

Sarnoff, Joshua D.

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TRIPS flexibilities on patent enforcement: Lessons from some developed countries relating to pharmaceutical patent protection

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TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection

Joshua D. Sarnoff



**SOUTH
CENTRE**



RESEARCH PAPER

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TRIPS FLEXIBILITIES ON PATENT ENFORCEMENT: LESSONS FROM SOME DEVELOPED COUNTRIES RELATING TO PHARMACEUTICAL PATENT PROTECTION

Joshua D. Sarnoff ^a

SOUTH CENTRE

OCTOBER 2020

^a Professor of Law, DePaul University College of Law, Chicago, Illinois, USA. The author thanks Sydney Warda for research assistance, and Professors Jorge Contreras and Norman Siebrasse for their prior work, which contributed substantially to the author's understanding, without attributing to them any views expressed in this paper.

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South Centre
Ch. du Champ d'Anier 17
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

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ABSTRACT

Authority for national judiciaries to issue permanent and preliminary injunctions is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Articles 44 and 50. But the TRIPS Agreement does not require the issuance of injunctions in any particular circumstances, and does not harmonize the laws on which national jurisdictions derive their injunctive relief authorities. Thus, countries remain free to refuse prohibitory injunctive relief for adjudicated or likely patent infringement, particularly if “reasonable compensation” is offered in the form of an “ongoing royalty” or an “interim royalty” payment, which acts similarly to a compulsory license. This paper explains the existing legal standards for permanent and preliminary injunctions in the United States and Canada and discusses trends regarding the issuance or denial of injunctions for pharmaceutical patents in those jurisdictions (with occasional reference to other common-law jurisdictions). Although judges in these jurisdictions more routinely deny preliminary prohibitory injunctions, legislation linking generic pharmaceutical regulatory approvals to the patent system and imposing stays of such approvals normally avoid the need for such preliminary injunctions. Consistent with the TRIPS Agreement, developing country judges may make different choices, based on the ability to provide reasonable compensation for harms or based on a different weighing of the importance of assuring affordable access to medicines relative to providing innovation incentives.

Les articles 44 et 50 de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) exigent que les tribunaux nationaux soient habilités, en matière de brevets, à prendre des mesures d'injonction permanentes et provisoires. Mais l'accord n'envisage aucune circonstance spécifique dans laquelle ces mesures peuvent être prises et ne propose pas de règle d'harmonisation concernant les règles sur lesquelles les juridictions nationales doivent se fonder pour décider de telles mesures. Ainsi, les pays restent libres de refuser que des mesures d'injonction interdisant l'utilisation d'un brevet jugé contrefait ou susceptible de constituer une contrefaçon soient prises, en particulier si une « rémunération d'un montant raisonnable » est offerte sous la forme d'une « redevance continue » ou d'une « redevance provisoire », qui fonctionne de la même manière qu'une licence obligatoire. Le présent document explique les normes juridiques applicables aux mesures d'injonction permanentes et provisoires aux États-Unis et au Canada et examine les principaux motifs invoqués pour justifier la délivrance ou le refus de délivrance d'une injonction concernant les brevets pharmaceutiques dans ces deux pays (et dans d'autres pays de common law). Si les juges américains et canadiens sont plus souvent enclins à rejeter les demandes de mesures provisoires d'interdiction, la législation, qui lie les autorisations de mise sur le marché de médicaments génériques au système des brevets et impose le respect de certains délais doit permettre normalement d'éviter le recours à ce type de mesures. Les juges des pays en développement peuvent, tout en respectant les dispositions de l'Accord sur les ADPIC, faire des choix différents qui tiendront compte de la capacité à proposer une rémunération raisonnable en réparation du préjudice subi ou s'appuieront sur une pesée différente des intérêts en jeu, à savoir l'importance d'assurer un accès abordable aux médicaments et la nécessité de promouvoir l'innovation.

Los artículos 44 y 50 del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC) exigen a las autoridades judiciales nacionales emitir mandamientos judiciales permanentes y preliminares. No obstante, el Acuerdo sobre los ADPIC no exige emitir mandamientos judiciales en ninguna circunstancia particular, y no armoniza las legislaciones en virtud de las cuales las jurisdicciones nacionales crean las autoridades que emiten los mandamientos judiciales. Por consiguiente, los países

siguen teniendo la libertad de rechazar los mandamientos judiciales de prohibición en relación con una infracción de patentes adjudicada o probable, especialmente si se ofrece una “compensación razonable” en forma de “regalía en curso” o un pago de “regalía provisional”, que actúa de manera similar a una licencia obligatoria. En este documento se explican las normas jurídicas existentes sobre los mandamientos judiciales permanentes y preliminares en los Estados Unidos y el Canadá, y se debaten las tendencias relativas a la emisión o denegación de mandamientos judiciales para las patentes farmacéuticas en esas jurisdicciones (con una referencia ocasional a otros ordenamientos de derecho anglosajón o common law). Aunque los jueces de esas jurisdicciones deniegan más habitualmente los mandamientos judiciales preliminares de prohibición, la legislación que vincula las aprobaciones reglamentarias de los medicamentos genéricos con el sistema de patentes, y que impone la paralización de dichas aprobaciones, normalmente evita la necesidad de esos mandamientos judiciales preliminares. Los jueces de países en desarrollo, coherentes con el Acuerdo sobre los ADPIC, pueden tomar distintas decisiones, en función de la capacidad de proporcionar una compensación razonable por daños o en función de una consideración diferente de la importancia que tiene garantizar un acceso asequible a los medicamentos en comparación con ofrecer incentivos a la innovación.

EXECUTIVE SUMMARY

Permanent and preliminary injunctions in the United States and Canada in pharmaceutical cases are authorized by statutes and court rules. However, decisions to grant or deny such injunctions are based on judicial precedents. Those precedents were originally derived from English common law (as opposed to civil law) equity courts. The judicial standards for granting or denying permanent and preliminary injunctions are therefore based on discretionary equitable principles. Those principles differ for each form of injunction, as well as varying between the jurisdictions and changing over time.

It is possible that these judicially developed standards for injunctions will change further. In particular, they could change in the present context of the COVID-19 pandemic and of increasing legislative solicitude for granting compulsory licenses to deal with supply shortages of patented pharmaceuticals and medical devices. Denials of injunctions that would prohibit potential or continuing infringement of pharmaceutical patents, while providing temporary or ongoing royalty compensation, could provide greater public access at lower prices to needed medicines. Denials of injunctive relief that would prohibit infringement, moreover, are consonant with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Articles 44 and 50 of the TRIPS Agreement only require Members to have judicial "authority" to issue permanent or preliminary injunctions to restrain infringements, but the agreement does not harmonize when such prohibitory injunctive relief must be granted.

Under Section 283 of the U.S. Patent Act and precedents established since at least the late 1980s by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), permanent injunctions were routinely granted to patent holders in the United States. However, in 2006, the U.S. Supreme Court in the *eBay v. MercExchange* patent case rejected the Federal Circuit's approach that a patent holder that successfully proved infringement and successfully defended against invalidity has a presumptive entitlement to an injunction. Rather, the Supreme Court established a four-part test (somewhat similar to the four-part test for preliminary injunctive relief) and placed the burden on the patent holder to establish its entitlement to this equitable remedy (in addition to obtaining a retrospective damage award). The four factors that the patent holder must establish are:

- (1) that it has suffered an irreparable injury;
- (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury;
- (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
- (4) that the public interest would not be disserved by a permanent injunction.

