hatch Waxman Act).

⁴¹ 21 U.S.C. § 355(j)(8)(B) (2)(A). The bioequivalence requirement replaced the need to conduct independent clinical trials to demonstrate safety and efficacy of the generic pharmaceutical – *see* Hemphill & Sampart, *supra* note 35 at 8; Dolin, *supra* note 34 at 9.

innovator's drug is patent-protected, the generic firm may challenge such protection by filing an ANDA containing a "Paragraph IV" certification. By so doing it alleges that the patents that are listed with the FDA database (commonly known as "the Orange Book") as protecting the innovator's drug are invalid or not infringed by its own generic product⁴². Such Paragraph IV filing normally triggers a patent infringement suit on part of the innovator, in which the questions of patent validity and infringement are litigated⁴³. In addition, and most important for our purpose, the Act further provides that the first generic filer of an ANDA under "Paragraph IV" is entitled, under certain conditions, to a 180-day period of generic exclusivity in marketing its own generic product⁴⁴. In other words, during the generic exclusivity period the first filer can market its generic product. while other filers of ANDA's with respect to the same drug must wait at least until the expiry of the generic exclusivity period before they can enter the market. When the drug in question enjoys substantial sales, the Paragraph IV exclusivity may be extremely valuable⁴⁵.

Recent empirical research conducted by Scott Hemphill and Bhaven Sampart demonstrates that this set of provisions, particularly the "quasiintellectual property right" set up by the Paragraph IV mechanism⁴⁶, was indeed successful in establishing an environment which encourages patent challenging among generic pharmaceutical firms⁴⁷. The number of patent challenges following its introduction has dramatically increased⁴⁸. Moreover, as may be expected, patent quality is one of the significant factors which influence the decision to challenge, and patent challenges

⁴² 21 U.S.C. § 355 (j)(5)(B)(iv).

⁴³ For a detailed review of this mechanism *see* Dolin, *supra* note 34, pp. 12-14.

⁴⁴ *Ibid.* The detailed conditions triggering the Paragraph IV exclusivity are immaterial for our purposes.

⁴⁵ See Higgins and Graham, *supra* note 38, at 370 (noting that the average potential payoff of the Paragraph IV challenging is 60 million dollars in the first 180 days alone); Scott C. Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch Waxman Act*, available at SSRN: <u>http://ssrn.com.abstract=1736822</u>, at p. 8-9 (analyzing the value of the exclusivity period under the Act).

⁴⁶See Hemphill and Lemley, *supra*, note 45, at 8 (referring to the Paragraph IV exclusivity as a "mini patent").

⁴⁷ Hemphill & Sampart, *supra* note 35.

⁴⁸ Higgins and Graham, *supra* note 38, at 370; Hemphill & Sampart, *supra* note 35 at pp. 3 and 14.

under the Hatch Waxman regime indeed seek to target those weaker patents that are more likely to create "patent overspills"⁴⁹.

Admittedly, the provisions of the Hatch Waxman Act in this context and their implementation are not immune from difficulties and criticism. Most of that criticism focuses on the practice of "reverse payment settlements" which developed under the Act. Under these practices the parties settle the Paragraph IV litigation, without a decision being obtained as to the validity (or non-infringement) of the challenged patent. Typically, generic entrance to the market is somewhat delayed, in return of a certain payment or other benefits from the innovator company⁵⁰. Current writing raises concerns that such settlements might deprive the public of at least part of the benefits resulting from patent challenges⁵¹.

A detailed review and evaluation of that criticism is certainly beyond the scope of this article. As already emphasized, my aim is not to propose a *verbatim* import of the Hatch Waxman mechanism into copyright law. For reasons discussed in the following Part, such a measure would be both impractical and undesirable⁵². I do suggest, however, a more general insight which can be drawn from the experience accumulated with respect to pharmaceutical patents during the last decades. The regime established under the Hatch Waxman Act carries an important *conceptual* lesson for copyright law: It demonstrates that an *ex post* market scrutiny of intellectual property overspills is an obtainable task, if the appropriate set of incentives is embedded in the relevant law. It further demonstrates that providing a significant incentive to challenge helps to overcome risk aversion, and makes a significant difference in the willingness of private actors to embark upon the challenging of intellectual property rights.

