# Canadian Intellectual Property Review

# Revue canadienne de propriété intellectuelle





INTELLECTUAL PROPERTY INSTITUTE OF CANADA
INSTITUT DE LA PROPRIÉTÉ INTELLECTUELLE DU CANADA

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**CANADIAN INTELLECTUAL PROPERTY REVIEW**
**REVUE CANADIENNE DE PROPRIÉTÉ INTELLECTUELLE**

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**ARTICLES**



**NOTE**

# MESSAGE FROM THE EDITORS

As my second tenure as editor-in-chief of the *Canadian Intellectual Property Review* (CIPR) comes to a close, I take the opportunity to introduce you to my successor, Athar K. Malik. His first and key qualification is that he has served for six years as a member of the CIPR Editorial Board. During that time he has been a highly active participant on many of its ad hoc committees, a keen, detail-oriented reviewer, and for the past six months my "shadow" and sounding board. Athar also serves on the litigation and trademark legislation committees of the Intellectual Property Institute of Canada (IPIC).

Mr. Malik graduated with the highest overall standing in commerce from Queen's University and received a JD from the University of Toronto. Upon his call to the Ontario bar, he practised with the IP group of Blake, Cassels & Graydon LLP in Toronto until 2013, when he moved to Saint John, New Brunswick. At that time, he was called to the New Brunswick bar and commenced practice with Cox & Palmer. A registered trademark agent, Athar's practice also includes copyright and general IP law matters, notably licensing and litigation. On a personal note, Athar is an active volunteer in his adopted city and, recently, a proud first-time father.

As an author himself of numerous articles on IP law, and as a member of International Trademark Association's Publications Committee, Athar brings a new and broad perspective to CIPR editorship. As you will read below, his vision for CIPR's next phase of development is inspirational.

In closing, I express sincere thanks to Véronique Coch at the IPIC office for her thoughtfulness and energy; to our editorial board members for their selfless dedication and sharp eyes; and to our contributors for their sheer intelligence and generosity. I have perceived my role as a facilitator of CIPR scholarship and am grateful for the honour it has been to serve.

Jeananne Kathol Kirwin, outgoing editor-in-chief

It is with mixed emotions and humility that I write this message to you. Mixed emotions because, while I am excited and honoured to be the incoming editor for the CIPR, it is also with sadness that I step into this role because of the sudden passing of our previous editor Euan Taylor (1963-2015). Euan was a bright light in our profession and he will be missed. Humility because, after years of being a reviewer, I step into the very large shoes of all the previous editors; their work is reflected in the excellent esteem in which CIPR is held.

I have been very fortunate to have been able to rely on Jeananne Kirwin (our penultimate and current acting editor) as I "learned the ropes," and I thank her for both her invaluable guidance and the level of dedication she has had to CIPR over the years. I would be remiss if I also did not acknowledge the support and organizational excellence that the IPIC staff, in particular Véronique Coch, bring to CIPR and to making the many day-to-day activities involved in publishing such a high-

quality journal seem effortless. Next, I would like to thank the diverse and excellent group that forms the CIPR Editorial Board for their considerate reviews (and feedback) that make each and every submission better. Last, but not least, I must mention the contributors; all busy people who take the time to share their insights and scholarship with others in the profession—without this most critical ingredient, there would not be a CIPR, so thank you! I am truly humbled when I compare myself to this cast of characters that have been and are central to getting to you a given edition of this journal.

I think I can say that a legacy of Jeananne's tenure has been the greater online accessibility and visibility of the journal. In a similar vein, a key goal that Euan had was to continue to broaden the exposure of and diversity in content of CIPR. My own vision is, in many ways, to continue along the same lines, because these themes remain critical to the health of any publication today; we must maintain high standards and remain relevant in content, but, to bring value to the profession, we must also be read, cited, and relied on! Another project that I hope to bring to a conclusion is a refresh in the design of CIPR.

A few words now on this issue. We have two interesting pieces with a copyright bent, looking at the topic of substantial similarity (Hutchison) and copyright in photographs (Wilkinson and Deluzio); a timely consideration of intellectual property issues in relation to the booming world of 3D printing (Dagne); last, two patent-focused pieces, looking at damages under the Patented Medicines (Notice of Compliance) regime (Stulberg and Mesiano-Crookston) and discovery/disclosure in patent litigation in Canada, the United States, and the United Kingdom (Beach, Parker, and Drew). Whether you practise in the particular area or agree with the authors, these are all works that will make you think and reflect. Enjoy!

Athar K. Malik, incoming editor-in-chief

# MESSAGE DES RÉDACTEURS EN CHEF

À l'approche de la fin de mon mandat de rédactrice en chef de la *Revue canadienne de propriété intellectuelle* (RCPI), je profite de l'occasion pour vous présenter mon successeur, Athar K. Malik. Le fait qu'il a servi au sein du comité de rédaction de la RCPI pendant six ans constitue sa principale et plus importante qualification. Au cours de cette période, il a participé activement aux travaux de nombreux sous-comités, en plus d'être un réviseur enthousiaste et minutieux et, au cours des six derniers mois, mon « ombre » et allié de rétroaction. Athar œuvre également au sein de deux autres comités de l'Institut de la propriété intellectuelle du Canada (IPIC), notamment le Comité des litiges et le Comité de législation en marques de commerce.

Athar a obtenu son diplôme de commerce de l'Université Queens, en obtenant les meilleurs résultats possible et il décrocha un doctorat en jurisprudence (J.D.) à l'Université de Toronto. Après avoir été admis au barreau de l'Ontario, il a pratiqué le droit avec le groupe de la propriété intellectuelle du cabinet Blake, Cassels & Graydon SRL de Toronto jusqu'en 2013, lors de son déménagement à Saint-Jean, N.-B. Suite à son admission au barreau du Nouveau-Brunswick, il a amorcé une pratique au sein du cabinet Cox & Palmer. Athar est agent de marques de commerce agréé et sa pratique comprend également des travaux sur le droit d'auteur et le droit général en matière de PI, notamment les licences et le litige. Sur une note personnelle, Athar est un bénévole actif dans sa ville d'adoption et plus récemment, il est devenu le fier parent d'un premier enfant.

À titre d'auteur de nombreux articles sur le droit de la PI et de membre du Comité des publications de l'International Trademark Association (INTA), Athar apporte une nouvelle perspective globale à la rédaction de la RCPI. Comme vous le lirez ci-après, sa vision de la prochaine phase de développement de la RCPI est inspirante.

En terminant, je tiens à remercier sincèrement Véronique Coch du bureau de l'IPIC pour sa prévenance et son énergie, les membres de notre comité de rédaction pour leur dévouement altruiste et leur vision perçante et nos contributeurs pour leur intelligence unique et leur pure générosité. J'ai perçu mon rôle de facilitateur de l'érudition de la RCPI et je vous remercie chaleureusement pour avoir eu l'honneur de vous servir.

Jeananne Kathol Kirwin, rédactrice en chef sortante

C'est donc animé de sentiments mélangés et empreint d'humilité que je vous écris ce message. Je suis animé de sentiments mélangés du fait que je suis très emballé et honoré d'être le nouveau rédacteur en chef de la RCPI, mais je suis également attristé d'assumer ce rôle en raison du décès soudain de notre ancien rédacteur Euan Taylor (1963-2015). Euan était une lumière vive dans notre profession et il nous manquera. Je suis empreint d'humilité, car après de nombreuses années à titre

de réviseur, je prends le relais et j'endosse les très grosses pointures des anciens rédacteurs; leurs travaux sont reflétés dans la haute estime reconnue de la RCPI.

J'ai été très chanceux d'avoir pu miser sur Jeananne Kirwin (notre antépénultième rédactrice et actuelle rédactrice intérimaire) au fur et à mesure que j'apprenais les ficelles du métier; je la remercie sincèrement pour ses conseils inestimables et pour son niveau de dévouement envers la RCPI au fil des ans. Je m'en voudrais de passer sous silence ma reconnaissance du soutien et de l'excellence organisationnelle du personnel de l'IPIC, et plus particulièrement de Véronique Coch, à l'égard de la RCPI, en plus de faire en sorte que les nombreuses activités quotidiennes liées à la publication d'une revue professionnelle de grande qualité semblent sans effort. Je tiens également à remercier l'excellent groupe diversifié qui forme le comité de rédaction de la RCPI pour son examen prévenant et sa rétroaction attentionnée qui contribuent à améliorer chaque article. Enfin, et ce n'est pas le moins important, je dois mentionner tous les contributeurs, des gens très occupés qui prennent le temps de partager leur perspicacité et leur savoir avec les autres membres de la profession … sans cet ingrédient extrêmement important, la RCPI n'existerait pas, je vous en remercie! Je suis vraiment ému lorsque je me compare avec cette galerie de personnages qui ont été et qui demeurent essentiels pour la production de chaque numéro de cette revue.

Je pense que je peux affirmer que Jeananne nous aura laissé un héritage précieux, soit une meilleure accessibilité et visibilité de la revue en ligne. Dans un même ordre d'idées, un des principaux objectifs d'Euan consistait à continuer d'élargir l'exposition de la RCPI et la diversité de son contenu. Ma propre vision est, à bien des égards, de poursuivre dans la même veine, car ces thèmes demeurent toujours essentiels pour la santé de toute publication; nous devons maintenir des normes élevées et veiller à ce que le contenu demeure pertinent; cependant, pour ajouter une certaine valeur à la profession, nos articles doivent également être lus et cités, en plus d'inspirer la confiance! Un autre projet que j'aimerais concrétiser est un rafraîchissement de la RCPI.

Permettez-moi d'exprimer quelques mots sur le numéro actuel. Nous avons deux articles très intéressants touchant le droit d'auteur, notamment l'examen du thème de la similarité substantielle (Hutchison) et du droit d'auteur dans les photographies (Wilkinson et Deluzio); une considération opportune des questions de propriété intellectuelle en rapport avec la forte croissance de l'impression 3D (Dagne); enfin, deux articles axés sur les brevets, soit l'examen des dommages-intérêts aux termes du *Règlement sur les médicaments brevetés (avis de conformité)* (Stulberg et Mesiano-Crookston) et la communication préalable/divulgation dans les litiges concernant des brevets au Canada, aux États-Unis et au Royaume-Uni (Beach, Parker et Drew). Peu importe si vous exercez dans le domaine particulier ou si vous êtes d'accord avec les auteurs, tous ces travaux aiguiseront vos pensées et vos réflexions. Bonne lecture!

Athar K. Malik, nouveau rédacteur en chef

# Articles

# SUBSTANTIAL SIMILARITY AFTER CINAR CORP v ROBINSON*

*Cameron J. Hutchison***

**ABSTRACT**

In recent years, the Supreme Court of Canada has rendered a series of illuminating and balanced judgments in the area of copyright law. *Cinar Corp v Robinson* is a departure from this tradition. The court's endorsement of a holistic approach, and its refusal to consider the use that is made of the borrowing in the alleged infringing work, appears to strengthen substantial similarity doctrine in favour of copyright holders; however, the impact of these rulings will likely turn on how lower courts interpret the ambiguities of the judgment. On one view, copyright protections will be bolstered even more by expanding the enquiry to include latent or structural elements of a work without in any way limiting the scope of this broader analysis, as well as the failure to provide any meaningful guidance on making substantial similarity comparisons. On another view, the court's silence on key issues, together with the ambiguity in how it executed the substantial similarity assessment, provides an opportunity for lower courts to refine the substantial similarity analysis in a more balanced fashion.

**RÉSUMÉ**

Au cours des dernières années, la Cour suprême du Canada a rendu une série de décisions éclairantes et équilibrées dans le domaine du droit d'auteur. Toutefois, le jugement de la Cour dans l'affaire *Cinar Corp c Robinson* s'éloigne de cette tradition. L'entérinement par le tribunal d'une approche globale et son refus de considérer l'utilisation faite des éléments empruntés à la prétendue œuvre contrefactrice semblent renforcer une doctrine de similitude substantielle en faveur des détenteurs de droits d'auteur. Cependant, l'impact réel de ces décisions dépendra de la façon dont les tribunaux inférieurs interpréteront les parties du jugement qui demeurent ambigües. Selon une première interprétation, la protection des droits d'auteur sera renforcée par l'élargissement par la Cour de la portée de l'analyse à effectuer pour y inclure certains éléments latents ou structurels de l'œuvre analysée sans pour autant que les limites de cette analyse n'aient été définies, ainsi que par l'absence d'indications claires de la part de la Cour sur la façon dont l'analyse des similitudes substantielles doit être effectuée. Selon une autre interprétation, le silence du tribunal sur certaines questions clés et la manière ambigüe dont il a évalué les similitudes substantielles offrent aux tribunaux inférieurs la possibilité d'affiner l'analyse des similitudes substantielles de manière plus équilibrée.

* Submission to the editor, December 3, 2014.

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## 1.0 INTRODUCTION

In recent years, the Supreme Court of Canada has rendered a series of illuminating and balanced judgments in the area of copyright law.[1] *Cinar Corp v Robinson*[2] is a departure from this tradition. The court's endorsement of a holistic approach, and its refusal to consider the use that is made of the borrowing in the alleged infringing work, appear to strengthen the substantial similarity doctrine in favour of copyright holders. However, the impact of these rulings will likely turn on how lower courts interpret the ambiguities of the reasoning in *Robinson*. On one view, copyright protections will be bolstered even more by expanding the inquiry to include latent or structural elements of a work without in any way limiting the scope of this broader analysis, or providing any meaningful guidance on making substantial similarity comparisons. On another view, the court's silence on key issues, together with the ambiguity in how it executed the substantial similarity assessment, provides an opportunity for lower courts to refine the substantial similarity analysis in a more balanced fashion.

Section 2.0 begins with an explanation of the substantial similarity doctrine in Canada pre-*Robinson*, highlighting some of the legal uncertainties in the area. Section 3.0 explores the *Robinson* case in terms of what it resolved and purported to resolve with respect to the substantial similarity doctrine, and also offers a critique of these aspects of the decision. Section 4.0 addresses what the *Robinson* case did not, but needed to, clarify and elaborate. Given the ambiguities within key aspects of the decision, the conclusion outlines two starkly different futures for the doctrine in Canada.

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[1] Consider the limits placed on copyright holder rights in *Théberge v Galerie d'Art du Petit Champlain Inc*, 2002 SCC 34 and *CCH Canadian Limited v Law Society of Upper Canada*, 2004 SCC 13 [*CCH*]. These judgments are also reasonably clear in articulating some guidelines for future decision-makers and in applying those guidelines to the facts at hand.

[2] 2013 SCC 73 [*Robinson*].

## 2.0 SUBSTANTIAL SIMILARITY BEFORE ROBINSON

Copyright offers exclusivity to the author of an original artistic, literary, musical, or dramatic work.[3] Typical works covered by copyright include books, movies, songs, and paintings. The requirement that a work be "original" means that the work must emanate from the author (authorial originality) and that the work must have a measure of creativity (creative originality). Important for our discussion is that when a work is not copied but nonetheless appears the same or substantially similar to a work under copyright, a defence of independent creation—that is, authorial originality—will shield the second author from a claim of copyright infringement. Creative originality is satisfied if the work reflects "skill and judgment," a standard that is not intended to be very high.[4]

Copyright protects expression and does not subsist in respect of the ideas or facts that underlie a work. For example, to describe a character as a "small furry creature" is to convey an idea of rough dimension and form. However, the expressive content that copyright protects lies in the elaboration of the many details that would make the character unique in relation to the infinite number of other possible manifestations of the very same idea.[5] In connection with dramatic and literary works in particular, copyright will also not protect stock themes[6] and *scenes a faire*.[7] As "unprotectable" features of a work not subject to copyright, these elements are in the public domain, available for all to use.

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[3] The scope of covered works is broad under the *Copyright Act*, RSC 1985, c C-42: see s 2 definitions. Furthermore, for copyright to subsist, the work must be fixed in a tangible form: see *CCH*, *supra* note 1.

[4] In rejecting a standard of either industriousness or creativity (as novel or unique) as the basis for originality, McLachlin CJC, in *CCH*, *supra* note 1 at para 16, opted for a middle ground between these poles:

> What is required to attract copyright protection in the expression of an idea is an exercise in skill and judgment. By skill, I mean the use of one's knowledge, developed aptitude or practiced ability in producing the work. By judgment, I mean the use of one's capacity for discernment or ability to form an opinion or evaluation by comparing different possible options in producing the work. The exercise of skill and judgment required to produce the work must not be so trivial that it could be characterized as a purely mechanical exercise.

[5] As relatively straightforward as this concept of "idea–expression" dichotomy may seem from this example, it has proven notoriously difficult to sift out the expression from the idea in a number of cases.

[6] For example, "the familiar figure of the Irish cop is a stock theme of police fiction": *Arden v Columbia Pictures*, 908 F Supp 1248 at 1259 (SDNY 1995).

[7] This "refers to incidents, characters or settings that are, as a practical matter, indispensable or standard in the treatment of a subject, setting or genre; e.g., a 'showdown' at high noon between gunfighters is not a protectable element of a western": Bob Tarantino, "'I've Got This Great Idea for a Show …' Copyright Protection for Television Show and Motion Picture Concepts and Proposals" (2004) 17 IPJ 189 at 201. According to Tarantino, the ineligibility of *scènes à faire* for copyright protection has not been adopted by a Canadian court.

Copyright infringement consists of violating an author's exclusivity in a work, or his or her "sole right to produce or reproduce the work or any substantial part thereof in any material form whatever."[8] The words "substantial part thereof" serve as the statutory basis for substantial similarity as infringement. In other words, infringement is found where a defendant's work is a copy or a substantial reproduction of a plaintiff's work, regardless of whether it is used in its original or derivative form. Once copyright in a work has been established, the plaintiff must prove two elements for substantial similarity infringement: (1) copying of, or access to, the work (remember, independent creation of the same or similar work is a complete defence to copyright infringement); and (2) appropriation of the work—that is, all or a substantial part of the work has been taken.

Although not always an easy determination, the methodology of satisfying the first requirement is not controversial. If a defendant admits to copying the plaintiff's work or there is otherwise direct evidence of access to the work, then copying will be established. In other cases, where access to the work is denied by the defendant, copying may still be inferred from circumstantial or indirect evidence. In *Preston v 20th Century Fox*,[9] for example, the issue was whether George Lucas had seen the plaintiff's script prior to creating *Return of the Jedi*. Though Lucas denied ever receiving the script, the court rightly noted that "access may be inferred in such circumstances where the work complained of is found to contain substantial similarity with a copyright work."[10] Because the issue is whether copying has occurred, courts do not limit the evidence to expressive elements but will also consider whether ideas and other non-protectable elements have been borrowed. Moreover, courts will generally consider expert evidence for proof of copying, though they may or may not do so for appropriation.

Once access has been established, the second part of substantial similarity analysis considers whether there is wrongful appropriation of the plaintiff's copyrighted work. Here, tests used by courts have varied considerably. There are points of convergence for all these tests, however: substantial similarity analysis involves a consideration not just of how much is taken from the plaintiff's work (the quantitative inquiry) but also the nature of what is taken (the qualitative element). Indeed, it will often be the case that a small quantitative portion of a work is borrowed relative to the whole; nonetheless, that portion may consist of the most aesthetically pleasing part of the work—for example, the 30-second chorus ringtone of a 5-minute song. Decision-makers have sometimes commented that the qualitative-taking inquiry is impressionistic and subjective.[11]

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[8] *Copyright Act*, *supra* note 3, s 3.

[9] [1990] FCJ 1011 [*Preston*].

[10] *Ibid*.

[11] *Re Collective Administration of Performing Rights and of Communications Rights*, [2006] CBC No 5 at para 41 (Copyright Board of Canada).

Beyond this, courts in Canada have rendered various formulations and practices in developing an approach to substantial similarity analysis. There seem to be two main areas of inconsistency. One is whether expert testimony on matters of appropriation is to be allowed.[12] The second area of inconsistency is in the approach adopted by courts for determining whether a qualitative taking has occurred. Three such approaches are: (1) holistic, (2) factor analysis, and (3) dissection.

The "holistic" approach assesses a qualitative taking by looking at the work as a whole. The taking may be "a vital, essential part"[13] or a part that on its own has "originality."[14] The general sense conveyed in these articulations is that the taking of an aesthetically pleasing or economically valuable part of work will constitute infringement, regardless of its quantitative size in relation to the whole of either work. In other words, if you take a "good" part of a work (in a qualitative sense) and incorporate it into your own much larger creation, you may still be liable for copyright infringement. Because the qualitative aspect is assessed in light of the work as a whole, the determination is made without factoring out unprotectable elements of the work—for example, ideas, facts, stock devices, or *scènes à faire*. To the extent that courts refuse to factor out these elements, it is because of a concern that the whole of a work may be greater, in a creative sense, than its constituent parts.

The second approach, "factor analysis,"[15] introduces considerations extraneous to whether or not the works are substantially similar in a qualitative or quantitative sense.[16] The factor analysis considers:

1. the quality and quantity of the material taken;
2. the extent to which the defendant's use adversely affects the plaintiff's activities and diminishes the value of the plaintiff's copyright;
3. whether the material taken is the proper subject matter of a copyright;
4. whether the defendant intentionally appropriated the plaintiff's work to save time and effort; and
5. whether the material taken is used in the same or similar fashion as the plaintiff's.

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[12] *Hutton v Canadian Broadcasting Corp*, [1989] AJ 1193 (Alta QB), where the court considered expert evidence in connection with substantial similarity generally without limiting it to the issue of access. But see *Preston*, *supra* note 9, where the court adopted "an average lay observer, the average person in the respective intended audiences" as the test, and where the court did not rely on expert evidence to evaluate appropriation.

[13] *Hawkes & Son (London) Ltd v Paramount Film Service Ltd*, [1934] Ch 593 (CA), Slesser LJ.

[14] *Ladbrooke (Football) Ltd v William Hill (Football) Ltd*, [1964] 1 WLR 273 (HL), Lord Pearce.

[15] Adopted in *U & R Tax Services Ltd v H & R Block Canada Inc* (1995), 62 CPR (3d) 257 (FCTD) and in *Hager v ECW Press Ltd*, [1999] 2 FC 287.

[16] Like the holistic approach, there is no initial dissection of the work into protectable and non-protectable elements.

Many observations may be made about this approach. First, the relationship between factors (1) and (3) is unclear.[17] Second, factor (2) considers the economic effect of the taking on the first work,[18] which may be relevant because one of the purposes of copyright protection is to provide incentive for authors to create; however, to the extent that it ignores other rationales for copyright protection, this consideration may actually distort the analysis.[19] Third, given that copyright infringement is determined on a strict liability basis, the motivation or intention of the infringer under factor (4) seems irrelevant, as well as incongruous with determinations of literal infringement. Finally, factor (5) inquires into the manner in which the borrowing is used. To the extent that the use of the work reflects one of the purposes of fair dealing, the inquiry may be superfluous. However, to the extent that use of the work looks at non-fair-dealing purposes of the copying, this factor arguably should have relevance, although as we will see this was rejected in *Robinson*. Though the factor analysis approach has been used by lower courts in Canada, it was not referenced in *Robinson*.

A third approach, termed here the "dissection approach," separates protectable expression from unprotectable elements in both works, then determines whether there has been a substantial taking of the former.[20] For dramatic or literary works, expression in the work is separated from ideas, facts, stock devices, *scènes à faire*, folklore, and stereotypes;[21] the alleged infringing work is then assessed according to whether or not the second author has borrowed too much expression from the first work. The test has a special application for computer programs. Where similarities are due to the nature or functional constraints of the program, the limited ways in which a program can be expressed, common tools of the trade, stock devices, or the use of information or code available in the public domain, then there is no copyright infringement.[22] In principle, the dissection approach more successfully integrates copyright doctrine by heeding the distinctions between protected original expression and elements in the public domain that are available for all to use. However, as alluded to above and more fully explained below, there is a concern that the dissection approach may eviscerate legitimate copyright protection.

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[17] For example, if the material taken does not reach the level of copyright protection on its own, can there still be a qualitative taking?

[18] As interpreted in *Hager*, *supra* note 15.

[19] *Théberge v Galerie d'Art du Petit Champlain Inc*, *supra* note 1 at para 30:

> The *Copyright Act* is usually presented as a balance between promoting the public interest in the encouragement and dissemination of works of the arts and intellect and obtaining a just reward for the creator (or, more accurately, to prevent someone other than the creator from appropriating whatever benefits may be generated).

On strict utilitarian terms, this factor should be a consideration, given that the economic impact on the first work affects the incentive structure of copyright. However, to the extent that "just rewards" are suggestive of more general fairness concerns in deontological terms, this factor may in fact distort the inquiry.

[20] The common name for this general approach in Canada is abstraction-filtration-comparison.

[21] *Preston*, *supra* note 9.

[22] *Delrina Corp v Triolet Systems Inc* (1993), 47 CPR (3d) 1.

## 3.0 WHAT ROBINSON RESOLVED (AND PURPORTED TO RESOLVE)

*Robinson* is the first pronouncement on the substantial similarity doctrine by the Supreme Court of Canada. As such, it resolves some of the controversies surrounding the doctrine; unfortunately, the judgment also sows uncertainty in this area. Before discussing the Supreme Court decision, some introduction of the case and the lower court rulings is needed.

In the early 1980s, Claude Robinson conceived a children's television series called *Robinson Curiosité*, so named for the main character who interacted with other characters living on a tropical island. He created a set of characters both graphically and by written description, wrote scripts and storyboards, and eventually registered his copyright in this creation. In 1985, he shopped this series around to various entities (at one time involving the defendant corporation), though no production deal was ever reached. In 1995, the first episode of a children's series entitled *Robinson Sucroe*, produced by the defendant corporation, was broadcast in Quebec. The plaintiff alleged many similarities in that production as compared with his work, which formed the basis of this copyright infringement action.

At trial, the court found that the defendant had access to the plaintiff's work and copied a substantial part of it.[23] In its judgment, the Quebec Court of Appeal adopted a holistic approach to substantial infringement.[24] According to the Court of Appeal, viewing the two works holistically helps to determine whether a substantial part of a work has been borrowed or whether the differences support a claim of independent creation.[25] Moreover, substantial similarity involves comparing the two

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[23] The trial judgment, *Robinson c Films Cinar inc*, 2009 QCCS 3793, has not been translated into English. According to the Quebec Court of Appeal, in analyzing appropriation, the trial court sought to identify the "substance" of the work as a necessary prior step to determining infringement: *France Animation, sa c Robinson*, 2011 QCCA 1361 at paras 41-43 [*France Animation*]. The Supreme Court, however, suggests that the trial court applied a holistic approach: *Robinson*, *supra* note 2 at paras 33 and 34.

[24] *France Animation, supra* note 23 at para 43.

[25] *Ibid* at para 61. Further, at paras 66 and 67:

> [66] In sum, the differences may have no impact if the borrowing remains substantial. Conversely, the result may be a novel and original work simply inspired by the first. Everything is therefore a matter of nuance, degree, and context … .
>
> [67] … [I]f there is substantial reproduction, the infringement remains despite a significant intellectual effort on the part of the infringer.

This formulation, cited in the Supreme Court judgment, appears to result in a neutral judgment: the holistic approach is as likely to result in non-infringement as infringement; such an understanding, however, would be misguided. One can imagine similarities in *ideas* between works that are beyond the level of inspiration and short of expression, but that under this formulation would result in infringement. More fundamentally, it is impossible to tell what in fact has been taken without first separating expression from non-protectable elements. This formulation of the holistic approach seems to replace the troublesome idea–expression dichotomy with an even more problematic inspiration–copying dichotomy.

works, but any similarities "must involve aspects that have a significant place in the original work as a whole."[26]

On appeal, the court further held that reliance on expert evidence is appropriate where such testimony is "necessary." If the works in question lend themselves to assessment by an ordinary lay observer, then expert evidence is not appropriate. However, where two works are at different stages of development, in different media, and are amenable to "separate methods of comparison," then expert evidence will be necessary. On this last point, the court noted that the works here had two forms: the "visible"—that is, that which can be seen directly, such as shapes, colors, layout, and the choice of words—and the "intelligible"—that is, the structure, the arrangement of characters, and the interactions between them.[27] Similarities in the intelligible form of the works may not be apparent to an ordinary observer and thus require the assistance of an expert in the genre to uncover. In this case, the underlying structure (or intelligible form) of the work facilitated a finding of infringement because, even though the graphic depictions of the characters did not always appear the same, there were nonetheless striking similarities in the elaboration of traits of *all* the characters and their relationships to one another. These similarities, based on the accepted expert evidence at trial (and summarized by the Court of Appeal), are identified in detail in the appendix to this article, together with graphic depictions of the characters.

### 3.1 A Holistic Approach (or Is It "Reverse Dissection"?)

The Supreme Court of Canada decision endorsed the holistic approach—that is, it held that substantial similarity is to be qualitatively assessed by looking at the two works as a whole and not in isolated parts.[28] To abstract a work into component parts, in the court's opinion, would undermine an accurate assessment of the "cumulative effect" of the features copied.[29] This reasoning appears to reflect a fear that reducing a work into component parts, as proposed by the dissection approach, risks overlooking what might otherwise be considered a qualitative taking of the work when viewed as a whole.[30]

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[26] *France Animation, supra* note 23 at para 45. The court also stated that determining substantial similarity involves a qualitative as well as a quantitative assessment.

[27] *Ibid* at paras 79 and 80.

[28] *Robinson*, *supra* note 2 at para 35.

[29] *Ibid* at para 36.

[30] This reasoning resembles a strand of US case law that supports a "total concept and feel" approach to substantial similarity where, in the absence of any literal copying, the taking of the "gestalt of creative elements" is enough to constitute infringement: Robert C Osterberg & Eric C Osterberg, *Substantial Similarity in Copyright Law* (New York: Practising Law Institute) (loose-leaf revision June 2013 supplement), ch 2 at 29 [Osterberg & Osterberg]; *TMTV Corp v Mass Prods, Inc*, 645 F3d 464, 470 (1st Cir 2011): "Infringement can occur where—without copying a single line—the later author borrows wholesale the entire backdrop characters, inter-relationships, genre, and plot design of an earlier work." In more concrete terms, see e.g. Jarrod M Mohler, "Toward a Better Understanding of Substantial Similarity in Copyright Infringement Cases" (2000) 68 U Cin L Rev 971 at 988:

There are at least five problems with the holistic approach and the way in which it was articulated and applied in this case:

1. The court did not instruct fact-finders to filter out unprotectable elements before assessing substantial similarity. The holistic approach, as articulated in this decision and in copyright scholarship, eschews the distinction between ideas (and other non-protected elements) and expression on the basis that such an analysis is reductive of the originality of the first work. However, the refusal to identify those elements not subject to copyright protection undermines a key balancing mechanism within copyright doctrine—that is, the idea–expression dichotomy. A substantial taking may now consist of unprotectable elements—in whole or in part—that heretofore were available for all to use.

2. A second problem is that a holistic approach rests on a faulty premise. It does not necessarily follow from a holistic approach that it is impossible or undesirable to distill expression from a work. The whole of the work may well be more than the sum of its parts, but that whole is not incapable of explication and analysis. For example, the expression borrowed in this case included not just the individual complex character descriptions—that is, component parts—but also the fact that so many of the characters *in the aggregate* were similar—that is, the whole.[31] It is possible, and desirable, to detail these expressive elements that make up the "whole" of the work, as even the Quebec Court of Appeal took pains to demonstrate in the excerpt reproduced in the appendix to this article. The failure of the Supreme Court to echo more of this analysis in its judgment may be interpreted by lower courts as permitting non-descriptive, impressionistic assessments of similarity.

3. A third problem is that the Supreme Court of Canada provided no specific guidance on conducting a substantial similarity analysis between the works in question. US courts in similar cases have attempted to discern core elements of fictional and dramatic works for the purpose of comparison—that is, plot, character, dialogue, theme, mood, setting, and pace.[32] If Canadian courts adopted

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> [T]he problem with dissection is that one could dissect anything down to unoriginal parts, without noticing the expressiveness of the ensemble. For example, if one dissected a song into component parts, such as the chord progression, the notes played, and the instrumentation, almost no popular song could be classified as "original." Yet, the parts put together make up an entirely original song.

[31] The lower courts in *Robinson* identified the elements that were taken in some detail—that is, the character descriptions, their relationships to one another, setting, and plot similarities—that formed the basis of infringement: see the appendix to this article.

[32] This, in fact, seems to be what most US courts do. In connection with fictional and dramatic works, Osterberg & Osterberg, *supra* note 30, ch 4 at 2 indicate that courts typically holistically consider the "concrete elements" of "plot/sequence of events, dialogue, characters, theme, mood, setting, and pace." Moreover, courts do so by also discounting unprotectable elements: Osterberg & Osterberg, ch 4 at 2ff. See also Amy B Cohen, "Making Copyright Decisionmaking: The Meaninglessness of Substantial Similarity" (1987) 20 UC Davis L Rev 719, wherein the author criticizes the substantial similarity doctrine in general as an inexact standard for determining infringement.

this approach in tandem with identifying the expressive elements borrowed in each of these subcategories, the law could be developed in individual cases to guide future courts.

4. A fourth problem is that, to the extent that its adoption reflects a concern for adequately protecting works from wrongful appropriation, the holistic approach may be unfounded. Empirical evidence in the United States suggests that the dissection approach does not result in significantly higher win rates for plaintiffs,[33] suggesting that copyrighted works enjoy a similar level of protection regardless of the approach adopted.