Where permanent injunctive relief is denied, courts may grant ongoing royalty injunctions to compensate the patent holder for harms from the continuing infringement. Since the *eBay* decision, the grant of such ongoing royalties are particularly likely where the patent holder is a non-practicing entity, which may be thought to be adequately compensated by an award of royalties. This is similar to approaches in jurisdictions such as India, where permanent injunctive relief is rarely arrived at (due to delays in concluding patent infringement trials) and where interim injunctive relief has been denied by the Indian Supreme Court and by the Delhi High Court where the patent holder had not worked the patent in the jurisdiction (notwithstanding the ability to seek a compulsory license).

In contrast, for a preliminary injunction, the Supreme Court in the 2008 *Winter v. United States* case generally established that a party seeking a preliminary injunction bears the burden to demonstrate:

- (1) that it “is likely to suffer irreparable harm in the absence of preliminary relief”;
- (2) “a likelihood of success on the merits” of its infringement claim, considering potential validity and other defenses;
- (3) that, “considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted”; and
- (4) that “an injunction is in the public interest.”

In addition to denying a prohibitory preliminary injunction, courts may order compensation to be paid if the patent is held after trial to be infringed and not invalid. Conversely, courts may order compensation to the alleged infringer if a prohibitory preliminary injunction is granted and the patent is later held not to be infringed or invalid.

Patented pharmaceuticals also are subject to a “patent linkage” regulatory regime under the Hatch-Waxman Act. That Act authorizes the issuance of an injunction to the U.S. Food and Drug Administration that automatically stays for 30 months the marketing approval of a generic competitor that claims that the patent is invalid or is not infringed, if the patent holder then sues the generic competitor for patent infringement. This permits the patent holder to keep the generic competitor off the market, normally for sufficient time for a trial court to decide the merits of the patent action. Accordingly, preliminary injunctions to stay patent infringement pending a merits determination are sought and granted relatively infrequently in pharmaceutical patent cases.

Since the *eBay* decision, permanent injunctions in American patent cases have been granted significantly less frequently, and preliminary injunctions also have been sought and granted significantly less frequently. However, such injunctions when sought continue to be routinely granted in pharmaceutical and biotechnology patent cases, even though they are more routinely denied in medical device patent cases. These results obtain although some of the permanent injunction cases suggest that harms from continuing infringement can be calculated (and thus should not be viewed as irreparable), and further suggest that the public interest in access to health products (which would include pharmaceuticals) should outweigh the public interest in assuring enforcement of patents. This is similar to at least some pharmaceutical cases addressing interim injunctions under Indian patent law, where the need for access to life-saving drugs was found to provide reasons for denying such relief.

The same considerations regarding the ability to compensate harms and the need to assure the public’s interests in access to health-care products also should apply *a fortiori* to preliminary injunctions, where infringement and lack of invalidity have yet to be fully adjudicated. The continued high injunction-granting rates for pharmaceutical patents in the United States thus may reflect in part that few pharmaceutical patent cases involve non-practicing entities, for which a royalty remedy is more likely to be viewed as sufficient to make the patent holder whole. Judges may be more likely to believe that pharmaceutical patent holders will face irreparable harm from continuing infringement than other patent holders. Alternatively, judges may be more concerned to protect pharmaceutical patent holders’ interest in recouping the high costs of investments in research, development, clinical trials, and regulatory approvals than to assure the public’s interest in affordable access to the patented drugs. Whether they should be more concerned with the former is certainly debatable.

Further, in both permanent and preliminary injunction contexts, the trial court’s grant or denial of an injunction in theory is reviewed under the highly deferential “abuse of discretion” appellate review standard. But particularly for denials of injunctions, appellate judges often

reverse district court denials. This may suggest that appellate court judges frequently substitute their own views of the equities for those of trial judges.

In Canada, under Patent Act Section 57(1) and Federal Court and provincial court rules, permanent injunctions also are granted based on equitable principles. However, the precise legal standard for granting permanent injunctions remains unclear. Under a frequently cited case from 2014, *1711811 Ontario Ltd. (Adline) v. Buckley Insurance Brokers Ltd.*, to obtain a permanent injunction “a party is required to establish its legal rights” and a “court must then determine whether an injunction is an appropriate remedy.” Nevertheless, as in the United States under the Federal Circuit before *eBay*, permanent injunctions are routinely granted in patent cases, including in pharmaceutical patent cases. This is true even though some recent interlocutory injunction cases in Canada and in the United Kingdom (like some permanent injunction cases in the U.S.) suggest that harms to patent holders from potential (or continuing) infringement can be quantified and therefore that infringement should be compensated rather than prohibited.

The standard for granting interlocutory injunctions was clearly established by the Canadian Supreme Court in 1994, in the *RJR-McDonald v. Canada (Attorney General)* case. Although formally a three-prong test with the burden placed on the movant, the Court held that the public interest should be considered as part of the third prong. Accordingly, the test looks very similar to that in the United States. The patent holder must establish its entitlement to the injunction, and the trial court must consider the following factors:

First, a preliminary assessment must be made of the merits of the case to ensure that there is a serious question to be tried.

Secondly, it must be determined whether the applicant would suffer irreparable harm if the application were refused.

Finally, an assessment must be made as to which of the parties would suffer greater harm from the granting or refusal of the remedy pending a decision on the merits....

Any alleged harm to the public interest should also be considered at th[e final] stage.

As in the United States, there is a patent linkage system in Canada, the Patented Medicine Notice of Compliance (PM(NOC)) Regulations, issued under the Food and Drug Act. By authorizing automatic 24 month stays of regulatory marketing approval, the PM(NOC) Regulations render resort to preliminary injunctions of infringement largely unnecessary to prevent generic competition until a decision on the merits of a patent action can be obtained. Nevertheless, injunctive relief in pharmaceutical patent cases has sometimes been denied to a generic competitor (in regard to a modification of an injunction) and to a patent holder's interim challenge to a notice of compliance (under earlier PM(NOC) rules). These cases, which have not generally been followed, also suggest that the temporary harms to the infringer (that are similar to those faced by patent holders from infringement prior to trial) or to the patent holder are calculable and thus do not cause irreparable harm.

As has frequently been noted, denying permanent or preliminary prohibitory injunctions and ordering permanent ongoing royalties or interlocutory compensation payments has the same economic effect as granting a compulsory license. However, various harms such as price erosion, loss of market share and goodwill, and loss of various opportunities are frequently argued by patent holders – and found by trial and appellate judges – to be incalculable, and therefore to establish irreparable harm to the patent holder. As noted above, a few cases in both jurisdictions have held that such economic and non-economic harms are in fact capable of being economically valued (although compensating for such harms may require continuing judicial supervision). This suggests that any harm from continuing or temporary infringement may not in fact be irreparable, and that prohibitory injunctions may not be needed or

desireable. If these precedents were broadened, injunctive relief in pharmaceutical cases likely would be denied more routinely. Similarly, such injunctions likely would be denied if judges were to change their views regarding the balance of public interests as between the patent holders' interest in recouping investments and the public's interest in affordable access to drugs.

We will have to wait to see to what extent these results will occur, particularly to address any shortages of needed medicines in public health emergencies such as the COVID-19 pandemic. Some judges in these jurisdictions (and others) already may be developing new norms of equity for denying permanent and preliminary injunctions that would prohibit the infringement of pharmaceutical patents, while awarding the patent holders ongoing or temporary royalties. Conversely, existing patent linkage legislation in these jurisdictions may continue to avoid the need for patent holders to seek preliminary injunctive relief for infringement. Such legislation therefore may deter potential competitors from promptly addressing supply shortfalls of affordable or alternative, potentially infringing medicines. It remains to be seen if a normative consensus will develop for changes to such legislation.