⁴⁹ Hemphill & Sampart, *ibid*, at pp. 18-26; Higgins and Graham, *ibid*.

⁵⁰ See, e.g., Hemphill and Lemley, *supra*, note 45 (further arguing that in order to achieve the goals of the Hatch Waxman Act the exclusivity under the Act should be granted to the first generic company that actually *enters* the market); Michael A. Carrier, 2025: Reverse Payment Settlements Unleashed, CPI ANTITRUST J. (2010)(criticizing the practice of "reverse payment settlements" from an antitrust perspective); Dolin, *supra* note 34 (calling for a patent re-examination in cases of "reverse payment settlement").

⁵¹ See references in note 50 *ibid.* Others are concerned with additional strategies for delaying generic entry which brand-name companies developed pursuant to the Hatch Waxman legislation – *see* Hemphill and Lemley, *supra* note 45, at 16-24.

⁵² See Part IV infra, notes 56-60 and accompanying text.

This is a lesson which copyright law should seek to explore. Like patent law (in the pharmaceutical field), copyright law cannot be confined to the prevailing narrative of providing an incentive to creation. Rather, in order to counterbalance its overspill externalities, copyright, too, should concern itself with providing an affirmative incentive to challenge. In the following Part I turn to explore possible manners of incorporating an incentive-to challenge regime into copyright law.

IV- APPLICATION TO COPYRIGHT

A. The Conceptual Framework

In light of previous analysis, several issues should be considered while searching for an incentive to challenge regime that is suitable for copyright law. *First*, the need to use private parties as effective guardians of the public domain, by providing them with an adequate set of incentives, may be even more crucial in the field of copyright than in the area of patents. The registration requirement that applies to patents entails an ex ante examination of patent applications prior to their grant. Despite its imperfections, the registration system does provide a certain level of administrative filtering of patent overspills⁵³. Such an administrative system does not exist with respect to copyright subject matter, whose protection does not depend on any formal registration. Indeed, several commentators have recently suggested establishing various administrative measures in order to inhibit copyright overspills⁵⁴. Yet, the Hatch Waxman experience suggests that a market based system which encourages an *ex post* review and challenge by private parties is feasible. Indeed, with an appropriate set of incentives such a scheme can be more efficient than administrative scrutiny⁵⁵. In addition, this market based approach may be more consistent with the current structure and operation

⁵³ But *cf.* Farrell and Merges, *supra* note 39 (arguing that the *ex ante* administrative scrutiny of patent applications by the Patent Office is limited and should be strengthened).

⁵⁴ See Peukert, supra note 12 (suggesting the establishment of a European public domain supervisor); Mazzone: Administering Fair Use, supra note 20 (making various proposals for regulating fair use through an administrative agency). See also Pamela Samuelson and Members of The CPP, *The Copyright Principles Project: Directions for Reform*, 25 BERKLEY TECH. L. J. 1175, 1198 (2011) (proposing to reinvigorate the copyright registration requirement).

⁵⁵ See Hemphill & Sampart, supra note 35.

of copyright law, and does not involve the costs entailed in establishing new regulatory mechanisms⁵⁶.

On the other hand, including an exact parallel of the Hatch Waxman exclusivity in copyright law is neither desirable nor realistic. The differences between the subject matter of copyright overspills and the overspills with which the Hatch Waxman Act is concerned are important and cannot be ignored. An early market entry of a generic producer of a life-saving pharmaceutical can be of vast significance to the public and may thus justify an incentive in the form of a generic marketing exclusivity, whose potential value may be immense⁵⁷. The fair use of books, articles, films or other copyright protected works, while undoubtedly significant from both economic and democratic perspectives, does not warrant such a powerful measure. Furthermore, successfully challenging the validity of a pharmaceutical patent carries immediate general benefits to other pharmaceutical players and to the public at large, as the invalid patent is erased from the registry. These benefits may justify the particular incentive provided under the Hatch Waxman Act to the first filer. On the other hand, asserting that a certain use of a copyrighted work is a permitted or a fair use is context specific. Although such holdings may have certain precedential value, their effect is less general.