5. A final criticism of this aspect of the case is that, in analyzing substantial similarity, the court did not actually apply the holistic approach it purported to adopt. Consider this passage in a different part of the judgment, addressing the issue of whether the defendant borrowed ideas or expression:

> The trial judge clearly grounded his finding of copying of a substantial part *not in the idea behind* Curiosity*, but in the way Robinson expressed that idea*. He concluded that the overall architecture of Robinson's submission for a television show was copied. He found that the graphic appearance and several aspects of *Curiosity*'s protagonist were copied; the personalities of the secondary characters that gravitate around *Curiosity*'s protagonist were copied; and the graphic appearance of the makeshift village that these characters inhabit was also copied in part … . *These findings are not confined to reproduction of an abstract idea; they focus on the detailed manner in which Robinson's ideas were expressed.*[34]

Is the court suggesting that the holistic approach involves filtering out non-protectable elements after the fact—that is, "reverse" dissection wherein stage one is a holistic assessment and stage two is filtering out ideas from expression? The ambiguity of the relationship between the idea–expression dichotomy and holistic analysis is reinforced by the absence of any discussion of the former in the part of the judgment endorsing the latter. The result is that the court has created confusion by commingling in the same judgment two concepts—holistic assessment and the idea–expression dichotomy—that have traditionally been at odds with one another.

Although the court endorsed holistic assessment, it is important to note that it did not altogether reject the dissection approach:

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[33] See Katherine Lippman, "The Beginning of the End: Preliminary Results of an Empirical Study of Copyright Substantial Similarity Opinions in the US Circuit Courts" (2013) Mich L Rev 513 at 545. This extensive study of US case law shows that there is no significant difference in win rates when courts use any one of the three main US tests—ordinary observer, extrinsic–intrinsic, and abstraction-filtration-comparison: 32.8 percent for ordinary observer; 25 percent for extrinsic–intrinsic, and 23.8 percent for abstraction-filtration-comparison.

[34] *Robinson*, *supra* note 2 at para 43 (emphasis added).

> I do not exclude the possibility that [the dissection] approach might be useful in deciding whether a substantial part of some works, for example computer programs, has been copied. But many types of works do not lend themselves to a reductive analysis.[35]

While the exception is intended to be limited to works such as computer programs, the basis on which such works are more amenable to a dissection approach is not clear. Are computer programs considered more appropriate for this approach because they have more easily identifiable public domain components, or because there is no whole that is greater than the sum of its parts? The court offered no rationale to guide future courts in further defining this exception.

### 3.2 The Taking in Relation to the Infringing Work Is Irrelevant

In *Robinson*, the Supreme Court affirmed that the proper inquiry is the extent of the borrowing from the plaintiff's work, not the extent to which the borrowing contributes to the defendant's work.[36] This seems to accord with extant copyright doctrine in that the focus is on the original work that is alleged to have been infringed and not on the use to which the borrowing is put. Along the copyright infringement continuum, the *use* that is made of the work resides in the domain of fair dealing.

However, it is at least arguable that the way in which the borrowing is used in the alleged infringing work should be relevant. For example, Vaver advocates, "[a] decision on substantiality is best reached by considering not only what was taken but the context of the taking, including what the taker did with it."[37] Although this may be out of step with copyright doctrine, such an approach could aid in arriving at intuitively just results in certain cases. For example, Robert Plant and Jimmy Page have been sued for copying the opening bars of their classic "Stairway to Heaven" from an unknown song that is basically composed of those opening bars repeated throughout;[38] while a qualitative taking may be said to have occurred with respect to the first work, a consideration of the context of its use (the musical genius that makes up so much of the rest of the second work) might be the only way

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[35] *Ibid* at para 35.

[36] *Robinson*, *supra* note 2 at para 39

[37] David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-marks*, 2nd ed (Toronto: Irwin Law, 2011) at 186. In a similar vein, US authority proposes that dissimilarities between the works may have an impact on a substantial similarity analysis—for example, when enough changes are made that the ordinary observer will not see the two works as substantially similar: Osterberg & Osterberg, *supra* note 30, ch 2 at 34 and 35. See also *Durham Industries, Inc v Tomy Corp*, 630 F2d 905 at 913 (2nd Cir 1980): "As a matter of logic as well as law, the more numerous the differences between the two works the less likely it is that they will create the same aesthetic impact so that one will appear to have been appropriated from the other."

[38] See Vernon Silver, "Stairway to Heaven: The Song Remains Pretty Similar," *Bloomberg News* (15 May 2014), online: BloombergBusiness <http://www.businessweek.com/articles/2014-05-15/led-zeppelins-stairway-to-heaven-vs-dot-spirits-taurus-a-reckoning>.

to avoid copyright infringement. After *Robinson*, the extent to which the borrowing truly contributes to the originality or appeal of the second work has no relevance so long as what is borrowed is substantial. As with the endorsement of the holistic approach, this ruling in *Robinson* strengthens the scope of copyright protection.

### 3.3 Expert Evidence Is Allowed Where "Necessary"

A main point of contention in *Robinson* was the reliance on expert evidence to aid in determining whether there was a qualitative taking. The Supreme Court held that expert evidence will be admitted if (1) it is relevant, (2) necessary, (3) does not involve an exclusionary rule, and (4) if the expert is properly qualified.[39] The appellants argued that expert evidence was not necessary because the test for substantial similarity is to be judged from the perspective of "the lay person in the intended audience."[40] Although this perspective is "useful," the court maintained that

> the question always remains whether a substantial part of the plaintiff's work was copied. The question should be answered from the perspective of a person whose senses and knowledge allow him or her to fully assess and appreciate all relevant aspects—patent and latent—of the work at issue. In some cases, it may be necessary to go beyond the perspective of a lay person in the intended audience for the work, and to call upon an expert to place the trial judge in the shoes of "someone reasonably versed in the relevant art or technology."[41]

The Supreme Court then justified the necessity of expert evidence with reference to three points. First, the intended audience of both works was young children. Second, the medium and stage of development of the two works were different. Finally, the works at issue had both patent and latent similarities. In other words, less obvious or latent similarities—atmosphere, dynamics, motifs, and structure—were not apparent to the lay observer and therefore justified expert evidence.[42] Because it will be the exceptional case where at least some of these factors are not present—that is, when the intended audience is a subset of the population, when works are expressed in different media or at different stages of development, or in the case of layered and complex works—it may become common for courts to admit expert evidence for substantial similarity analysis.

It is important to note that there is some overlap between "lay person in the audience" and what is referred to here as an "expert of the genre," either or both of which might be necessary after *Robinson*. Both types of evidence are "expert" to the extent that these perspectives offer insights into similarity not apparent to an ordinary observer. A person in the intended audience, if the target audience of the

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[39] *Robinson*, *supra* note 2 at para 49.

[40] *Ibid* at para 50.

[41] *Ibid* at para 51.

[42] *Ibid* at para 55.

work is children, may necessitate the "expert" evidence of an individual qualified in childhood perception. To the extent, however, that there are aspects to a work that are beyond the perception of even the intended audience, an "expert of the genre" in question would be necessary.[43]

### 3.4 Works May Have Layered Qualitative Content

Another significant development in *Robinson* was the court's acknowledgement that works may vary in their complexity; where works are complex, multidimensional creations, such as a novel or a movie or television series, wrongful appropriation of a work may be found in the underlying elements, which are not obvious to the "ordinary observer." This represents a break from established copyright analysis of substantial similarity, which has tended to focus on the superficial similarities, as apparent to an ordinary observer, between works. With the inclusion of latent or structural aspects as part of the qualitative analysis, the Supreme Court has opened the door to an expanded horizon of substantial similarity analysis. The implications of this holding are far reaching, and are discussed in the following section.

## 4.0 WHAT ROBINSON DID NOT RESOLVE

As much as *Robinson* clarified some aspects of the substantial similarity doctrine, it raised at least as many questions about the way in which the doctrine should be applied in future cases. Some of these problems have been mentioned above—that is, the incoherent relationship between the court's endorsement of a holistic approach and its seeming application of a dissection analysis, in addition to the lack of any guidance for making substantial similarity determinations. As part of the latter criticism, two further points are advanced in this section. First, does the amount of the taking change depending on the complexity of the work? Second, how are courts to make substantial similarity determinations with regard to cross-media adaptations of a work?

### 4.1 Qualitative Amount

In copyright law, courts do not purport to make judgments about the artistic merit of a work;[44] however, to determine whether there has been a qualitative taking invites one to make a subjective judgment about what is "good" or creative about a work in the first place. The *Robinson* case expands the inquiry to both observable

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[43] The authority cited for the "necessary" test was a Supreme Court trademarks case: *Masterpiece Inc v Alavida Lifestyles Inc*, 2011 SCC 27 at paras 75ff.

[44] It is often repeated in the US literature on copyright that courts are loath to make qualitative judgments about the artistic value of a work. Justice Holmes's "dangerous undertaking" sentence in *Bleistein v Donaldson Lithography Co*, 188 US 239 (1903) is often cited: "It would be a dangerous undertaking for persons trained only to the law to constitute themselves final judges of the worth of pictoral illustrations, outside the narrowest and most obvious limits."

and latent dimensions. The question becomes whether a greater portion of the quality must be borrowed to constitute a substantial taking as compared with more rudimentary works. Put another way, does a qualitative taking remain constant across all kinds of works, or does it vary in accordance with the complexity and layered quality of a work?

One option is to measure the qualitative taking in proportion to the complexity of the work. In other words, infringement of higher-quality works would demand that a greater qualitative amount be borrowed than that for rudimentary works. The proportionality aspect of this solution may be intuitively appealing: if we are going to expand the pie, then we should correspondingly expand the amount that needs to be taken. The problem with this approach is that it de facto discriminates against higher-quality works that may have many dimensions of originality associated with it. If we define Q as a unit of quality, and work A has $Q \times 1$ while work B has $Q \times 6$, then a proportionate qualitative taking might mean that 2 units of quality would need to be taken from work B, and 1 unit of quality from work A, to constitute substantial infringement. If work C borrows 1 unit of quality from each of A and B, then only A is entitled to an infringement remedy. It does not accord with any of the rationales for copyright to offer greater protection to less original works.

A second option would require that the same qualitative amount be taken for all works. However, expanding the pie of analysis without setting some limits as to what constitutes a qualitative taking would likely overprotect works and have a negative impact on creativity. These concerns can be mitigated by (1) acknowledging and emphasizing the centrality of the idea–expression dichotomy, and (2) articulating a high standard for substantial taking. This was not done in *Robinson*, although the silence and ambiguity of the Supreme Court should not prevent future courts from introducing these limiting devices.

Delineating between idea and expression is an essential mechanism to prevent the overextension of copyright protection under the expanded inquiry. For literary and dramatic works, for example, the latent element transferred between works often consists of the narrative structure. But such similarities may often start and end at a level of abstraction that falls short of expression. For example, the general plot line of the movies "Shane" and "Pale Rider" are basically the same, yet "both works appear to have created distinct overall impressions as a result of differing details."[45] Accordingly, "[m]any infringement claims have failed because similarities in the general pattern or skeleton of the plot were not accompanied by protected details of expression."[46] Under the same rubric, obvious similarities of expression can also be identified. If one looks at the similarity of description of the main characters in the two works in *Robinson*, one sees not only that each character was curious and

[45] Osterberg & Osterberg, *supra* note 30, ch 4 at 6.0

[46] *Ibid*.

childlike (non-protectable) but also that both are "sulky, childish, moody, in the process of developing, clumsy, naive, versatile, messy, curious, kind, and generous, but sometimes hot-tempered and impatient." These elaborations reach into the realm of expression, and because this pattern is repeated with the other characterizations, it is reasonable to make a finding of substantial similarity. When the expanded pie is viewed through the prism of idea–expression, it does not unjustifiably extend copyright protection.

Equally important, the bar for substantial taking needs to be raised. Developing case law on this basis, in tandem with explicitly identifying the expressive elements taken on a case-by-case basis, should ensure that the amount of expression that must be taken is deservedly high. This means that for simple works like Mickey Mouse, near literal infringement would be the standard, whereas for more complex works, such as many movies or novels, the same standard might be met by the kind of borrowing that occurred in *Robinson*—that is, extensive borrowing of complex character descriptions.

### 4.2 Derivative Works and Cross-Media Comparisons

An issue that continues to be ignored by Canadian courts, including the court in *Robinson*, is the problem of comparing works in different media—for example, production of a movie (visual and verbal medium) based on a book (textual medium). American courts have adopted a pragmatic approach to cross-media comparison. While substantial similarity analysis remains intact for cross-media applications, differences in format or medium are accounted for in the analysis.[47] Thus, for example, when a comparison is made between a book and a TV series, the multiple episodes of the TV series will be considered as one unit; or when a movie is adapted from a theatrical production, the ability of the film medium to show more incidents of expression will be discounted.[48] This method is probably best illustrated in the following passage:

> Obviously, there will be some differences between a motion picture and the book upon which it is based because of the differences in the nature of the medias [*sic*]. In adapting a book to a motion picture it is necessary to breathe life into a limited number of characters by giving them speeches and actions that will convey the same or similar message within a circumscribed period of time. With respect to most of the books here involved, this meant compressing over 300 pages into 65 minutes. As a consequence of this process, some of the speeches and actions which may have been attributed to a number of characters in the books were transferred to one or more characters in the pictures. In other instances, roles were completely eliminated with the action of another narrated into the script by one character.[49]

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[47] *Ibid*, ch 14 at 3.

[48] *Ibid*.

[49] *Filmvideo Releasing Corp v Hastings*, 509 F Supp 60 (SDNY 1981).

To varying degrees, medium changes expression. Recognizable equivalencies can be found to translate some elements—for example, dialogue from textual to verbal media. But for many other kinds of expressions, equivalencies are less obvious and sometimes impossible.[50] According to an eminent scholar of adaptation studies, for example, the internal content of thought—so much a part of literature—cannot adequately be translated into film. At most, film can infer thoughts but cannot directly show them to us.[51]

To take this point even further, a change in medium may even eviscerate expression—for example, if a character's physical description is taken from a book and portrayed in a movie, does its "translation" from a textual to a visual medium make it an idea regardless of how much detail is adapted?[52] Identifying the loss of expression inherent in the adaptation of a work into a derivative form will help to maintain a balance in copyright doctrine that might otherwise be upset by expanding the expressive pie to include latent aspects.[53] Future courts will need to be clear when making detailed factual comparisons between expression that successfully transfers from one medium to another.

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[50] See Douglas Y'Barbo, "Aesthetic Ambition Versus Commercial Appeal: Adapting Novels to Film and Copyright Law" (1998) 10 St Thomas L Rev 299. Y'Barbo claims that a book relies on its prose and literary devices, such as internal monologue, whereas filmmakers rely on visual stimuli, actors, linear juxtaposition of images, and editing to achieve a pleasing effect: at 356-59; the time constraints (and thus editing) of film means that the "pace" of a movie will usually differ from the literary text: at 360; while a movie adaptation may follow the storyline or "plot" of a book, this is generally not protectable per se: at 362; often, as well, a "theme" or meaning will change as the filmmaker alters the novel's ending to a happy one; filmmakers often simplify the story line and present a linear "sequence of events" (and perhaps even present material in a familiar genre quite different from that of the book) in an effort not to confuse audiences and to meet the two-hour or less time frame: at 362-63; and the portrayal and development of "character" are often simplified because of time constraints and the general inability to rely on devices, such as internal monologue, and depend heavily on actor portrayal: at 364.

[51] George Bluestone, *Novels into Film* (Berkeley, Cal: University of California Press, 1968) at 48. For more on differing perspectives on the possibility of adaptation, see Cameron Hutchison, "Adapting Novel into Film" in B Courtney Doagoo, Mistrale Goudreau, Madelaine Saginur & Teresa Scassa, *Intellectual Property for the 21st Century: Interdisciplinary Perspectives* (Toronto: Irwin, 2014).

[52] Paul Goldstein "Derivative Rights and Derivate Works in Copyright" (1983) 30 J Copyright Soc'y USA 209.

[53] Moreover, it is seems misguided to assert that the plaintiff's work should be "faithfully adapted" to the infringing medium for the purpose of a substantial similarity comparison, as argued in Douglas Campbell Rennie, "This Book Is a Movie: The 'Faithful Adaptation' as a Benchmark for Analyzing the Substantial Similarity of Works in Different Media" (2014) 93:1 Or L Rev, online: Social Science Research Network <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2427917>. This assertion has two problems. First, it assumes that there is only one way to adapt a work into the second medium. Second, it unnecessarily strengthens the derivative right by compensating for the loss of expression that occurs when a work is transferred to a new medium.

## 5.0 CONCLUSION: TWO FUTURES FOR SUBSTANTIAL SIMILARITY

While *Robinson* resolved some juridical uncertainty about the substantial similarity doctrine—in particular, when expert evidence is necessary, and the irrelevance of the use to which the taking is put in the second work—the case raised as many questions as it answered. It remains unclear whether the Supreme Court of Canada truly adopted a holistic approach or, in fact, applied a "reverse dissection" analysis. Moreover, the court failed to elaborate much-needed guidelines for the substantial-taking analysis, nor did it address the issue of cross-media comparisons. These ambiguities and omissions mean that lower courts will likely interpret and apply *Robinson* in different ways. Although many more nuanced interpretations might arise, this conclusion presents, in the starkest of terms, two possible futures for the substantial similarity doctrine.

The more likely (and in my view wrong) interpretation would be for courts to make general impressionistic assessments of substantial similarity, without either engaging in a detailed comparative analysis of the expressive elements in both works or discounting non-protectable elements or loss of expression because of change in medium. Academics have long bemoaned copyright's premise that the author's genius is responsible for the entirety of his or her creative works. The holistic approach is an essential part of that mythology, as Jaszi observed:

> "Totality" [holistic] analysis is yet another doctrinal reflection of the ideology of Romantic "authorship." In this interpretation of copyright doctrine, "authors'" rights in their "works" extend not only to the content of their own devising, but also to what they have themselves borrowed from the intellectual "commons"—presumably because they have subsequently impressed their artistic personalities on the borrowed materials. This vision marginalizes yet other "authors," who arrive still later on the scene, and denies that they might have an equally important role to play in the continuing process of cultural transmission by which texts are reformulated and elaborated. In effect, "totality" analysis converts copyright into a textual *Homestead Act*.[54]

The Supreme Court's decision only reinforces this misguided premise, and the holistic approach will likely be applied in ways that unduly strengthen copyright protection. Perhaps even more troubling is that infringement findings will increase after *Robinson*, because courts will now have an expanded pie (observable and latent elements) from which to find a qualitative taking, again without discounting unprotectable elements. And, because it appears that many comparisons between works will now necessitate expert evidence, the party with the greater resources to recruit the best (meaning court-savvy) witnesses will have an advantage.

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[54] Peter Jaszi, "On the Author Effect: Contemporary Copyright and Collective Creativity" (1992) 10:2 Cardozo Arts & Ent LJ 293 at 305.

A second (and in my view more positive) scenario would be for lower courts to understand the *Robinson* case not so much in terms of the test it said it adopted but in how it applied that test. It is reasonable to conclude that *Robinson* does not stand for the proposition that unprotectable expression is irrelevant to copyright infringement. In other words, while courts may make holistic comparisons between works at the initial stage of assessing infringement, a second stage of analysis requires the court to ensure that what is taken is substantial expression. Moreover, the brevity of the Supreme Court's analysis with respect to the factual record should be viewed in light of the appeal court's function of reviewing for legal error, and not as suggesting that triers of fact should not make detailed analyses of the works in issue. In other words, impressionistic assessments of the works should not be acceptable as a method of judicial analysis (indeed, in what other area of law do judges analyze or categorize on the basis of "I know it when I see it?"). Moreover, lower courts may rightly find that the standard for a substantial taking is intended to be high, considering the extensive borrowing that occurred on the facts in *Robinson*.

In conclusion, the *Robinson* case seems out of sync with Supreme Court jurisprudence that has sought to strike a balance between the rights of copyright holders and users of copyright works. Copyright protections have ostensibly been extended by the rulings in this case without the offset of balancing mechanisms. As a result, there is the danger that the decision will be interpreted to justify stronger copyright protections. Lower courts, however, should not hesitate to recognize the inconsistencies and omissions in the judgment, and develop the law in a way that will restore balance in this critical doctrine of copyright law.

## 6.0 APPENDIX

**France Animation, sa c Robinson**
2011 QCCA 1361

[Note: pictures from the trial judgment, *Robinson c Films Cinar inc*,[55] are added beneath the corresponding description of the works by the Court of Appeal.]

[99] As for the similarities accepted by the judge following the testimony of the expert Perraton; they are amply described in paragraphs 505 to 663 of the judgment.

[100] Without citing the judgment word for word, the main similarities accepted were as follows:

- The main character, **Robinson**: graphic resemblance and similar personalities: both are sulky, childish, moody, in the process of developing, clumsy, naive, versatile, messy, curious, kind, and generous, but sometimes hot-tempered and impatient;

Robinson Curiosité

Robinson Sucroë

[55] *Supra* note 23.

- **Vendredi Férié** and **Mercredi**: graphic resemblance, resemblance of names[56] and similar personalities: father figures and therefore paternalistic in their interactions with Robinson, scientific, intelligent, erudite, knowledgeable, ingenious, good at explaining, kindly;

Vendredi Férié


Mercredi

- **Boum Boum** and **Duresoirée** (her real name being Hildegarde Van Boum Boum): two characters that are physically large[57] with similar personalities: sulky, irritable, emotional. It should also be noted that, in the first synopsis of Robinson Sucroë ([TRANSLATION] The treasure hunt), the name Duresoirée was given to a pachyderm;

Boum Boum

Duresoirée

[56] Vendredi férié (holiday) being a day of rest, and mercredi (Wednesday) a day off for French schoolchildren.

[57] A baby elephant and a lady.

- **Gertrude** and **Gladys**: graphic resemblance (young, pretty, tall, thin, and elegant; both have freckles) and similar personalities: strong-willed women with very definite ideas, independent, self-sufficient;

Gertrude


Gladys

- **Charlie le pilote** and **Courtecuisse**: graphic resemblance and similar personalities: sloppy, strange and repulsive tastes in food, gruff, but lose their heads when in the presence of either Gertrude (for the one) or Duresoirée (for the other);

Charlie le pilote


Courtecuisse

- **Paresseux** and **Dimanchemidi**: graphic resemblance and similar personalities: eyes half-open, very lazy, always sleeping or struggling to stay awake, very slow movements, talk slowly, slack-jawed;

Parasseux

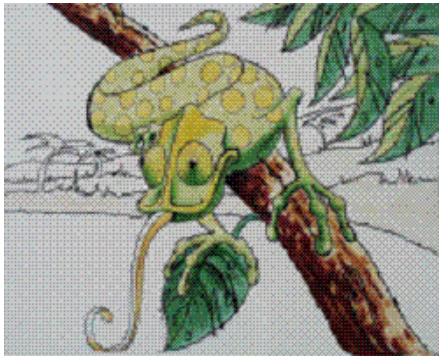
Dimanchemidi

- **Général Schloup** and **Capitaine Brisk**: graphic resemblance (tall, thin, elegant, slender faces and hollow cheeks) and similar personalities: dishonest, bossy;

Général Schloup


Capitaine Brisk

- **Léon le Caméléon** and **Petitevacances**: no graphic resemblance, but similar personalities: mischievous, like to play tricks and disguise themselves, they can change their appearance in spite of certain traits by which they can be recognized; they often help Robinson;



Léon le Caméléon


Petitevacances

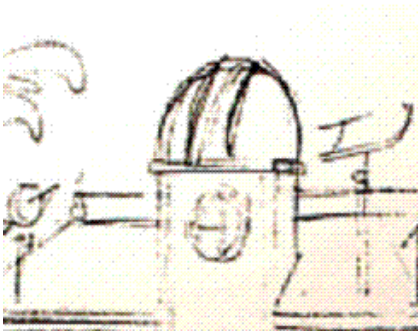
- The **main house**: an L-shaped bungalow, topped by a slender tube that serves as a chimney and an observatory, or a cone-shaped observation tower with a telescope, a retractable dome, lit by a skylight, along with a porch covered by an awning supported by bamboo trunks, as can be seen in another drawing from *Robinson Curiosité*;

*Robinson Curiosité* main house


*Robinson Sucroë* main house

*Robinson Curiosité* porch


*Robinson Sucroë* porch

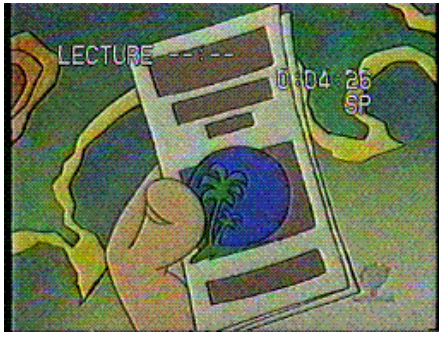


*Robinson Curiosité* observatory


*Robinson Sucroë* observatory

- Numerous **duplications**; i.e., the infringer uses the same borrowing on more than one occasion for different characters;
- **Vehicles used for transportation**;
- The **logo** used in both works.


*Robinson Curiosité* logo




*Robinson Sucroë* logo

[101] One might disagree with some of the similarities accepted by the judge (for instance, the graphic resemblance between Boum Boum and Duresoirée). It remains that the evidence allowed him to find that there was substantial reproduction of Mr. Robinson's work, even if the plot was not in question and even if *Robinson Sucroë* as a finished product contains a great many new elements that are distinct from *Robinson Curiosité*. It is the accumulation of perceptible and intelligible elements that is determinative here.

[102] Finally, the appellant's other criticisms cannot be accepted either. It is therefore inaccurate to say that the judge erred by not setting aside similarities that were from the public domain. He did this in paragraphs 620 and 621 of the judgment, amongst others. He also set aside the similarities particular to children's programs, which the appellants had brought to his attention.[58] As for the time period in which the adventure of Robinson Sucroë takes place, it is not relevant since the respondents do not claim any reproduction of the storyline.

[103] In conclusion, even if the Court does not share all the reasons for the trial judgment, it is not convinced by the appellants that the judge committed a reviewable error by finding that there was substantial reproduction of the work *Robinson Curiosité*, except as regards music rights, which we will later see.

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58 *Robinson c Films Cinar inc*, *supra* note 23 at paras 648, 649, and 660.

# OVERVIEW OF IMPLICATIONS OF THREE-DIMENSIONAL PRINTING ON CANADIAN INTELLECTUAL PROPERTY LAW*

*Teshager W. Dagne***

**ABSTRACT**

The article provides general overview of diverse questions that consumers' use of 3D printing technology brings under Canadian intellectual property law. At the backdrop of recent incidents in which the different applications of 3D printing technology were put to light, the discussion explores the intersection of 3D printing technology with patent law, copyright law and trademark law. The discussion demonstrates the need for legislative and judicial response to prevent the "chilling effect" of excessive demands by intellectual property owners. It concludes with recommendations as to how best to balance the rights of consumers, innovators, and other stakeholders in dealing with competing intellectual property interests involving 3D printing.

**RÉSUMÉ**

L'article présente un aperçu général des diverses questions soulevées par l'utilisation des technologies d'impression 3D dans le contexte des lois canadiennes en matière de propriété intellectuelle. Dans la foulée des récents incidents qui ont mis en lumière les différentes applications des technologies d'impression 3D, l'auteur explore les liens entre les technologies d'impression 3D et les lois sur les brevets, les lois sur le droit d'auteur et les lois sur les marques de commerce. La discussion démontre la nécessité d'intervenir sur le plan législatif et judiciaire pour prévenir « l'effet paralysant » engendré par les demandes excessives des titulaires de droits de propriété intellectuelle. L'article se termine par la formulation de recommandations sur la meilleure façon de trouver un juste équilibre entre les droits des consommateurs, des innovateurs et de toute autre partie intéressée lorsque confronté à des intérêts concurrents en matière de propriété intellectuelle dans le domaine de l'impression 3D.

* Submission to the editor, March 7, 2015.

** © 2015 Teshager W. Dagne, Assistant Professor, Thompson Rivers University Faculty of Law, Kamloops, British Columbia.

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## 1.0 INTRODUCTION

Three-dimensional (3D) printing has emerged as one of the most significantly disruptive technologies in the digital economy. From the manufacturing of guns to food preparation, 3D printing has the potential to revolutionize (and improve) many aspects of our lives, in much the same way as the Internet has revolutionized communication. The process of 3D printing involves the preparation of a computer-assisted digital (CAD) file, which may be derived either from pictures or drawings, scanned from goods using a 3D scanner, or made using 3D modelling software. Such a file can easily be distributed, copied, modified, and then "printed" by a device using fine strands of molten plastic, ceramic, or even metal powder. This makes it possible to turn digital content into physical objects at the press of a button. In this respect, the technology's potential as a game changer presents challenging legal questions that need to be addressed before the technology becomes more accessible.

This article, which focuses mainly on consumers' use of the new technology, provides an overview of the diverse questions that 3D printing will give rise to in Canadian intellectual property (IP) law. As in any new technology, legislatures, judges, and policy-makers will soon be called on to regulate aspects of 3D printing activities and sort out the IP issues that apply to 3D printing. Based on trends that have emerged in the wake of other disruptive technologies, questions will arise about the accessibility of the technology and limits on the rights of manufacturers to control and enforce their IP rights in the use of the technology. These questions have yet to receive critical discussion in IP scholarship.

This article explores how existing IP law affects the rights of consumers who embrace 3D printing. The discussion starts in section 2.0 with a brief description of the steps and processes in the 3D printing process. Section 3.0 examines how 3D printing intersects with IP laws. This discussion refers to four recent incidents in which these intersections were brought to the fore: (1) the "Left Shark," a backup dancer that ended up stealing the spotlight at the 2015 Super Bowl half-time show; (2) the iron throne from HBO's series *Game of Thrones*; (3) figurines based on the game Warhammer 40,000®; and (4) the Penrose triangle, an optical illusion that cannot exist in normal three-dimensional Euclidean space. Although these incidents occurred within the purview of the US *Digital Millennium Copyright Act*, they have

relevance for Canadian IP law, given the similarities in the liability of Internet intermediaries under the copyright law of the two countries.[1]

After an overview of potential questions that 3D printing brings to bear on Canadian IP law, the article concludes with recommendations as to how best to balance the rights of consumers, innovators, and other stakeholders in dealing with competing IP interests in the context of 3D printing. In this respect, I propose that realizing the full potential of 3D printing technology requires an express recognition of users' rights, in a fashion similar to Canada's unique approach to regulating the activities of individuals over the Internet as balanced against a number of users' rights integrated in copyright law. The recognition of users' rights will enable greater public access to culture, knowledge, information, and education in the use of the technology.

## 2.0 3D PRINTING: THE PHENOMENON

Also referred to as additive manufacturing, 3D printing is a process whereby a solid object is produced, based on a digital model in a computer, similar to how a cartridge printer prints letters on paper. *The Economist* lauded 3D printing as marking the arrival of a "third industrial revolution."[2] *The Globe and Mail* reported that 3D printing is expected to "drive innovation" and "open a new world of both challenges and opportunities in Canada."[3] Cognizant of the technology's potential to transform the economy, the Federal Economic Development Agency for Southern Ontario funds an $18.9 million project to advance 3D printing.[4]

Developments in the three elements of 3D printing have brought technology to the forefront of discussion, where law and technology intersect: 3D printing machines, CAD files, and the materials used to print physical goods.

First, the expiry of patents on industrial 3D printers has made 3D printers potentially accessible at consumer prices.[5] It is envisaged that "soon, probably in the next few years, the market will be ready for a mainstream 3D printer sold by the mil-

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1 With respect to the liability of Internet intermediaries, the US *Digital Millennium Copyright Act* (DMCA) incorporates the notice and takedown rules in which intermediaries are required to remove infringing content on their website. Under the Canadian *Copyright Act*, intermediaries have notice-to-notice obligations whereby they are required to forward notices of infringement to their subscribers: see *Copyright Act*, RSC 1985, c C-42, s 41.25(1).

2 Paul Markillie, "A Third Industrial Revolution," *The Economist* (21 April 21 2012), online: <http://www.economist.com>.

3 Brenda Bouw, "The 3-D Printing Revolution Has Begun," *The Globe and Mail* (1 February 2013), online: <http://www.theglobeandmail.com>.

4 See "On Labour, Unions and 3D Printing," online: Arbitrage <http://www.arbitragemagazine.com/technology-2/on-labour-unions-and-3d-printing/2>.

5 See John Hornick & Dan Roland, "Many 3D Printing Patents Are Expiring Soon: Here's a Round Up & Overview of Them" (29 December 2013), online: 3D Printing Industry <http://3dprintingindustry.com/2013/12/29/many-3d-printing-patents-expiring-soon-heres-round-overview>.

lions at Walmart and Costco."[6] Even individuals who do not own a 3D printer can access the technology from a growing number of online 3D printing platforms, merely by uploading their own design files over the Internet.[7] The US Postal Service predicts significant increases in its revenue thanks to 3D printing, as customized objects are ordered online for printing and same-day delivery.[8]

The second aspect of 3D printing involves a CAD file containing instructions to be sent to a printer, guiding the creation of a tangible object. A CAD file can be designed from scratch using a 3D modelling program, producing a digital representation of the object to be printed. A 3D scanner can also be used to replicate an existing product in a digital file; a photograph can be taken; or a drawing made of an object, which can then be converted into a CAD file. Such a file can be easily modified, distributed, and redistributed to other users through an increasing number of file-sharing websites.[9]

The third aspect of 3D printing is the material used to make the output—namely, the tangible, 3D printed object. Just as an inkjet printer uses toner to print documents, a 3D printer uses molten or powdered plastics, glass, ceramics, or metal sintering powders, as well as a wide range of other materials, depending on the area of application.[10] Liquid baths and post-production chemicals used in 3D printing have also become available at consumer prices.