It is possible that developing (or even developed) countries may choose to exercise TRIPS flexibilities more routinely to deny preliminary and permanent injunctive relief in regard to pharmaceutical patents, based on the ability to compensate patent holders or based on a different view of the public's interest in balancing affordable access to medicines with innovation incentives for their development. Injunctive relief in equity remains an "extraordinary" remedy, and could become more extraordinary rather than routine in the pharmaceutical patent context as well. Further, if developing countries do not employ such national law flexibilities authorized by the TRIPS Agreement, they may paradoxically end up imposing more stringent levels of protection through remedies law than is required in more developed jurisdictions.

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SECTION 1: GENERAL AND INTERNATIONAL TREATY CONSIDERATIONS

It is important to view the remedy of injunctive relief for intellectual property rights infringement in light of the unprecedented actions taken by countries following the onset of the COVID-19 pandemic to impose compulsory licensing to assure affordable access to needed medicines.¹ As many have observed, refusing to grant permanent (sometimes called perpetual) injunctive relief while requiring ongoing (or continuing) damages payments has the same effect as a compulsory license.² Further, given limits on research and development and production capacities of first-party or third-party-licensed, for-profit companies, many patent, copyright, and data owners have pledged to donate for free their intellectual property rights for the duration of the pandemic.³ They have done so in order to encourage otherwise unlicensed third-party research and development, as well as to expand production of needed medical devices and other supplies. But such voluntary sharing appears to be much more limited in regard to patented pharmaceuticals and biologics. The public's interest, moreover, is not limited to the voluntary beneficence of a limited number of private rights holders.

The World Trade Organization (WTO) in the 2001 Doha Declaration explicitly recognized authority for countries to issue compulsory licenses of intellectual property rights to address public health needs, subject to providing adequate remuneration and various other conditions.⁴ (The Doha Declaration, moreover, is not limited to patent rights, which are the focus of this paper.) Specifically, Article 31(b) of the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) explicitly authorizes compulsory patent licenses without prior negotiation with the rights holder in "national emergencies or other circumstances of extreme urgency or in cases of public noncommercial use."⁵ The Doha Declaration specifically reaffirmed the right of each country to determine what circumstances constitute an emergency or circumstance of extreme urgency, as well as the conditions on which to grant compulsory licenses (which presumably would prevent countries from filing disputes in the WTO arguing that inadequate remuneration had been paid).⁶

As I have explained in an earlier work,⁷ the TRIPS Agreement does not require the granting of permanent or of preliminary injunctions (also known as provisional, interlocutory, interim or

¹ See, e.g., S Horowitz & Co., Unusual Times, Unusual Measures: the Israeli Ministry of Health Permits the Exploitation of Abbvie's Patents Covering KALETRA® to Allow Importation of Generic Version, LEXOLOGY (Mar. 19, 2020), at <https://www.lexology.com/library/detail.aspx?g=12272bd5-c581-4c21-a1af-f253595d23e4>; Olser Hoskin & Harcourt LLP, Government COVID-19 Response Includes Compulsory Licenses for Patented Emergency Medical Needs, LEXOLOGY (Mar. 31, 2020), at <https://www.lexology.com/library/detail.aspx?g=de2942bb-82c2-40c5-9ba9-7bdb4cbd655f> (discussing Canadian Bill C-13, The COVID-19 Emergency Response Act).

² See, e.g., Benjamin Petersen, *Injunctive Relief in the Post-eBay World*, 23 BERKELEY TECH. L.J. 193, 194 (2008).

³ See, e.g., Open COVID Pledge, at opencovidpledge.org.

⁴ WTO, Declaration on the TRIPS agreement and public health (adopted Nov. 14 2001) (available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm); see World Health Organization, The Doha Declaration on the TRIPS Agreement and Public Health (available at https://www.who.int/medicines/areas/policy/doha_declaration/en/) [hereinafter WTO, Doha Declaration].

⁵ WTO, Agreement on Trade-Related Aspects of Intellectual Property ["TRIPS Agreement"] (Apr. 15, 1994) 33 ILM 81 (entered into force 1995), art. 31(b), at https://www.wto.org/english/tratop_e/trips_e/trips_e.htm ("This requirement [for prior negotiation with the rights holder] may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use."). See also *id.*, art. 31(h) ("the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization").

⁶ See WTO, Doha Declaration, *supra* note 4, at ¶¶ 5b, 5c.

⁷ Joshua D. Sarnoff, *Lessons from the United States in Regard to the Recent, More Flexible Application of Injunctive Relief*, in 2 RESEARCH HANDBOOK ON THE INTERPRETATION AND ENFORCEMENT OF INTELLECTUAL PROPERTY UNDER WTO RULES 48 (Carlos M. Correa ed. Edward Elgar Publ. 2010).

temporary injunctions⁸) in all cases where infringement is found or is likely to be found. Rather, the TRIPS Agreement contemplates that countries may sometimes limit remedies to the payment of adequate remuneration, and may justify even categorical exclusions of injunctive relief for specific types of infringing conduct. Specifically, the TRIPS Agreement in Articles 44.1 and 50.1 only requires that countries provide *authority* for their judiciary to issue injunctions that terminate or prevent infringement.⁹ Article 44.2 *explicitly* authorizes payments of compensation rather than injunction of infringing conduct for government uses and compulsory licenses.¹⁰

Box 1: WTO TRIPS Agreement Article 44 Injunctions

TRIPS Agreement Article 44.1

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

TRIPS Agreement Article 44.2

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

TRIPS Agreement Article 50.1

The judicial authorities shall have the authority to order prompt and effective provisional measures: (a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance; (b) to preserve relevant evidence in regard to the alleged infringement.

As I previously stated:

[Under] Article 44.1 ... Members are not required to provide such injunctive relief authority in regard to protected subject matter ... against parties that lack 'reasonable grounds to know' of infringement. Similarly, Article 45.1 of TRIPS requires that judicial authorities 'shall have the authority to order' payment of

⁸ Such injunctions are normally preliminary to a trial, and may be interlocutory to an appeal that occurs before trial if jurisdiction for such an appeal exists. Sometimes, such injunctions may issue *ex parte* (without the defendant being heard) at an early stage, in which case it also may be referred to as an "interim injunction" or as a "temporary restraining order." See, e.g., Canada Federal Court Rules, SOR/98-106, r. 374(1); U.S. Fed. R. Civ. P. 65(b). However, "interim" is sometimes used to refer to temporary injunctions prior to trial, and interlocutory is sometimes used to refer to injunctions to stay other decisions, such as orders of an administrative agency.

⁹ TRIPS Agreement, *supra* note 5, at art. 44.1 ("The judicial authorities shall have the authority to order a party to desist from an infringement..."); *id.*, art. 50.1 ("The judicial authorities shall have the authority to order prompt and effective provisional measures: (a) to prevent an infringement of any intellectual property right from occurring...").

¹⁰ *Id.*, art. 44.2 (notwithstanding provisions for government use and compulsory licensing, "Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31"). See also *id.* ("where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available").

damages 'adequate to compensate for the injury the right holder has suffered' from infringers with 'reasonable grounds to know' of the infringement....