Moreover, in light of the differences in subject matter and in market structures, providing a limited exclusive right to users is unlikely to create any substantial incentive to challenge overspills in the copyright arena. Let us consider, again, the hypothetical *Martin Luther-King* example⁵⁸. Imagine that the newspaper seeking to use the segment from the speech successfully challenges the copyright owners position, and succeeds in litigating its fair use argument. In return, it is granted a 180 days exclusivity in utilizing and licensing that segment. However, due to the modest license fee requested for this use⁵⁹ and the dispersed and incidental nature of potential licensees⁶⁰, the value of such an exclusive right is likely to be rather limited. It is unlikely to counterbalance the *exante* anticipated costs of copyright challenging nor to create a real incentive to challenge.

⁵⁶ Notwithstanding, adopting my proposal for an incentive to challenge as detailed in the following section does not necessarily exclude administrative or other measures.

⁵⁷ See the references cited in note 45 supra.

⁵⁸ See Part II supra, notes 24- 27 and accompanying text.

⁵⁹ In our example- 400 dollars per use.

⁶⁰ See the discussion in Part II *supra*, notes 11-13 and the accompanying text.

The interim conclusion, then, is that despite being inspired by the pharmaceutical patent field, creating an incentive to challenge regime in copyright law cannot be based upon providing exclusive rights with respect to the challenged material. Rather, an incentive-to-challenge has to be integrated in copyright law in a manner which would suit both copyright markets and copyright subject matter. This is where I turn in the following Section.

<u>B.</u> Incentive to Challenge and Copyright Misuse

My proposal is rather simple. Copyright law should employ the copyright misuse principle as a vehicle for introducing an incentive-tochallenge regime into copyright doctrine⁶¹. The proposal is twofold: the first is the introduction of statutory damages, equal to the statutory damages for willful copyright infringement, as a potential remedy for copyright misuse. The second is the recognition of copyright misuse as an affirmative doctrine, that entitles users to initiate legal proceedings against right-holders. Under this proposed scheme, unduly objecting to a legitimate use (such as a fair use, or a use of a work in which copyright expired) would constitute copyright misuse on part of the right holder ⁶². Moreover, a decision that copyright was indeed misused would give rise to a variety of remedies, including a right to statutory damages for users whose rights were prejudiced.

Notably, the introduction of statutory damages as a remedy for copyright misuse will most likely necessitate legislative intervention: the current statutory damages provision in the Copyright Act concerns copyright infringement, not copyright misuse. Moreover, the entire misuse doctrine is judge-made and still relatively unformed, and the consequences of misusing copyright are not entirely clear⁶³. It is already apparent,

⁶¹ For the doctrine of copyright misuse in general *see, e.g.,* Brett Frischmann and Dan Moylan, *The Evolving Common Law Doctrine of Copyright Misuse: A Unified Theory and Its Application to Software* 15 BERKLEY TECH. L. J., 865, 901-902 (2000); Ramsey Hanna, *Misusing Antitrust: The Search for Functional Copyright Misuse Standards*, 46 STANFORD LAW REV. 401 (1994); Tom Bell, *Codifying Copyright's Misuse Defense* 2007 UTAH L. REV. 573; Katryn Judge, *Rethinking Copyright Misuse* 57 STAN. L. REV. 901 (2004); Paul Goldstein, GOLDSTEIN ON COPYRIGHT (3rd. ed. 2008), at 11:37.