The simplified process of making almost any kind of object using a combination of these elements means that there are no limits to what 3D printing technology can produce. From the printing of everyday consumer goods to that of human organs, food, cars, airplane wings, and other large structures, including houses and large buildings or, even, bases on the moon and Mars, 3D printing holds significant potential to transform the economic landscape of product development, manufacturing, and distribution.

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[6] Chris Anderson, "The New MakerBot Replicator Might Just Change Your World," *Wired* (12 September 2012), online: <http://www.wired.com>.

[7] For example, Shapeways, the leading 3D printing service provider, reported that it had printed more than 1,000,000 products for over 300,000 users by the middle of 2013: see Shapeways <http://www.shapeways.com>.

[8] Office of Inspector General, United States Postal Service White Paper, "If It Prints, It Ships: 3D Printing and the Postal Service" (7 July 2014), online: <https://www.uspsoig.gov>.

[9] For example, another leader in 3D printing, MakerBot, has a website called Thingverse dedicated to CAD files of some standard goods. MakerBot describes Thingverse as "a place for you to share your digital designs with the world … so that all can benefit from them": see MakerBot <http://www.makerbot.com/community>.

[10] Depending on the area of 3D application—for example, the field of medicine—diverse materials are used—for example, wood-like materials, bonelike materials, organic compounds, and thin film transistors: see John F Hornick, "3D Printing and the Future (or Demise) of Intellectual Property" (2014) 1:1 3D Printing & Additive Manufacturing 34-43, online: Mary Ann Liebert <http://online.liebertpub.com>.

## 3.0 INTERSECTIONS WITH INTELLECTUAL PROPERTY LAW

The widespread accessibility of 3D printing has prompted an emerging body of literature that analyzes the implications of consumer 3D printing in the field of IP across different jurisdictions.[11] Bradshaw, Bowyer, and Haufe observed that,

> as with home computers, [3D printing] may have wider effects. The convergence of the Internet, digitized music and media players has had dramatic consequences for music copyright. 3D printing technology may have similar implications for artistic copyright, design right, trademarks and patents, but in a rather more diverse legal framework.[12]

Although the impact of the technology has not yet been examined in Canada, there is general understanding that 3D printing opens "new dimensions for Canadian IP law"[13]—for example, individuals may prepare a CAD file that is copied from an existing copyright-protected or patent-protected good using a scanner. Questions have already arisen as to whether copyright subsists in the shape, configuration, pattern, and aesthetic aspects of a physical good depicted in a CAD file. For example, in a recent US-based incident, Katy Perry's lawyers sent a cease-and-desist letter to an artist who created and printed a "left shark" figure, similar to that depicted in the artist's halftime show in the 2015 Super Bowl. If the incident arose in Canada, questions would arise as to whether there is a distinction between the idea of a shark dancing as depicted in the halftime show and an expression of it in a drawing of the shark in other formats. In another incident, HBO sent a cease-and-desist letter to a designer who was selling 3D printed iPhone docks modelled after the iron throne in the series *Game of Thrones*.[14] A third incident involved an individual who used a MakerBot 3D printer to produce machine-printed figurines—a war mecha and a tank for use in the game Warhammer 40,000®—and uploaded the CAD file on the file-sharing website Thingiverse. The Games Workshop—the maker of Warhammer 40,000®—sent a takedown notice to Thingiverse under the US *Digital Millennium Copyright Act*.[15] Although these instances arose in the context of

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[11] See IP Australia, *Australian Intellectual Property Report 2014* (Woden, Austl: Australian Government, 2014), online: IP Australia <http://www.ipaustralia.gov.au>; *Legal Aspects of 3D Printing*, online: European Parliamentary Research Service <http://epthinktank.eu/2014/03/17/legal-aspects-of-3d-printing>; under US law, see Kyle Dolinsky, "CAD's Cradle: Untangling Copyrightability, Derivative Works, and Fair Use in 3D Printing" (2014) 71:1 Wash & Lee L Rev 591, online: <http://scholarlycommons.law.wlu.edu>; Davis Doherty, "Downloading Infringement: Patent Law as a Roadblock to the 3D Printing Revolution" (2012) 26 Harv JL & Tech 353.

[12] S Bradshaw, A Bowyer & P Haufe, "The Intellectual Property Implications of Low-Cost 3D Printing" (2010) 7:1 ScriptEd 5.

[13] Teresa Scassa, "3-D Printing: New Dimensions for Canadian IP Law," onine: Teresa Scassa <http://www.teresascassa.ca>.

[14] See Nathan Hurst, "HBO Blocks 3-D Printed Game of Thrones iPhone Dock," *Wired* (13 February 2013), online: <http://www.wired.com>.

[15] See Dolinsky, *supra* note 11.

the notice-and-takedown provisions of US copyright law, similar incidents are likely to arise under the Canadian notice-and-notice regime when it comes to allegedly infringing content distributed over the Internet. Under the Canadian *Copyright Act*, intermediaries such as Internet service providers (ISPs) are required to forward notifications to their subscribers upon receiving notices of alleged infringement from a copyright owner.[16] The following subsections demonstrate how 3D printing potentially impacts Canadian IP law.

### 3.1. Copyright and Industrial Design Law

Under Canadian copyright and industrial design law, constructing a physical object from a physical depiction of a 2D drawing constitutes an infringement of the 2D drawing.[17] However, it is not clear as to when producing or reproducing a digital copy of a physical good through 3D printing constitutes copyright infringement. This will be particularly difficult when the design of the good is purely functional, but the non-functional features of the good depicted in the CAD file are often inseparable from its functional features. In such cases, the good depicted in the CAD file may not be protected under the *Copyright Act* or the *Industrial Design Act* as architectural design, industrial design, or sculpture.[18]

A CAD file may also have been prepared from a photograph, picture, or drawing that is copyright-protected, but was subsequently modified using a software program. In this circumstance, questions arise as to whether a CAD file incorporating a picture or drawing and customizing it through the use of a software program infringes copyright in the underlying image or drawing. In this respect, 3D printing is likely to reignite debate under Canadian copyright law about whether converting a photograph, picture, or drawing into a CAD file constitutes "re-production" or "re-fixation" of such photograph, picture, or drawing.[19] In some cases, whether such an act infringes copyright in the photograph, picture, or drawing may depend on the ambiguous "substantial similarity" doctrine that the Supreme Court endorsed in the recent *Cinar Corp v Robinson* decision.[20]

Questions may also arise as to whether copyright exists in the CAD file itself. Given the unique features of a CAD file, some of the following issues may arise:

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[16] *Copyright Act*, *supra* note 1.

[17] See *Bayliner Corporation v Dorval Boats Ltd* (1985), 5 CPR (3d) 289 (FCTD).

[18] See *Industrial Design Act*, RSC 1985, c I-9; Richard G Frenkel, "Intellectual Property in the Balance: Proposals for Improving Industrial Design Protection in the Post-TRIPS Era" (1999) 32 Loy LA L Rev 531.

[19] See Orit Fischman Afori, "Copyright Infringement Without Copying: Reflections on the Théberge Case" (2007-8) 39 Ottawa L Rev 23.

[20] 2013 SCC 73, [2013] 3 SCR 1168; see Cameron J Hutchison, "Substantial Similarity After Cinar Corp v Robinson" (21 August 2014), SSRN working papers series, online: Social Science Research Network <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2484816>.

1. Does a CAD file incorporate an expression worthy of copyright protection? This may depend on whether the CAD file is prepared using pictures or drawings, scanned from goods using a 3D scanner, or made from scratch using 3D modelling software.

2 Do CAD files fit within the categories of copyright subject matter as

   a. a digital file (like a PDF file);

   b. a design (along with architectural plans and other technical drawings);

   c. a literary work—namely, software (written in a computer code for a 3D printer to read); or

   d. a visual work—namely, a picture (based on the visual component of a CAD file)?

These uncertainties show that the issues related to 3D printing are clearly related to discussions of copyrightable subject matter and authorship, which are already in a state of flux with respect to software, video games, and works generated by computer programs.[21]

An example can also be drawn from a recent controversy involving the Penrose triangle optical illusion. In 1934, Swedish artist Oscar Reutersvärd created the first "impossible" triangle, which the mathematician Roger Penrose popularized in the 1950s by explaining that the triangle is "impossibility in its purest form."[22] In 2011, a designer created a CAD file for the triangle and challenged others to see how it might have been done.[23] When another individual replicated the 3D rendering and posted it on the Internet, the original CAD file designer sent a copyright infringement notice, despite not being the original owner of copyright in the Penrose triangle. Rather, the author of the CAD file claimed copyright over the digital file.[24] In other instances, individuals have been asked to remove CAD files of 16th-century sculptures, which, if legally enforceable, would unduly extend copyright protection to sculptures that have been in the public domain for more than 400 years.[25]

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[21] See Andrew J Wu, "From Video Games to Artificial Intelligence: Assigning Copyright Ownership to Works Generated by Increasingly Sophisticated Computer Programs" (1997) 25 AIPLA QJ 131.

[22] See Al Seckel, *Masters of Deception: Escher, Dalí & the Artists of Optical Illusion* (New York: Sterling Publishing, 2004).

[23] See Cory Doctorow, "3D Printing's First Copyright Complaint Goes Away, but Things Are Just Getting Started" (21 February 2011), online: boingboing <http://boingboing.net/2011/02/21/3d-printings-first-c.html>.

[24] See Brian Rideout, "Printing the Impossible Triangle: The Copyright Implications of Three-Dimensional Printing" (2011) 5 J Bus Entrepreneurship & L 161.

[25] An artist was asked to remove a CAD file of Michelangelo's famous 16th-century sculpture of Moses, which sits on the campus of Augustana College in Sioux Falls, South Dakota: see Ariel Bogle, "Good News: Replicas of 16th-Century Sculptures Are Not Off-Limits for 3-D Printers" (26 January 2015) Future Tense, online: Slate <http://www.slate.com/blogs/future_tense/ 2015/01/26/_3_d_printing_and_copyright_replicas_of_16th_century_sculptures_are_not.html>.

Given the ease with which individuals may create, copy, share, and modify CAD files in the Internet age, 3D printing highlights unique dilemmas regarding copyright infringement over the Internet and the liability of intermediaries for such infringement. Courts in the United States have held that manufacturing and providing peer-to-peer file-sharing software that enables sharing copyright-protected content over the Internet constitutes "authorizing" infringement by others because peer-to-peer file-sharing technologies are primarily used to infringe copyright.[26] The Canadian Supreme Court considered the question of liability for authorizing others to infringe copyright using technology, but only with respect to the provision of self-serve photocopying equipment.[27] No court in Canada has directly addressed the question whether providers of advanced technologies, such as peer-to-peer file-sharing systems, will be liable when individuals use these technologies to infringe copyright.[28] It is therefore not clear in Canada whether 3D printing service providers, and even manufacturers of 3D printers and 3D printing raw materials, will be treated in the same way as peer-to-peer file-sharing service providers, self-serve photocopy service providers, or ISPs.

CAD files may be uploaded to or downloaded from the Internet via peer-to-peer file-sharing systems. The Canadian *Copyright Act* requires intermediaries to forward notifications to their subscribers upon receiving a notice of alleged infringement from a copyright owner.[29] Three-dimensional printing will bring to the fore the application of this obligation on intermediaries. As an early sign of things to come, Thingiverse—a CAD file-sharing website—has on two occasions under US copyright law been forced to remove files on the ground that CAD files uploaded via the website infringe copyright.[30] Therefore, given the lack of clarity on the infringing and non-infringing nature of some of the activities inherent in 3D printing, the technology necessitates the re-examination of Internet intermediaries' liability for the action of those who use their services in the course of 3D printing.[31] The question of copyright infringement over the Internet also brings into focus the parallels that

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[26] See *MGM Studios, Inc v Grokster, Ltd*, 545 US 913 (2005).

[27] See *CCH Canadian Ltd v Law Society of Upper Canada*, 2004 SCC 13, [2004] 1 SCR 339.

[28] In a case that dealt with disclosing the identity of individuals who participated in file sharing over the Internet, the Federal Court stated: "I cannot see a real difference between a library that places a photocopy machine in a room full of copyrighted material and a computer user that places a personal copy on a shared directory linked to a P2P service," whereas the Court of Appeals ruled: "[A]t the early stages of this case, it is premature to reach any conclusion as to … whether the users' act of copying the Songs onto their shared directory could constitute authorization": *BMG Canada Inc v John Doe*, 2004 FC 488, [2004] FCR 241, aff'd 2005 FCA 193.

[29] *Copyright Act*, *supra* note 1.

[30] See "Is This the First DMCA Notice Over 3D Printer Plans?," online: Techdirt <https://www.techdirt.com>.

[31] See Jeremy de Beer & Christopher D Clemmer, "Global Trends in Online Copyright Enforcement: A Non-Neutral Role for Network Intermediaries?" (2009) 49:4 Jurimetrics 375 [de Beer & Clemmer]; Jeremy de Beer, "Legal Strategies to Profit from Peer Production" (2008) 46:1 Can Bus LJ.

can be created between users' rights in accessing copyright-protected digital media content and that of 3D printing technology.

### 3.2 Patents

Under patent law, a manufacturer may acquire patent rights over a good or over a method of producing it—that is, the right of "constructing and using the invention and selling it to others."[32] Once consumers buy the good, Canadian patent law allows them to either repair or reconstruct it for their private use, under the assumption that the patentee permits such an act.[33] In the case of 3D printing, the extent to which a patent owner can control other activities in which consumers engage—whether they can remake the good, print parts of the good, or replicate the good—is not clear.[34]

Canada's Supreme Court has ruled that mere possession of genetically modified crops brings the presumption of "use" under the *Patent Act*, and hence infringement of the rights of the owner of self-replicating technologies.[35] It is thus pertinent to examine whether consumers' use of 3D printing to print a replica of a good, its spare parts, or replacements will be treated as a use of "self-replicating technology," and, hence, whether 3D printing of goods under patent will constitute infringement of patent rights under Canadian patent law.[36]

3D printing technology also raises new patent law questions with respect to the possible Internet distribution of patent-infringing 3D printing CAD files.[37] Courts may be asked to decide whether ISPs, website hosts, and content administrators would be considered to have induced patent infringement in cases where Internet users share CAD files,[38] and whether Internet intermediaries should comply with takedown or notice-to-notice requests relating to CAD files that infringe the rights of patent owners, in a fashion similar to that of copyright owners who are entitled to make such requests under the *Copyright Act*.[39]

Another possible patent law issue with respect to 3D printing pertains to manufacturers' attempt to control the behaviour of consumers who purchase their goods. Although some in the manufacturing industry have embraced 3D printing technology

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[32] *Patent Act*, RSC 1985, c P-4, s 42.

[33] *MacLennan v Produits Gilbert Inc*, 2008 FCA 35; Mark D Janis, "A Tale of the Apocryphal Axe: Repair, Reconstruction, and the Implied License in Intellectual Property Law" (1999) 58 Md L Rev 423.

[34] Jeremy de Beer & Robert J Tomkowicz, "Exhaustion of Intellectual Property Rights in Canada" (2009) 25:3 CIPR [de Beer & Tomkowicz].

[35] See *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902.

[36] See de Beer & Tomkowicz, *supra* note 34.

[37] See Davis Doherty, "Downloading Infringement: Patent Law as a Roadblock to the 3D Printing Revolution" (2012) 26:1 Harv JL & Tech.

[38] See de Beer & Clemmer, *supra* note 31.

[39] See *Copyright Act*, *supra* note 1.

and built new business models on it, a number of manufacturers have tried to limit the expansion of the technology through different strategies, including the use of manufacturing control systems.[40] Should patent owners be allowed to use technology control systems that prevent certain activities in 3D printing?

Intellectual Ventures acquired a patent in respect of a "manufacturing control system" to prevent consumers from using unauthorized CAD files for 3D printing. A manufacturing control system works in the same way that a digital rights management system does in relation to copyright-protected content—that is, to prevent the copying, sharing, and use of digital content (music, videos, software).[41] If a printer is not authorized to print a CAD file, the control system will prevent it from doing so. The sweeping scope of the patent claim sparked controversy regarding its restriction on unauthorized printing of any CAD files, but questions also arise as to whether circumventing such technologies would be considered infringement under the *Patent Act*, similar to the circumvention of digital locks under the *Copyright Act*. Such questions expand the controversy over these technologies with copyright law into the realm of patent law.[42]

### 3.3 Trademarks

Three-dimensional printing will also impact trademark law. From a consumer's perspective, fewer identifiable issues are likely to arise under trademark law, given that most trademark disputes arise in the context of commercial relations between traders. Following are some issues that arise in the context of consumers' use of the technology.

If a good with a registered mark or with a distinctively shaped trademark is printed using 3D technology displaying such a mark, then the registered owners' rights may be infringed. Even in the absence of a mark displayed on a 3D-printed good, conflicts may arise between two traders if a trader passes off printed goods for original models. The same questions may arise if a trader uploaded CAD files over the Internet, instead of printing the goods.

Questions would also arise about the implications of 3D printing in circumstances where consumers upload CAD files for goods that display a registered trademark or of a distinguishing guise and the files are printed in the thousands or millions. In the latter case, the action of the individual who uploaded the CAD file may negatively impact the value attached to the trademark.[43]

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[40] For example, the firm Intellectual Ventures acquired US Patent No 8286236 on 3D printer manufacturing control system.

[41] See Ian R Kerr, "Digital Locks and the Automation of Virtue" in Michael Geist, ed, *From "Radical Extremism" to "Balanced Copyright": Canadian Copyright and the Digital Agenda* (Toronto: Irwin Law, 2010) ch 9.

[42] See Peter Yu, "Anticircumvention and Anti-Anticircumvention" (2006) 84 Denv UL Rev 13.

[43] See Michael Racicot, Mark S Hayes, Alec R Szibbo & Pierre Trudel, "The Cyberspace Is Not a 'No Law Land': A Study of the Issues of Liability for Content Circulating on the Internet" (1998) 14:2 Computer L & Security Rev 96.

## 4.0 ADDRESSING INTELLECTUAL PROPERTY ISSUES IN 3D PRINTING TECHNOLOGY

It is apparent from the discussion thus far that 3D printing requires the re-examination of existing views on IP in the context of an emerging technology. On the one hand, the 3D printing phenomenon allows for development of the law in an area in which the existing system does not fulfill current and future needs. On the other hand, 3D printing may trigger aggressive litigation or restrictive IP law reform that will constrain consumers' ability to tinker with their 3D printer machines, create designs for their goods, customize and print their designs for their own use, and share their discoveries and creations.[44] Unprecedented IP law reform has taken place in the wake of other disruptive technologies—for example, cassette recorders, MP3 players, computers, peer-to-peer file sharing, and the Internet—largely because of intense lobbying by impacted industry players in digital music, movies, and video games.[45] The question arises, therefore, as to how IP law and policy should respond to 3D printing in a manner that prevents the "chilling effects" of current IP laws in the various activities and, instead, encourages cultural creativity and participation through the unconstrained use of the technology.

As a reflection of the Canadian legal tradition on copyright in the digital arena, the appropriate approach should be to strike a balance between the rights of IP owners and those of individuals in accessing 3D printing. IP is a means of regulating the promotion of culture as a form and source of "participation, livelihood, and shared meaning."[46] This balanced approach departs from a purely utilitarian orientation that focuses on owners' rights; instead, it draws inspiration from an eclectic cluster of IP theories that, in addition to owners' rights, focuses on the right of the user to access innovation and creativity.[47] The focus on users' rights balances the

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[44] See observation in Michael Weinberg, "It Will Be Awesome if They Don't Screw It Up: 3D Printing, Intellectual Property, and the Fight Over the Next Great Disruptive Technology," Public Knowledge Whitepaper (2010), online: Public Knowledge <https://www.publicknowledge.org>.

[45] See Carys Craig, "Locking Out Lawful Users: Fair Dealing and Anti-Circumvention in Bill C-32" in Geist, *supra* note 41, ch 7; Kerr, *ibid*.

[46] See Rosemary J Coombe, Darren Wershler & Martin Zeilinger, *Dynamic Fair Dealing: Creating Canadian Culture Online* (Toronto: University of Toronto Press, 2014); see also Madhavi Sunder, *From Goods to a Good Life: Intellectual Property and Global Justice* (New Haven, Conn: Yale University Press, 2012).

[47] These approaches include open access, open source, access to knowledge (A2K), creative commons, open development, and cultural economy: see William Fisher III, "Theories of Intellectual Property" in Stephen Munzer, ed, *New Essays in Legal and Political Theory of Property* (Cambridge: Cambridge University Press, 2001); Lawrence Lessig, *Free Culture: How Big Media Uses Technology and the Law to Lock Down Culture and Control Creativity* (New York: Penguin, 2004); Gaelle Krikorian & Amy Kapczynski, *Access to Knowledge in the Age of Intellectual Property* (Cambridge, Mass: MIT Press, 2010); Lea Shaver, "The Right to Science and Culture" (2010) 1 Wis L Rev 121; Steve Weber, *The Success of Open Source* (Boston: Harvard University Press, 2004); Joseph Feller, Brian Fitzgerald, Scott A Hissam & Karim R Lakhani, eds, *Perspectives on Free and Open Source Software* (Cambridge, Mass: MIT Press, 2005).

rights of copyright holders with the need of the public to engage with copyright-protected work.[48] In 2002, Canada's Supreme Court advocated for balance between owners' rights and users' rights in copyright law, stating:

> The proper balance … lies not only in recognizing the creator's rights but in giving due weight to their limited nature. In crassly economic terms it would be as inefficient to overcompensate artists and authors for the right of reproduction as it would be self-defeating to undercompensate them.[49]

Two years later, the court emphasized its approach:

> In order to maintain the proper balance between the rights of a copyright owner and users' interests, [the *Copyright Act*] must not be interpreted restrictively. … "User rights are not just loopholes. Both owner rights and user rights should therefore be given the fair and balanced reading that befits remedial legislation."[50]

In 2012, the Supreme Court issued a series of decisions that preserved the same balance between owners of IP rights and users in the digital environment, just as it did with traditional artistic and literary works in a non-digital environment.[51] In a similar fashion, the *Copyright Modernization Act* of 2012 attempted to address digital challenges to copyright law by regulating the infringing activity of individuals using the Internet in the privacy of their homes as balanced against a number of new defences to copyright infringement.[52] The Act uniquely recognizes users' rights to generate, for example, music remixes, mashup videos, and home movies over the Internet.[53] It also incorporates broad exceptions and limitations to owners' rights that allow users to exploit copyright-protected content using the Internet.[54]

From the manufacturers and IP owners' perspective, 3D printing significantly challenges the IP system, given its capability to make and share multiple copies of works using the technology. There are different ways in which the law can preserve IP owners' interest against the appropriation of works via the technology.[55] Among

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[48] See Yu, *supra* note 42.

[49] *Théberge v Galerie d'Art du Petit Champlain inc*, 2002 SCC 34 at para 31, [2002] 2 SCR 336.

[50] *CCH Canadian Ltd v Law Society of Upper Canada*, *supra* note 27 at para 48.

[51] See *Entertainment Software Association v Society of Composers, Authors and Music Publishers of Canada*, 2012 SCC 34, [2012] 2 SCR 231; Michael Geist, *How the Supreme Court of Canada Shook the Foundations of Canadian Copyright Law* (Ottawa: University of Ottawa Press, 2013).

[52] *Copyright Act*, *supra* note 1.

[53] See *Copyright Act*, *ibid*, s 29.21; see also Peter K Yu, "Can the Canadian UGC Exception Be Transplanted Abroad?" (2014) 26 IPJ 177.

[54] See *Copyright Act*, *supra* note 1, s 29; S Chan, "Canadian Copyright Reform: 'User Rights' in the Digital Era" (2009) 67:2 UT Fac L Rev 233; Rosemary J Coombe, Darren Wershler & Martin Zeilinger, *Dynamic Fair Dealing: Creating Canadian Culture Online* (Toronto: University of Toronto Press, 2014).

[55] See Timothy R Holbrook & Lucas S Osborn, "Digital Patent Infringement in an Era of 3D Printing" (2015) 48 UC Davis L Rev 1319.

other things, the law should consider allowing owners to use technology control systems that prevent certain specified activities in 3D printing.

Given the role of the Internet in 3D printing activities, there are a number of parallels that can be drawn between users' rights to access copyright-protected digital content and 3D printing technology.[56] Copyright law should be adapted to allow individuals to freely create, copy, improve on, and distribute CAD files while preserving owners' rights. Patent law and trademark law should also respond to the unique challenges that the technology brings. Such considerations are necessary because 3D printing will soon face legal challenges. Thus, users' rights in various 3D printing activities ought to be incorporated and balanced with owners' rights in IP law to encourage cultural creativity and participation. Therefore, to facilitate the progress of the technology, unconstrained by legal threats and takedown notices, it is necessary that Parliament intervene with clear and explicit *ex ante* guidelines addressing questions that the technology brings. The reform of the law in this manner will help realize the societal benefits of 3D printing and guide the technology's development and its impact on individuals' lives, the economy, and general public welfare.

[56] See David Vaver, "Copyright and the Internet: From Owner Rights and User Duties to User Rights and Owner Duties" (2006-7) 57 Case W Res L Rev 731.

# DAMAGES UNDER SECTION 8 OF THE PATENTED MEDICINE (NOTICE OF COMPLIANCE) REGULATIONS: THE FINANCIAL CONSEQUENCES OF A STATUTORY INJUNCTION*

*Ephraim Stulberg and Jonathan Mesiano-Crookston***

**ABSTRACT**

In the past few years, the Federal Court has begun to issue decisions dealing with the quantification of the financial remedy applicable under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*. In the first part of this article (Sections 1 to 4), we provide an overview of these decisions, outline the areas in which a consensus appears to have been reached, and highlight areas that still require clarification. We show the tension between the desire by the courts to use section 8 to provide compensation that is fair to both parties and the need for the court to adhere to the wishes of Parliament and adhere to the wording of the Regulations as a "complete code" governing this particular area of law. In the second part (Section 5), we analyze the net effect of the section 8 remedy from an economic perspective. We show how decisions dealing with section 8 damages have arrived at an understanding that on the whole successfully balances the competing economic interests of all parties within the wording Parliament has laid down.

**RÉSUMÉ**

Depuis deux ans, la Cour fédérale rend des décisions concernant la quantification des réparations financières applicables aux termes de l'article 8 du *Règlement sur les médicaments brevetés (avis de conformité).* Dans la première partie de cet article (sections 1 à 4), nous présentons une vue d'ensemble de ces décisions, en plus de souligner les sujets qui semblent faire l'unanimité et de mettre en évidence les sujets qui doivent encore faire l'objet de plus amples éclaircissements. Nous montrons la tension qui existe entre le désir des tribunaux d'utiliser l'article 8 pour fournir une compensation équitable pour les deux parties et la nécessité, pour le tribunaux,

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d'exaucer les vœux du Parlement et de respecter le libellé du *Règlement* à titre de « code complet » qui régit ce domaine particulier du droit. Dans la deuxième partie de l'article (section 5), nous analysons l'effet net de la réparation prévue par l'article 8, d'une perspective économique. Nous démontrons comment les décisions qui traitent des dommages-intérêts versés en vertu de l'article 8 ont mené à une compréhension qui, en général, réussit à trouver un juste équilibre entre les intérêts économiques concurrents de toutes les parties à l'intérieur du libellé énoncé par le Parlement.

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## PART I

## 1.0 INTRODUCTION

In the past few years, the Federal Court has begun to issue decisions dealing with the quantification of the financial remedy applicable under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*. Section 8 outlines the financial remedy available to generic drug companies for being wrongly held off the Canadian market as a result of regulatory proceedings initiated by brand drug companies.

This article provides an overview of these decisions, outlines the areas in which a consensus appears to have been reached, and highlights areas that still require clarification. The article highlights the tensions between, on the one hand, the desire by the courts to use section 8 to provide compensation that is fair to both parties and, on the other hand, the need to adhere to the plain meaning of the Regulations.

This article is divided into two main parts. The first (Sections 1 to 4) is descriptive. It introduces section 8 of the Regulations and its general purpose, and then surveys the issues that the courts have encountered while quantifying damages under the Regulations and how the courts have treated those issues.

In the second part (Section 5), we analyze the net effect of the section 8 remedy from an economic perspective. We argue that, thus far, decisions dealing with section 8 damages have struggled to reconcile legislative intent, commercial fairness, and the plain wording of the Regulations, but that, in aggregate, section 8 (as interpreted thus far by the courts) has resulted in a relatively fair set of outcomes given the confines within which the courts have had to operate—namely, the wording of the Regulations.

Note at the outset that some of the most contentious issues described in this article around the application of section 8 were argued before the Supreme Court of Canada on April 20, 2015.[1] In a decision from the bench, the Supreme Court dismissed the appeal, affirming the Federal Court of Appeal's decision and reasoning. The authors reviewed the litigants' facta as well as their oral argument in the preparation of this article.[2]

## 2.0 A BRIEF EXPLANATION OF THE PATENTED MEDICINE (NOTICE OF COMPLIANCE) SYSTEM

A company wishing to sell an originating drug product (its "sponsor") must submit a new drug submission (NDS) to Health Canada, which, pursuant to the *Food and Drugs Act*,[3] is the government body responsible for approving drugs as safe and effective. If the NDS is approved, Health Canada will grant its sponsor a notice of compliance (NOC) and a drug identification number (DIN) that grants the sponsor approval to market and sell that drug product in Canada.

If another company wishes to sell a generic form of an originating drug product, it typically files an abbreviated new drug submission (ANDS). An ANDS filing is approved by Health Canada in a way similar to an NDS filing, except that the ANDS filing, being a generic form of an already approved originator product, must principally show that its drug product is bioequivalent to that originator product—that is, the generic must show that its drug product behaves the same way in the body—but does not have to prove independently the safety and efficacy of the drug product itself. The ANDS sponsor is not required to recreate the clinical data that supported the approval of the originator product, but can rely on the originator's clinical data for this purpose.

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[1] *Sanofi-Aventis v Apotex Inc*, 2015 SCC 20, [2015] 2 SCR 136 [*Sanofi-Aventis v Apotex* (SCC)], aff'g *Apotex Inc v Sanofi-Aventis,* 2014 FCA 68 [*Apo-ramipril* appeal], aff'g *Apotex Inc v Sanofi-Aventis*, 2012 FC 553 [*Apo-ramipril*]. The materials filed on appeal to the Supreme Court of Canada are accessible online: Supreme Court of Canada <http://www.scc-csc.gc.ca/case-dossier/info/dock-regi-eng.aspx?cas=35886>.

[2] *Sanofi-Aventis v Apotex* (SCC), *supra* note 1, available online from the Supreme Court of Canada website.

[3] RSC 1985, c F-27, as amended.

The *Patented Medicines (Notice of Compliance) Regulations*[4] serve as the linkage between the health and safety function of Health Canada and its approval of the drug product and the *Patent Act*,[5] which protects inventions. The Regulations accomplish this function in two ways. First, they allow the drug sponsor to submit patents containing claims to inventions embodied in the drug product at issue to the minister of health to be listed on a "patent register." In this article we refer to drug sponsors who file for approval of drug products covered by patents, referred to by the Regulations as "first persons," as "brand" companies, or "brands" for short. Second, the Regulations establish an expedited litigation process to determine whether a generic drug submission will infringe an originator's patents.

If a generic company (called a "second person" under the Regulations, but also referred to as "generic" companies or "generics" in this article) uses, directly or indirectly, the safety and efficacy data provided by an originating drug sponsor, the Regulations require that the second person must, in its ANDS filing, and for each patent on the patent register, indicate either that:

1. it accepts that the NOC will not issue until all relevant patents have expired; or
2. it alleges that the patent:
    a. is not owned by, or licensed to, the first person;
    b. has expired;
    c. is not valid; or
    d. will not be infringed by the second person.[6]

Furthermore, on or after the date the ANDS is filed, the generic company must serve the brand company with a notice of allegation (NOA) that contains:

1. a description of the particulars of the drug product sought to be approved in the ANDS filing;
2. a detailed statement of the legal and factual basis for the allegation; and
3. the minister's certification of filing of the ANDS.[7]

Once an NOA is served, the brand has 45 days in which to make application to the Federal Court of Canada for an order permanently prohibiting the minister of health from granting the generic an NOC until the patent at issue has expired or is rendered invalid. This order is often called a "prohibition order."

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[4] SOR/93-133 [Regulations].

[5] RSC 1985, c P-4.

[6] Regulations, *supra* note 4, s 5(1).

[7] *Ibid*, s 5(3).

As soon as such an application is filed, the minister of health is immediately enjoined from granting an NOC to the generic company for up to 24 months. This injunction, which has been referred to as "draconian" because it arises automatically without any judicial oversight,[8] is designed to keep the generic off the market while the prohibition application is pending.[9]

This 24-month period is known as the "statutory stay" period, and ends if and when the matter is resolved in the generic company's favour, the patents at issue expire, or the 24-month period expires.

During the statutory stay period, the court application proceeds to a hearing, at which the judge may conclude that the allegations in the NOA were "unjustified" and the generic's allegations that it ought to have been allowed to receive its NOC were incorrect. In this case, the court will grant a permanent injunction barring the minister of health from granting the generic company an NOC for the drug product in question.

Alternatively, the court may conclude that the allegations in the NOA were "justified" and dismiss the brand company's prohibition application. The generic company will within a matter of days receive an NOC for the drug product from the minister of health.

In these cases, the generic's allegations of non-infringement or invalidity were accepted by the court as being justified in the case before it, and yet the generic was kept off the market by the regulatory injunction for the duration of the court proceeding. The mechanism by which the Regulations compensate a generic that finds itself in this situation is through section 8, particularly sections 8(1) and 8(5):

> 8(1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period
>
> (a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that
>
> (i) the certified date was, by the operation of *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*,

[8] *Merck Frosst Canada Inc v Canada (Minister of National Health and Welfare)*, [1998] 2 SCR 193 at para 33.