Article 44.2 of TRIPS provides additional policy flexibility. Members are not required to provide injunctive relief authority but rather may limit judicial remedies to the payment of remuneration in accordance with Article 31(h) – which requires payment of 'adequate remuneration' – in the special circumstances of governmental use or compulsory licensing, so long as they comply with other TRIPS provisions applicable to governmental use or compulsory licensing.... Finally, Article 44.2 provides that where injunctive relief would be inconsistent with national law, Members may provide for a declaratory judgment and 'adequate compensation.' For this reason, resort to Article 13, Article 30, or any other limited authorizations to adopt domestic exceptions to exclusive rights are wholly unnecessary to justify even categorical legislative exclusions of injunctive relief.

...

It is critically important not to confuse such ongoing royalty injunctions, damage awards authorizing future conduct, or refusals to grant preliminary injunctive relief with compulsory licenses granted by the government. (For this reason, the Paris Convention's authorization for and limits on the grants of compulsory licenses also are inapplicable.). Ongoing royalty injunctions (or other injunctions that do not order infringement to stop) and damage awards incorporating payment for prospective infringing conduct have long been part of the judicial arsenal of equitable and legal remedies....

[T]he negotiating history of the TRIPS Agreement reflects significant concerns to preserve differences among national legal systems in regard to enforcement authorities. These concerns resulted not only in a provision assuring that Members were not required to enforce intellectual property differently from other laws, but more importantly on the limitation in Article 44.1 on the requirement for members to supply injunctive relief authority in cases of innocent infringement. It is only in the context of *limiting* Members' judicial obligations that any reference is made to compulsory licenses, and it seems highly unlikely that the drafting parties would have imposed *additional* obligations for judges to comply with Article 31 when doing so.¹¹

In light of the enforcement flexibility preserved by the TRIPS Agreement (and as a reason for that Agreement's preservation of such flexibility), countries have historically adopted different approaches to the granting of preliminary and permanent injunctive relief in general, in regard to intellectual property rights, and more specifically in regard to patent rights. Injunctive relief approaches to patent rights vary based on the historical background of a country's legal system (as a common-law or as a civil law jurisdiction) and over time.

For comparative purposes, the various legal systems can be divided into three broad categories: the United States, other common law countries, and civil law countries. In most civil law countries, such as Germany, a successful patentee is considered to be entitled to an injunction as a matter of right. The ability to

¹¹ Sarnoff, *supra* note 7, at 58-60 (citing, *inter alia*, Paris Convention for the Protection of Industrial Property, Mar. 20, 1983, last revised July 14, 1967, 21 UST 1583, 828 UNTS 305, Art. 5(A)(2)&(4)). *Cf.* TRIPS Agreement, Art. 21 (prohibiting compulsory licenses for trademarks); Norman V. Siebrasse *et al.*, *Injunctive Relief*, in PATENT REMEDIES AND COMPLEX PRODUCTS: TOWARD A GLOBAL CONSENSUS 117 (Brad Biddle *et al.* eds. Cambridge Univ. Press 2019) ("TRIPS itself makes clear that 'Members may limit the remedies available against [infringing] use to payment of remuneration,' a provision that some commentators argue gives member nations broad discretion to limit injunctions.") (quoting TRIPS Art. 44(2); citing Christopher A. Cotropia, *Compulsory Licensing Under TRIPS and the Supreme Court of the United States' Decision in eBay v. MercExchange*, in PATENT LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 580 (Toshiko Takenaka, ed., Edward Elgar Publ. 2008), and Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1608 n.223 (2009)).

obtain injunctive relief may be restrained, however, through various types of generally applied defenses, such as abuse of rights or lack of good faith, as well as by competition law. In countries with a common law tradition, such as England and the United States, injunctive relief has long been recognized as being discretionary in principle, notwithstanding the traditional practice of granting injunctions almost automatically in patent cases. However, since the Supreme Court of the United States decision in *eBay*, practice in the common law countries has diverged.¹²

As explained in Section 2 below, however, the “traditional” approach of granting injunctions as a matter of course may not in fact always have been the traditional approach in the United States, and in any event preliminary and permanent injunction practices have been altered in the United States, although less so for pharmaceuticals than for medical devices. As explained in Section 3 below, the “traditional” approach also has not uniformly been followed in other common-law jurisdictions, such as Canada. At least prior to Brexit, injunctive relief also was subject to substantial limitations in the United Kingdom, and it remains subject to those limitations in European civil law jurisdictions.¹³ It is possible that these countries may now take a somewhat more restrictive approach to the routine granting of injunctions, or at least as to their scope.¹⁴ This paper, however, surveys and focuses on only the approaches of the common-law jurisdictions of the United States and Canada, with particular regard to their differing approaches to permanent and preliminary injunctions of continuing or potential infringement of patent rights in pharmaceuticals.

As discussed in the remainder of this paper for each of the two surveyed countries, the public interest in assuring affordable access to pharmaceutical products is or should be one of the factors to evaluate. At least in the United States, and in Canada for interlocutory injunctions, a party seeking an injunction has the burden to adequately demonstrate its entitlement thereto under each prong of a multi-prong test, rather than for a court to determine whether to grant an injunction based on an overall balancing of relevant decisional factors.

However, the public interest prong of consideration may be viewed very differently depending on particular judges’ views of the relative importance of recouping research, development, clinical trial and regulatory approval costs and providing investment incentives through patent rights, as compared to providing immediate and longer-term public health benefits through

¹² Siebrasse *et al.*, *supra* note 11, at 125 (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)).

¹³ See, e.g., *id.* at 126 (discussing Article 12 of the European Union Enforcement Directive, which “provides that injunctive relief may be refused, and pecuniary compensation awarded instead, if the infringer ‘acted unintentionally and without negligence, if execution of the measures in question would cause him/her disproportionate harm and if pecuniary compensation to the injured party appears reasonably satisfactory.’”) (citations omitted).

¹⁴ See, e.g., *id.* (“[I]t is possible that [national law adherence to traditional principles of routinely granting injunctions to stop adjudicated patent infringement] will change in the years to come, particularly in light of recent, additional Communications from the European Commission that emphasize the Enforcement Directive’s principle of proportionality. European Commission, at 18, COM (2017) 708 final (stating, inter alia, that courts should ensure, on a case-by-case basis, that injunctions be consistent with the principle of proportionality; that injunctions ‘should have the minimal scope necessary to accomplish this objective’; and that it ‘is not necessary that the measures required by the injunction lead to a complete cessation of the IPR infringements’); European Commission, at 10, COM (2017) 712 final (similar.); Stephen Bennett *et al.*, *Shifting Attitudes Towards Injunctions in Patent Cases*, ManagingIP 2-3 (Feb. 2015), available at https://www.hoganlovells.com/~media/hogan-lovells/pdf/publication/managingintellectualproperty3915_pdf.pdf (“The UK, it seems, is now at a crossroads with a clear mandate from the Supreme Court to the lower courts to look again at the question of granting injunctions and an emphasis on the issue of whether damages are an adequate remedy.... European civil law jurisdictions have no legally unified approach to granting final injunctions.... French patent law does allow for situations of compulsory or forced licences (even if applications of such provisions are extremely scarce) and where a third party would be held by a court to be eligible to receive such a licence, there would be no room for the granting of a final injunction.”).

more widespread, alternative, or lower-cost access to patented medicines. To date, in both the United States and Canada, judges in pharmaceutical patent injunction cases tend to be more solicitous of the former concerns than of the latter concerns, particularly as pharmaceutical patent litigation rarely involves non-practicing entities (NPEs). Those judges therefore tend to grant rather than to deny permanent and preliminary injunctions (where applicable, in light of linkages of the patent system to the pharmaceutical regulatory approval system). This tendency exists even though the legal doctrine would likely permit those judges to reach the opposite, discretionary result, based on a lack of irreparable harm to the patentee or on a different view of the overall public interest.