 $^{^{62}}$ The term "unduly" implies that not every objection to a permitted use would be deemed copyright misuse on part of the right holders – *see* the discussion *infra*, note 69 and accompanying text.

⁶³ See the references cited in note 61 supra.

however, that the misuse doctrine can apply in a range of different circumstances and can yield a range of potential outcomes, and that a holding of misuse does not result in the complete expiry of copyright⁶⁴. This state of affairs constitutes a rather convenient background for implementing the current proposal.

This article does not purport to draw a complete set of statutory provisions applying the principles suggested above. Rather, I merely aim to sketch a structure for a proposed solution, which reflects the conclusions of the discussion in the previous sections. This structure, however, warrants a few words of explanation.

First, employing copyright misuse in order to create an incentive to challenge copyright overspills is theoretically consistent with the *raison d'être* of the misuse doctrine. The fundamental problem which this article seeks to address is the undue (and often successful) attempts on part of right holders to expand copyright beyond its statutory scope. However, preventing copyright's expansion beyond the monopoly granted under the Copyright Act is also the underlying rationale of the copyright misuse principle, as acknowledged by several courts⁶⁵. Moreover, the principle of copyright misuse possesses inherent flexibility and can thus accommodate the doctrinal analysis proposed in the previous sections⁶⁶.

In addition, the proposed structure conceptualizes copyright misuse as an affirmative right of users, rather than merely a defence against infringement. This perspective is consistent with recent writing, which calls for recognizing various copyright doctrines as users' rights, rather than mere defenses⁶⁷. Joseph Liu has recently observed, that this approach

⁶⁴ GOLDSTEIN, supra note 61.

⁶⁵ For prominent case law recognizing the principle and its underlying rationale see, e.g., Lasercomb Inc. v. Reynolds 911 F2d 970 (4th. Cir. ,1990) ;Alcatel USA Inc. v. DGI Technologies, Inc 166 F3d. 772 (5th. Cir. 1999); Practice Management Information Corp. v. American Medical Association 121 F3d 516 (9th. Cir. 1997).

⁶⁶ *Cf.* Tadlock, *supra* note 16, at 644-45 (acknowledging the current limitations of copyright misuse and proposing its expansion by courts in order to encompass overly broad "copyright warnings" by sports and media companies).

⁶⁷ See Liu, supra note 15, at 113 (proposing to regard fair use as an affirmative right). Cf. also Guy Pessach, Reverse Exclusion in Copyright Law - Reconfiguring Users' Rights (2011), available at SSRN: <u>http://ssrn.com/abstract=1813082</u> (further proposing to conceptualize users' rights as "rights to exclude") ;Niva Elkin-Koren, Users' Rights, in AUTHORING RIGHTS: READING THE NEW ISRAELI COPYRIGHT ACT (Michael Brinhack and

recognizes that certain permitted uses have intrinsic value, and should thus be encouraged⁶⁸. Challenging copyright overspills is, I believe, a prominent example of an act which bears such an inherent value.

Yet, I do not imply that each holding according to which a certain use of a copyright work is permitted should be deemed copyright misuse on part of the right holders⁶⁹. Rather, the proposed mechanism will only be triggered by an *undue* objection to a certain permitted use. Thus, for example, a good faith objection to a certain use whose *ex ante* permissibility is doubtful would not be considered "undue", while a bad faith attempt to prevent the use of a work in which copyright has already expired may well give rise to a misuse claim. This restriction is supported not only by intuitive notion of fairness, but also by the need to avoid overdeterrence of copyright owners, and minimize abuse on the part of users⁷⁰. I do not purport to sketch here an exhaustive set of circumstances which would be deemed "undue" objection by right-holders. The inherent flexibility of the misuse doctrine would enable the development of those on a case-by-case basis.