[9] The Regulations contain other provisions that allow for earlier expiry of the statutory stay, but they deal with uncommon situations, including where the brand does not commence a court action and the minister is therefore free to grant the generic its NOC immediately, where all patents on the patent register relating to the drug submission have expired, or where the brand company withdraws its prohibition application.

chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or

(ii) a date other than the certified date is more appropriate; and

(b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

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(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

## 3.0 SECTION 8 REMEDY: WHAT IT IS AND WHAT IT IS DESIGNED TO ACHIEVE

The purpose of section 8 is to compensate the generic for the losses it suffered as a result of being kept off the market because of the Regulations' prohibition injunction. How are these losses to be quantified? Cases have determined that, put succinctly, the question to be answered is:

> What would have happened if [the brand] had not brought an application for prohibition?[10]

This requires the court to create a "but-for" world in which the Regulations did not stop the successful generic from entering the market with its product. From this but-for world, the court then calculates the profits that the generic *would otherwise have made* had it not been kept off the market by the brand's prohibition application.

In the past several years, courts have grappled with recreating this but-for world. The jurisprudence dealing with section 8 damages is replete with references to "broad axes" and other blunt instruments, and courts have noted on more than one occasion that the but-for world can never be recreated with any precision.[11] In one case, the trial judge noted that "the use of multiple scenarios underscores the speculative nature of the parties' positions and [is] generally unhelpful."[12]

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[10] *Apo-ramipril*, *supra* note 1 at para 6.

[11] *Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2012 FC 552, 410 FTR 1 [*Teva-ramipril*] at para 128, citing Lord Shaw in *Watson, Laidlaw & Co Ltd v Pot, Cassels and Williamson* (1914), 31 RPC 104; *Apotex Inc v Takeda Canada Inc*, 2013 FC 1237 [*Pantoprazole*] at para 20 (that section 8 is a speculative exercise), at para 116 (the court can only take a broad axe to an issue of market size), and at para 167 (reference to "broad axe" with respect to rebates); *Apotex Inc v Merck Canada Inc*, 2012 FC 1418 [*Alendronate*], where Hughes J noted at para 8 that "at best, one can approximate 'what would have' happened. It is not an area where exactitude or sophisticated calculations have a place."

[12] *Pantoprazole*, *supra* note 11 at para 26.

Nonetheless, this article concludes that the overall analysis conducted by the courts thus far has struck an appropriate balance between adhering to the wording of the Regulations and balancing the economic impact of its decisions on both brands and generics.

## 4.0 HOW TO CONDUCT A SECTION 8 ANALYSIS

Although the Regulations were introduced in 1993, court cases dealing with section 8 began resolving preliminary issues only by 2010, and there were no final decisions *awarding* section 8 damages until 2012.[13] However, since that time, the Federal Court has released quite a number of section 8 damages cases, which have established, and generally follow, the following analytical framework:

- as a preliminary legal matter, determine the burden of proof;
- determine the period of liability ("the relevant period");
- determine the overall size of the market for the relevant pharmaceutical during the relevant period;
- determine the portion of the relevant pharmaceutical market that would have been held by generic manufacturers during the relevant period ("the generic market");
- determine the portion of the generic market that would have been held by the plaintiff;
- quantify the damages that would have been suffered by the plaintiff in respect of the plaintiff's lost volume;
- consider discretion to lower the award based on misconduct ("section 8(5) reduction");
- determine pre- and post-judgment interest on the award; and
- determine legal costs of the section 8 proceeding.[14]

The parties in section 8 cases often disagree on a number of these variables. The combined effect of putting forth multiple hypothetical situations involving a number of variables is to create so many permutations of possible but-for worlds that by the time accounting experts attempt to assess the financial losses suffered by the generic, the number of scenarios can be overwhelming. Furthermore, in the end, the court may choose values for these variables—for example, market size or pricing—that differ from those used by the experts, thus creating scenarios not envisioned by the parties.

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[13] See notes 1 and 11 above for a listing of cases that have been decided since 2012; in addition, see *Teva Canada Limited v Pfizer Canada Inc*, 2014 FC 248 [*Venlafaxine*].

[14] See the cases cited in notes 1, 11, and 13 above.

It is therefore impossible to prepare estimates of all the possible financial outcomes of a section 8 case. One possible solution to this problem is for the parties to attempt to agree or resolve by early trial of an issue as many variables as possible. For example, in one recent case, a bifurcation order was granted in order to first determine the relevant period[15] before dealing with other damages issues.[16]

### 4.1 Burden of Proof

Just as with any civil proceeding, the burden of proof lies with the party making an assertion to prove it on a balance of probabilities.[17] For the court to accept it, the evidence must more likely than not support the assertion being made.

The burden in section 8 cases is initially on the generic company to prove its losses. This includes, as will be discussed below, proving that had it not been kept off the market by Regulations proceedings it would have entered the market and would have had enough capacity to supply the market and thereby justify its claimed damages.

Once the generic has proven its losses, the burden shifts to the brand company to prove any reductions to these damages. For example, if arguing that a generic's losses should be reduced because of other generic competition, the brand company must prove which other generics would have entered the market, when they would have done so, and how much of the market they would have occupied.[18]

### 4.2 Relevant Period for Loss

The Regulations provide that a generic company improperly kept off the market as a result of the statutory stay can recover any losses suffered during the relevant period, which is defined in section 8.

Correctly defining this "relevant period" is important because, according to the language of the Regulations, only losses within this time frame can be recovered, even though "there is no requirement that the actual loss commences on the first day or that it continues through to the last day of the Relevant Period."[19]

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[15] The period over which the generic's lost profits are to be calculated. Clearly, it has an impact on all later calculations in a s 8 case. The concept of the relevant period is discussed in detail below.

[16] *Apotex Inc v Pfizer Canada Inc*, 2014 FC 159.

[17] *Pantoprazole*, *supra* note 11 at para 22: "The evidentiary standard for any proposition asserted must be the civil standard of balance of probabilities that the proposition would be realized."

[18] *Ibid* at para 23.

[19] *Venlafaxine*, *supra* note 13 at para 42:

> The Relevant Period is the period within which the loss suffered by the plaintiff generic is compensable. In my view, there is no requirement that the actual loss commences on the first day or that it continues through to the last day of the Relevant Period. Rather, the Relevant Period is merely the period of time within which any loss suffered is compensable.

Often, the beginning and end dates of the relevant period will be uncontroversial. For example, in *Pantoprazole*, the minister of health indicated that if not for the Regulations, it would have granted Apotex an NOC for its generic pantoprazole product on March 9, 2007. Takeda's prohibition application was not resolved or dismissed by the court until March 5, 2008. The parties agreed that the relevant period was March 9, 2007 to March 5, 2008.[20]

In other cases, however, determining the beginning and end dates of the relevant period has not been as straightforward.

### 4.2.1 Beginning Date

The default "beginning" date is the date, as certified by the minister, on which an NOA would have been issued in the absence of the Regulations—the "patent hold" date—unless the court concludes that another date is more appropriate. A party who wishes to rely on some other beginning date bears the burden of proving the appropriateness of that date.[21]

#### 4.2.1.1 Beginning Date After Patent Hold Date

In some cases, there is no immediate financial loss to the generic company at the patent hold date—for example, where the generic acknowledged that it would not have launched its generic drug product until the expiry of a second patent, the relevant period has been held to begin when that second patent expires, because that is when the generic's financial losses would have started accruing.

In *Teva-ramipril*,[22] for example, Snider J ruled that the beginning date was neither Teva's patent hold date of October 14, 2003 nor the date it received approval to market its drug product. Instead, because Teva had certified that it would not launch its drug product until December 13, 2005, when another patent dealing with ramipril expired (the 457 Patent), Snider J found that Teva suffered no damage until that day.

Similarly, in *Venlafaxine*, Health Canada had put Ratiopharm's[23] ANDS on patent hold on December 7, 2005. Ratiopharm filed an NOA on December 23, 2005 in which it made allegations about the 778 Patent, but accepted that it would not market its product until expiry of the 540 Patent on January 10, 2006. Zinn J accepted that this later date was a more appropriate beginning date.[24]

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[20] *Pantoprazole*, *supra* note 11.

[21] *Astrazeneca Canada Inc v Apotex Inc*, 2012 FC 559 [*Omeprazole* (FC)] at para 163.

[22] *Supra* note 11.

[23] Ratiopharm was later acquired by Teva.

[24] *Venlafaxine*, *supra* note 13 at para 57, and selecting the beginning date as other than the patent hold date at para 65. Note that the generic in this case did not argue that it suffered any loss before January 10, 2006.

On a separate issue, Wyeth argued that the relevant period can never commence before the actual prohibition application was commenced, which in this case was 13 February 2006. The court held otherwise, referring to the unambiguous wording of the Regulations for support: see para 57.

#### 4.2.1.2 Beginning Date Before Patent Hold Date?

In *Venlafaxine*, Zinn J noted in passing that it was theoretically possible that the beginning date could be earlier than the patent hold date—for example,

> where the plaintiff generic can prove that it suffered a loss prior to that date as a result of it being improperly delayed in getting its product to market. One such situation may be where prior to the Patent Hold Date, the generic had entered into a supply agreement with an API [active pharmaceutical ingredient] manufacturer and had paid it a deposit which it was unable to recover or reuse after it was subsequently prevented from marketing the drug.[25]

#### 4.2.1.3 Discretion to Move the Beginning Date

Section 8 allows the court to select a beginning date that is "a date other than the certified date" where the court concludes that this other date is "more appropriate." In at least two cases, a brand company has argued that the court ought to exercise this discretion and delay a beginning date because a generic had deliberately delayed delivering its notice of allegation, thereby artificially increasing its damages by remaining on patent hold longer than necessary.

In both cases, the evidence on these points was not sufficient to prove delay.[26] In one of these cases, the court noted that the generic is under no duty to serve an NOA at any particular time, and also that the burden of proof to show a failure to mitigate is on the party alleging it.[27]

From a purely economic perspective, this conclusion makes sense. There is *typically* little benefit to a generic company wilfully remaining on patent hold or delaying delivery of an NOA. To do so would be to forgo actual revenue in exchange for the possibility of increased future damages in a section 8 proceeding that, remember, the generic would only possibly receive after successfully prosecuting a Regulations proceeding.[28]

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[25] *Venlafaxine*, *supra* note 13 at para 60.

[26] *Omeprazole* (FC), *supra* note 21 at para 161; see also *Apotex Inc v Merck & Co Inc*, 2008 FC 1185 at paras 103-116.

[27] *Omeprazole* (FC), *supra* note 21 at para 171 (about mitigation) and at para 172 (about service of NOA).

[28] One exception to this statement would be a case in which the generic has decided not to enter the market for fear that it will later be found to have infringed the patent in question (see Section 4.3.4.3 for further discussion of this risk). In such situations, the generic may have an incentive to delay delivery of its NOA, timing things such that any dismissal of a subsequent prohibition order will occur close to the patent expiry date. If the prohibition order is dismissed while the patent still has many months until it expires, the generic will be in the uncomfortable position of needing to actually enter the market (and expose itself to patent infringement litigation) in order to prove an entitlement to damages under section 8.

### 4.2.2 End Date

The relevant period runs until an "end date," which is defined as the date that the Regulations proceeding is withdrawn, discontinued, dismissed, or reversed on appeal.[29] Unlike the "beginning date," the Regulations do not expressly allow for selection of an alternate end date, and the jurisprudence is conflicted on whether courts can exercise discretion and adjust the "end date."

In most cases, the end date will be self-explanatory—it will be the date on which a judge finds that the generic's allegations were justified and that the prohibition application has improperly kept the generic off the market. For example, in *Venlafaxine*,[30] the parties agreed it was the date on which the Federal Court of Appeal ended the Regulations proceeding at issue by finding that the brand's patents ought not to have been listed and were no obstacle to the generic. (The minister issued the plaintiff generic, Ratiopharm, its NOC the next day.)

However, in other cases, the determination of the end date can be more complicated. In *Apo-ramipril*,[31] Apotex delivered an NOA about an existing patent. In response, Sanofi commenced a prohibition proceeding. Sanofi then added two more patents to the patent register (the 549 and 387 Patents), and took the position that Apotex needed to address them in Regulations litigation before it could receive an NOC.

The first proceeding was dismissed in Apotex's favour on June 27, 2006. However, because subsequent litigation dealing with the 549 and 387 Patents had been commenced, Apotex did not receive an NOC at that time. Instead, the minister of health issued Apotex an NOC six months later, on December 12, 2006, after determining that Apotex was not a "second person" in respect of the 549 and 387 Patents even while those prohibition proceedings were ongoing. Apotex entered the market shortly after receiving its NOC.

In the subsequent section 8 proceeding, Apotex argued that the relevant period should end on May 2, 2008, the date on which the *last* prohibition proceeding regarding the 549 and 387 Patents ended. Sanofi, by contrast, argued the end date should be June 27, 2006, the last day of the first proceeding. Sanofi argued that after Apotex was found *not* to be a "second person" in respect of the 549 or 387 Patents, the proceedings about those patents became irrelevant, and Apotex could not claim section 8 damages for them.[32]

Snider J ruled that although the prohibition application about the 549 and 387 Patents was technically not dismissed until 2008, it was "effectively" moot as of December 12, 2006, when the minister issued Apotex its NOC. This decision

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[29] Regulations, *supra* note 4, s 8(1)(b).

[30] *Supra* note 13 at para 43.

[31] *Supra* note 1.

[32] *Ibid* at paras 65-76.

allowed Apotex damages for the period beginning when it would otherwise have received its NOC and ending when it *actually did* receive its NOC. As Snider J noted:

> [R]ejecting June 27, 2006 as an end date is consistent with the fact that s. 8 compensates a second person for the loss occasioned by the operation of the statutory stay … . The dismissal of the proceeding in T-1499-04 on June 27, 2006 did not allow Apotex to enter the market at that time.[33]

On the other hand, Zinn J in *Venlafaxine* disagreed with the idea of adjusting the end date, holding that the language of the Regulations simply does not allow for such adjustment:

> [T]he statutory language is explicit as to when the end date for the period of liability must be fixed. Even though the end date is fixed, it may be that the loss ends at an earlier date, as was the effect of Justice Snider's judgment. In the unique circumstances of *Apotex-Ramipril FC 2012*, the NOC had issued notwithstanding that procedurally, the Prohibition Application was still outstanding. Accordingly, the Prohibition Application was no longer a barrier to the generic's entry into the market and there was no evidence establishing a causal connection between it and any subsequent loss. In such circumstances, where a plaintiff generic is unable to establish that connection, it will be precluded from recovering damages, despite the fact that the period of liability and potential for recovery extends further to the end date fixed by the *PMNOC Regulations*.[34]

Zinn J's adherence to the textual definition of "end date" in the Regulations might have had a significant impact on section 8 damages in *Apo-ramipril*. In *Apo-ramipril*, Snider J refused to award damages relating to "double ramp-up" (discussed below)[35] because they occurred outside the relevant period. If Zinn J's interpretation of the "end date" had been used, the relevant period would have extended much later in time, capturing the actual ramp-up period and allowing those damages to be awarded.

### 4.3 The Loss Suffered

After determining the relevant period, the court will calculate the plaintiff generic's damages as the "loss suffered during the [relevant period]." Losses suffered *outside* the relevant period will not be recoverable, however creatively they may be presented to the court.

Furthermore, courts have clarified that certain *types* of damages are not recoverable in section 8 actions because they do not meet the definition of "losses suffered." These include punitive damages, exemplary damages, and disgorgement of the brand's lost profits. A detailed discussion of these items is provided in Section 5 of this article.

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[33] *Ibid* at para 79.

[34] *Venlafaxine*, *supra* note 13 at para 44.

[35] See Section 4.4.2.

To calculate the loss suffered during the relevant period, the Federal Courts have settled on the following framework:

1. determine the *overall size of the market* for the drug during the relevant period;
2. determine the *overall generic share* of that market during the relevant period;
3. determine the *percentage of this generic share* of the market that would have been captured by the plaintiff generic; and
4. determine the *price at which the plaintiff generic* would have sold its drug.

Each of these steps is discussed in turn.

### 4.3.1 Size of the Total Market for the Drug Product

Two pieces of information from the real world can be instructive in estimating the market in the but-for hypothetical world. They are:

1. the actual size of the market for the drug product during the relevant period; and
2. the actual size of the market at the point that the generics entered the market upon dissolution of the statutory stay.

#### 4.3.1.1 Is Total Market Size Affected by Generic Entry?

Section 8 cases have questioned whether the introduction of a generic drug into the market has an impact on the overall size of the market. If not, then the actual size of the market during the relevant period can be used to develop the basis for calculating the plaintiff's losses. If so, then a downward adjustment factor will need to be applied to the actual market size during the relevant period to reflect this impact.

Theoretically, the introduction of generic versions of a branded drug may be expected to have several impacts. Some will tend to increase market size, and others decrease it. First, generic drugs cost less than branded drugs. Generally speaking, all else being equal, the lower the cost of a product, the greater its demand. There are two limitations to this argument. One is that this effect may be largely obviated by the fact that the payer for most drugs is private and public insurance, which have their own drivers of demand and sensitivities to cost.[36] A second is that the "elasticity of demand"—that is, how much consumers change their demand for a product based on its price—may be relatively low for drugs that are necessary to alleviate significant health problems. People may be prepared to purchase the drugs regardless of the price. Second, the owner of the brand drug product may be unwilling to divert resources to promote its own product just before that product falls off patent,

[36] Approximately 98 percent of all Canadians are covered under either public or private insurance plans: see Canadian Competition Bureau, "Canadian Generic Drug Sector Study" (October 2007) at 3 [Competition Bureau].

because any additional spending would primarily benefit the generic companies poised to enter the market.

A US-based study conducted in 2011 by Huckfeldt and Knittel[37] found that the utilization of a particular formulation of a drug product two years after the introduction of a generic is approximately half of that before generic introduction.[38] The authors attribute the decline in total market size to:

1. a decrease in advertising spending on the part of brand companies; and
2. a tendency for brands to introduce extended release reformulations of any of their drug products falling off patent, which reformulations also take market share from sales of the original formulation.

The study also concluded that different drugs performed differently upon generic introduction—for example, the overall market for metformin, a drug used to treat type-2 diabetes, rose significantly following generic introduction, rather than falling.

A study by Lakdawalla, Philipson, and Wang found that the effect of genericization was not consistent—in only 40 percent of cases did overall market size decline after generic introduction.[39] In Canada, the Patented Medicine Prices Review Board prepared a study that came to the general conclusion that the introduction of a generic version of a drug product does *not* decrease the drug's overall market.[40] This study was criticized by a brand company's economic expert witness in his testimony for the *Apo-ramipril* trial and also afterward.[41]

#### 4.3.1.2 Current Case Law on Total Market Size

In some of the early section 8 cases, expert economists expressed different views as to how to calculate what the total market size for the drug at issue would have been in order to calculate section 8 damages.

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[37] Peter J Huckfeldt & Christopher R Knittel, "Pharmaceutical Use Following Generic Entry: Paying Less and Buying Less" (May 2011), NBER Working Paper No w17046, online: Social Science Research Network <http://www.ssrn.com>.

[38] Note that the authors of this study define the "pre-genericization" market as two years prior to the actual introduction of the generic, on the ground that advertising declines well in advance of generic entry. This was an attempt to remove the distorting effect from the study of the brand's cessation of advertising leading up to patent expiry.

[39] Darius N Lakdawalla, Tomas Philipson & Richard Wang, "Intellectual Property and Marketing" (December 2007) Reg-Markets Center Working Paper No 07-20, online: Social Science Research Network <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1089045>.

[40] Patented Medicine Prices Review Board, "The Impact of Generic Entry on the Utilization of the Ingredient" (September 2011) (Revised May 2012), online: Patented Medicine Prices Review Board <http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Analytical%20Studies/NPDUIS-GenericEntryImpact-REDO-e-may7.pdf>.

[41] See E Richard Gold & Robert Carbone, "(Mis)reliance on Social Science Evidence in Intellectual Property Litigation: A Case Study" (2012) 28:2 CIPR 179.

In *Apo-ramipril*,[42] Apotex's expert suggested that generic introduction would have had a negligible impact on the overall market size, whereas Sanofi's expert contended that it would have reduced overall market size because the brand would have ceased advertising and promoting its drug product upon generic entry. Both experts created statistical models using the *actual* market for ramipril before and after the introduction of generic ramipril to try to determine whether the generic had changed the market size. Snider J preferred Apotex's expert. She noted that, although it may be the case that the brand's ceasing to advertise normally results in a reduction of overall market size, in the particular case before her, Sanofi had not ceased advertising until several months after the generic entered the market. Conversely, in *Teva-ramipril*,[43] Snider J accepted evidence that the overall market during the relevant period would have been smaller had there been generic entrants.[44] This underscores that each section 8 case is determined on its own evidence.

In *Venlafaxine*,[45] both experts used the actual change in market size after generic entry in the Quebec market (which continues to compensate brands at higher prices for a period of time following generic entry) relative to that in other provinces (which do not) in order to estimate the impact of a brand ceasing to advertise. The plaintiff's expert concluded that there was no significant decline in sales from a brand's ceasing to advertise after generic entry in the real world and that any change in market size in other provinces (as compared with Quebec) following generic entry was because of other factors irrelevant to the but-for world. The defendant's expert, on the other hand, concluded that generic entry caused a decline in the overall market size.

The court rejected the defendant's expert's view, noting that, in the real world, such a decline did not begin to occur until 18 months after generic entry, well after the end of the relevant period. The court also accepted that the actual market for venlafaxine in the real world could serve as a proxy for the but-for world, in particular given that an authorized generic was introduced very soon—that is, less than two months—after the start of the relevant period in the real world.[46]

In other cases, the size of the overall market in the but-for world has not been an issue, with the parties accepting that the actual market size of the brand drug during the relevant period should be used to estimate the size of the market in the but-for world.[47] This was also the approach adopted in a recently decided pharmaceutical patent infringement case.[48]

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[42] *Supra* note 1.

[43] *Supra* note 11.

[44] *Ibid* at para 91.

[45] *Supra* note 13 at para 66.

[46] *Ibid* at para 80.

[47] *Alendronate*, *supra* note 11 at para 40; *Pantoprazole*, *supra* note 11 at para 6.

[48] *Eli Lilly and Company and v Apotex Inc*, 2014 FC 1254 [*Cefaclor*].

### 4.3.2 Size of the Generic Market

After determining the overall size of the market during the relevant period, one must estimate the portion of that market that would have been captured by generic competitors as a whole. In *Apo-ramipril*, the court endorsed one expert's view that one ought to begin with the presumption that the observed data from the actual market post-generic entry is an accurate predictor of the but-for world unless there is good reason to believe that there are significant differences between these two worlds.[49]

In the same case, the court considered whether "erosion rates" in the brand share of the market can be affected by either (1) the number of generics or (2) the size of the overall market. In this case, the court was unable to arrive at a conclusion on the basis of the expert evidence proffered and concluded that the

> attempt to distinguish between the "but for" world and the real world based on the number of generic entrants is at best an incomplete explanation and, in my view, insufficient to deviate from the baseline assumption that the size of the generic market in the real world is a good predictor of that market in the "but for" world.[50]

In other cases, the parties have agreed that the size of the generic market in the but-for world could be estimated using the actual size of the generic market in the real world, subject to differences in the timing of formulary listings.[51]

### 4.3.3 The Plaintiff's Share of the Generic Market

In assessing the size of the total market and the generic portion of that market in the but-for world, there is comparable observed data from the real world to guide the analysis. Determining what the particular plaintiff's share of the generic market would have been in the hypothetical world, things become much more uncertain. As noted in *Apo-ramipril*:[52]

> This is a difficult assignment. Whereas the estimates of the size of the Ramipril Market and the Generic Market were reasonably based on the total ramipril market and total generic market in the real world, there are no comparables in the real world to assist us in assigning a hypothetical market share to Apotex in the "but for" world.

The plaintiff bears the burden of proving that it would have come to market and had the ability to manufacture and sell sufficient drugs during the relevant period to justify its damages. This requires, among other things, identifying a suitable supplier of the drug and showing that the supplier was capable of supplying sufficient quantities over the relevant period.[53]

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[49] *Apo-ramipril*, *supra* note 1 at paras 107-108.

[50] *Ibid* at para 114.

[51] *Venlafaxine*, *supra* note 13 at paras 82-83; *Alendronate*, supra note 11 at para 42; *Pantoprazole*, *supra* note 11 at para 4.

[52] *Supra* note 1 at para 208.

[53] *Venlafaxine*, *supra* note 13 at paras 144 and 148, citing *Alendronate*, *supra* note 11.

This does not require proving that the plaintiff had a supply contract in place in the real world. In *Venlafaxine*, the defendant brand company argued that while the plaintiff had a contract with an active pharmaceutical ingredient (API)[54] manufacturer to supply it with venlafaxine, the plaintiff cancelled it once the brand obtained a second patent covering the drug product in question, and therefore the plaintiff could not have supplied the market. The court noted:

> Wyeth has misunderstood the burden that Ratiopharm must discharge. Ratiopharm only has to show that it "had the capacity" to supply the market in the Relevant Period: See *Alendronate FC 2012* at para 44. Ratiopharm called off its order in the real world in response to the high probability of the 778 Patent being listed. Had it been required to address the 778 Patent, it is true that Ratiopharm would not have had enough product to supply the full market. However, in the but-for world, Ratiopharm does not have to address the 778 Patent; the 778 Patent should never have been an impediment to Ratiopharm's entry into the market. Ratiopharm must be presumed to behave in accordance with the fact that the 778 Patent would not impede its entry. In such a scenario, it would not have called off its order.[55]

One factor that significantly affects the size of the market that a particular generic could have occupied is when the drug product at issue is listed as eligible for provincial drug benefit plans—referred to as being listed on the "formulary"—because a significant portion of revenue for generic drug manufacturers arises from provincial drug plans. Once the generic has had a product so listed, sales of that product substantially increase. As one expert explained in *Apo-ramipril*:

> 62. … [G]enerally speaking, across Canada, the cost of prescription pharmaceuticals for seniors and the indigent is covered by the provincial drug benefit plans once the drugs achieve formulary listing. Collectively, this makes the provincial drug benefit plans the largest payers for prescription pharmaceuticals, accounting for approximately 40% of expenditures in 2005. For generic pharmaceuticals, the listing on formularies is even more critical because, typically, formulary listings permit and, in some cases require, the pharmacist to substitute a lower-priced generic version of the branded drug product.
>
> 63. For ramipril, as for most other drugs, retail sales increase markedly when listed on provincial formularies (although significant wholesale sales can occur before then in the expectation of formulary listings). In constructing the hypothetical sales data, therefore, it is important to account for the likely listing dates on provincial formularies.[56]

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[54] The "active pharmaceutical ingredient" (API) is the active ingredient in a drug product—for example, in a ramipril-containing drug product, the API is the ramipril.

[55] *Ibid* at para 158.

[56] *Apo-ramipril*, *supra* note 1 at para 116.

The level of analysis concerning the timing of formulary listings can be quite detailed. For example, in *Apo-ramipril*,[57] experts offered evidence about the speed of formulary listings from 2004, whether it would have changed by 2006, the number of days between approval and formulary listing for various Apotex products, and whether what was observed in the real world would hold in the but-for world.

### 4.3.4 Other Generics

The hypothetical but-for world must take other generic competition into consideration. The Federal Court of Appeal has confirmed that considering the plaintiff to be the only generic on the market in the but-for world would result in a windfall, and is nowhere stipulated in the Regulations.[58] Because it is in the defendant's interest to argue and prove that other generics would have entered the market, since this reduces the plaintiff's market share and losses, the burden of proving other generic entrants lies on the defendant.[59]

To determine the plaintiff's market share in the but-for world, the courts have examined the following factors:

1. whether, when, and how many other generics would have entered the market during the relevant period; and
2. the plaintiff's share of the generic market upon entry of other generics.

To determine whether and when other generics would have entered the market during the relevant period, the courts have considered the following factors:[60]

1. When would other generics have discharged their regulatory hurdles and received their notices of compliance?
2. When would the other generics have had the practical capacity to manufacture or acquire enough API to supply the market?
3. Was there anything to motivate or dissuade the other generics from entering the market?
4. When, if at all, would the product have been accepted by each of the provincial formularies?

Factors 2 and 4 are identical to those considered for the plaintiff generic and are only touched on briefly below. Factors 1 and 3 are examined in greater depth.

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[57] *Ibid* at para 118.

[58] *Teva Canada Limited v Sanofi-Aventis Canada Inc*, 2014 FCA 67 [*Teva-ramipril* appeal] at paras 86-89.

[59] *Apo-ramipril*, *supra* note 1 at para 150; *Teva-ramipril*, *supra* note 11 at para 141; *Alendronate*, *supra* note 11.

[60] *Ibid* at para 44.

#### 4.3.4.1 Factor 1: When Would the Third-Party Generics Have Received Their Notices of Compliance?

In determining when the other generics might have received their NOC, two schools of thought have been advanced, called the "case-by-case" and "open-season" methodologies.

##### 4.3.4.1.1 Case-by-Case Methodology

The case-by-case methodology reconstructs the but-for world in a way that *only the plaintiff generic* is relieved from the obligation to serve an NOA and the statutory stay that would normally follow. All other generics remain fully bound by the Regulations.

In *Venlafaxine*,[61] the court noted:

> [130] The plaintiff generic need not comply with the *NOC Regulations* in the but-for world as they relate to the patent(s) that were the subject of the Prohibition Application for the reasons provided above. However, any competing generic manufacturer must do so because in the real world it has not addressed the patents on the Patent Register. Determinations in proceedings under the *PMNOC Regulations* are decisions specific to the parties and not *in rem* determinations against the world at large: *Eli Lilly Canada Inc v Novopharm Limited*, 2007 FCA 359, [2008] 3 FCR 449 at para 40.

Eliminating the Regulations only with respect to the plaintiff has a few effects. First, while other generics in the real world are normally able to "follow on the footsteps" of the plaintiff and "unlock" the regulatory door to market, this is assumed not to be the case in the hypothetical universe.[62] The fact that the plaintiff is assumed not to file an NOA can also have an impact on the decision of the brand to launch an authorized generic in the but-for world.[63] Finally, the brand's actual behaviour in the real world is considered. For example, in *Pantoprazole*, the brand argued that it would have allowed other generics onto the market shortly after the plaintiff, Apotex, had. Phelan J dismissed this argument, holding that in the real world, Takeda had continued to fight the other generics "to the bitter end."[64]

In summary, when it comes to generics, the but-for world looks very much as follows:

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[61] *Supra* note 13 at paras 130-131.

[62] *Apo-ramipril*, *supra* note 1, citing the Federal Court of Appeal decision in *Merck Frosst Canada & Co v Apotex Inc*, 2011 FCA 329 at para 75, which phrased the issue as follows:

> [I]t must be remembered that the Federal Court had to assess Apotex's damages on the basis of a hypothetical question: what would have happened had Merck not brought an application for prohibition?

[63] Authorized generics are discussed in Section 4.3.4.4.1.

[64] *Pantoprazole*, *supra* note 11 at para 64.

1. The plaintiff would not have needed to file an NOA.
2. The defendant (brand) would not have sought a prohibition order against the plaintiff.
3. All *other* generics would have filed their NOAs when they did in the real world, and their strategies would have been the same as in the real world.
4. The brand would have commenced prohibition proceedings against those other generics at the same time as it did in the real world. Alternatively, if in the real world the brand let other generics onto the market following the dismissal of its prohibition order against the first generic, it is assumed to have done the same in the but-for world.
5. The disposition of *all* the prohibition orders in respect of each patent would have occurred either approximately 24 months following the filing of the *first* prohibition order or when the prohibition orders were actually dismissed.

The case-by-case approach was also adopted in other Federal Court cases,[65] and was upheld by the Federal Court of Appeal in a split decision in which, writing for the majority, Sharlow J noted that this approach is consistent with

- the requirement that each section 8 damages claim be determined on its own merits;[66] and
- the language of the Regulations, which speaks of calculating damages "in the absence of these Regulations" only when it comes to determining the "beginning date" of the relevant period. The inference here is that, in other contexts, the Regulations are considered to exist.[67]

#### 4.3.4.1.2 Open-Season Methodology

Various brand companies have raised the issue that, in constructing the but-for world across multiple cases, the assumptions used in each case must be consistent with one another; otherwise, across all cases, the court can award damages that exceed 100 percent of the total generic market for a drug, resulting in a windfall to that generic that does not represent its "losses" caused by operation of the Regulations.[68]

In *Apo-ramipril*, while sympathetic to the point, Snider J held:

> By their very nature, damages in this action are hypothetical. It follows that estimates must be made and a market constructed that will not be perfect. As I rewrite history,

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[65] See e.g. *Pantoprazole*, *ibid* at paras 33-35.

[66] *Apo-ramipril* appeal, *supra* note 1 at para 158.

[67] *Ibid* at paras 159-161. This theme also received comment by several of the Supreme Court of Canada justices during oral argument in *Sanofi-Aventis v Apotex* (SCC), *supra* note 1.

[68] *Apo-ramipril*, *supra* note 1 at paras 128-132; *Pantoprazole, supra* note 11 at para 58.