As discussed in Sections 2 and 3 below, both the United States and Canada have generally granted permanent injunctions for patents on pharmaceuticals and biologics. In contrast, the United States has been more restrictive in granting permanent injunctions in regard to patents on medical devices. Both countries have been more likely to *deny* preliminary injunctions than permanent injunctions in regard to patents on medicines, particularly as in Canada preliminary injunctions are almost never granted to any patentee. Unlike in regard to patents on non-pharmaceutical inventions, however, potentially infringing generic medicines in both jurisdictions may be subject to patent linkage legislation and regulations that provide for automatic stays of drug regulatory approvals pending the outcome of patent infringement litigation.¹⁵ This linkage largely avoids the need for patent holders to seek preliminary injunctions against infringement until after trial on the merits.

Nevertheless, in the United States, judicial injunctive relief practices in general have changed substantially in light of the seminal U.S. Supreme Court's decision in the *eBay Inc. v. MercExchange, L.L.C.* case.¹⁶ Although they have not yet done so in Canada, it is possible that they could similarly change in the post-COVID-19 environment.¹⁷ Further legislative changes, however, may be needed in both jurisdictions to address patent linkages that authorize automatic stays of generic medicine approvals, so as to assure that supply chain shortages can be promptly addressed (including more rapidly than by the granting of compulsory licenses).¹⁸

As discussed in more detail in Section 2, in the United States, most pre-*eBay* permanent and preliminary injunction decisions reflect the traditionally greater solicitude of American judges for patent holders' innovation incentives than for the public's need for access to patented

¹⁵ See 21 U.S.C. § 355(j)(5)(B)(iii); Patented Medicines (Notice of Compliance) Regulations, SOR/93-13.

¹⁶ *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

¹⁷ See generally Jeff Berryman, *When Will a Permanent Injunction Be Granted in Canada for Intellectual Property Infringement? The Influence of eBay v. MercExchange*, 24 INTELL. PROP. J. 159 (2012).

¹⁸ *Cf., e.g.*, Valerie Bauman, *Generic Drug Decisions Stall as Virus Forces Patent Court Delays*, Pharm. & Life Sci. News, Bloomberg Law (May 4, 2020), at <https://www.bloomberglaw.com/document/XADE8K6S000000?b> (noting six cases where courts are unlikely to rule on the merits within the 30-day automatic stay period; "One option is for judges to ask both parties to informally agree to wait for a specific period of time or until the resolution of the case before an FDA-approved generic can move forward with a launch. Generic companies often agree to these extensions rather than risking an injunction."); Matthew Bultman, *Virus Delays Stir Deadline Concerns in Drug Patent Cases*, Bloomberg Law (Mar. 23, 2020), at https://www.bloomberglaw.com/document/X8KVK2DG000000?bna_news_filter=bloomberg-law-news&jcsearch=BNA%252000000170f890d6dda1feff9687750001#jcite ("Brand name drug makers aren't going to accept simply allowing the 30-month window to come and go") (citing Bruce Wexler, lawyer at Paul Hastings). Whether to adopt legislation that would fully immunize generic or alternative production from the threat of infringement actions and injunctive relief when there is unmet demand (including because of prices), however, would likely prove highly controversial. Such legislation may be much more difficult to enact than simply directing the judiciary to consider denying injunctions when affordable pharmaceutical supplies are needed. Presumably generic or alternative suppliers would be more willing to risk providing such supplies with legislative authorization, even without full immunity from suit or from injunctive relief. *Cf. Bauman, supra*, ("Launching a generic drug at risk of losing in court later sometimes happens under normal circumstances—typically when the generic company is confident based on earlier proceedings that it will win, or if the drug patent is particularly weak.... However, it's dangerous because generic companies that later lose must reimburse the brand-name company for lost revenues and other damages) (citing Professor Michael Carrier, Rutgers Law School).

technologies. In regard to pharmaceuticals, judges to date have focused on the patent holders' long-term ability to recoup their extensive investments, given the high costs of pharmaceutical research and development and especially of clinical trials and regulatory approvals. In contrast, judges have not weighed as heavily the public's short-term and long-term health interests, particularly the need for affordable access to medicines. In *eBay*, however, the U.S. Supreme Court rejected the U.S. Court of Appeals for the Federal Circuit's (Federal Circuit's) "general rule" that "a permanent injunction will issue once infringement and validity have been adjudged," held that injunctions were subject to "well-established principles of equity," and instructed lower courts that injunctions should not issue as a matter of course following findings of infringement and lack of invalidity, but rather the patent holder must demonstrate its entitlement to the remedy of an injunction.¹⁹

eBay's changed approach to permanent injunctive relief has not been limited to patent cases,²⁰ and also has spilled over to preliminary injunction decisions. Preliminary injunctions now are sought and obtained less frequently, and judges in the U.S. (and in other jurisdictions²¹) are more skeptical of allegations of irreparable harm from continuing infringement. This is particularly true given increasing recognition of the ability to measure the asserted harms and to remedy them through temporary or more permanent ongoing royalty injunctions. Nevertheless, these changing standards have yet to make a significant difference to injunctive relief decisions regarding patented medicines.

In Canada, in contrast, the historic judicial solicitude for granting permanent injunctions (under a general standard of whether injunctive relief is appropriate) appears to remain largely in place. This is true even though Canada has been much more receptive at the legislative level to compulsory licensing of pharmaceuticals, which an ongoing royalty injunction mimics in its economic effect.²² There are, however, a few decisions in Canada and the United Kingdom in regard to permanent and preliminary injunctions in the pharmaceutical context suggesting that continuing infringement harms are capable of being measured and thus of being adequately remedied through royalty payments. Nevertheless, those cases have yet to be generally followed. In particular, interlocutory injunctions are rarely granted based on the difficulty of proving irreparable harm, but are rarely sought for infringing generic medicines given the linkage provisions for automatic stays of generic medicine marketing approvals.

In contrast, it is possible that developing countries such as India may be moving away from their ability to exercise TRIPS flexibilities to *deny* preliminary and permanent injunctive relief, based on the ability to compensate patent holders (particularly in the absence of local working

¹⁹ See *eBay*, 547 U.S. at 391-92.

²⁰ See, e.g., Mark P. Gergen *et al.*, *The Supreme Court's Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203, 215-19 (2012) (citing cases).

²¹ Cf., Sandeep K. Rathod, *Interim Injunctions and Working of Patents*, J. GENERIC MEDS. 1-2 (Feb. 5, 2020), available at <https://journals.sagepub.com/doi/10.1177/1741134320905341> (comparing Bayer Intellectual Property GmbH v. Ajanta Pharma LTD & ORS [CS(COMM) 1648/2016], Order of Jan. 4, 2017, available at http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=4898&yr=2017, with Bayer Intellectual Property GmbH v. BDR Pharmaceuticals International [CS(COMM) No.107/2017], Order dated 14 February 2017, http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=30334&yr=2017, and discussing Franz Xaver Huemer vs New Yash Engineers (AIR 1997 Delhi 79), which denied injunctions in India based on the non-practicing entity status of the infringer); *Bayer v. Ajanta*, Order of Jan. 4, 2017, at ¶13 ("particularly the admitted non-user in India of the patents by the plaintiff till date and the fact that neither sides sells its products in India, bearing in mind the elements of *public interest and equity*, as indeed the balance of convenience, the ex-parte ad interim injunction granted by order dated 20th December, 2016 is modified . . . it is clarified that the earlier order of ad interim injunction against making/manufacturing, distribution, offer for sale or sale of the impugned products *for purposes of exports* stands suspended") (emphasis added).