My proposal, then, envisages the following scenarios: unduly objecting to a fair use or to other permitted uses would constitute copyright misuse. A user would be able to raise a misuse allegation in response to a right-holder claim, but also to initiate independent proceedings against a right-holder, alleging misuse of copyright⁷¹. Notably the latter strategy, in which the user is the plaintiff rather than a defendant, may minimize the

Guy Pessach, eds., in Hebrew) (2009)(arguing that the Israeli Copyright Act of 2007 should be read as establishing users' rights rather than mere defenses).

⁶⁸ Liu, *supra* note 15, at 113 (observation made in the context of fair use).

⁶⁹ Nor do I argue that each and every contractual restriction of the rights of users of copyright works should automatically be considered misuse of copyright. For a discussion of this complex question, which is beyond the scope of this essay *see*, *e.g.* Niva Elkin-Koren, *Copyright in Cyberspace – Rights Without Laws?* 73 CHL-KENT L. REV. 1155 (1998); David Nimmer, Elliot Brown, Gary Frischling, *The Metamorphosis of Contract into Expand* 87 CAL. L. REV. 17 (1999); Mark Lemley, *Beyond Pre-emption: The Law and Policy of Intellectual Property Licensing* 87 CAL. L. REV. 111 (1999);Maureen O'Rourke, *Drawing the Boundary Between Copyright and Contract: Copyright Preemption of Software License Terms*, 45 DUKE L.J. 479 (1995); Julie Cohen, *Copyright and the Jurisprudence of Self Help*, 13 BERKELEY TECH. L.J. 1089 (1998).

⁷⁰ See in more detail the discussion *infra*, notes 76- 80 and accompanying text.

 $^{^{71}}$ Cf. Judge, supra note 61, at 932 (suggesting that copyright misuse should not be confined to a mere defense, but could serve as a basis for requesting declaratory judgment).

implications of the proceedings on the costs of insurance. A decision that copyright was misused could give rise to a variety of remedies, among them a right to statutory damages for prejudicing users' rights, in a maximum amount equivalent to that set out in the Copyright Act as damages for willful copyright infringement⁷².

Let us return for a moment to the "I Have a Dream" example discussed above⁷³, and consider it under the proposed regime. Imagine now, that the newspaper decides to challenge the right-holders position and object to their attempt to limit its alleged fair use, either by filing a misuse claim, or by filing a counterclaim in response to the right-holders. From an *ex ante* perspective it is now facing an 80% prospects of being awarded statutory damages in a maximum amount of 150,000\$. The economic balance of incentives may shift in favor of copyright challenging⁷⁴. The right holders' *ex ante* "incentive to over-enforce", on the other hand, decreases in a respective manner. This shift in the balance of incentives may cause the holders of the rights to act with more restraint, and to grant an *ex-ante* consent to the requested use of the short segment of the speech.

On a more general level, decisions that copyright was misused (by undue objection to permitted uses) will have a certain precedential value, which is likely to affect other right holders. Over time, then, creating an incentive to challenge in the manner proposed here, may encourage greater self-restraint *ab initio* on the part of copyright owners⁷⁵.

Lastly, a prominent objection which may be raised in this context is that providing an incentive to challenge would harm the incentive to create and disseminate copyright protected works⁷⁶. This objection raises a much broader question, namely whether the rights provided under the Copyright Act are indeed required to incentivize the creation of copyright protected subject matter. This question is certainly beyond the scope of this article,

⁷² 17 U.S.C. § 504(c)(2) (2006).

⁷³ Part II *supra*, notes 24-28 and accompanying text.

⁷⁴ Compare to the situation in the absence of an incentive – supra note 27.

⁷⁵ *Cf.* Michal Shur-Ofry, *Popularity as a Factor in Copyright Law*, 59 U. TORONTO L. J. 525, 576 (2009) (arguing, in a different context, that the development of the copyright misuse doctrine is likely to increase self restraint on part of right holders, in comparison to reliance on fair use alone).