> hypotheses must be constructed and evaluated. Those hypotheses will necessarily change depending on the facts of *each* case. I am striving to be reasonable and fair—I cannot achieve perfection. … Since Sanofi is the defendant in all three cases, it is well aware of the total damages being claimed. If that amount raised a real threat that Sanofi's total liability would exceed the bounds of rationality, Sanofi could urge the Court to consider an adjustment to the compensation pursuant to s. 8(5) of the Regulations.[69]

In *Pantoprazole*, Phelan J dismissed this concern as an issue of "loser's risk."[70]

In his dissent in the appeal of *Teva-ramipril* appeal, Mainville J disagreed with the case-by-case approach and advocated the use of an open-season methodology[71] pursuant to which:

> [97] [I]n the hypothetical world, once a generic drug manufacturer is deemed to have been issued a NOC under paragraph 8(1)(a) of the *NOC Regulations* as if the Regulations were non-existent ("in the absence of these Regulations"), then competition from other generic drug manufacturers should be considered. In this respect, it should further be assumed that, save rare exceptions, these other generic drug manufacturers will be in a position to receive a NOC subject only to the delays and timelines set out in the *Food and Drug Regulations*.
>
> [98] Put otherwise, for the purposes of constructing the hypothetical market, once a NOC is deemed to have been issued to the claimant under paragraph 8(1)(a) of the *NOC Regulations*, those Regulations should be disregarded not only with respect to the claimant generic drug manufacturer, but also with respect to any other generic drug manufacturer that is found, on a balance of probabilities, to also be a market participant. The regulatory hurdles of the NOC Regulations are therefore disregarded, but the other regulatory and legislative restraints flowing notably from the *Food and Drug Regulations* and the *Patent Act* are considered for each participating generic drug manufacturer individually.
>
> [99] This approach constructs a hypothetical market that reflects a level regulatory playing field in that market.[72]

The merits of each of the open-season and case-by-case methodologies were the main focus of the appeal of *Apo-ramipril* before the Supreme Court.[73] The economic merits of both methodologies are discussed in the Section 5 of this article.

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[69] *Ibid* at paras 137-138.

[70] *Pantoprazole*, *supra* note 11 at para 58.

[71] The term is used by Sharlow JA in the decision for the majority in *Apo-ramipril* appeal, *supra* note 1 at para 156.

[72] *Teva-ramipril* appeal, *supra* note 58.

[73] *Sanofi-Aventis v Apotex* (SCC), *supra* note 1, and the underlying appeal and trial decisions.

#### 4.3.4.2 Factor 2: Manufacturing Capacity and Practical Considerations

The court will next look to whether the generic (or its manufacturer) would have had capacity to fill the projected market demand for the generic's drug product, and over what time frame it would have rolled that product out.[74] This factor has been relatively uncontroversial in the reported cases:

- In *Apo-ramipril*, both parties agreed that Teva would have had capacity to manufacture.[75]
- In *Teva-ramipril*, Teva argued that Sanofi had not established that Apotex had sufficient capacity to enter the market; however, based on the testimony of Apotex's CEO as well as on Apotex's actual performance upon entry into the market, Snider J was satisfied that Apotex would not have faced significant barriers.[76]
- In *Alendronate*, Hughes J found that he had not been provided sufficient evidence to determine whether one of the other generics (Cobalt) had sufficient capacity to enter the market.[77]
- In *Venlafaxine*, a key issue was when Novopharm, Wyeth's authorized generic, would have entered the market. In the real world, Novopharm contracted with Wyeth that it would receive an NOC as soon as a first generic received one. On this basis, "Novopharm would have had every motivation to come to market as soon as possible once ratiopharm received its NOC."[78] However, the court had to determine whether, in the but-for world, Novopharm would have known of Ratiopharm's impending market entry in advance, and how quickly Novopharm would have itself been able to enter the market. The court concluded that even if Ratiopharm received its NOC immediately, Novopharm would not have been in an operational position to enter the market before December 2006, when it did in the real world.[79]

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[74] *Venlafaxine*, *supra* note 13 at paras 144-159.

[75] *Apo-ramipril*, *supra* note 1 at para 152.

[76] *Teva-ramipril*, *supra* note 11 at paras 157-163.

[77] *Alendronate*, *supra* note 11 at para 46.

[78] *Venlafaxine*, *supra* note 13 at para 95.

[79] *Ibid* at para 129.

#### 4.3.4.3 Factor 3: Was There Anything to Motivate or Dissuade the Generic from Entering the Market During the Relevant Period?

Even if the other generics have the capacity to enter the market, it does not mean that they would have. In *Alendronate*, a representative of one generic (Cobalt) testified that his company would not have launched while a patent was still in place.[80] The litigation risk[81] would have outweighed the potential benefits.

In *Venlafaxine*, the court noted that there would have been little incentive for Pharmascience to serve an NOA and try to enter the market five months after Ratiopharm (the first generic). The court noted that even if Wyeth did not commence a prohibition application, Pharmascience would likely not have risked a patent infringement action in which the possibility of a claim by Wyeth for lost profits would have significantly exceeded the potential profits that Pharmascience could have earned from its position as the second or third generic on the market.[82]

#### 4.3.4.4 Factor 4: Timing of Coming to Market and of Formulary Listing

This issue is discussed in Section 4.3.3, "The Plaintiff's Share of the Generic Market."

##### 4.3.4.4.1 Authorized Generic

In some cases, brand companies have argued that, faced with imminent market entry of the plaintiff, they would have licensed an authorized generic (AG) to enter the market first.

> [T]he term "authorized generic" refers to a drug that is manufactured by an innovative drug company … but sold by a generic company under the generic's name. … The introduction of an AG allows an innovator to participate in both the brand and generic

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[80] *Alendronate*, *supra* note 11 at para 49.

[81] This concept is not well explained in the case law, and warrants a brief comment:

- If the generic is found to have infringed, the brand will file a claim for lost profits. The lost sales will be measured at the *brand's* selling price multiplied by the number of units sold, not the generic's selling price.
- If the generic's gross selling price is 70 percent of the brand's, it risks being found liable for the remaining 30 percent if it is found to have infringed the brand's patent. In other words, if found to have infringed, it will not simply be ordered to disgorge *its* profits, but will be found liable for significantly *more* than 100 percent of its profits. The more the generic discounts its prices, the more it stands to lose if subsequently found to have infringed.
- The increase in market share derived from lowering the net price of generic drugs may increase the generic's profit if the generic is never found to have infringed a patent, but can become a liability if the generic is later found to have infringed.

[82] *Venlafaxine*, *supra* note 13 at paras 140-141.

> markets, as the innovator effectively sells two distinct, but identical products. The brand company can thus recoup some of the market that has been lost to generics. It is obvious that a brand company will not introduce a generic until and unless there is an unauthorized or "true" generic manufacturer coming on to the market. Otherwise, the AG would only have the result of cannibalizing sales of the brand drug.[83]

In *Apo-ramipril*, Apotex argued that section 8 should not consider AGs, because "it creates a windfall for the originator who has been found not to be entitled to its monopoly." Snider J disagreed:

> In the absence of clear statutory language, I cannot simply, as urged by Apotex, exclude the AG from the s. 8 assessment. … Excluding an AG where the evidence demonstrates that an AG would have been present would artificially increase Apotex's compensation under s. 8.[84]

The Federal Court of Appeal has upheld that the hypothetical world includes AGs, as applicable.[85]

In determining whether a particular brand company would have introduced an AG, courts have looked to past practice, company policies with respect to AGs, and also whether or not (and how quickly) an AG was introduced in the real world. With respect to the timing of the AG's market entry, the courts have considered how quickly the brand company could have reacted to the generic plaintiff's market entry, on the assumption that the plaintiff's ANDS filing would have been kept secret if not for the Regulations, and that the brand company may have been caught by surprise.

#### 4.3.4.4.2 Brand Extensions and Reformulations

Aside from creating an AG, a brand can maintain market share upon expiry of its patent by introducing new formulations of the same drug. A study by the Competition Bureau of Canada noted that "[b]rand extensions may reduce the potential demand size available to the generic industry once the original drug loses patent protection."[86]

From a review of the reported cases to date, it does not appear that any defendant has argued that it would have launched a new formulation of its drug had it been faced with generic entry.

### 4.3.5 Market Share

Having determined the size of the generic market as a whole, and the number and timing of market entry of generic competitors to the plaintiff, the generic market must now be allocated among those participants. Economic experts have modelled

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[83] *Apo-ramipril*, *supra* note 1 at paras 170-171.

[84] *Ibid* at paras 178-179.

[85] *Teva-ramipril* appeal, *supra* note 58 at paras 100-103.

[86] See note 37 *supra*; see also Competition Bureau, *supra* note 36 at 10.

these scenarios using econometric models with numerous variables, looking at the market share of various generics under various entry patterns. Courts have found that the plaintiff's market share is a function of:

- the number of generics on the market;
- the order in which those generics entered the market; and
- the time between entry of each generic.

### 4.4 Calculation of Generic's Lost Revenue

Once the plaintiff's market share has been calculated, the next step in the analysis is to determine the price at which the plaintiff would have sold its drugs.

#### 4.4.1 Price

In determining the price at which the plaintiff would have sold its generic, courts have considered two separate periods:

1. the period before the introduction of other generics, when the plaintiff would have been the sole generic on the market; and
2. the subsequent period when multiple generics would have been on the market.

Although litigants have offered evidence about the price at which their generic drugs would have been sold, this issue has largely been decided based on the basis of testimony of provincial health officials and the provincial regulations in place governing generic drug price.

Table 1 sets out the prices accepted by the courts in each of the section 8 decisions, expressed as a percentage of the brand drug product price.[87]

#### 4.4.2 Double Ramp-Up

The issue of double ramp-up was well explained in *Pantoprazol*:[88]

> [122] Ramp up is the initial period during which the generic drug has to be made or acquired, orders received from customers and the drugs shipped to those customers. It covers the period before Apo-pantoprazole achieves steady state sales.

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[87] In more recent years, the prices paid by the provinces for generic drugs (as a percentage of the brand price) have declined significantly. For a useful summary of provincial policies in more recent years, see the Patented Medicine Prices Review Board, *Generic Drugs in Canada, 2013: National Prescription Drug Utilization Information System* (Ottawa: Patented Medicine Prices Review Board, 2014), online: <http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/2013-GenReport/PMPRB_NPDUIS_GenericDrugs2013_2014-12_EN.pdf>, particularly Appendix C, "Pricing Policies for Generic Drugs in Provincial Drug Plans."

[88] *Pantoprazole*, *supra* note 11.

**Table 1**

| | Period | | Sole Generic | | | | Multiple | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | From | To | Ontario | Quebec | Alberta | Other | Ontario | Quebec | Alberta | Other |
| *Pantoprazole* | 9-Mar-07 | 05-Mar-08 | 75% | 60% | 75% | 70% | 50% | 50% | 63% | 63% |
| *Alendronate* | 03-Feb-04 | 26-May-05 | 70% | 70% | 70% | 70% | 63% | 63% | 63% | 63% |
| *Apo-ramipril* | 26-Apr-04 | 12-Dec-06 | 70% | 70% | 70% | 70% | 65% | 65% | 65% | 65% |
| *Teva-ramipril* | 13-Dec-05 | 27-Apr-07 | n/a | n/a | n/a | n/a | 63%* | 63% | 63% | 63% |

* 50 percent commencing in 2007.

> [123] In the real world, Apotex experienced ramp up after it was successful in resisting Takeda's attempt to obtain a prohibition order which lasted until it reached steady state.
>
> [124] In the hypothetical world, the calculation of Apotex's loss reflected this ramp up incurred or experienced in the Relevant Period.
>
> [125] The effect of the calculation is that Apotex experiences the effect of ramp up in the hypothetical world resulting in a deduction from what would be steady state revenue and then in the real world it experiences the same ramp up consequences. This is double counting for the same circumstance; a disadvantage to Apotex and an advantage to Takeda.

The effect can best be shown graphically (see Figure 1).

In Figure 1, the generic's sales absent the Regulations are in light grey. Its *actual* sales in the real world, having been kept off the market by the Regulations, are in dark grey. In the but-for world, the plaintiff's sales would have ramped up in the first few months following issuance of an NOC. Similarly, upon dissolution of the statutory stay in month eight, the generic's sales do not immediately jump to where they would have been had there been no stay. Instead, it takes several months before sales ramp up to a steady state. This has been called the "double ramp-up," because the generic is forced to undergo the process twice—once in the notional world, and a second time in the real one.

From a pure loss-quantification perspective, the totality of the plaintiff's lost sales is the entire light grey area of the graph. However, because the Regulations allow for recovery of losses only during the relevant period (months 1 to 8 in Figure 1), as confirmed by the Federal Court of Appeal,[89] only that portion of the light grey area to the left of the vertical line—that is, between months 1 through 8—is recoverable.

In *Alendronate*, Hughes J (after having been overturned by the Federal Court of Appeal in having originally awarded future lost profits relating to the period beyond the relevant period under section 8) refused to grant damages in respect of double ramp-up.[90] Snider J also ruled likewise in *Apo-ramipril* and *Teva-ramipril*, and was upheld in by the Federal Court of Appeal.[91]

In *Pantoprazole*, Phelan J looked to the principle underlying the Regulations "to return the enjoined party to the position it would have been in if the injunction/stay had not been granted."[92] He ruled that section 8(5) of the Regulations allows the court to consider "all circumstances it considers relevant" in assessing damages,

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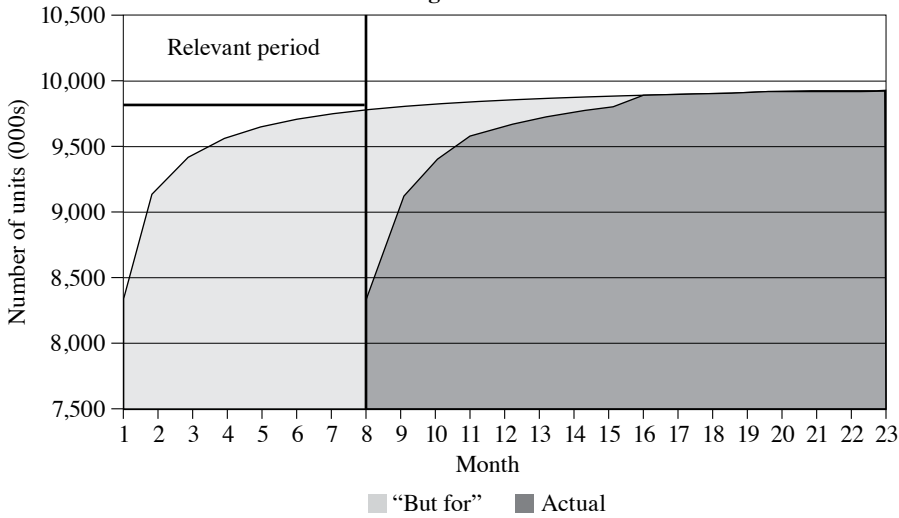
[89] *Apotex Inc v Merck & Co Inc*, 2009 FCA 187 (re alendronate); *Teva Canada Limited v Nycomed Canada Inc*, 2012 FCA 129, leave to appeal to SCC refused, [2012] 3 SCR xiv.

[90] *Alendronate*, *supra* note 11.

[91] *Teva-ramipril*, *supra* note 11 at paras 265-270.

[92] *Pantoprazole*, *supra* note 11 at para 135.

**Figure 1**




and justified an adjustment to the damages award to avoid a double ramp-up in the following terms:

> In calculating "… the loss suffered during the period … ," the Courts, through expert opinion, create a hypothetical world—an attempt to replicate what would have happened had there not been a stay and award damages on the basis of what the successful party would have otherwise earned. However, this hypothetical world exercise is not mandated by law; it is a useful tool in trying to arrive at proper compensation. It is not a formula nor is it to be rigidly applied. [93]

In *Venlafaxine*, Zinn J addressed the issue of double ramp-up from both legal and economic perspectives.[94] Legally, he concurred with Snider and Hughes JJ and ruled that any adjustment for the double ramp-up is an unrecoverable loss outside the relevant period. However, he also raised several important economic points. He noted that the ramp-up experienced in the real world would likely be different from that experienced in the hypothetical world but for the statutory stay.[95]

### 4.4.3 Inventory Adjustment

In order to properly use available sales data to estimate the plaintiff's lost sales during the relevant period, accounting experts must adjust for two factors. The first can be called a "pipe-fill" adjustment, and the second an "underreporting" adjustment.

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[93] *Ibid* at para 141.

[94] *Venlafaxine*, *supra* note 13 at paras 240-254.

[95] *Ibid* at para 247. It is worth noting that differences between hypothetical ramp-up and actual ramp-up could theoretically be adjusted for. This does not avoid the issue that the Regulations, on a plain-language reading, simply do not account for recovery of losses outside the relevant period.

#### 4.4.3.1 Pipe-Fill Adjustment

Section 8 damages cases concern themselves with compensating a generic drug manufacturer for its lost sales, which would have been made to wholesalers or pharmacies. However, in Canada, sales of pharmaceuticals are measured by a company called IMS; IMS prescription data measure sales of drugs to end consumers.

There is a period of time after a generic enters the market when its sales to pharmacies exceed the sales from pharmacies to individuals.[96] After a certain period, once inventory levels at pharmacies have been built up, "ex-factory" sales by the generic should approximately equal sales made to consumers for any given period of time. The phenomenon is illustrated in Figure 2, where, over the first six or seven periods, the ex-factory sales exceed the ex-pharmacy sales. Thereafter, the two sets of sales data are approximately identical.

IMS sales figures therefore need to be adjusted to reflect the generic company's sales to its customers over the period where the two sets of sales figures differ, because using IMS prescription data for this period would underreport the generic's sales over this period of time.

#### 4.4.3.2 Underreporting

IMS prescription data do not capture all sales made by pharmacies. Therefore, even at the "steady state," it is necessary to adjust IMS prescription data to account for this underreporting.

The simplest manner to adjust both pipe-fill and underreporting issues is to compare the total sales reported by the generic during the first number of months following market entry with the data reported by IMS over that same period. From this, one can derive an adjustment factor that will adjust for both pipe-fill and underreporting. This was the approach adopted in *Apo-ramipril*.[97]

Alternatively, one could calculate the two adjustments separately, as was done by both experts in *Pantoprazole*:[98]

- The pipe-fill adjustment can be estimated by comparing the plaintiff's internally reported sales during the ramp-up period with those reported by IMS for that period.
- The underreporting adjustment can be calculated by comparing internally reported sales to IMS sales during the steady-state period.

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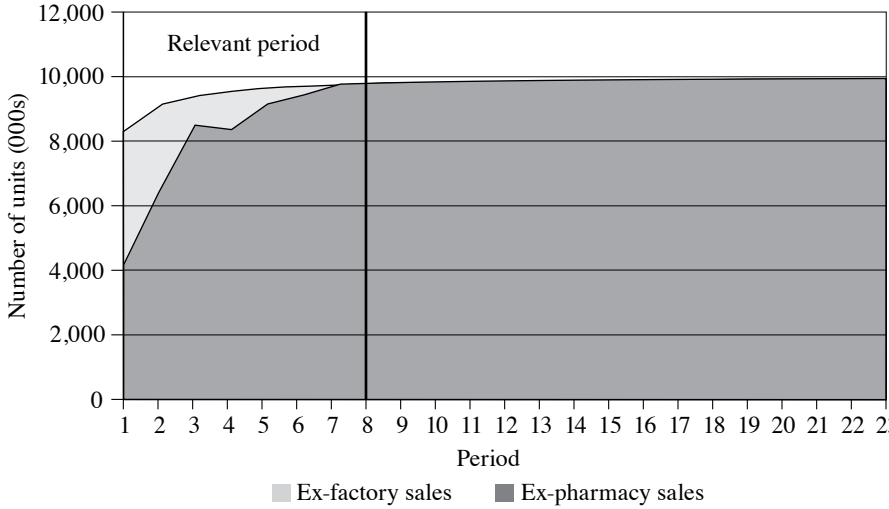
[96] See *Pantoprazole*, *supra* note 11 at para 111, and *Apo-ramipril*, *supra* note 1 at para 221.

[97] *Ibid* at paras 221-226.

[98] *Pantoprazole*, *supra* note 11 at paras 111-120.

**Figure 2**




### 4.4.4 Unapproved or "Off-Label" Indications

In some instances, a brand drug product may have received Health Canada approval for more than one medical use, or "indication." A generic submitting an ANDS for a bioequivalent form of that drug product may not wish (or be able) to seek approval for all such medical indications, including, for example, to avoid infringing medical-use patents covering certain indications.

This can complicate a calculation of the generic's lost sales during the relevant period, because, as brands have pointed out, a generic that has carved out certain indications from its product monograph, and specifically not sought approval from Health Canada to market and sell its product for those indications, should not be able to recover damages for any sales of the drug product relating to those indications. This was specifically argued by Sanofi-Aventis at the Supreme Court of Canada hearing in April 2015.

This issue arose in *Apo-ramipril* and *Teva-ramipril*. The plaintiffs had removed all mention of certain indications (the "HOPE" indications[99]) from their product monographs and had therefore not sought approval from Health Canada to sell their generic ramipril for those indications to avoid patent infringement issues relating to the use of ramipril for these indications. Sanofi argued that some of the plaintiffs' hypothetical sales would be necessarily related to the HOPE indications and these should be deducted from the section 8 damages.

[99] HOPE stands for "heart outcomes prevention evaluation," and refers to use of ramipril to treat various cardiovascular conditions.

The trial judge disagreed and refused to apply any deduction because:

- generic manufacturers do not promote drug products for specific indications;
- off-label prescribing and substitution do, in fact, take place;
- product monographs and their content are not found relevant to physicians; and
- Sanofi could have brought or could bring a patent infringement action relating to the HOPE indications as infringing Sanofi's patents covering those indications.

Furthermore, the evidence indicated that Sanofi had not objected to the drug being listed as fully interchangeable with Sanofi's product and that it was therefore

> more likely than not that Apotex would have been able to make sales for the HOPE indications during the Relevant Period, without objection. It follows that any sales made during the Relevant Period which were solely related to the HOPE indications are still lost sales that Apotex would have made in the absence of Sanofi's statutory stay, and losses for which Apotex is entitled to recover under s. 8.[100]

The court specifically noted that this finding did not mean that *all* generics can recover sales relating to unapproved indications and other cases might raise clear defences or different facts that would warrant a downward adjustment to the second person's damages pursuant to section 8(5).[101]

### 4.5 Deductions from Lost Sales

After calculating lost sales, one must next determine the costs that would have been incurred to make those sales, because costs of making the hypothetical lost sales must be deducted from those sales in order to correctly calculate lost profits.

Saved costs will typically be limited to the plaintiff's variable costs of production and selling. Variable costs are those that will fluctuate directly with changes in levels of production or sales. Some examples include:[102]

- cost of sales,
- cost of active pharmaceutical ingredient (API),
- sales commissions,
- freight and distribution,
- prompt payment discounts, and
- sales returns.

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[100] *Apo-ramipril*, *supra* note 1 at para 292.

[101] *Ibid* at para 295.

[102] *Ibid* at para 238; and see *Alendronate*, *supra* note 11 at para 88.

These categories have not generated much debate in the case law, but several points are worth mentioning:

- With respect to sales returns, they should only be deducted if the market sales data from which they are being deducted do not already include returns.[103]
- With respect to API, courts have ruled that even if the plaintiff purchases its product from related-party manufacturers at prices that are above what would have been paid to third parties, those higher costs should be considered in calculating the but-for cost of goods sold. This is so, even if the plaintiff is able establish an arm's-length price based on actual transactions.[104]
- Given that the cost of the API may change over time because of changes in markets, cost data from a period close to the relevant period are to be preferred.[105]

Generally, courts have assumed that no "step" fixed costs would be associated with the production of the but-for generic drugs. In *Apo-ramipril*, the issue of overtime premiums for extra shifts was raised, but the court concluded that it was not presented with sufficient evidence, and asked the parties "to determine that any such costs would be incurred during the Relevant Period … whether, over the Relevant Period, there would be a need for added encapsulating machinery or other added costs (such as shift premiums)—not already accounted for—to produce the Lost Volumes."[106]

### 4.5.1 Rebates

The expense that is the most difficult to quantify, and that has generated considerable debate over the years, is rebates or "trade spend."

Most generic drugs are covered by either private or government drug plans. The pharmacies that dispense these drugs to the plan members are reimbursed for the invoice price of the drugs by these insurers up to a fixed percentage of the brand's listed price. This practice has led generic drug companies to invariably sell their drugs at precisely those prices.

Price competition among generic companies takes place, in part, in the form of rebates provided by the generic companies to pharmacies based on the volume of product ordered. Rebates may also vary depending on whether the generic company is the sole generic in the market or one of several (rebates are typically much higher in multiple-generic markets), and also whether the customer is a drugstore chain, a "banner" or buying group, or an individual store.[107]

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[103] See e.g. *Apo-ramipril*, *supra* note 1 at paras 241-243.

[104] See *ibid* at paras 256-259. The courts have not, to our knowledge, addressed a fact situation in which the related-party cost is significantly lower than the third-party cost.

[105] *Teva-ramipril*, *supra* note 11 at paras 281-282.

[106] *Apo-ramipril*, *supra* note 1 at para 264.

[107] *Pantoprazole*, *supra* note 11 at para 151.

As a result of these rebates, pharmacies are reimbursed the full invoice price of the drug from the insurance payer but also receive money back from the generic manufacturers, making the effective cost of the drug to the dispensing pharmacy less than the invoice price, while the insurance payer has paid full price. As one decision noted, "[w]hile various explanations may be given for this practice, one must be blunt. It is a kick back."[108] As a result of the lack of transparency relating to rebates, various provinces have moved to ban them—Ontario, for example, introduced legislation in 2006 that eliminated payments of rebates from drug companies to pharmacies.[109]

Rebates can be hard to determine because, for competitive reasons, information concerning the level of rebates that would have been paid by the plaintiff generic on its lost sales is closely guarded. As a result, approaches to estimating rebates in section 8 cases have varied considerably:

- In *Pantoprazole*, Phelan J accepted the testimony of Apotex's CEO as to a sole generic rebate level of 8.9 percent. For the multiple-generic period, he applied a "broad axe" and accepted a figure of 15 percent.
- In *Alendronate*, Hughes J estimated the sole-generic rebate level based on several "comparable" drugs presented by one of the accounting experts. For the non-exclusive period, Hughes J used the actual rebate level paid by Apotex.

### 4.6 Discretion to Reduce Award Based on Misconduct (Section 8(5))

Section 8(5) of the Regulations contains a clause that allows the court to take account of anything it considers relevant to assessing a second person's losses, including conduct of the parties that would delay the proceeding.

In *Apotex Inc v Merck & Co*,[110] the Federal Court of Appeal held that section 8(5) allowed the trial judge broad discretion to assess the factual situation in its entirety in order to assess whether the losses ought to be reduced because of a second person's infringement of a patent—that is, notwithstanding that its allegations in the Regulations were justified, that the generic had entered the market using an infringing process and therefore that its damages ought to be reduced. In legal language, this defence is referred to as *ex turpi causa no oritur actio—ex turpi causa* for short—meaning "from a dishonorable cause an action does not arise," or "no action can arise from wrongful conduct."[111]

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[108] *Apotex Inc v Merck Canada Inc*, 2012 FC 1235 (re alendronate) at para 93.

[109] The *Transparent Drug System for Patients Act, 2006*, SO 2006, c 14 (formerly Bill 102). This Bill, and this legislative regime as a whole, was discussed in *Katz Group Canada Inc v Ontario (Health and Long-Term Care)*, 2013 SCC 64, [2013] 3 SCR 810.

[110] 2011 FCA 364 [*Apotex v Merck* (2011 FCA)].

[111] The latter from *Apotex Inc v Pfizer Canada Inc*, 2013 FC 493 at para 3 [*Apotex v Pfizer* (azithromycin)].

> The Court's broad discretion under subsection 8(5) allows [the trial judge], when considering arguments based on *ex turpi causa*, to have regard to the factual situation in its entirety, including its nuances. In the present case, one such nuance is that not all the tablets sold by Apotex were found in the infringement action to contain lovastatin made by the infringing process. A court is likely to find it easier to apply the *ex turpi causa* principle through an exercise of judicial discretion than through the definition of liability. Discretion enables the court to assess the appropriate amount of compensation payable (including nil) in a manner that properly takes account of all the relevant facts.[112]

The applicability of the *ex turpi* discretionary modification to section 8 damages was affirmed in *Apotex v Merck* (2011 FCA), in which the Federal Court of Appeal said that the judge has discretion under section 8(5) to "reduce the damages based on an argument of *ex turpi causa* which could include an infringement claim."[113] As stated in another case:

> [A] conclusion [that a generic's allegations were justified], though, does not prevent the issue of infringement from being raised before [a judge hearing a section 8 damages case]. Pfizer is entitled, now that Apotex's product is actually on the market and can be tested, to introduce evidence showing that Apotex may have actually infringed the '876 patent.[114]

Typically, the *ex turpi* reduction to section 8 damages is argued in cases where a brand company attempts to show that a generic has entered the market with an infringing product. For example, in one case, Merck's patent claimed lovastatin prepared using a particular process from a particular species of fungus—*Aspergillus terreus*. Apotex had planned and filed an ANDS to make lovastatin using two other species—*Aspergillus flavipes* and *Aspergillus obscurus*, which it alleged would not infringe Merck's patent. Unfortunately, the scientific community had not yet discovered that these three species were the same, and therefore anything made pursuant to the ANDS that Apotex had filed would infringe Merck's patent.

When the matter was sent back to Snider J,[115] Merck argued that Apotex should be precluded from receiving section 8 damages for any lovastatin made by processes that infringed Merck's patent. The court agreed and held that

- the relevant period was May 25, 1996 (the earliest date Apotex would have received an NOC[116]) to March 26, 1997 (the date the PM(NOC) proceeding was dismissed as moot, as described above); and

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112 *Apotex v Merck* (2011 FCA), *supra* note 110 at para 38.

113 *AstraZeneca Canada Inc v Apotex Inc*, 2013 FCA 77 [*Omeprazole* (FCA)] at para 4, citing to *Apotex v Merck* (2011 FCA), *supra* note 110.

114 *Apotex v Pfizer* (azithromycin), *supra* note 111 at para 23.

115 *Apotex Inc v Merck & Co, Inc*, 2012 FC 620 [*Lovastatin*].

116 *Ibid* at para 15.

- any lovastatin prepared by Apotex before February 27, 1997 would have been made through a process that infringed Merck's patent, and therefore Apotex should not receive any section 8 damages for lost sales during this period. (Those sales would be calculated at a later phase of the section 8 trial).

In *Apotex Inc v Pfizer Canada Inc*,[117] Pfizer raised the *ex turpi* defence, arguing that Apotex's section 8 damages ought to be reduced or nullified because Apotex had entered the market with an infringing product. The court considered the defence, but ultimately found that Pfizer had not made out infringement on a balance of probabilities.[118]

In *Pantoprazole*, Takeda argued that Apotex had made an enforceable undertaking to the regulators that it would not market its pantoprazole for a patented use. Later, it was discovered that Apotex's pantoprazole had, in fact, been prescribed for that use. However the trial judge held that a bare pleading was not an enforceable undertaking, and that there was no evidence showing Apotex intended to market its product in infringing ways.[119]

### 4.7 Interest on the Damages Award

An important component of any section 8 damages award is the interest on the award, which often represents millions of dollars, both because of the large size of the principal damage award and the long amount of time that has elapsed since the beginning of the statutory stay.

At law, there are two types of interest applicable to a damages award—pre-judgment and post-judgment interest:

- *Pre-judgment interest* is interest added to a plaintiff's damages award to compensate the plaintiff for not having the damage award in its hands from the time it was harmed—that is, from when the cause of action arose—until the time the proceeding was determined and the plaintiff was determined to be owed its damages.
- *Post-judgment interest* is interest accruing on a damages award starting from the moment it is pronounced by the court and running until it is paid. This interest compensates the plaintiff for not having the money representing the damages award in its hands at the moment of judgment and also serves as an incentive for the defendant to pay the award promptly. Calculation of post-judgment interest has been uncontroversial in section 8 cases, and we do not deal with it further.

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[117] *Apotex v Pfizer* (azithromycin), *supra* note 111.

[118] *Ibid* at para 79.

[119] *Pantoprazole*, *supra* note 11 at para 186.

### 4.7.1 General Federal and Ontario Approach to Interest

All damages resulting from Federal Court cases, whether action or application, attract pre-judgment and post-judgment interest pursuant to sections 36 and 37 of the *Federal Courts Act*, which provides that if the cause of action "arises" in a single province, then the pre-judgment and post-judgment interest law of that province applies.[120] Most Regulations section 8 proceedings appear to have proceeded on the basis that the cause of action "arose" in Ontario and, therefore, many of these cases apply Ontario's law of pre- and post-judgment interest.

In Ontario, the relevant legislation governing interest is the *Courts of Justice Act*:

> 128(1) A person who is entitled to an order for the payment of money is entitled to claim and have included in the order an award of interest thereon at the prejudgment interest rate, calculated from the date the cause of action arose to the date of the order.[121]

Furthermore,

- "prejudgment interest rate" is defined as the bank rate—rounded to the nearest tenth of a percentage point—at the end of the first day of the last month of the quarter preceding the quarter in which the proceeding was commenced—for example, for proceedings commenced April 8, this would be the bank rate at March 1;
- the "bank rate" is the bank rate established by the Bank of Canada as the minimum rate at which it makes short-term advances to Canadian banks; and
- the "date of the order" is the date the court order is made.