²² See, e.g., Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of WTO Rules*, 37 J. L. & Med. Ethics 222 (2009); Dennis Crouch, *CAFC Approves Compulsory License (but calls it an "ongoing royalty")*, *Patently-O* (Oct. 19, 2007), at <https://patentlyo.com/patent/2007/10/cafc-approves-c.html> (citing *Paice v. Toyota*, 504 F.3d 1293 (Fed. Cir. 2007)).

of the patent like the post-*eBay* focus on adequacy of royalties for NPE patent owners) or based on public interest concerns (to assure public health and affordable access to medicines).²³ As with other common-law countries like the US and Canada, India's injunctive relief authorities are based on equitable principles and are codified in the Indian Patent Act and judicial civil procedure code.²⁴ Early Indian cases established that preliminary injunctions of potential pharmaceutical patent infringements could be denied when the patent holder failed to work the invention within India (and thus could be adequately compensated for any infringement),²⁵ and that the public interest in affordable access to life-saving drugs tilted the balance of convenience in favor of infringers (particularly as loss of money but not loss of

²³ See, e.g., Dinesh K. Sharma, India: Patent Infringement Litigation in India and Interim Injunctions: Jurisprudence on "Public Interest" Continues to Evolve!, Lex Orbis (Mar. 14, 2017), at <https://www.lexorbis.com/patent-infringement-litigation-in-india-and-interim-injunctions-jurisprudence-on-public-interest-continues-to-evolve/> ("Apart from the aforementioned three prongs i.e. *Prima facie* case, irreparable loss and balance of convenience that were subsequently adopted in Indian law, another crucial prong that the test for interim injunctions involve is 'public interest'.").

²⁴ See, e.g., Patent Act 1970, as amended (through 2017), Art. 108 ("Reliefs in suit for infringement.—(1) The reliefs which a court may grant in any suit for infringement include an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the plaintiff, either damages or an account of profits."); Yogesh Pai, *Patent Injunction Heuristics in India*, in INJUNCTIONS IN PATENT LAW 11-12 (Rafal Sikorski ed. 2018), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3305029 ("Much of the discretion in awarding an exclusionary remedy is governed by the case-law jurisprudence developed in the context of Specific Relief Act, 1963 and the Code of Civil Procedure, 1908 that forms the general law on civil remedies. The grant of injunctions has its foundations in the principles of equity in India's preindependence period, which were codified in the Specific Relief Act, 1887.... [T]o preserve the equities before a permanent injunction can be issued, Rule 1 to 5 of Order XXXIX of the CPC grant courts the power to grant interim injunctions. Section 94(c) and (e) of the CPC empowers to court to grant interlocutory reliefs in the form of interim injunctions and other interim orders to prevent the ends of justice from being defeated as may appear to the Court to be just and convenient in the given circumstances. Rule 1 to 5 of Order XXXIX regulate grant of Interim injunctions in India, specifically Rule 1(a) allows court to grant an injunction wherein any property in dispute is in danger of being wasted, damaged or alienated by any party to the suit. However, Court's power is not limited to Order XXXIX. Section 151, provides for inherent powers of the Court to grant injunctions in cases not covered by these Rules. Rules 2(2) allows the court to grant injunctions 'on such terms as to the duration of the injunction, keeping an account, giving security, or otherwise, as the Court thinks fit'. This in a way allows the court to require cross-undertaking in damages by the plaintiff."). Compare, e.g., *id.* at 2 ("As a common law jurisdiction, Indian courts have conclusively resolved in favour of evaluating the grant or denial of injunctions based on equitable principles.") and Namratha Murugesan, No Reasons Why: Questioning Delhi HC's Interim Injunction against Sun Pharma in Novartis' Nilotinib Patent Infringement Suit, SpicyIP Blog (Mar. 11, 2020), at <https://spicyip.com/2020/03/no-reasons-why-questioning-delhi-hcs-order-granting-interim-injunction-for-infringement-of-novartis-nilotinib.html> ("Injunctions are discretionary and equitable reliefs and are not available to parties as a matter of right. Therefore if there is an equally effective remedy available, then an injunction will not be granted.") with Pravin Anand & Aashish Somasi, Patent litigation in India: overview, Thompson Reuters Practical Law Country Q&A (May 1, 2018) ("Whether the grant of a permanent injunction is discretionary is yet to be decided by Indian courts, and there are no specific rules in this regard").

²⁵ See, e.g., Pai, *supra* note 24, at 19 ("In both these cases injunction was refused on the ground that the patent was not being worked in India.... [I]t is now well settled that if patent has not been sufficiently exploited in India and there is no user of the said patent in commercially viable form in India, the court may refuse to grant an injunction.") (citing NRD Corporation of India v. DC & G Mills 1980 AIR Delhi 132 (Del. High Ct.), Franz Xaver Huemer v. New Yash Engineers 1997 AIR Delhi 79 (Del. High Ct.), and Sandeep Jaidka v. Mukesh Mittal & Anr, 50 PTC 234 (Del. High Ct. 2014)). See also Lex Orbis, Consolidating Law of injunction in patent infringement – Indian experience (Sept. 27, 2019) ("Another factor which worked against the grant of interim injunction was the non-working/non user of patent.") (citing *Franz Xaver Huemer, Sandeep Jaidka, Glaverbel S.A. v. Dave Rose & Ors*, 2010 (43) PTC 630 (Del), and *Novartis Ag And Anr. v. Mehar Pharma And Anr.* (Dec. 23, 2004), 2005 (3) BomCR 191; noting in regard to the latter case the trial judge's concern not to dismantle the defendant's manufacturing and marketing network and the patent holder's promise to meet working requirements by future imports). Cf. *Franz Xaver Huemer*, *supra*, ¶¶ 30, 33 ("In a recent intellectual, property case concerning trade mark, the Supreme Court after referring to [American] Cyanamid, still observed that plaintiff has to prove prima facie case, balance of convenience and irreparable injury if injunction is to be granted. *Gujarat Bottle Mfg. Co. Ltd. v. Coca Cola Co.* That would mean that the rule of 'triable issue' stands mellowed down in favour of prima facie case, in intellectual property matters.... Balance of convenience has also an important role to play. Stultification of defendants investment, loss of employment, public interest in the product (such [as] a life saving drug), product quality coupled with price, or the defendant being smaller in size, may go against the plaintiff."); Pai, *supra* note 24, at 19 ("[A]lthough some courts have viewed public interest as a separate factor, this case stands for the proposition that public interest may be evaluated in the context of applying the test of balance of convenience.").

health or life can be adequately compensated).²⁶ Some more recent cases, however, have either failed adequately to address the non-practicing nature of the patent holder or the public's interest in affordable access to medicines,²⁷ or have focused on assuring adequacy of the returns to the patent holder during the life of the patent grant.²⁸

Whatever the reasons for this new approach are, the trend seems somewhat odd. Injunctive relief and particularly preliminary injunctive relief is an “extraordinary” remedy, and judges should consider equity to the public as well as to both of the parties to the litigation. Further, if developing countries do not employ such national law flexibilities authorized by the TRIPS Agreement, they may paradoxically end up imposing more stringent levels of protection through remedies law than is at least required in more developed jurisdictions like the United States. In this way, they may accede to pressures to adopt enhanced levels of patent protection to which even developed countries would not submit. Conversely, it is unclear why developed country judges have refused to recognize the principles developed earlier by developing country judges, regarding the ability to measure harms and compensate nonworking patent holders and particularly regarding the overriding public interest in assuring affordable access to needed medicines.