⁷⁶ *Cf.* Higgins and Graham, *supra* note 38 (arguing that the Paragraph IV incentive under the Hatch Waxman Act has damaged the incentive of innovative pharmaceutical companies to develop new drugs).

which takes the current copyright legislation as its baseline⁷⁷. However, under the current framework, too, the argument seems normatively flawed: copyright law is not designed to afford copyright owners rights to prevent permitted uses or rights that are broader than those granted under the Copyright Act, and incentivizing innovation should not be performed by allowing copyright overspills⁷⁸.

An additional, related, argument which may be raised in this context is the concern of over-deterrence or "misuse overspills". To a certain extent, this argument mirrors the concerns of copyright overspills discussed earlier: an incentive to challenge regime may deter copyright owners from enforcing valid rights, due to legal uncertainty coupled with risk-aversion. Indeed, this is a concern which should not be ignored. Embedding an incentive to challenge in copyright law should be performed in a careful manner, so as to correct the current structural imbalance without producing another (opposite) imbalance. In the context of the present doctrinal proposal, this concern is addressed by confining misuse to "*undue*" objections to permitted uses on part of right holders⁷⁹. Such a requirement would minimize potential abuse on part of users, and would reduce the risk of over-deterrence⁸⁰. Thus, a cautious introduction of an incentive to challenge would indeed help to minimize the gap between the de jure scope of rights, and their de facto expansion, and to calibrate the scope of copyright to the actual level set out by the legislator.

⁷⁷ For an interesting discussion *see*, e.g., Dianne Leenheer Zimmerman, *Copyrights as Incentives: Did We Just Imagine That?* 12 THEORETICAL INQUIRIES IN LAW, article 3 (2011) (highlighting the existence of multiple motivations for creation, including the significance of intrinsic factors). Additional broad questions which arise in this context pertain to copyright's underlying rationales – *see* note 30 *supra*.

 $^{^{78}}$ *Cf.* Hemphill & Sampart, *supra* note 35, at 28 (discussing a similar argument raised in the context of the Hatch Waxman Act, and further noting that granting patents that do not meet the PTO's patentability standards is not an adequate way to incentivize).

⁷⁹ See notes 69-70 supra and accompanying text.

⁸⁰ Interestingly, similar concerns have also arisen in the context of the Hatch-Waxman regime. The legislation was amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which contained certain provisions designed to prevent generic companies from abusing the incentive granted to them - see, in general, Stephanie Greene, A Prescription for Change: How the Medicare Act Revises Hatch Waxman to Speed Market Entry of Generic Drugs, 30 J. CORP. L. 309 (2005).

IV- CONCLUSION

Copyright law is designed around the prevailing narrative of providing an incentive for innovation. It is quite oblivious to providing users with an incentive to challenge undue attempts to broaden copyright's scope. Recent proposals raised in literature – particularly those concerned with clarifying the fair use doctrine -- are insufficient for resolving the copyright overspills problem that is rooted in users' risk aversion. However, the problems of overspills and of under-challenging are not unique to copyright law, but exist in other areas of intellectual property as well. Looking beyond the contours of copyright reveals its dynamic interrelations with other branches of intellectual property law. More specifically, it reveals that in one area – the field of pharmaceutical patents – an effective intellectual property challenging mechanism was introduced under the Hatch Waxman Act.

The regime established under the Hatch Waxman Act carries an important *conceptual* lesson for copyright law: it indicates that an *ex post* market scrutiny of intellectual property overspills is an obtainable task, if the appropriate set of incentives is embedded in the relevant law. It further demonstrates that providing a significant incentive to challenge helps to overcome users' risk aversion, and makes a significant difference in the willingness of private actors to embark on the challenging of intellectual property overspills.

Inspired by the Hatch Waxman solution, copyright scholarship should explore how an incentive-to-challenge can be incorporated in the law, in manners which would suit both copyright markets and copyright subject matter. While not attempting to present a complete detailed solution, the article's proposal is to create such an incentive by developing an affirmative copyright misuse doctrine, that would entitle successful challengers to statutory damages. Developing this incentive-to-challenge scheme in further detail is a challenge that remains for future research.