The Act also allows the court discretion to disallow interest, order higher or lower interest rates than would otherwise be payable, or order interest over a different period than would otherwise be payable. Among the factors that can be considered are changes in market interest rates, circumstances of the case, amounts claimed and received in the proceeding, and the conduct of the parties.[122]

### 4.7.2 In Regulations Cases

Pre- and post-judgment interest is payable on damages awards made in section 8 proceedings, and these proceedings occasionally raise contentious issues involving interest. In *Apo-ramipril*, the court awarded simple pre-judgment interest calculated separately for each year since April 26, 2004 at the average annual bank rate established by the Bank of Canada.[123] The decision did not describe why a single interest

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120 *Federal Courts Act*, s 36(1), for pre-judgment interest, and s 37(1), for post-judgment interest.

121 *Courts of Justice Act*, RSO 1990, c C.43, s 128.

122 *Ibid*, s 130. This section also applies to post-judgment interest.

123 *Apo-ramipril*, *supra* note 1 at para 298.

rate at the commencement of the relevant period was not used, but was instead varied for each year.

In *Pantoprazole*, the parties disagreed about which pre-judgment interest rate was to be used and the date from which it was to be applied:

- With respect to rate, Apotex argued it ought to be 4.5 percent, the rate at March 2007 (the beginning of the relevant period). Phelan J held that Ontario law called for the pre-judgment interest rate to be the "bank rate at the end of the first day of the last month of the quarter preceding the quarter in which the *proceeding was commenced*," which was 3.3 percent as of September 30, 2008 (the quarter before the quarter in which the statement of claim was issued).[124]
- With respect to commencement date, Takeda argued that interest ought to accrue from the date the prohibition application was dismissed.[125] Phelan J held, again referring to Ontario law, that it runs from the "date the *cause of action arose*," and that this date properly referred to the patent hold date—that is, when the plaintiff began to suffer damages—and not the date on which a party *could have* commenced an action.[126]

In *Venlafaxine*, the parties agreed that Teva's damages were to be $92.2 million, calculated on a monthly basis.[127] Later, in dealing with interest on this award, Teva argued for pre-judgment interest on the entire amount, calculated from the *beginning* of the relevant period. Zinn J held, in subsequent reasons,[128] that this would overcompensate Teva and that pre-judgment interest in section 8 cases ought to accrue monthly, as the loss accrued. Zinn J therefore calculated pre-judgment interest over two separate time periods, combining them to produce the full amount of pre-judgment interest:

- First, for damages *during* the relevant period, he calculated pre-judgment interest for each month of damages from the first of that month, and multiplied by the number of months through to the end of the relevant period. This meant that the first month of lost profits would accrue pre-judgment interest for the entire relevant period, but the last month would only accrue one month of interest.
- Next, the total damages award was multiplied by the pre-judgment interest rate over the number of years between the end of the relevant period and the date the court released its final decision.

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[124] *Pantoprazole*, *supra* note 11 at paras 171-172.

[125] Presumably because, according to Takeda's argument, the cause of action to sue for section 8 damages would only arise when the underlying Regulations case is dismissed. This would tend to undercompensate the generic, because it would provide that the damages for the improper two-year injunction period would run interest-free over those two years—an unfair result.

[126] *Pantoprazole*, *supra* note 11 at paras 173-174 (emphasis in original).

[127] *Venlafaxine*, *supra* note 13.

[128] *Teva Canada Limited v Pfizer Canada Inc*, 2014 FC 634 (re venlafaxine).

#### 4.7.2.1 Special Investment Opportunities

In *Bank of America Trust v Mutual Trust Co*,[129] the Supreme Court of Canada acknowledged that the simple pre-judgment interest rates described by the Ontario *Courts of Justice Act* and similar legislation generally do not fully compensate a plaintiff because:

- in most commercial contexts, interest accrues on a compound basis; and
- most individuals or commercial entities cannot borrow at the Bank of Canada short-term lending rate, but will instead pay a premium for risk.

The Supreme Court ruled that in certain circumstances, it may be appropriate to depart from the statutory pre-judgment interest rates. This principle has been accepted in intellectual property cases as well. Zinn J noted in a recent patent infringement case that "in today's world, there is a presumption that a plaintiff would have generated compound interest on the funds otherwise owed to it and also that the defendant did so during the period in which it withheld the funds."[130] Instead of applying the rate stipulated pursuant to section 36(4)(f) of the *Federal Courts Act*, he awarded compound pre-judgment interest of just over $75 million on the plaintiff's patent infringement damages of $31.2 million, both of which together were based on the estimated cost to the plaintiff of not having its lost profits and royalties available to it over the intervening period. Although not expressly laid out in the reasons for decision, this award of interest appears to represent approximately 8.5 percent compounded over roughly 17 years.[131]

It appears that the only section 8 case in which a plaintiff argued in favour of a higher interest rate is *Teva-ramipril*, in which Teva advanced a claim for "loss of profits on lost profits." The claim was rejected both at trial and on appeal. Although the court held that such damages could be recoverable, and was open to granting such damages in principle, and although it is not clear from either decision exactly what evidence was put forth by Teva or its expert witnesses, the Federal Court of Appeal noted that if a party wanted to show that it was deprived of an opportunity that would have allowed it to earn more than the pre-judgment interest rate, it was up to that party to do so on clear and non-speculative evidence.[132] If a party is unable to

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[129] *Bank of America Trust v Mutual Trust Co*, 2002 SCC 43, [2002] 2 SCR 601.

[130] *Cefaclor*, *supra* note 48 at para 118.

[131] Zinn J calculated the interest rate with reference to the plaintiff's historical profit margins. This choice of reference is strange, because typically profit margins are calculated by taking an entity's profits and dividing by its *revenue*, but do not necessarily bear a relation to the profit a firm earns on its invested *capital*.

Separately, for a useful discussion of pre-judgment interest, see Michael S Knoll & Jeffrey M Colon, "The Calculation of Prejudgment Interest" (2005) U Pa Faculty Scholarship Paper 114, online: Penn Law <http://scholarship.law.upenn.edu/faculty_scholarship/114>.

[132] *Teva-ramipril*, *supra* note 11 at paras 121ff.

point to a specific project it passed up because of lack of funds, generics may wish to adduce clear and non-speculative evidence of debts that could have been paid off had lost profits been available to it during the two years it was kept off the market by section 8 proceedings. These debts would likely run at interest rates higher than the simple pre-judgment interest rate under the *Courts of Justice Act*. This was the approach adopted in one recent pharmaceutical dispute involving pre-judgment interest on an accounting of profits.[133] On the other hand, the court's wording requiring clear and non-speculative evidence was a clear indication that courts will be scrutinizing such claims and looking to award "real" losses and not merely after-the-fact suggestions as to how lost profits might have been better invested.

## PART II

## 5.0 AN ECONOMIC ANALYSIS OF SECTION 8

Having described the existing section 8 case law in some detail, we are now in a position to examine the overall economic impact of section 8, as interpreted thus far by the courts. In doing so, we take what may be called a "proximate" approach to our analysis. We do not examine the broader public policy objectives of (1) fostering and rewarding the significant expenditures on research and development undertaken by brands,[134] or (2) supporting a strong generic drug industry as a means of delivering drugs to the public at a low cost. We also do not compare the section 8 regime with the compulsory licence regime that preceded it. Instead, our approach is simply focused on examining the economic balance of the effect of section 8 on the parties before the courts, as it has been interpreted by those courts.

### 5.1 Certain Damages Have Been Excluded from Section 8 Cases

In spite of various attempts on the part of generics to argue otherwise, the courts have held that certain types of damages that are normally available to plaintiffs in regular patent infringement/impeachment cases are simply not recoverable in section 8 proceedings by the wording of the Regulations. These are:

- an accounting of the brand's profits,
- punitive/exemplary damages, and
- any losses (damages) outside the relevant period.

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[133] *ADIR v Apotex Inc*, 2015 FC 721 at paras 153-155.

[134] For a brief overview of how these broader considerations played a role in the development of the Regulations, see the facta of the parties in *Sanofi-Aventis v Apotex* (SCC), *supra* note 1, online: Supreme Court of Canada <http://www.scc-csc.gc.ca/WebDocuments-DocumentsWeb/35886/FM010_Appellants_Sanofi-Aventis-et-al_Redacted.pdf> and <http://www.scc-csc.gc.ca/WebDocuments-DocumentsWeb/35886/FM020_Respondents_Apotex-Inc.pdf>.

### 5.1.1 Accounting of Profits

At one point in its existence, section 8(4) of the Regulations was worded so as to allow the court "to make such order for relief by way of damages *or profits* as the circumstances require." This was read by some generic companies as providing the option for an accounting of the defendant's profits.

The Regulations were amended in 2006 to remove this possibility, by removing the words "or profits." As was expressly noted in the Regulatory Impact Analysis Statement (RIAS) published alongside these amendments:

> [T]he Government is aware of a number of ongoing section 8 cases in which it is argued that in order for this provision to operate as a disincentive to improper use of the PM(NOC) Regulations by innovative companies, the term "profits" in this context must be understood to mean an accounting of the innovator's profits. … [I]n light of the proposed tightening of the listing requirements under amended section 4, and on the introduction of the frozen register mechanism under amended section 5, the Government believes that this line of argument should no longer be open to generic companies that invoke section 8.[135]

As a result, the defendant's profits are not available to be disgorged. The Federal Court of Appeal has clarified that an accounting of the brand's profits is not available under section 8, and the Ontario Court of Appeal has held that a claim for unjust enrichment for these profits is not available in Ontario court.[136] It is clear that a generic can only recover *its* lost profits over the relevant period.

### 5.1.2 Punitive Damages or Exemplary Damages

A successful generic company cannot receive punitive or exemplary damages.[137] There are two reasons for this:

1. Section 8 allows a successful generic company to receive compensation for its actual "losses suffered" in being kept off the market only as a result of a wrongful prohibition application, and this wording is to be strictly interpreted.
2. Furthermore, section 8(5), which allows the court to take any conduct of the first or second person into consideration when setting "compensation," also allows the court to adjust compensation as a result of the parties' behaviour in the Regulations proceeding. By its terms, section 8(5) does not allow punitive or exemplary damages because those damages are not "compensatory."[138]

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[135] Cited in *Apotex Inc v Merck & Co Inc*, 2008 FC 1185, [2009] 3 FCR 234 at para 33.

[136] See *Omeprazole* (FCA), *supra* note 113; *Apotex Inc v Abbott Laboratories Ltd*, 2013 ONCA 555; *Apotex Inc v Eli Lilly & Co*, 2015 ONCA 305 [*Apotex* (2015 ONCA)].

[137] *Teva Canada Ltd v Pfizer Canada Inc*, 2014 FCA 138 [*Teva* (2014 FCA)].

[138] *Ibid*:

> [12] However, by its terms, paragraph 8(5) cannot sustain a claim for punitive damages since, by their very nature, punitive damages are not "compensation": *Hill* at para 196; *Whitten* at paras 36 and 68.

### 5.1.3 Losses Outside the Relevant Period, Including Permanent Loss of Market Share, Reputational Damages, and Lost Sales of Other Products

Typically, a plaintiff in a patent infringement claim (or other litigation) would not be limited to damages occurring over any particular period,[139] but could claim any loss that could be proven to have resulted from the defendant's wrongful actions. However, courts have ruled that the phrase "suffered during the period" in section 8(1) of the Regulations means that any losses resulting from the statutory stay but not occurring "during" the period are not compensable. This excludes from a generic's scope of recovery any losses outside this period, and tends therefore to undercompensate a generic for its losses.

Plaintiffs in section 8 cases have attempted to claim these losses under a variety of names including "permanent loss of market share," "loss of business value,"[140] reputational damages, and loss of market share of other products flowing from reputational damages. However, courts have held that such damages, although they may have been *caused* by the statutory stay, are not covered by the wording of the Regulations, because they have not been "*suffered*" during the relevant period. For the same reason, the plaintiff generic is forced to undergo a double ramp-up (once in the but-for world and a second time in the actual world) for which it is not compensated.

## 5.2 The Interplay Between Regulations Cases and Patent Infringement Cases

Regulations proceedings, regardless of which party is successful, are often followed by patent infringement and patent invalidity proceedings in which the unsuccessful party in the Regulations proceeding brings either a patent invalidity action (in the case of the generic) or a patent infringement action (in the case of a brand) and seeks to invalidate or enforce the patent at issue.

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[139] Other than perhaps limitations periods.

[140] A loss of business value is measured as the difference between what the value of the plaintiff's business *would have* been but for the statutory stay and what *it is* as a result of the stay—and this differential can be calculated at the beginning of the statutory stay period. Ostensibly, this occurs during the relevant period. However, the value of a business is a function of the magnitude and risk of all the cash flows or profits that the business is expected to earn. One projects the profits and discounts them to a lump-sum present value based on their inherent risk. Thus, the decline in business value is simply a function of the lower magnitude of the plaintiff's projected cash flows following the relevant period as a result of the stay.

In *Teva-ramipril*, the court rejected the plaintiff's attempt to fit the square peg of "loss of business value" into the round hole of the relevant period on precisely those grounds. In that case, Teva had not actually been sold during the relevant period, and the court disapproved of the attempt to redefine the future loss of profits as a loss of business value.

The interplay between the earlier section 8 damages and the later patent impeachment or patent infringement damages is an interesting one, and, again, one that appears to disadvantage generics.

### 5.2.1 No Retroactive Section 8 Damages Available for a Generic That Later Invalidates the Patent at Issue

What happens if a generic loses its Regulations proceedings and is held off the market, but later invalidates the patent at issue? Does it get damages for those two years it was subject to the statutory stay? In other words, does it receive retroactive section 8 damages?

It was held in *Apotex v Syntex*[141] that if a generic is successful in invalidating a patent in a later impeachment action—that is, not a Regulations proceeding, but a full-blown patent trial—that generic is not entitled to "reach back" and be granted damages for its losses in being kept off the market during the pendency of the Regulations proceeding. This is despite the patent trial judgment being an *in rem* judgment holding the patent invalid as against the world. The reasoning from this decision was applied again by the Federal Court of Appeal in *Pfizer v Canada*:

> [18] The scope of application of section 8 and its interplay with impeachment proceedings were reviewed by our Court in *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, 2010 FCA 155. Writing for a unanimous court, Dawson J.A. held at paragraph 36:
>
> > [36] Under the 1993 version of the Regulations, when an innovator commenced a proceeding seeking a prohibition order it obtained the equivalent of an interlocutory injunction prohibiting the issuance of a notice of compliance for up to 30 months. The innovator need not have satisfied the criteria for obtaining injunctive relief and no undertaking for damages was required. *In that circumstance, section 8 of the Regulations was intended to provide redress to the generic where the innovator failed to establish that the generic's allegations of invalidity or non-infringement were not justified. In my view, section 8 was not intended to provide redress where the innovator prevailed in the prohibition proceeding, even if the generic was later successful in patent litigation. It follows that I agree with the Judge that Apotex cannot "reach back and apply the finding of invalidity in the action so as to argue that the '671 patent had 'expired' within the meaning of section 8" of the 1993 version of the Regulations.*[142]

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[141] *Apotex Inc v Syntex Pharmaceuticals International Inc*, 2010 FCA 155, aff'g 2009 FC 494 on this point. This case was followed in *Bayer Inc v Cobalt Pharmaceuticals Company*, 2013 FC 1061. Although argued under the 1993 version of the Regulations, this principle likely remains applicable to the Regulations generally.

[142] *Pfizer Canada Inc v Canada (Health)*, 2011 FCA 215 [*Pfizer v Ratiopharm*] (emphasis in original).

This passage has been repeatedly cited, most notably by the Federal Court of Appeal, which has "unequivocally" held that there would be no retroactive dismissals of Regulations proceedings that would allow generics to retroactively seek section 8 damages.[143] These holdings suggest that Regulations proceedings are independent of patent infringement/validity trials, and the damages for the first have nothing to do with the second.

### 5.2.2 Section 8 Damages Are Not Clawed Back If the Brand Is Later Successful in a Patent Infringement Trial

What if the generic succeeds in the Regulations proceeding, but the brand, at a subsequent trial, proves that the generic's infringement or invalidity allegations are false? Are the section 8 damages that the brand must pay the generic from the Regulations case "clawed back" by a later finding of infringement?

As discussed above, it appears settled that section 8 damages can be reduced pursuant to section 8(5) by application of the principle of *ex turpi causa*. However, whether later infringement damages ought to include consideration of earlier section 8 damages is an unsettled point of law. The Federal Court of Appeal has certainly held that a section 8 damages hearing need not wait until a subsequent action for infringement has been determined, because the judge hearing the infringement action has discretion to craft a remedy that is appropriate to the situation, including consideration of any section 8 damages earlier paid by the brand to the generic:

> A Court hearing the pending infringement action, if it concludes that the patent is valid and has been infringed by Apotex in making the omeprazole drug that is the subject of these proceedings, can at that time craft a remedy that is appropriate, having in mind any compensation awarded in these proceedings.[144]

Although this statement was *obiter dictum*—and is therefore not binding on later courts and does not decide the point—it certainly suggests that Regulations proceedings are *not*, in fact, completely independent from later patent infringement or invalidity proceedings, and therefore contrasts with the outcome when generics suggest section 8 damages ought to be reversed later when patents are invalidated. Overall, therefore, brands *may* be able to reduce their damages exposure in a patent

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[143] *Apotex Inc v Eli Lilly Canada Inc*, 2013 FCA 282, stating:

> [6] This Court has unequivocally held on several occasions that a finding that a patent is invalid does not enable the Court to reach back and retroactively dismiss an application for an order of prohibition granted earlier on the ground that an allegation of non-infringement or invalidity in a Notice of Allegation was not justified: see, in particular, *Syntex* at para. 36; *Pfizer Canada Inc. v. Ratiopharm*, 2011 FCA 215 (*Ratiopharm*).

In addition to the cases cited in the quote above, see also *Apotex Inc v Warner-Lambert Company LLC*, 2012 FC 202 (quinapril) at para 41, concluding at para 50 that it is clear on the law that there is no "reach back"; and *Bayer v Cobalt*, *supra* note 141 (drospirenone).

[144] *Omeprazole* (FCA), *supra* note 113 at para 6, aff'g *Omeprazole* (FC), *supra* note 21.

impeachment action by reference to an earlier section 8 damages case, but generics may not "reach back" and claim section 8 damages.

### 5.3 The Effect of the Plaintiff Recovering Its "Losses" as Opposed to the Defendant's Profits

As noted above, section 8 cases have held that disgorgement of the defendant's profits is simply not available according to the language of the Regulations. The effect of this, combined with the fact that the brand drug price tends to be substantially higher than the provincially capped generic price, is that the Regulations often may not provide a strong disincentive against commencing unsuccessful Regulations proceedings.

When a brand company commences a Regulations proceeding, the generic is immediately kept off the market for two years, without any analysis of the strength of either party's case. This provides the brand company with the immediate economic benefit of two additional years during which it may maintain monopoly pricing. Furthermore, cases thus far have assumed that the overall market for a drug is generally inelastic with respect to the availability of a generic drug—that is, the overall size of the market is assumed to be constant, regardless of whether lower-cost generic drugs are available.[145] It follows that any sale that a generic company was precluded from making during the relevant period is a sale that was, in the "real world," made by the branded drug company. The sole differences are:

- In the real world, the brand will make that sale at its brand price, which is set in a monopolistic world. By contrast, in the cases surveyed above, the generic is assumed to make sales at approximately 50 to 75 percent of the branded price, depending on the period and province in question. In subsequent years, generic prices have been cut even further, to 25 to 35 percent of the branded price (and as low as 18 percent for some drugs).[146]
- The level of rebates provided by branded drugs in a monopolistic world will be negligible compared with the rebates that would have been granted by generics in the hypothetical world. There are only two decisions in which rebate rates were not redacted from the published reasons, and the rebate rates disclosed were between 5 to 15 percent for sole generics and upward of 40 percent where there were multiple generics competing.

The combined impact of these points is that the actual profits per unit made by the brand during the statutory stay period will likely exceed the hypothetical profits that

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[145] See the discussion above in Section 4.3.

[146] See Canadian Pharmacists Association, "Generic Drug Pricing—Provincial Policies" (February 2013), online: <http://blueprintforpharmacy.ca/docs/resource-items/generic-drug-pricing---provincial-pricing_cpha_feb2013.pdf>.

the generic would have made during the two years it was kept off the market.[147] For example, if a brand company sold a drug for $1.00 per tablet in the real world, and was later found to have wrongly kept a generic off the market, it will pay as little as $0.30 per tablet in damages to the generic to compensate the generic for its losses.[148]

A brand company will therefore almost always receive a net benefit from having initiated a statutory stay, no matter how the Regulations proceeding is resolved, at least as against a single generic, and is therefore has a monetary incentive to commence such proceedings even where its position is legally weak.[149]

These economic pressures may tend to push a brand company to maximize the chances of its being able to bring Regulations proceedings to protect its monopoly pricing and also to maximize its chances of success in those proceedings by having multiple patents to assert against generic companies. This may incentivize brand companies to employ, quite rationally, strategies such as listing as many of its patents on the patent register as possible, in order to best protect its product and maximize its ability to take advantage of the statutory stay.

Generics have argued that it is unfair that they are unable to disgorge the brands' profits. For example, in *Teva-ramipril*, Teva submitted that the court should not consider *any* generics in the but-for world, and that it should award Teva damages equating to 100 percent of the generic market, because the profit made by the brand would always outweigh the damages paid to generics even if each generic was considered in a section 8 analysis to have occupied 100 percent of the market. The court, although sympathetic, did not accept Teva's position, finding it contradictory to the wording of the Regulations:

> [119] Teva's second argument—that Sanofi's liability would be "capped inappropriately" if the Court considered other generic competitors—is also unpersuasive. The heart of this argument appears to be the fact that Sanofi's total s. 8 liability is less than its profits. Including other generics in the s. 8 analysis, Teva says, would further reduce each generic's damages, as they "would be left fighting over damages that cumulatively amount to substantially less than the profits Sanofi actually made.

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147 In discussing the relative profitability of brands and generics in this section, we refer only to the revenue received, and costs incurred, during the period in which the drug in question is being sold to the public. Brand drug companies also incur significant research and development costs to develop new drugs, including drugs that never make it to market but whose research and development costs must be paid out of revenue generated by commercially successful drugs, all of which is outside the scope of this article.

148 This calculation assumes that the variable costs of producing and selling the medications are similar between the brand and the generics, which is typically the case. The calculation is based on the following assumptions:

$$\$1.00 \times 50\% \text{ (formulary standard)} \times (1 - 40\% \text{ rebate}) = \$0.30$$

149 Although the case-by-case methodology, discussed above, may hypothetically allow for the award of damages totalling more than 100 percent of the market value for the drug in question where there are multiple generics involved, the courts have also stated that they may exercise their discretion to reduce the total awarded damages in such cases.

> [120] While Teva's argument may have some appeal from a policy perspective, it fundamentally misconceives the nature of s. 8 damages. … Teva's argument attempts to obtain a form of disgorgement by another means, and must be rejected.[150]

The courts have repeatedly held that the Regulations are a "complete code" that attempts to strike a balance between the interests of the brands, the generics, and the Canadian public.[151] If the government wished to disgorge all of the brands' profits earned during the relevant period, it could easily have done so.[152] In fact, as noted above, the Regulations were amended in 2006 to remove such an interpretation.[153] It is difficult to see how a court could possibly rationalize disgorgement of profits where that language had been removed from the Regulations. Parliament always has the opportunity to reintroduce this language, if felt to be appropriate.

As a further note, *even if* there may be sound policy reasons to order the brands to disgorge their profits over the relevant period, it is not necessarily the generic companies that ought to be the recipients of those profits. Without the Regulations, the brand company would not have made the profits that it did; however, the generic companies in question would also not have earned those profits. Instead, provincial formularies, private insurers, and the general public would likely have benefited through lower drug prices. As noted by the Ontario Court of Appeal:

> Effectively, Apotex is asking the court to designate it as the *de facto* beneficiary of the wrongfully-obtained monopolistic profits despite recognizing in its pleadings that it was the public that suffered actual deprivation as a result of the monopolistic pricing. Unlike the plaintiffs in the "profiting from wrong" cases discussed above, Apotex is not positioned as the sole party with a legitimate right to "enforce" or "deter" the underlying wrong. The pecuniary interests of consumers, and potentially other generic companies, are also implicated.[154]

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150 *Teva-ramipril*, *supra* note 13.

151 In *Apotex Inc v Eli Lilly and Company et al*, 2015 ONSC 5396, Dunphy J rejected Lilly's motion to strike Apotex's claim for treble damages and double costs under the British *Statute of Monopolies* of 1624 (as well as its more recent Ontario counterpart of 1897). He noted that the "complete code" argument—that the Regulations are a complete code that governs and precludes other sources of legal damages—has not been conclusively determined to apply to the Regulations by any appellate court. For this reason, he ruled that these statutory causes of action ought not be dismissed on a preliminary motion, but instead allowed to proceed to trial where they can be determined on a full factual record. Note that causes of action will only be struck on preliminary motion where it is "plain and obvious" that the cause of action stands no chance of success, which was not the case here; therefore, little more can be said at this point about the ultimate merits of the case on these statutes.

152 *Apotex Inc v Eli Lilly Canada Inc*, 2011 FCA 358, 98 CPR (4th) 323 at para 22, leave to appeal to SCC refused, 35714 (24 April 2014) and 35886 (15 December 2014).

153 See note 135 *supra*.

154 *Apotex* (2015 ONCA), *supra* note 136 at para 55.

### 5.4 Case-by-Case Versus Open-Season Methodology

Based on the analysis thus far, it appears that several aspects of the Regulations are more favourable to the brands than to the generics. But there are also some areas in which the Regulations tend to favour the generics. Recall that the case-by-case methodology, in recreating the but-for world, assumes that only the plaintiff generic would be unfettered by the requirements of the Regulations; all other generics are still constrained.[155] Under the case-by-case methodology, it is possible that the brand will need to pay out an amount equal to, or even more than, 100 percent of the generic market.

The issue was raised in the appeals of the two *Ramipril* decisions. Sanofi noted that the combined effect of the Federal Court's rulings in *Apo-ramipril* and *Teva-ramipril* was to require Sanofi to pay more than 100 percent of the generic market. Table 2 shows the market share determined by Snider J for each of the two plaintiffs in their separate cases. It shows that for a period of approximately 8 months (December 2005 to August 2006), Sanofi was required to pay damages for lost profits representing 103 percent of the *total* generic market.[156]

In his dissent, Mainville J agreed with Sanofi's objection, noting that by treating each case in isolation, Sanofi was required to pay for lost profits representing more than 100 percent of the overall generic market:

> [92] In my view, a construction of a hypothetical market in which Teva enters the market free of the regulatory constraints of the *NOC Regulations*, while the market entry of other potential generic manufacturers is not considered or is impeded by these Regulations, invariably ensures that there will be a windfall for Teva and the other generic manufacturers [availing] themselves of section 8 of [the] Regulations in their respective proceedings.
>
> [93] A simple example illustrates the problem with the Trial Judge's methodology. Two generic drug manufacturers seek a NOC at the same time for their respective versions of an innovator drug, each challenges at the same time the relevant patent under notices of allegation, and each is impeded from entering the market for two years as a result of unwarranted prohibition proceedings initiated by the innovator drug manufacturer. Under the methodology supported by Teva and retained by the Trial Judge, each of the two generic drug manufacturers would be entitled to 100% of the generic market during the two years at issue for the purposes of determining compensation under section 8 of the *NOC Regulations*. In my considered view, this is a result which could not have been contemplated by the Governor-in-Council when adopting the *NOC Regulations* and which the language of the Regulations does not allow in any event.[157]

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[155] See Section 4.3.4.1.1.

[156] The table does not consider any amounts that will be paid by Sanofi to a third generic plaintiff in the ramipril market, Laboratoire Riva Inc; nor does it include AGs that were assumed to enter the generic market as part of the hypothetical worlds, earning a portion of the generic market share.

[157] *Teva-ramipril* appeal, *supra* note 58.

**Table 2**

| Period | | Damages Award to | | |
|---|---|---|---|---|
| From | To | Apotex | Teva | Total |
| 26-Apr-04 | 24-Jul-04 | 100% | 0% | 100% |
| 24-Jul-04 | 13-Dec-05 | 70% | 33% | 103% |
| 13-Dec-05 | 01-Aug-06 | 70% | 33% | 103% |
| 01-Aug-06 | 12-Dec-06 | 50% | 33% | 83% |
| 26-Dec-06 | 25-Apr-07 | 0% | 33% | 33% |

At first glance, the idea that the brand should have to pay more than 100 percent of the value of the generic market over the relevant period does seem unreasonable, and the rationale to cap it at 100 percent is attractive. Sanofi argued before the Supreme Court of Canada during its April 2015 appeal that to allow more than 100 percent recovery to a generic would represent a "windfall" for generics. Sanofi compared the situation under the Regulations to a situation involving multiple plaintiffs, each of whom claims lost profits relating to a tender for contract, and argued that the Regulations ought to be interpreted in the same way—that is, the total damages awarded cannot be greater than 100 percent of the total profits that would have been earned by whichever party would have won the contract.[158]

The idea that damages in excess of 100 percent of the market are a windfall is circular. It is premised on the idea that the but-for world is one in which *no* generic is constrained by the existence of the Regulations, and so when the first hits the market, so too do the others. This is certainly one possible reading of the Regulations, but it is not the one adopted by the trial judge.

If one assumes, as the trial judge did, that the Regulations intend that the damages suffered by each generic are to be considered in the context of each action separately,[159] there is nothing wrong with assessing each generic's damages based on the hypothetical construction of each case, even if, in aggregate, the award across all actions implies that the plaintiff generics would have captured more than 100 percent of the generic market. This is the reading of the Regulations adopted by the majority of the Federal Court of Appeal and upheld by the Supreme Court.

A slightly different argument might have been that by forcing the *brand* to pay damages that would arise in each of these multiple but-for worlds, the brand may

[158] *Sanofi-Aventis v Apotex* (SCC), *supra* note 1, in particular Sanofi's factum at paras 71-74.

[159] It is noteworthy that Snider J, in hearing *Apo-ramipril* and *Teva-ramipril*, went to great pains to treat each case separately, going so far as to issue rulings that were in some details contradictory—for example, in *Apo-ramipril*, she ruled on the basis of the evidence that the introduction of a generic does not lead to a reduction in overall market size; in *Teva-ramipril* she ruled that it does: see Section 4.3.1.2.

unfairly end up paying damages on more than 100 percent of the generic market. This argument would have focused less on the "windfall" to the generics and more on the onerous burden borne by the brands.

### 5.4.1 Can a Section 8 Award Exceed the Defendant's Profits?

This raises the question whether it is possible, under the case-by-case methodology, for the defendant to have to pay more than 100 percent of the profits that *it* earned during the relevant period. Such a result would be truly harsh, and might provide a more solid basis on which to reject the case-by-case methodology.

We conclude using the example invoked by Sanofi in *Apo-ramipril*, as summarized by Snider J:[160]

> [129] Sanofi attempted to illustrate the potential "absurdity" of Apotex's position through the use of a hypothetical example. In the example, Sanofi assumed three generic manufacturers, with A approvable at year 0, B approvable at year 1 and C approvable at year 2. The other assumptions were:
>
> - total generic market of 20 units/year;
> - NOC proceedings against each generic;
> - NOC proceeding against A dismissed at year 3;
> - all generics enter at year 3; and
> - each generic advances a s. 8 claim.
>
> [130] If each of A, B and C commence an action for recovery of damages under s. 8 and if the claims are assessed as three independent "but for" markets with no other hypothetical entrants, the results, as posited by Sanofi, would be the following:
>
> - A would claim three years at 20 units/year for a total of 60;
> - B would claim two years at 20 units/year for a total of 40 units;
> - C would claim one year at 20 units/year for a total of 20 units.

In this scenario, the brand company sells an additional 60 units (the entire but-for generic market). Assume that its selling price is $1.00 per unit, it offers no rebates (because it has a monopoly), and its variable costs are $0.25 per unit.[161] Its incremental profit from keeping A, B, and C off the market is therefore 60 × ($1.00 – 0.25) = $45. In addition, the brand also benefits by earning additional profits in the

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[160] *Apo-ramipril*, *supra* note 1.

[161] The reasons in *Apo-ramipril* and *Teva-ramipril* do not disclose the variable costs of producing and selling ramipril. Also, because most Canadian generic drug companies are privately held, it is difficult to determine a normal variable profit margin. Based on Teva Pharmaceutical Industries Ltd's annual reports, Teva's overall variable profit margin on all products (across all countries) is in the range of 40 to 60 percent.

first few months following the granting of NOCs to A, B, and C following year 3 during the ramp-up period.

Having had its prohibition orders dismissed, the brand must now pay damages to A, B, and C as follows:

- A would be assumed to be the sole generic for three years, selling 60 units at \$0.70[162] and offering rebates of 10 percent, for a net selling price of \$0.63. Because A has the same variable costs as the brand, its damages award is equal to 60 × (\$0.63 − \$0.25) = \$22.80.
  - Note that while A's selling price (net of rebates) is *63 percent* of the brand's, its variable costs are the same as the brand's; therefore, its profit is only approximately *50 percent* of the brand's.
  - The higher the variable cost to manufacture and sell each unit, the greater the disparity between the profit levels of the brand and the generics. In this example, if variable costs were \$0.40 per unit, the brand's profit would be \$1.00 − \$0.40 = \$0.60, while the generic's profit would be \$0.63 − \$0.40 = \$0.23, or only *38 percent* of the brand's profit.
- B is assumed to be the sole generic for two years, selling 40 units. Its damages are equal to 40 × (\$0.63 − \$0.25) = \$15.20.
- C is the sole generic for a single year, selling 20 units; its lost profits are \$7.60.