²⁶ See, e.g., *F. Hoffman-La Roche Ltd. & Anr. v. Cipla Ltd.*, 148 DLT 598 (Del. High Ct. 2008), ¶ 86 (“this Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a lifesaving drug, the balance has to be tilted in favor of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendant's product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus, irreparable injury would be caused if the injunction sought for is granted.”), *aff'd*, 2009 (40) PTC 125 (Del.) (DB), ¶ 81 (“This Court is inclined to concur with the learned single Judge that in a country like India where question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for.”). Cf. 148 DLT 598, ¶¶ 61-65 (tracing the interim injunction standards to the American Cyanamid Co. v. Ethicon, Ltd., [1975] A.C. 396 (U.K.)); Pai, *supra* note 24, at 19 (“[A]lthough some courts have viewed public interest as a separate factor, th[e] *Franz Xaver Huemer* case stands for the proposition that public interest may be evaluated in the context of applying the test of balance of convenience.”).

²⁷ See, e.g., Rathod, *supra* note 21, at 2-3 (“In court, Dr Reddy's relied on *Franz Huemer* (amongst other grounds) and argued against the issuance of any interim injunction in favor of Eisai as Eisai was not working its invention in India. Eisai, on the other hand, based its defense on the BDR ruling (noted earlier). The Single Judge of the same court (Delhi High Court) gave a detailed order granting an interim injunction in favor of Eisai and rejected Dr Reddy's argument on non-working of the patent” based on the failure of the alleged infringer to seek a voluntary or compulsory license, and seeking to distinguish *Franz Huemer* based on continued infringement being vital for the domestic textile industry and on changes to the compulsory licensing regime since 2005, and finding that the loss to the plaintiff could not be compensated in money) (*Eisai Co. Ltd. v. Satish Reddy*, CS COMM 1169/2018 (High Court of Delhi) (Order of May 6, 2019), ¶¶ 50.11-50.12, 52); *Eisai Co.*, ¶¶ 24-25, 50 (granting interlocutory injunction in light of unused ability of defendant to seek compulsory license); *Dr Reddys Laboratories Ltd v. Eisai Co Ltd* [FAO(OS) (COMM) 122/2019] (Order of May 27, 2019); Murugesan, *supra* note 24 (“[T]he public interest argument was that given the defendant's medicines were cheaper than the plaintiff's, an injunction would restrict access to affordable medicines for consumers and hence, again go against the decision to grant an injunction. [That was a] crucial factor that has been missed in the *Novartis* order.”) (citing *Novartis Ag & Anr. v. Sun Pharma. Indus.*, CS COMM 85/2020 (Del. HC) (Feb. 20, 2020)). Cf. Rathod, *supra* note 21, at 3 (criticizing the trial judge's reasoning in *Eisai*); Murugesan, *supra* note 24 (“Given the Patent Office's high error rate in granting pharmaceutical patents, the practice of presuming the validity of a patent in cases of granting an injunction comes under serious doubt.”).

²⁸ See, e.g., Ranjan Narula & Suvarna Pandey, *Injunctions: Paradigm shift for India's innovators*, *World Intell. Prop. Rev.* (Aug. 13, 2019) (“The High Court of Delhi took a completely different view when deciding the injunction in the case of *Sterlite Technologies v ZTT India Private* (CS [COMM] 314/2019, IA No. 8386/2019, IA No. 8389/2019 & IA No. 8390/2019), decided on May 31, 2019.... This case, although not related to the pharmaceutical domain, has brought a paradigm shift whereby the court has taken completely different view on how to approach a request for preliminary injunction in a patent infringement case. The court's comments—that the patent term is short and that if protection is not given to the patentee it will be counterproductive to the entire patent protection system—augur well for promoting innovation and encouraging innovators to seek patent protection.”).

The surveyed American and Canadian precedents, however, were (mostly) derived prior to emergencies like the COVID-19 pandemic. As noted earlier, recent events have unsettled prior assumptions and have led to more favorable views by some legislators of the use of compulsory licensing to address health care emergencies and supply chain shortages. Similar views, however, have yet to emerge from American and Canadian judges to grant permanent ongoing royalty injunctions or preliminary injunctions that provide “adequate remuneration,” rather than prohibit future or potential, temporary infringements. But it remains possible that such views may arise in the future,²⁹ further expanding *eBay*’s change to judicial views regarding equitable injunction practices. Denying such prohibitory injunctions would expand access to needed or more affordable medicines, which effectively may be unavailable to significant segments of the public. In such situations, the patent holder may be more likely to be viewed like an NPE, prohibiting others from but not itself serving the relevant market.

It is also possible that judicial tendencies to grant permanent and preliminary injunctions in pharmaceutical cases will change in light of the international views on compulsory licensing that have been developing since the COVID-19 pandemic. Denial of injunctions and payment of ongoing or temporary royalty compensation has been found in some cases from the U.S., Canada, and other common-law jurisdictions to be an appropriate method to address alternative or affordable access to needed pharmaceuticals, particularly given the public’s interest in life-saving medicines.³⁰ Since the pandemic, moreover, the public’s interest in affordable access to needed treatments, vaccines, and other medical products may more frequently be recognized to supply the conditions for a TRIPS-compliant “emergency” or “situation of extreme urgency.”³¹ If such conditions authorize the grant of compulsory licensing without consultation with the patent holder, a fortiori they should also authorize the denial of a prohibitory injunction in favor of an ongoing or temporary royalty injunction having similar

²⁹ As noted above, various reasons for denying such prohibitory injunctions have been articulated in Indian judicial precedents, although they have generated significant controversy. See, e.g., *supra* notes 24-27 and accompanying text. Cf. *Pai*, *supra* note 24, at 7-8 (“[T]he existence of specific grounds for compulsory licences to remedy certain situations such as unmet demand, high prices and lack of territorial working have been specifically provided in the Patent Act. It is simplistic to assume that a denial of an injunction is effectively a judge made compulsory license, although in effect it is a liability rule.... The courts have held that while grounds for a compulsory licence, such as non-working, does not prove lack of prima facie case for the plaintiff, it could definitely be factored in the analysis of public interest.”) (citing *Cipla Limited v. Novartis AG*, 2017 SCC OnLine Del 7393 (Del. High. Ct.)); *id.* at 9 (injunctions “can be refused in case a party can adequately be compensated in terms of money or the court can sufficiently protect the interest of the plaintiffs by passing certain other directions”) (citing *Vringo Infrastructure v. India Mart*, 2014 SCC OnLine Del 3970 (Del. High Ct 2014)). *But cf.* *Rathod*, *supra* note 28 and accompanying text, at 3 (criticizing the recent refusal to deny a preliminary injunction in *Eisai*, based on distinguishing prior cases denying such injunctions to non-practicing entities, in light of the ability of the alleged infringer to obtain a compulsory license, given that such ability had existed at the time of the earlier cases).