In this example, even without assuming a multiple-generic market at any point in time, the brand will still break even once its prohibition orders have been dismissed and it has been forced to pay damages. Its incremental profit of \$45 during the three-year period is virtually identical to the lost profits of A, B, and C (\$22.80 + \$15.20 + \$7.60 = \$45.60) that it must pay for bringing its unsuccessful prohibition proceedings against the generics.

Other fact patterns may leave the brand in a better, or worse, position. The hypothetical launch of an authorized generic company in the but-for world significantly tilts the balance of this calculation in the brand's favour. Conversely, if A, B, and C had all been put on patent hold on the same date, and no authorized generic company introduced, the total damages award to A, B, and C would exceed the brand's profits.

Given that in recent years provinces have significantly lowered the prices they pay for generic drugs under provincial drug-benefit plans, the likelihood that a brand will ever have to pay out more than 100 percent of its profits earned during the statutory stay period is becoming more and more remote.

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[162] Using the old 70–90 regime for Ontario provincial reimbursement in force from 1998 to 2006, in which the first generic sells at 70 percent of the brand price and subsequent generics must sell at 90 percent of the first generic price.

## 6.0 CONCLUSION

This article has reviewed the economic analysis conducted in section 8 cases, and then proceeded to look more closely at some of the points of uncertainty, noting particularly where they advantage or disadvantage one or another of the parties.

Are the Regulations, as written and interpreted thus far, commercially "fair"? This is a difficult question to answer. It is impossible for any legislative text to anticipate all the possible fact patterns that may emerge. In attempting to formulate a balance in preparation of the legislative text, there is bound to be ambiguity that, especially in an area of litigation such as pharmaceutical patents where the financial stakes are quite high, tends to lead the parties to contentious litigation and may lead to judicially pronounced unexpected results.

We have seen that some of the limitations on the scope of compensation allowed by the Regulations tend to advantage brand companies. However, express rejection of the open-season methodology in favour of the case-by-case approach has the opposite effect, because it potentially makes brand companies liable for more than 100 percent of the generic market.

These results are, by and large, created by the courts' interpretations of the Regulations, taking them to be a complete code governing this area of law, as opposed to any sense of judicial activism. Attempts to depart from the wording of the Regulations, even where the parties have argued that it might be more economically neutral to the parties themselves, have been rejected by the courts in favour of a stricter adherence to the legislative text.

# THE TERM OF COPYRIGHT PROTECTION IN PHOTOGRAPHS*

*Margaret Ann Wilkinson and Tierney G.B. Deluzio***

**ABSTRACT**

Among the many changes made by the *Copyright Modernization Act* in 2012 were a number that affected copyright in photographs. The removal in 2012 of section 10 of the *Copyright Act*, which had previously made special provisions for the length of copyright in photographs, leaves section 6 of the *Copyright Act*, the general term provision, as the one governing photographs, because there is no other section in the current *Copyright Act* applicable to photographs. The life of the author of a work plus 50 years after the end of the calendar year of the author's death will clearly be the period of copyright for photographs going forward. This article examines whether, because of this change, copyright subsists in all photographs in Canada whose authors have died within the past 50 years or whether, as some have suggested, a group of such photographs exists in which copyright has expired. We conclude that all such photographs are in copyright.

**RÉSUMÉ**

En 2012, plusieurs importantes modifications ont été apportées par la *Loi sur la modernisation du droit d'auteur*, dont un certain nombre concernaient la protection des droits d'auteur dans le domaine de la photographie. La suppression, en 2012, de l'article 10 de la *Loi sur le droit d'auteur*, lequel comportait déjà des dispositions spéciales sur la durée des droits d'auteur pour les photographies, fait en sorte que l'article 6 de la *Loi sur le droit d'auteur*, la disposition générale sur la durée des droits d'auteur, est le seul article qui régit les photographies, car aucun autre article de l'actuelle *Loi sur le droit d'auteur* ne s'applique aux photographies. Dorénavant, il est clair que les droits d'auteur pour une photographie subsisteront pendant la vie de l'auteur/du créateur, puis jusqu'à la fin de la cinquantième année suivant celle de son décès. Cet article examine la question à savoir si, en raison de cette modification, les droits d'auteur subsiste pour toutes les photographies au Canada dont les auteurs/créateurs sont décédés au cours des cinquante dernières années, ou, comme certains l'ont suggéré, si les droits d'auteur ont déjà expiré pour certaines de ces photographies. Nous arrivons à la conclusion que toutes ces photographies sont protégées par droit d'auteur.

* Submission to the editor, August 27, 2015.

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**CONTENTS**



## 1.0 INTRODUCTION

Controversy has arisen regarding the copyright status of some photographs created before December 31, 1948 under present Canadian law. This comment demonstrates the position of this article's authors—nothing turns on that date under the current law.

## 2.0 BACKGROUND

At its inception, the *Copyright Act* ["the Act"] made unique provisions for the term of copyright in photographs.[1] Photographs were originally given copyright protection for 50 years[2] (a "50-year flat term") as opposed to the general term of "life of the author plus 50 years" given to works generally by section 5[3] (now section 6[4]). It has been speculated that photograph copyrights were given this shorter term of protection because they were "considered to be only industrial objects rather than art."[5]

The provisions relating to the term of photograph protection have been amended a number of times since 1985.[6] The first change to section 10 occurred in 1993, when

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[1] Margaret Ann Wilkinson & Charles Painter, "Shifting the Balance of Copyright Control for Photographic Works in Canada" (1999) 13 IPJ 353 at 355 and 371ff.

[2] *Copyright Act*, SC 1921, c 24, s 7, later s 10 (see *Copyright Act*, RSC 1985, c C-42 prior to 1993).

[3] *Copyright Act*, SC 1921, c 24.

[4] *Copyright Act*, RSC 1985, c C-42.

[5] David Vaver, *Intellectual Property Law: Copyrights, Patents, Trade-marks*, 2nd ed (Toronto: Irwin Law, 2011) at 145-46 [Vaver, *Intellectual Property Law*].

[6] By SC 1993, c 44, s 60; SC 1994, c 47, s 69(F); SC 1997, c 24, s 7; SC 2012, c 20, s 6. Note that before 2012 there were also special provisions in the Act giving ownership of photographs to those commissioning them rather than to the photographers (see, originally, SC 1921, c 24, s 11). Such provisions were only completely removed by SC 2012, c 20, s 7; at present, determining the first owner of all photographs is aligned with the determination of the first owner of any other work.

the Act was amended to allow photographs to be "authored" by corporations, but the term of protection remained a 50-year flat term, whoever the author was.[7] In 1997, section 10 was significantly altered—natural authors were removed from its special provisions[8] and individual-dominated small corporations were given protection for 50 years plus the life of the individual "at the heart" of the corporation, while large corporate owners continued to have the shorter 50-year flat term of protection.[9]

These changes seemed to raise the question, if natural persons were no longer included under the special provisions outlined in section 10, what term of copyright protection applied to photographs they created? The 1997 *Act to Amend the Copyright Act* contained a general provision, section 54.1, which stated that section 6 of the *Copyright Act* applied to all photographs authored by natural persons. The latter section states:

> 6. The term for which copyright shall subsist shall, except as otherwise expressly provided by this Act, be the life of the author, the remainder of the calendar year in which the author dies, and a period of fifty years following the end of that calendar year.

In 2012, under the *Copyright Modernization Act*,[10] section 10 of the Act was entirely repealed, completely doing away with its special provisions for photographs.[11] The only provision now in the Act that can apply to the term of copyright in photographs is section 6—and it declares that it applies "except as otherwise expressly provided by this Act."

This brief legislative history indicates that Parliament has now left all photographs to be covered by the general term of copyright protection outlined in section 6—that is, copyright subsists in them for the life of the author plus 50 years. Despite the logic of this conclusion, some more recent commentators seem to have taken the legal commentary originating from the changes made in 1997 as the basis for an argument that some photographs, although their authors are either alive or have died within the past 50 years, have nonetheless "fallen" out of copyright; Normand

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However, whether first ownership of a photograph lay with a commissioning party or otherwise, even prior to the latest amendments, is not material to this discussion of the period of protection in photographs since 2012.

7 SC 1993, c 44, s 60.

8 *An Act to Amend the Copyright Act*, SC 1997, c 24, s 7.

9 David Vaver, *Copyright Law* (Toronto: Irwin Law, 2000) at 104 opines that the 1997 Act tried to mix and match new and old provisions [Vaver, *Copyright Law*].

10 SC 2012, c 20, s 6.

11 Ysolde Gendreau, "Canada" in Ysolde Gendreau, Axel Nordemann & Rainer Oesch, eds, *Copyright and Photographs: An International Survey* (London: Kluwer Law International, 1999) at 109 noted in respect of the situation in Canadian law prior to 2012:

> Given the entanglements of the new [1997] rules, which are probably unique in the world, one can only hope that the government will continue to want to maintain a correlation between the rules on the term of protection and those on authorship and that it will fully abrogate the special rules during the next revision process.

Our position is that the government *has* done so.

Tamaro and archivist Jean Dryden appear to take this position in their post-2012 writing.[12] On the other hand, the majority of legal commentators make no argument that the current period of copyright for any photograph in Canada is anything other than the life of the author plus 50 years.[13]

The source of the line of thinking put forward by Tamaro, Harris, and Dryden, that certain photographs do not now enjoy copyright protection for the life of the author plus 50 years, appears to lie in pre-2012 writings of David Vaver.[14] The following is an explanation of that position.

The statutory basis for the belief that, post-2012, some photographs do not enjoy the same term of protection as other works, even though their authors are alive or have died within the past 50 years, appears to rest on the effect of the 1997 changes and that of the transitional provisions found in the 1997 amending statute. The 1997 amendments came into force on January 1, 1999—without them, under the law since 1921, copyright protection would have automatically expired in any photograph taken more than 50 years prior to December 31, 1998 (that is, on or before December 31, 1948) regardless of whether the author was alive or dead, a human, or a corporation. The question becomes whether and how the 1997 amendments changed this outcome—did they cause any photographs taken before January 1, 1949 to be *in* copyright? As set out in the brief history above, it seems that section 6 would have applied to the term of protection in photographs owned by natural persons (directly or as "the heart" of a corporation), and that these photographs would have enjoyed copyright protection even if they were created before December 31, 1948 if their creators were still alive. Indeed, the date December 31, 1948 would have remained relevant to the period of protection in photographs only for those owned by large corporations. However, the 1997 *Act to Amend the Copyright Act* contained a general transitional provision, section 54.1 (which did not become part of the Act):

> Section 6 of the *Copyright Act* applies to a photograph in which copyright subsists on the date of the coming into force of this section, if the author is
>
> (a) a natural person who is the author of the photograph referred to in subsection 10(2) … [if the photographer was a natural person]; or
>
> (b) the natural person referred to in subsection 10(1.1) … [if the natural person was central to a closely held corporation].

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[12] Normand Tamaro, *The 2006 Annotated Copyright Act* (Toronto: Thomson Carswell, 2005) at 320-21; Lesley Ellen Harris, *Canadian Copyright Law*, 4th ed (Hoboken, NJ: Wiley, 2014) at 128; Jean Dryden, *Demystifying Copyright*, 2nd ed (Ottawa: Canadian Library Association, 2014) at 23-24 [Dryden, *Demystifying Copyright*]. Dryden's treatise does not contain any footnotes or references.

[13] E.g. Halsbury's Laws of Canada (online), *Term of Protection*, "General" (IV.1) at HCY-38 "Term of copyright" (Cum Supp), and Gendreau, *supra* note 9. See also Sheldon Burshtein, *The Corporate Counsel Guide to Intellectual Property Law* (Aurora, Ont: Canada Law Book, 2000).

[14] See Vaver, *Intellectual Property Law*, *supra* note 5 at 145-47, and Vaver, *Copyright Law*, *supra* note 9 at 104-7. David Vaver is currently a professor at Osgoode Hall Law School, York University.

The opening words of this section—that is, "section 6 … applies to a photograph in which copyright subsists on the date of the coming into force of this amendment" led Vaver to interpret section 54.1 as being applicable only to "photographs taken as from 1 January 1999 and also to pre-1999 photographs that were still in copyright at that date—those taken after 31 December 1948."[15]

The transitional provision (section 59(1)) of the 2012 *Copyright Modernization Act* states that "[t]he repeal of section 10 of the *Copyright Act* by section 6 does not have the effect of reviving copyright in any photograph in which, on the coming into force of that section 6, copyright had expired." If the approach taken by David Vaver toward the 1997 amendments were maintained, then this 2012 provision might be suggested to mean that any photograph in which copyright protection had expired under the Act as it stood on November 6, 2012[16] is not protected thereafter, whatever the new provisions. Moreover, it might be argued, the term of copyright was extended by the 2012 amendments only in photographs that would still have protection after November 6, 2012 under the prior enactment had the new one not been enacted.[17] However, the better interpretation of section 59(1) is set out below.

## 3.0 WHY ALL PHOTOGRAPHS NOW ENJOY PROTECTION FOR THE LIFE OF THE AUTHOR PLUS FIFTY YEARS

We disagree with Vaver's approach and take the position that copyright now exists in all photographs in Canada for the life of the author plus 50 years. We take this position for a number of reasons.

### 3.1 The Concept of "Subsistence" Is Key to Interpreting the Reach of the Amendments Made Concerning Photographs in Both 1997 and 2012

The changes in copyright protection for photographs in Canada from fixed terms to terms based on the subsistence of copyright, partially through the 1997 amendments and completely in the 2012 amendments, are fundamental and require that the wording of both the 1997 *Act to Amend the Copyright Act* and the 2012 *Copyright Modernization Act* be interpreted consistent with those fundamental changes.

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[15] Vaver, *Intellectual Property Law*, *supra* note 5 at 146; Vaver, *Copyright Law*, *supra* note 9 at 105. Jean Dryden follows this line of interpretation, although she does not cite to David Vaver, in her doctoral dissertation, "Copyright in the Real World: Making Archival Material Available on the Internet" (Toronto: University of Toronto, 2008) at 27 [Dryden, "Copyright in the Real World"].

[16] The *Copyright Modernization Act* came into force on November 7, 2012—Order Fixing Various Dates as the Dates on which Certain Provisions of the Act Come into Force (SI/2012-85) (2012) C Gaz II, 1392 (*Copyright Modernization Act*).

[17] See e.g. Bob Tarantino, "Canada's New Photography Copyright Regime: Clearance Challenges" (3 December 2012) (blog), online: Entertainment & Media Law Signal <http://www.entertainmentmedialawsignal.com/canadas-new-photography-copyright-regime-clearance-challenges>.

In 1997, Parliament changed the term of protection for photographs of which natural persons were the authors by simply removing any specific provision dealing with these photographs. As described above, this left those works protected under section 6, which declares that "copyright shall subsist." In 2012, Parliament changed the term of protection for all photographs by removing all remaining specific provisions dealing with rights holders' rights in photographs and leaving *all* photographs governed by section 6.

Canadian courts have already dealt with the dramatic effect of the introduction into Canadian law of the concept of the subsistence of copyright where there had previously been only copyright protection for a period of years. Prior to the 1921 *Copyright Act* (under which, with revisions, Canada continues to be governed), the general period of protection for works was a set term of 28 years after registration.[18] It was the 1921 Act, derived from the English *Copyright Act of 1911*,[19] which abolished the requirement of registration and included a term of protection expressed similarly to that in the current section 6: "The term for which copyright shall *subsist* shall, except as otherwise expressly provided by this Act, be the life of the author and a period of fifty years after his death."[20]

The subsistence of copyright without formalities and a period of protection based on the life of the author have become international norms of copyright law,[21] and yet it has been noted that "the historical development of these norms is also notable for an almost complete absence of debate of the policy and theoretical issues involved."[22] Nonetheless, after the dramatic change occurring in 1924,[23] to focus on subsistence of the work as the point of origin of copyright in Canada, rather than registration, it was held that Canadian judges would henceforth be required "to revise one's ideas of what copyright means and how it is secured. … [Copyright] is a proprietary right which arises from authorship alone. It is sometimes called 'automatic copyright,' for without any act beyond the creation of a … work it is acquired by the author."[24] Subsequently, the importance of the concept of subsistence to

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[18] *An Act Respecting Copyrights*, RSC 1906, c 70, s 4.

[19] *Copyright Act 1911* (UK), 1 Geo V, c 46, s 1: "[C]opyright shall subsist throughout the parts of His Majesty's dominions to which this Act extends for the term hereinafter mentioned." The British enactment was itself designed to bring Britain into compliance with the 1909 *Berlin Revision* to the *Berne Convention* requiring protection without compliance with any formalities for the life of the author plus 50 years: see Gillian Davies, *Copyright in the Public Interest*, 2nd ed (London: Sweet & Maxwell, 2002) at 4-008.

[20] SC 1921, c 24, s 5 (emphasis added). Note that in 1921 photographs did not enjoy a period of protection based on the life of the photographer—the discussion focuses on the introduction of the notion of subsistence into Canadian copyright law.

[21] *Berne Convention for the Protection of Literary and Artistic Works*, 9 September 1886, 828 UNTS 221, art 5(2) (last revised 24 July 1971 and amended 28 September 1979).

[22] Davies, *supra* note 19 at 10-002, quoting Sam Ricketson, "The Copyright Term" (1992) 23 IIC 755.

[23] When the 1921 legislation came into effect.

[24] *Gribble v Manitoba Free Press Co*, [1931] 3 WWR 579 at para 38 (Man CA), Dennistoun JA [*Gribble*].

modern copyright in Canada has often been noted, including in Justice Linden's 2002 majority judgment in the Federal Court of Appeal in *CCH Canadian Ltd v Law Society of Upper Canada*.[25]

Justice Thorson (president of the Exchequer Court of Canada), writing in 1950 about the effect of the change from pre-1921 registration for copyright to post-1921 subsistence, stated that "the registration of copyright [in 1950] does not confer upon the author of a literary work any right that did not already belong to him by virtue of his authorship."[26] Indeed, the proposition that copyright arises automatically from authorship alone, requiring no formal action beyond the creation of a work, has since become axiomatic in Canadian copyright law.[27] It is therefore important to note that "to 'subsist' is to 'have being or existence.'"[28] If the only section now in the *Copyright Act* dealing with the period of copyright in photographs is the general one that governs all works in which copyright subsists (section 6), it must govern all original photographs created by living authors and created by any photographer who has died since 1965.

In 1998 the Supreme Court in *Re Rizzo & Rizzo Shoes Ltd* held unanimously that

> with regard to the scheme of the legislation, since the [*Employment Standards Act*] is a mechanism for providing minimum benefits and standards to protect the interests of employees, it can be characterized as benefits-conferring legislation. As such, according to several decisions of this Court, it ought to be interpreted in a broad and generous manner. Any doubt arising from difficulties of language should be resolved in favour of the claimant.[29]

Similarly, because the *Copyright Modernization Act* has made changes to the *Copyright Act* that establish further rights for photographers as copyright holders (a

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[25] 2002 FCA 187 at para 55, rev'd 2004 SCC 13, [2004] 1 SCR 339, Linden J (Rothstein concurring): "[S]ome compilations may be comprised of elements that are copied … in which copyright may or may not subsist."

[26] *Moreau v St Vincent* (1950), 3 CPR 32 at para 9 (Ex Ct).

[27] See e.g. *Planet Earth Productions Inc v Rowlands (HCJ)* (1990), 73 OR (2d) 505 at para 38 (Sup Ct); *Fletcher v Polka Dot Fabrics Ltd* (1993), 44 ACWS (3d) 783 at para 8 (Ont Ct J (Gen Div Sm Cl Ct)); *Wall v Horn Abbot Ltd*, 2007 NSSC 197 at para 481, citing S Handa, *Copyright Law in Canada* (Markham, Ont: Butterworths, 2002) at 193-94.

[28] *The Oxford English Dictionary*, 2nd ed, *sub verbo* "subsist." See also Bryan A Garner, *Garner's Dictionary of Legal Usage*, 3rd ed (Oxford: Oxford University Press, 1995); *Webster's New International Dictionary*, 2nd ed, *sub verbo* "subsist."

[29] [1998] 1 SCR 27, 36 OR 3d) 418 at para 36 [*Rizzo*], citing *Abrahams v Canada (Attorney General)*, [1983] 1 SCR 2 at 10; *Hills v Canada (Attorney General)*, [1988] 1 SCR 513 at 537, 48 DLR (4th) 193. *Rizzo* was cited with approval by the Supreme Court in *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 49(e), [2000] 2 SCR 1067. More recently, the Federal Court of Appeal stated, in *Weatherford Canada Ltd v Corlac*, 2011 FCA 228 at para 135, 95 CPR (4th) 101, that *Rizzo* "and its progeny dictate that the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act and the intention of Parliament" (citations omitted). The Supreme Court has again recently looked to *Rizzo* where "existing case law does not settle the question" in *R v ADH*, 2013 SCC 28 at para 19, [2013] 2 SCR 269.

term of protection consistent with the term given for other works), the statutory provisions establishing those rights ought to be interpreted such that any doubt arising from difficulties in the language establishing those rights should be resolved in favour of the photographers.

### 3.2 The Transitional Provisions in 1997 and 2012 Do Not Have the Effect of Barring the Protection of Life Plus Fifty from Any Photographs in 2012

The 1997 transitional provision in section 54.1, rather than limiting the cases in which photographers who were natural persons were to henceforth enjoy copyright protection for the same periods as other authors enjoyed, was intended precisely to emphasize that, where natural persons were either themselves the authors or owners (section 54.1(a)) or were the majority shareholders of a corporation (section 54.1(b)) that was the author or owner, the 1997 amendments meant their photographs were to have protection for their lifetimes plus 50 years.

Support for this interpretation of Parliament's intention in passing section 54.1 lies in the fact that when the same Parliament made another radical change to the Act—namely, explicitly transitioning to a situation where unpublished works are given the same copyright treatment as published works—Parliament included explicit "phasing in" provisions for such works; although Parliament in 1997 gradually brought the terms of protection for unpublished works to be identical to that in place for published works, it did so by providing an explicit series of transition provisions (sections 7(3) and 7(4)) revising the Act itself (and not solely appearing in the amending legislation) applying to unpublished works posthumously.[30] Had that same Parliament intended the period of protection for copyright in photographs owned by natural persons (directly or indirectly through corporations) to be similarly phased in, it would have provided the same type of explicit provisions in their case, directly in the Act, that it did for unpublished works—and it did not so provide.

In the case of the changes to the *Copyright Act* as it existed prior to 1997 that involved unpublished works, there was much discussion in the meetings of the Standing Committee on Canadian Heritage (the committee to which the House of Commons had referred Bill C-32, which ultimately effected the 1997 changes) about how to phase in the proposed changes that would be made to section 7 of the Act by the Bill. Several experts took issue with the transitional provisions to be included in section 7, and lobbied for further amendments to these provisions. Archivist Jean Dryden herself[31] addressed the committee about the proposed phasing in of the amendments regarding unpublished posthumous works: "Bill C-32 provides a welcome limit to

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[30] *Copyright Act*, *supra* note 3, s 7.

[31] See Dryden, *Demystifying Copyright*, *supra* note 12, and Dryden, "Copyright in the Real World," *supra* note 15. Note that Dr. Dryden, among her various submission points, did not mention the provisions involving the proposed new period of copyright for photographs.

the perpetuity of copyright in unpublished works; however, it includes a lengthy transition period."[32] The national archivist also addressed the committee:

> Bill C-32 has, in line with many other countries and according to international convention, also introduced a limit on the term of protection on unpublished works, the life of the author plus fifty years, the same term as for published works. This change is most welcome. However, in practical terms, with the transition provisions as described in Bill C-32, many works will still be protected for a very long time.[33]

The president of the Canadian Historical Association, J.R. Miller, directly addressed the question of transitional provisions for unpublished works:

> In the case of proposed section 7, especially the transitional provisions, the proposed changes will impede and restrict photocopying for research purposes for a longer period than seems either necessary or socially useful. It seems to us that a shorter period, such as 30 years, might be a more appropriate length of copyright in posthumous unpublished works. … We urge the committee to amend proposed section 7, in particular its transitional provisions, to shorten the period of copyright in posthumous works and to reduce significantly the period of protection accorded works created by people who have died less than a century prior to the coming into force of the measure.[34]

There is no record of any submission directed to any question about "phasing in" the proposed revisions in Bill C-32 related to the period of protection for photographs, although various submissions did address those substantive changes.[35]

The fact that, although there were directed submissions seeking to have Bill C-32's transitional provisions for unpublished works changed or removed, Parliament chose to keep specific transitional provisions for unpublished works serves as evidence of Parliament's intent to phase in the changes to copyright protection of these works, but not to phase in the changes to the period of protection for photographs made at the same time.

Turning to the situation in 2012, recall that the *Copyright Modernization Act* has removed all special treatment for photographs in terms of rights holders' rights and left all photographs to henceforth be dealt with just as are other works under section 6.

Just as in 1997 there was a transitional provision in respect of photographs,[36] in 2012, section 59(1) of the *Copyright Modernization Act* provided that "[t]he repeal

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[32] House of Commons, 35th Parl, 2nd Sess, Standing Committee on Canadian Heritage, Meeting No 31 (29 October 2011) (Jean Dryden).

[33] *Ibid* (Jean-Pierre Wallot).

[34] *Ibid*, meeting No 38 (19 November 1996) (JR Miller).

[35] See e.g. the submission of Richard Bell, copyright liaison for the Professional Photographers of Canada.

[36] See *An Act to Amend the Copyright Act*, *supra* note 8, s 54.1.

of section 10 of the *Copyright Act* by section 6 does not have the effect of reviving copyright in any photograph in which, on the coming into force of that section 6, copyright had expired." The "that section 6" referred to in section 59(1) is section 6 of the *Copyright Modernization Act*, mentioned specifically earlier in section 59(1), which repeals section 10 of the *Copyright Act* (the special provisions for photographs), and not section 6 of the *Copyright Act* itself (which states that copyright shall subsist in all works). Therefore, section 59(1) simply ensures that no one interprets the change being made in 2012 as recreating copyright in photographs beyond what section 6 of the *Copyright Act* now provides—that is, section 59(1) ensures that it is understood that no copyright is created in photographs in which the author, as now defined under the current *Copyright Act*, has died more than 50 years ago. It is possible that the provision was intended, because the fixed-term copyright in photographs between the 1997 amendments and 2012 existed for large corporate authors of photographs, to ensure that no copyright was somehow interpreted to have been revived in respect of a situation of corporate ownership: section 59(2) then follows and is at pains to explain exactly how the transition from previously corporate authorship to ongoing individual authorship of photographs is to be handled. *All* individual authors of photographs previously deemed to have had corporate authors under section 10(2) will now have terms, as section 59(2) says explicitly, determined according to section 6 (the general term), section 6.1 (for anonymous or pseudonymous works), section 6.2 (for anonymous or pseudonymous works of joint authorship), section 9 (for joint authorship), section 11 (for cinematographic works), or section 12 (works prepared or published by or under the direction or control of Her Majesty or any government department). The reference in section 59(2) is only to the now repealed section 10(2) and is a reference only to the status of author being a "body corporate." The meaning of section 59(2) does not depend on a given photograph being within or beyond the period of copyright protection previously provided for corporate photograph authors under section 10(1) (now repealed), nor is section 10(1) referenced in section 59(2). The provisions of section 59(2), therefore, further support the interpretation of the term of protection in copyright in photographs post-2012 being urged here—that all photographs in Canada enjoy the same period of protection.

To accept the interpretation advanced by Dryden and others—that copyright in photographs whose authors are alive or have died within the past 50 years has not, in every case, been "recaptured" to give those authors and their heirs copyright in the photographs—is to ignore the proper interpretation of the word "subsist" in the governing *Copyright Act*, section 6.[37]

To illustrate the argument thus far, it may be useful to re-examine an example that Vaver provided in his pre-2012 books while discussing the 1997 amendments. Vaver analyzed the photographic portrait of Winston Churchill taken by Yousuf Karsh in 1941 as illustrating his argument that some photographs in 1997, because

[37] And in sections 6.1, 6.2, 9, and 11.

of section 54.1 of the *Act to Amend the Copyright Act*, did not enjoy the period of protection enjoyed by other photographs authored by natural persons and those corporations centred on natural persons after the 1997 amendments to section 10 of the *Copyright Act* had come into force.[38] All would agree with Vaver that, according to section 10 of the *Copyright Act* as it was before the 1997 amendments, copyright protection in Karsh's photograph of Churchill would have expired at the end of 1991, 50 years after the year in which it was taken. We disagree, however, with Vaver's subsequent analysis both concerning the existence of copyright in Karsh's 1941 photo-portrait of Churchill post-1997 and, by extension, post-2012. A proper reading of the word "subsists" in section 6 of the *Copyright Act* means that, when the 1997 amendments came into force on January 1, 1998 and Karsh was still alive, Karsh, as a natural person, actually owned copyright in *all* his œuvre, including the Churchill photograph, through the *Copyright Act*, section 6:

> The term for which copyright shall subsist shall, *except as otherwise expressly provided in this Act*, be the life of the author, the remainder of the calendar year in which the author dies, and a period of fifty years following the end of that calendar year.[39]

There has not been in the *Copyright Act*, either post-1997 when Vaver was writing (when the Act was amended by the *Act to Amend the Copyright Act*) or post-2012 (with the Act amended by the *Copyright Modernization Act*), any provision expressly providing for any term of copyright in photographs owned by the individual photographer other than the life of the person who is the photographer plus 50 years.[40] Karsh died on July 13, 2002, so his work, including the photograph of Churchill, must be in copyright until the end of December 31, 2052.[41] Post-2012, this calculation would yield the same result for any photograph (whereas between 1997 and 2012 the calculation would have been correct in Karsh's case and in cases where photographs were owned by small corporations dominated by the individual photographer, but not for photographs whose authors were then deemed by the statute to be large corporations).

### 3.3 There Is No Evidence in the Historical Record That Parliament Intended Various Photographs to Have Different Periods of Protection After the 2012 Provisions Were Enacted

The intent of Parliament, vis-à-vis photographers, in enacting the *Copyright Modernization Act* was clearly outlined in the official summary affixed to the Act,

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[38] Vaver, *Intellectual Property Law*, *supra* note 5 at 146; Vaver, *Copyright Law*, *supra* note 9 at 104-5.

[39] *Copyright Act*, *supra* note 3 (emphasis added).

[40] The sections being argued by Vaver and others were in the amending statutes, in 1997 the *Act to Amend the Copyright Act* (s 54.1), and in 2012, the *Copyright Modernization Act* (s 59(1)), and do not appear in the *Copyright Act* itself, as previously pointed out.

[41] Copyright protection continues for the remainder of the year in which the author died plus 50 years, such that copyright expires on December 31 in the year of expiration regardless of the actual date of the author's death.

which recites the fact that "this enactment amends the *Copyright Act* to … (f) give photographers the same rights as other creators."[42] Any perceived conflict between this goal Parliament had for the *Copyright Modernization Act* and a literal interpretation of wording in the *Copyright Modernization Act* should be resolved in favour of the interpretation that accords most closely with the Act's legislative purpose.[43]

The *Interpretation Act* states that "the preamble of an enactment shall be read as a part of the enactment intended to assist in explaining its purport and object."[44] Reference to this provision of the *Interpretation Act* would assist if there were an ambiguity to be resolved either in terms of the meaning of the *Copyright Act* provision for the protection of photographs or about the effect of either the 1997 *Act to Amend the Copyright Act* or the 2012 *Copyright Modernization Act* provisions relating to the term of protection in photographs. The preceding discussion demonstrates that there is no ambiguity on the face of section 6 of the current *Copyright Act* regarding the term of protection that all photographs in Canada currently receive—the life of the photographer plus 50 years. Nor, as has been explained, is there any doubt that either section 54.1 of the 1997 *Act to Amend the Copyright Act* or section 59(1) of the *Copyright Modernization Act*, read properly, introduces any ambiguity about the period of protection for photographs as it existed between 1997 and 2012 (under section 6 for all photographs except those where large corporations were the legislated authors) or as it currently exists (all photographs governed under section 6). However, even if there were such an ambiguity and the courts need to have recourse to the *Interpretation Act*, the preamble to the *Copyright Modernization Act* states that "copyright protection is enhanced when countries adopt coordinated approaches, based on internationally recognized norms."

One internationally recognized norm of copyright is the *WIPO Copyright Treaty*,[45] which Canada has signed and ratified.[46] Article 9 of that treaty states that there is no shortened term for copyright in photographs, which means that article 7(1) of the *Berne Convention for the Protection of Literary and Artistic Works*—life of the author plus 50 years—is to govern photographs.[47] The preamble indicates that, in enacting the *Copyright Modernization Act*, Parliament recognized that Canada was adopting approaches to copyright therein that were coordinated with other countries

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[42] *Copyright Act*, *supra* note 3.

[43] On this principle derived from *Rizzo*, see further Randal N Graham, *Statutory Interpretation: Theory and Practice* (Toronto: Emond Montgomery, 2001) at 25-31.

[44] RSC 1985, c I-21, s 13.

[45] *WIPO Copyright Treaty*, 20 December 1996, 36 ILM 65 (entered into force 6 March 2002).

[46] Signed by Canada December 22, 1997, ratified May 13, 2014, with effect August 13, 2014: see World Intellectual Property Organization <http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=16>.

[47] *Berne Convention*, *supra* note 21. As Patricia Akester lays it out, in describing the *WIPO Copyright Treaty, 1996*, in *A Practical Guide to Digital Copyright Law* (London: Sweet & Maxwell, 2008) at 16: "The term of protection for photographic works is no longer subject to special rules."

and based on internationally recognized norms. This would, in turn, in the case of any perceived ambiguity, lead a court to find that copyright protection in all photographs in Canada must be based on a consistent period of the life of the individual photographer plus 50 years.

Further evidence of the international norms of copyright supports the interpretation of section 6 of the *Copyright Act* focused on the concept of subsistence and reading section 6 of Canada's *Copyright Act* as being properly interpreted to focus on and reinforce the concept of subsistence as outlined above. The notion of subsistence in relation to copyright is part of the bedrock understanding of copyright in international copyright law, in both public international law and international trade law. In the European Court of Justice, in 1999,[48] consideration was given to the question of revival of rights created by the European *Term Directive*[49] designed to bring the disparate copyright term provisions of the European member states into a common minimum-term framework.[50] The court noted that introducing longer terms of protection for all European countries (generally, life plus 70 years) had the effect of bringing some works back into copyright and, although states could individually enact precisely how and to what extent the acquired rights of third parties might be protected, "it was not permissible to allow such rules to have the overall effect of preventing the application of the new term of protection on the date laid down by the Directive."[51]

In terms of accepting the notion of subsistence as an international norm of copyright (when considering the preamble to the *Copyright Modernization Act*), as discussed above, or in the case of a Canadian court looking for assistance in interpreting the meaning of "subsist" when considering section 6 of the *Copyright Act* in the international trade context, it may be relevant to observe that the 1995 *Agreement on Trade Related Aspects of Intellectual Property Rights* specifically uses the word "subsist" in relation to the protection of compilations of data or other materials[52] and adopts the language of the *Berne Convention*, including "subsist," as the foundation of all its required copyright protection.[53]

Finally, the Supreme Court in *Rizzo*, looking specifically to the Legislature of Ontario Debates (including the statement of the minister responsible for introducing the Bill), made it clear that "the use of legislative history as a tool for determining

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[48] *Butterfly Music Srl v Carosello Edizioni Musicali E Discografiche Srl*, [1999] ECR I-3939.

[49] [1993] OJ L209/0.

[50] See Guy Tritton & Richard Davis, *Intellectual Property Law in Europe*, 2nd ed (London: Sweet & Maxwell, 2002) at 4-086.

[51] *Term Directive*, *supra* note 49 at 4-097.

[52] *Agreement on Trade Related Aspects of Intellectual Property Rights*, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299, art 10 [TRIPS].

[53] *Ibid*, art 9: "Members shall comply with Articles 1 through 21 of the *Berne Convention* (1971)."

the intention of the legislature is an entirely appropriate exercise."[54] Therefore, the evidence from the parliamentary debates leading to the changes to the term of copyright in photographs may become relevant when considering how courts will interpret the statutory changes enacted.

The Honourable James Moore (then minister of Canadian Heritage and Official Languages) said in 2011, at the introduction of Bill C-11, "Canadian photographers will benefit from the same authorship rights as creators. Currently, photographers are not considered authors of commissioned works. This legislation changes that."[55]

All of the subsequent references in the House of Commons during the passage of the *Copyright Modernization Act* support the proposition that all photographers were to benefit from the term of protection of "life plus fifty years." In discussing Bill C-11 in the House in February 2012, Gordon Brown (Leeds-Grenville, PC) stated that

> the bill would make photographers the first owners of copyright of their photographs. The copyright would be protected for 50 years after the life of the photographer, harmonizing the treatment of photographers under Canada's copyright law with that of other creators. It would also harmonize it with the laws of many other countries.[56]

Corneliu Chisu (Pickering-Scarborough E, PC) said that "[p]hotographers will also be given the same rights as other creators. They will be first owner of copyright in their photographs and they will receive the same benefits as other creators."[57]

When the Bill reached the report stage on May 15, 2012, Brian Storseth (Westlock-St Paul, PC) stated that "[t]he bill ensures that photographers are the first owners of copyright on [*sic*] their photographs, and that copyright will be protected for 50 years after the photographer's death."[58] John Weston (W Vancouver-Sunshine Coast-Sea to Sky Country, PC) said that "[t]his copyright would be protected for the life of the photographer plus 50 years."[59]

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[54] *Rizzo*, *supra* note 29 at para 31, Iacobucci J (for the court). Iacobucci J continues that it is "one which has often been employed by this Court (see e.g. *R v Vasil*, [1981] 1 S.C.R. 469, at p. 487; *Paul v The Queen*, [1982] 1 S.C.R. 621, at pp. 635, 653 and 660)."

[55] *House of Commons Debates*, 41st Parl, 1st Sess, Vol 146, No 31 (18 October 2011) at 2110 (Hon James Moore).

[56] *Ibid*, No 75 (8 February 2012) at 5020 (Gordon Brown).

[57] *Ibid*, No 78 (10 February 2012) at 5148 (Corneliu Chisu).

[58] *Ibid*, No 124 (15 May 2012) at 8089 (Brian Storseth).

[59] *Ibid*, No 124 (15 May 2012) at 8092 (John Weston).

When the Bill reached the Senate, the change that Bill C-11 would bring to copyright protection for photographers was also specifically discussed: Honourable Stephen Greene, in moving the second reading of Bill C-11, pointed out that "notably, this bill will finally give photographers the authorship rights that are already enjoyed by other creators."[60]

## 4.0 CONCLUSION

The present period of protection for photographs is no more complex than it is for any other work in Canada. All photographs are in copyright in Canada if the photographers are alive. All photographs are in copyright in Canada if the photographers have died within the past 50 years. No photographs are in copyright if the photographer died more than 50 years before December 31 of this year (2015).

[60] *Debates of the Senate*, 41st Parl, 1st Sess, Vol 146, No 124 (20 June 2012) at 2217 (Stephen Greene).

# Note

# NAVIGATING DISCOVERY/DISCLOSURE IN PATENT LITIGATION IN CANADA, THE UNITED STATES, AND THE UNITED KINGDOM*

*Greg Beach, Marissa Parker, and Catherine Drew***

**CONTENTS**



## 1.0 INTRODUCTION

To the uninitiated, the discovery/disclosure process in patent litigation may appear arduous, expensive, and unmanageable. Litigants in Canada, the United States, and the United Kingdom face similar challenges with regard to the scope and expense of the discovery/disclosure process. Legislators and courts in these jurisdictions have expressed their desire to contain, limit, and sequence discoveries, and in the United States and the United Kingdom have established rules specifically tailored to address the unique considerations of patent litigation. In Canada, the Federal Court has recently established guidelines aimed at streamlining discoveries. The following discussion considers applicable rules, case law, and legislation that inform the substance and sequence of discovery/disclosure in an effort to navigate this stage in patent litigation.

## 2.0 CANADA

The right to examination for discovery generally arises after the close of pleadings and the production of documents. The party being examined must answer questions

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relevant to any unadmitted allegation of fact in a pleading.[1] Discoveries in patent cases are typically conducted by way of oral examination, but may also be conducted in writing. Only one representative of each party need be put forth to be examined for discovery, unless the court orders, on motion, to examine a substitute representative.[2] In contrast to the United States, there are typically (absent a third-party discovery order) no depositions.

In *Reading & Bates*,[3] the court set out six principles concerning the scope of discovery:

1. Relevance is a question of law, not a matter for the exercise of discretion.
2. Questions that are too general or call for opinion need not be answered.
3. Questions on discovery must be relevant to the facts pleaded.
4. The court should not compel answers to questions that are relevant but not likely to advance the party's legal position.
5. Before compelling an answer, the court should weigh the usefulness of the response with the inconvenience and expense of obtaining it.
6. The court will restrict vague, far-reaching, or irrelevant lines of questioning.

The primary consideration in discovery is relevance, but it is not sufficient that a document merely relate to the facts at issue in the case. The Federal Court of Appeal has set out the "train of inquiry" test, which informs the assessment of relevance. The test is whether it is reasonable to conclude that the answer to a question might lead the examining party to a train of inquiry that may either advance its case or damage the case of the opposing party.[4] It is not enough to say that a document might conceivably lead to other documents that, although not in themselves relevant, might lead to usable information. A party seeking production must establish a reasonable likelihood that the document sought will lead to usable information; an outside chance is not sufficient.[5]

The goal of discovery is not to elicit the opposing party's evidence, but rather to elicit relevant facts and documents. A party is not required to disclose all evidence it will rely on at trial, but rather, only information within its knowledge or means of knowledge.[6] Thus it is not proper for one party to ask another party what evidence is being relied on by the other party in support of an allegation.

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[1] *Federal Court Rules*, 1998, SOR/98-106, r 240.

[2] *Federal Courts Rules*, *ibid*, r 237(3).

[3] *Reading & Bates Construction Co v Baker Energy Resources Co* (1988), 24 CPR (3d) 66 (FCTD).

[4] *Eli Lilly Canada Inc v Novopharm Ltd*, 2008 FCA 287 at para 56; *Bristol-Myers Squibb Co v Apotex Inc*, 2007 FCA 379 at paras 30-31.

[5] *Eli Lilly Canada Inc v Novopharm Ltd*, *supra* note 4 at paras 61-63.

[6] *Beloit Canada Ltée/Ltd v Valmet Oy* (1981), 60 CPR (2d) 145 at para 7 (FCTD).

Judges and prothonotaries may properly exercise their discretion not to compel production of documents that, although technically relevant, would have no benefit to the party seeking production.[7] The court will not allow discovery to be used as a fishing expedition, nor will it require a party to answer a question outside of its means of knowledge.[8] Furthermore, speculative questions asking "what would have been done if [x] had/had not happened" require conjecture and speculation and, as such, are not questions as to the deponent's knowledge, information, and belief. Such questions are not proper.[9]

Discovery is meant to be an intermediate process between pleading and trial and not an end in itself. The purpose of discovery is production of information and documents that a party truly requires for trial. In *Astrazeneca Canada Inc v Apotex Inc*, Justice Hughes of the Federal Court said:

> Prothonotaries of this Court are burdened, to a large extent, with motions seeking to compel answers to questions put on discovery. Often hundreds of questions must be considered. Hours and often days are spent on such motions. It appears that in many cases the parties and counsel have lost sight of the real purpose of discovery, which is directed to what a party truly requires for trial. They should not slip into the "autopsy" form of discovery nor consider discovery to be an end in itself.[10]

The standard to be applied on discovery concerns the relevance of information sought as related to the pleadings; any doubt as to relevance should be resolved in favour of disclosure.[11] However, as stated above, the Federal Court has cautioned against "autopsy" discovery, whereby one party seeks to uncover as much as possible from the opposing party, even if the information is only marginally relevant. The court should protect against abuses by considering factors such as the degree of relevance, how onerous it is to provide an answer, whether the answer requires an opinion, and whether the question is unreasonable or unnecessary.[12]

Despite the Federal Court's frequent criticism of exhaustive discoveries and motions to compel answers, the court has tended to tacitly allow such abuses. There is no legislation limiting the length of oral discovery, the number of rounds of oral discovery, or the scope or conduct of refusals motions. However, in light of a notice to the profession issued in June 2015 by Justice Crampton, chief justice of the Federal Court, it appears that is likely to change.[13] The notice to the profession was prepared

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7 *Eli Lilly Canada Inc v Novopharm Ltd*, *supra* note 4 at paras 68-70.

8 *Crestbrook Forest Industries Ltd v Canada (MNR)*, [1993] 3 FC 251 (CA).

9 *James River Corp of Virginia v Hallmark Cards Inc* (1997), 72 CPR (3d) 157 at paras 22-24 (FCTD).

10 *Astrazeneca Canada Inc v Apotex Inc*, 2008 FC 1301 at paras 6 and 19.

11 *Chingee v Chingee* (1998), 149 FTR 113 (Proth).

12 *Federal Courts Rules*, *supra* note 1, r 242(1); *Astrazeneca Canada Inc v Apotex Inc*, *supra* note 10 at para 18.

13 Federal Court of Canada, Notices to Parties and the Legal Profession-Miscellaneous Notice, "Case Management: Increased Proportionality in Complex Litigation before the Federal Court" (24 June

by the Federal Court Case Management Working Group, composed of judges and prothonotaries, who were tasked with improving the case management of actions. Under the notice to the profession, absent special circumstances or the parties' consent, the length of oral discoveries is limited according to the length of trial, as follows:

| *Length of trial* | *Length of oral discovery* (per party) |
|---|---|
| 1 week or less | 1 day |
| 1-2 weeks | 2 days |
| 3-4 weeks | 3 days |
| 5+ weeks | 4 days |

Irrespective of the length of trial, second-round discoveries are limited to one day per party.

Furthermore, the notice to the profession states that no questions are to be taken under advisement. All questions should be answered unless clearly improper or prejudicial, or would result in disclosure of privileged communication.

The guidelines also take aim at motions to compel, which are limited to one hour per day of discovery, with heightened cost consequences against losing parties. At the date of this writing, the effect of these guidelines on oral discoveries in patent cases, which have typically far exceeded the new guidelines in terms of the length of first- and second-round discoveries and motions to compel, remains to be seen.

### 2.1 Patent-Specific Issues

Under the *Patent Act*, the patentee must be a party to an infringement action,[14] and the *Federal Courts Rules* allow for examination of the inventor (they state that where an assignee is a party to an action, the assignor may also be examined for discovery).[15] Defendants typically choose to examine the inventor.

Interpretation of documents and speculation as to the meaning of documents are not the proper subject of discovery.[16] Although questions that require the witness to draw on his or her expertise to opine on technical issues are proper, those that require an opinion regarding the patent at issue, or construction of the patent at issue, are improper. This is so even when the patentee him or herself is being examined.[17]

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2015) online: Federal Court <http://cas-ncr-nter03.cas-satj.gc.ca/fct-cf/pdf/NOTICE TO THE PROFESSION - case management FINAL (ENG).pdf>.

[14] *Patent Act*, RSC 1985, c P-4, s 55(3).

[15] *Federal Courts Rules*, *supra* note 1, r 237(4).

[16] *Kun Shoulder Rest Inc v Joseph Kun Violin & Bow Maker Inc* (1997), 76 CPR (3d) 488 at para 12 (FCTD) (Proth).

[17] *Nekoosa Packaging Corp v AMCA International Ltd* (1994), 56 CPR (3d) 470 at paras 12, 13, 23 (FCA).

Note, however, that questions that use the terms employed in the patent, when asked of an alleged infringer, have been found to be proper and to not offend the principle that questions regarding the interpretation of the patent are improper. It is proper to ask an inventor what he or she considers to be the substance of the invention, for that is considered to be a question of fact.[18]

Similarly, questions as to the state of the prior art or common general knowledge are matters for expert evidence and need not be answered.[19] Discovery questions related to prosecution history or file wrapper of the patent are not relevant to construction of the patent.

Furthermore, questions as to the factual basis underlying the patentee's sound prediction argument, while purportedly framed as factual questions, have been found to be essentially legal questions and as such improper.[20] More broadly, questions as to utility and novelty of the patentee's invention are matters for the court and are not proper subject matter for discovery. Questions as to the utility of the invention over the prior art are not relevant. However, any written communication or advertisement to that effect must be produced.[21]

## 3.0 UNITED STATES

As with all federal litigation in the United States, discovery in patent litigation is governed by the *Federal Rules of Civil Procedure* ("Fed R Civ P"), including its core principle of permitting "discovery of any matter relevant to the subject matter involved in the action."[22] This standard broadly encompasses information that "appears reasonably calculated to lead to the discovery of admissible evidence," subject to the timing, frequency, and mechanisms as set forth in the Rules. But the idiosyncrasies of patent litigation have motivated a number of district courts to adopt local patent rules and default orders to better control the pace and scope of discovery and claim construction.[23] Proponents of these patent-specific rules have

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[18] *Letourneau v Clearbrook Iron Works Ltd*, 2004 FC 1422 at para 28 (Proth), rev'd on other grounds 2005 FC 475.

[19] *Ibid* at para 26; *James River Corp of Virginia v Hallmark Cards Inc* (1997), 72 CPR (3d) 157 at para 37 (FCTD).

[20] *Apotex Inc v Sanofi-Aventis Canada Inc*, 2011 FC 52 at paras 58 and 62.

[21] *Letourneau v Clearbrook Iron Works Ltd*, *supra* note 18 at para 27.

[22] Fed R Civ P 26(b)(1). Rules 26-37 of the *Federal Rules of Civil Procedure* govern discovery.

[23] These jurisdictions include the US District Courts for the Northern and Southern Districts of California; the Northern District of Georgia; the Northern District of Illinois; the District of Massachusetts; the District of Minnesota; the District of New Jersey; the Southern and Eastern Districts of New York; the Eastern District of North Carolina; the Western District of Pennsylvania; the Southern District of Ohio; the Eastern, Northern, and Southern Districts of Texas; and the Western District of Washington. The Northern District of California was the first to formulate and adopt local patent rules in 2000, and its rules and case law are often looked to for guidance by other jurisdictions formulating and interpreting local patent rules.

cited a desire to streamline and narrow the key issues at bar, avoid spiralling costs of e-discovery and attendant discovery battles, and enter standardized pre-trial orders. The Federal Circuit Advisory Council issued model orders in 2011 and 2013 reflecting similar goals, leading to adoption of the model orders' principles by federal district courts.[24] Trial attorneys should consider patent-specific local rules and model orders as strategic tools in both controlling and neighbouring jurisdictions when navigating pre-trial discovery in patent litigation.

### 3.1 Local Patent Rules

The creation and adoption of local patent rules originated at the district court level, where judges and local bar members demonstrated a common desire to streamline patent litigation in their respective districts.[25] As one court commented, "the resolutions suggested by the various local patent rules embody the collective wisdom and experience of groups of judges and practicing patent lawyers who, on repeated occasions, have addressed the very discovery issues covered by the local patent rules."[26]

Local patent rules in most jurisdictions impose far more structure than the Federal Rules, both in terms of timing and substance, particularly with respect to initial disclosures. Under Fed R Civ P 26(a), which establishes standard initial disclosures for federal litigation, each party need only identify known witnesses and categories of documents and things that a party may rely on, along with an initial computation of damages and identification of available insurance, within 14 days after the parties' initial discovery conference.[27] Local patent rules, on the other hand, generally command the prompt disclosure of far more information by both parties. A patent holder asserting patent infringement typically has less than 30 days after the court's initial scheduling conference to submit its preliminary infringement contentions.[28] Specific document production requirements accompany the preliminary infringement contentions, including a copy of the patent's file history, evidence of ownership

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[24] The US Court of Appeals for the Federal Circuit is the US appellate (intermediate) court with jurisdiction over all appeals from patent cases, including cases determined by US federal district courts (trial level). The Federal Circuit's Advisory Council reviews, studies, and makes recommendations regarding the rules of practice and internal operating procedures of the court.

[25] Xuan-Thao Nguyen, "Dynamic Federalism and Patent Law Reform" (2010) 85 Ind LJ 449 at 474-75.

[26] *Suncast Techs v Patrician Prods*, No 07-80414-CIV, 2008 WL 179648 at *9 (SD Fla 17 January 2008) (reviewing local patent rules from a number of districts and commenting that certain rules "provide instructive insight into identifying proper topics of discovery unique to a patent suit," which assisted the court in adopting "the correct sequencing" of patent discovery).

[27] Fed R Civ P 26(a)(1) and 26(f).

[28] Fed R Civ P 16 (establishing framework for initial scheduling conference); see e.g. ND Cal Patent LR 3-1 (requiring service of "Disclosure of Asserted Claims and Infringement Contentions" within ten days after the initial case management conference); ED Tex PR 3-1 (same); ND Ga Patent LR 4.4 (requiring plaintiff to serve "Disclosure of Infringement Contentions" within 30 days after filing joint preliminary report and discovery plan).

rights, and documentation evidencing known sales or offers of sales.[29] With equal speed, defendants are expected to serve preliminary invalidity contentions and an accompanying production of documents sufficient to show the operation or structure of any accused elements identified in plaintiff's infringement contentions, along with prior art outside of the patent file.[30]

Initial infringement and invalidity contentions not only establish the parties' theories of infringement and invalidity, but also lay markers for staging discovery and encouraging appropriate disclosure by the parties. Local patent rules require "both the plaintiff and the defendant in patent cases to provide early notice of their infringement and invalidity contentions, and to proceed with diligence in amending those contentions when new information comes to light in the course of discovery. The rules thus seek to balance the right to develop new information in discovery with the need for certainty as to the legal theories."[31]

Infringement contentions, typically accomplished through the charting of asserted claims against the specific accused products or processes, replace the series of interrogatories that an opposing party would serve under Fed R Civ P 33. They were conceived to "provide structure to the entire discovery process" and require the patentee "to crystalize its infringement theory early in the case and adhere to it once disclosed."[32] Certain jurisdictions treat the preliminary infringement contentions as final after a short period of time and allow patentees to amend their contentions only with leave of court and good cause shown,[33] while others explicitly provide for the later filing of final infringement contentions and disfavour amendment thereafter.[34] A party may be denied discovery regarding accused products/processes if that party has not timely filed adequate infringement contentions for each allegedly infringing product/process.[35] A plaintiff's inadequate infringement contentions may

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[29] See e.g. DNJ L Pat R 3.2 (identifying documents for production accompanying infringement contentions).

[30] See e.g. DNJ L Pat R 3.3 (requiring service of invalidity contentions within 45 days of receipt of infringement contentions) and 3.4 (identifying documents for accompanying production).

[31] *Symantec Corp v Veeam Corp*, No 12-05443, 2013 WL 3490392 at *2 (ND Cal 11 July 2013) (quoting *O2 Micro Int'l Ltd v Monolithic Power Sys, Inc*, 467 F 3d 1355, 1365-66 (Fed Cir 2006)).

[32] Order, *Oplus Techs, Ltd v Sears Holding Corp*, No 2:12-cv-05707-MRP-E (CD Cal 3 April 2013); *Nova Measuring Instruments Ltd v Nanometrics, Inc*, 417 F Supp 2d 1121 at 1123 (ND Cal 2006).

[33] ED Tex PR 3-6.

[34] See e.g. D Md L R 805.1.e ("Amendment of a Claims Chart or a Responsive Claims Chart may be made only on stipulation of all parties or by Order of the Court, which shall be entered only upon a showing of excusable subsequent discovery of new information or extraordinary good cause").

[35] Order, *California Institute of Tech v STMicroelectronics NV*, No 2:10-cv-09099-MRP-VBK (CD Cal 13 April 2012) (rejecting plaintiff's argument that their infringement contentions for six sensors were sufficient on their own to show infringement of 30 additional sensors, finding plaintiff's six infringement contentions "woefully inadequate" and granting motion for protective order on discovery regarding 30 additional sensors).

also foreclose any further discovery until the contentions are supplemented, and may foreclose the presentation of infringement theories at trial.[36]

Invalidity contentions, also typically accomplished through charts matching claim language to prior art references, have equal significance and effect on discovery. Amendments to invalidity contentions are limited in the same manner as infringement contentions.[37] Failure to timely or fully disclose theories of invalidity and prior art references can result in the striking of invalidity contentions or the exclusion of such theories at trial, mainly because such concealment prohibits full and fair discovery by the party's opponent.[38]

While many district courts' local rules have similar features, local rules differ from forum to forum, and can have a meaningful effect on discovery and general case management. For example, in the Eastern District of Texas and the District of Delaware, patent plaintiffs will find that local rules and procedural orders tilt in their favour with respect to the pace of litigation, the scope and order of discovery, the availability of summary judgment, the availability of stays pending re-examination or other related proceedings before the US Patent and Trademark Office, and the joinder and/or consolidation of tenuously related defendants.[39]

### 3.2 Federal Circuit Advisory Council Model Orders

E-discovery persists as a top driver of litigation cost, which prompted the Federal Rules Advisory Council to amend Fed R Civ P 26 to specifically address proportionality in e-discovery.[40] Furthermore … , the Federal Circuit Advisory Council issued a 2011 Model Order Regarding E-Discovery in Patent Cases to appropriately tailor e-discovery for patent cases.[41] The Advisory Council was motivated by the

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[36] *Bender v Maxim Integrated Prods, Inc*, No C09-01152 SI, 2010 WL 1135762 at *2 (ND Cal 22 March 2010) ("Until plaintiff meets the burden of providing infringement contentions compliant with Patent LR 3-1, the Court will not order defendant to proceed with discovery"); see also *Verinata Health, Inc v Sequenom, Inc*, No C 12-00865 SI, 2014 WL 4100638 at *3 (ND Cal 20 August 2014) ("a party may not use an expert report to introduce new infringement theories, new infringing instrumentalities, new invalidity theories, or new prior art references not disclosed in the parties' infringement contentions or invalidity contentions").

[37] See e.g. D Md L R 805.2.d.

[38] *Carrier Corp v Goodman Global, Inc*, No CV 12-930-SLR, 2014 WL 3976575 at *11 (D Del 14 August 2014); *ASUS Computer Int'l v Round Rock Research, LLC*, No 12-CV-02099 JST (NC), 2014 WL 1463609 at *8 (ND Cal 11 April 2014).

[39] For detailed statistics and trends on filings in certain forums, including Texas and Delaware, see Daniel Klerman & Greg Reilly, "Forum Selling," Center for Law and Social Science Research Papers Series No CLASS14-35, Legal Studies Research Papers Series No 14-44 (Feb. 19, 2015), online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2538857>.

[40] The new version of rule 26 is slated to become effective 1 December 2015.

[41] An E-Discovery Model Order (2011), online: <http://www.cafc.uscourts.gov/sites/default/files/announcements/Ediscovery_Model_Order.pdf>. The Advisory Council's model orders are not endorsed by the Federal Circuit, but are nevertheless utilized by district courts and litigants.

"staggering time and production costs" associated with disproportionate, overbroad email and e-document collection and production, and the reality that parties' routine document requests seeking all categories of electronically stored information often resulted in mass productions of marginally relevant and cumulative documents. Moreover, the Advisory Council noted that the most consequential information in patent litigation "centers on what the patent states, how the accused products work, what the prior art discloses, and the proper calculation of damages," which are not topics likely to be advanced by far-reaching e-discovery, such as mass email searches. Thus, the model order sets up a discovery process through which the parties exchange core documentation concerning the patent, the accused product or process, the prior art, and the finances before making email production requests. It also presumptively limits the number of custodians and search terms for all email production requests, which are encouraged to be focused on a particular issue warranting discovery. The model order for e-discovery has prompted other jurisdictions such as Texas, Delaware, and Oregon to adopt similar model orders.

In 2013, recognizing that the sheer numbers of asserted claims, claim terms, allegedly infringing products, and prior art references in patent cases had become "problematically excessive," the Advisory Council issued a model order to stave off the rising costs on courts and litigants associated with such sprawling discovery.[42] The Advisory Council noted that the inclusion of superfluous claims and prior art can function to "hide the ball," placing an asymmetrical burden on the responding party (and the trial court) because no mechanism existed to enforce limits on the asserting party, who often has a better sense of which issues it will ultimately pursue at trial. Intending to impose such limits, the model order sets the maximum number of claims and prior art references that may be asserted before claim construction to 10 claims per patent/32 claims total and 12 prior art references per patent/40 references total. Then, within 28 days after the court issues a claim construction ruling interpreting the asserted claims for each patent, the parties must serve a final election of asserted claims and prior art, limited to 5 claims per patent/16 claims total and 6 prior art references/20 references total, respectively. The model order contemplates that only on a showing of diligence, specific explanation of necessity, and with due consideration for prejudice, may a party move to include additional asserted claims or prior art references.[43]

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[42] A Model Order Limiting Excess Patent Claims and Prior Art (2013), online: <http://patentlyo.com/media/docs/2013/07/model-order-excess-claims.pdf>. The US District Court for the Eastern District of Texas issued General Order 13-20 adopting many provisions of the 2013 model order. See also *Keranos, LLC v Silicon Storage Tech*, No 2:13-CV-17, 2013 WL 5763738 at *4 (ED Tex 5 August 2013), relying on the Federal Circuit model order in limiting the accused infringer to two or three prior art references per claim.

[43] See *In re Katz Interactive Call Processing Patent Litig*, 639 F 3d 1202 at 1312-13 (Fed Cir 2011).

## 4.0 UNITED KINGDOM

Historically, disclosure in English patent proceedings concerned a similar range and number of documents as would be considered in proceedings in the United States. Under the current regime, disclosure in England and Wales should be rather more limited; however, even with the current provisions for much more limited disclosure, it may still become a very time-consuming and potentially expensive exercise for litigants.

For many years, the scope of disclosure was determined by reference to the *Peruvian Guano* test.[44] The *Rules of the Supreme Court* required that the parties give discovery of "the documents which are or have been in their possession, custody or power relating to the matters in question in the action."[45] In the *Peruvian Guano* case, Brett LJ set out what this in fact meant for litigants. In his view, documents within the scope of this obligation would be all those that contained information that may either directly or indirectly enable the party either to advance his own case or damage the case of an opponent. Importantly, he also indicated that any other documents that may fairly lead a party to a train of inquiry which may have either of those two consequences would fall within the scope. Consequently, in many cases there was a virtually unlimited range of potentially relevant documents that parties were obliged to review, list, and disclose.

The law regarding disclosure has since been codified and reformed by the *Civil Procedure Rules* (CPR). Part 31 of the CPR, which came into force in April 1999, removes this arduous obligation. In accordance with these Rules, in cases brought before the High Court of England and Wales, shortly after the close of pleadings, directions will be determined, either by agreement between the parties or by order of the court at a case management hearing. One direction will pertain to the timing and scope of disclosure.

Pursuant to the CPR, standard disclosure requires all parties to disclose all documents on which they rely, together with documents that are adverse to their case or the case of another party, and all documents that support the case of another party.[46] When the Rules were initially implemented,[47] there was a presumption that standard disclosure would be ordered. The Rules were subsequently amended such that the court may now make any order for disclosure that it sees fit, including an order for disclosure on an issue-by-issue basis or indeed an order dispensing with disclosure in its entirety.[48] The order will be one that the court sees as proportionate having

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[44] As described by Brett LJ in *Compagnie Financiere du Pacifique v Peruvian Guano Company* (1882), 11 QBD 55.

[45] RSC Order 24 Rule 1(1).

[46] CPR 31.6.

[47] Prior to amendment to CPR 31.5 in April 2013.

[48] CPR 31.5(7).

regard to the size, complexity, and nature of the case, with a view to limiting disclosure to those documents necessary to deal with the case justly.

Whatever the order made by the court, a party is obliged to make a reasonable search for documents. In determining the reasonableness of the search, regard should be had to the number of documents involved, the nature and complexity of the proceedings, the ease and expense of retrieval, and the significance of any document likely to be obtained via such search.[49] In the electronic age, searches can become long, involved, and expensive, and often identify a huge volume of documents outside the scope of the ordered disclosure. An attempt to address this is contained in CPR Practice Direction (PD) 31B, which sets out principles for identifying and disclosing electronic documents. Essentially, the parties are obliged to meet to discuss how they will conduct the search, including a consideration of "key word" searches to ensure that a reasonable search is undertaken to identify relevant documents within the scope of the disclosure ordered.

In patent cases the scope of standard disclosure is more limited.[50] Where infringement is in issue, documents pertaining to the infringement need not be disclosed, provided that full particulars of the product or process alleged to infringe are provided. This is usually done by way of a product or process description. In relation to validity, disclosure is limited to documents created within a period of two years prior to and two years post the earliest claimed priority date of the patent.

Discussed above is disclosure in cases before the High Court of England and Wales, generally claims where significant sums are in dispute. For lower value claims (those where damages will likely not exceed £500,000), the Intellectual Property Enterprise Court may be a more attractive forum, offering a more streamlined procedure. In keeping with this approach, disclosure is available in proceedings only if ordered by the court.[51] Such an order will concern only specific and identified issues and only if the court is satisfied that the value in those documents in helping resolve the identified issues justifies the additional cost in producing the disclosure.[52] This is the same approach that will be taken in the Unified Patent Court, the pan-European forum for patent litigation, which is currently under development.[53]

Whatever the scope of the disclosure ordered in the Intellectual Property Enterprise Court, the parties must produce a list of documents to be disclosed. Any documents that are privileged must be listed in a party's disclosure statement but may not be inspected by any other party. For example, legal advice produced by either

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[49] CPR 31.7.

[50] CPR PD63, para 6.1.

[51] CPR PD63, para 29.1.

[52] CPR PD63, para 29.2.

[53] The date for this court to be operational is currently unknown, but estimated to be during the course of 2016. Once implemented, European patents will be litigated in the Unified Patent Court, rather than being litigated in each national jurisdiction in which the European patent is in force.

internal or external counsel would not be provided to an opposing party, unless privilege is waived. As for the documents disclosed, they may be used only for the proceedings in which they are disclosed—that is, the proceedings before the English court. They may not be used in, for example, parallel proceedings in other European jurisdictions.

It is also worth noting that in the United Kingdom a party may obtain disclosure of specific documents or classes of documents held by a potential defendant. The court has the discretion to make an order for pre-action disclosure if the documents are in the control of a person likely to become a party to proceedings, if the documents would fall within the scope of standard disclosure should proceedings be initiated, and pre-action disclosure is considered desirable to dispose of the matter without recourse to litigation, or to save costs.[54] This can be a useful tool for patentees in respect of suspected infringers, although the court has made it clear that it does not entertain "fishing expeditions." Furthermore, the court is able, at its discretion, to order that non-parties to the case disclose specific documents.[55] This can be helpful, for example, for patentees to seek disclosure of material relating to suspected infringers—for example, to obtain documents held by customs authorities relating to material imported into the United Kingdom.

## 5.0 CONCLUSION

The rules and case law regarding the discovery/disclosure process in Canada, the United States, and the United Kingdom continue to evolve, ostensibly making the process less burdensome and more efficient. The process in each jurisdiction is shaped to varying degrees by jurisprudence and legislation but has a common goal—namely, to balance parties' disclosure obligations against the burden on the courts and litigants.

[54] CPR 31.16(3)(d).

[55] Such an order is called a Norwich Pharmacal order.