³⁰ See, e.g., *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1380 (Fed. Cir. 2008) (reversing district court injunction in light of ongoing royalty based on “upfront entry fee that contemplates or is based upon future sales by Abbott in a long term market. When a patentee requests and receives such compensation, it cannot be heard to complain that it will be irreparably harmed by future sales.”); *Aventis Pharma S.A. v. Novopharm Ltd.*, 2005 FC 815, ¶ 109-10, 113 (rejecting interlocutory injunction as not having demonstrated irreparable harm that could not be compensated by payments); *Roche v. Cipla*, 148 DLT 598 (Del. High Ct. 2008) (denying injunction, stating “this Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a lifesaving drug, the balance has to be tilted in favor of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendant’s product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus, irreparable injury would be caused if the injunction sought for is granted.”). See generally Julie A. Berger & Justin Brunner, *A Court’s Dilemma: When Patents Conflict With Public Health*, 12 Va. J.L. & Tech. 7, 51 (2007) (After *eBay*, the “public interest can no longer merely mean the public’s interest in the enforcement of the patent system but must also take into account public health, safety, and need.”).

³¹ See TRIPS Agreement, *supra* note 5, art. 31(b).

effect, particularly given that the patent holder can argue its position in order to represent its interests to the court.³²

³² Cf. Siebrasse *et al.*, *supra* note 11, at 150 (“we agree that, in deciding whether to issue injunctions, courts *should* consider, as a potential basis for denying injunctive relief, harms to the public that substantially outweigh the costs inherent in a functioning patent system – i.e., negative consequences to the public that are substantially beyond what a patentee could reasonably and legitimately have expected in vindication of its patent rights –to the extent such harms are likely to be realized. Such a requirement aligns with existing *de jure* compulsory licensing regimes, which generally take effect only in exceptional circumstances.”) (emphasis added).

SECTION 2: UNITED STATES OF AMERICA

A. *Permanent Injunctions*

Box 2: U.S. Patent Act Section 283

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

Under current U.S. law, federal district courts have nearly exclusive jurisdiction over most patent law issues in the United States, including infringement and validity.³³ Thus, there is essentially a unitary court system for deciding patent issues of both infringement and validity, as well as a single appellate court to hear all patent appeals from district courts. The Federal Circuit, which was created in 1981, now has exclusive jurisdiction over all patent appeals in infringement cases.³⁴ Federal Circuit precedents are therefore extremely important, although they are subordinate to the Supreme Court's precedents.³⁵ Appeals in patent cases to the Supreme Court are discretionary, although in recent years the Supreme Court has accepted patent cases for review with increasing frequency.³⁶

Section 283 of the U.S. Patent Act provides that patent injunctions shall issue based on "the principles of equity."³⁷ Those principles typically and historically have included a broad range of factors and considerations, permitting judicial discretion to balance the private need for an injunction (and to address the good faith or conduct of the requestor) against the private harm to the party enjoined and the third-party effects on the public.³⁸

At least since the late 1980s, a finding of infringement of a U.S. patent would normally lead a U.S. federal district court (based on Federal Circuit precedents) to issue a permanent injunction preventing continuing patent infringement, notwithstanding the broad equitable

³³ See 28 U.S.C. § 1338(a) (2019) ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights.").

³⁴ See *id.*, § 1295(a) ("The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction— (1) of an appeal from a final decision of a district court of the United States, the District Court of Guam, the District Court of the Virgin Islands, or the District Court of the Northern Mariana Islands, in any civil action arising under, or in any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents or plant variety protection....") (revising the holding of *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 520 U.S. 826 (2002), to provide exclusive jurisdiction in the Federal Circuit for compulsory patent counterclaims). In contrast, copyright claims are generally appealed to the regional circuit appellate court in which the district court is located (absent a patent claim or compulsory counterclaim). See *id.*, § 1291.

³⁵ See, e.g., Ryan T. Holte & Christopher B. Seaman, *Patent Injunctions on Appeal: An Empirical Study of the Federal Circuit's Application of eBay*, 92 WASH. L. REV. 145, 163-64 (2017) ("The Federal Circuit, as the sole appellate court for claims arising under the Patent Act, plays a central role in the shaping and application of patent law.").

³⁶ See 28 U.S. Code § 1254(1) (2019) (discretionary review by writ of certiorari). See generally, e.g., Paul Gugliuzza, *How Much Has the Supreme Court Changed Patent Law?*, 16 CHI.-KENT J. INTELL. PROP. 330, 330 (2017) ("The U.S. Supreme Court has decided a remarkable number of patent cases in the past decade, particularly as compared to the first twenty years of the Federal Circuit's existence.").

³⁷ 35 U.S.C. § 283 (2019).

³⁸ See, e.g., Gergen *et al.*, *supra* note 20, at 208 ("Under traditional principles, any of a number of equitable defenses, such as the movant's 'unclean hands,' laches, or estoppel, might provide a basis for refusing an injunction....").

discretion of federal district courts to balance various concerns.³⁹ This approach was based on the view that patent right was a property interest and that the only way to adequately protect that right was through an exclusionary property-rule remedy, rather than a liability-rule compensatory remedy.⁴⁰ Injunctions thus were granted even when the patent holder had not worked the patent to supply the public with the patented product.⁴¹

In 2006, in *eBay Inc. v. MercExchange, L.L.C. (eBay)*,⁴² however, the U.S. Supreme Court made clear that the Federal Circuit had erred in “articulat[ing] a general rule, unique to patent disputes, that a permanent injunction will issue once infringement and validity have been adjudged.”⁴³ The Supreme Court instead required federal district courts to apply a four-part test (which is somewhat similar to the traditional preliminary injunction standard) when deciding whether to issue or to deny permanent injunctions in patent cases.⁴⁴ The *eBay* decision therefore resulted in significant changes to U.S. judicial injunction practices for patents, for other intellectual property rights, and for other legal rights.⁴⁵

³⁹ See, e.g., *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1338 (Fed. Cir. 2005), vacated and remanded, 547 U.S. 388 (2006) (“Because the ‘right to exclude recognized in a patent is but the essence of the concept of property,’ the general rule is that a permanent injunction will issue once infringement and validity have been adjudged.”) (quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1246–47 (Fed.Cir.1989)). Cf. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 395 (2006) (Roberts, C.J. concurring) (“From at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases.”). *But cf.* Jared A. Goldstein, *Equitable Balancing In the Age of Statutes*, 96 VIRGINIA L. REV. 485, 488 (2010) (“Balancing the equities is a demonstrably modern practice. It first developed during the period of rapid industrialization following the Civil War [of the 1860s], when some state courts sought a mechanism to protect industrial interests from injunctions in common law nuisance actions challenging air and water pollution.”); *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 866 (Fed. Cir. 1984) (“Counsel are equally mistaken in their apparent belief that once infringement is established and adjudicated, an injunction must follow.”) (citing *Hecht Co. v. Bowles*, 321 U.S. 321, 329-31 (1944)).

⁴⁰ Cf. Holte & Seaman, *supra* note 35, at 159-60 (“studies of eBay’s impact in the district courts suggest that it has created a bifurcated regime of patent remedies, where some patentees are generally awarded a property-rule remedy (via an injunction against future infringement), while others are limited to a liability rule (usually monetary compensation, such as an ongoing royalty)”). *But cf.* *eBay*, 547 U.S. at 392 (“the creation of a right is distinct from the provision of remedies for violations of that right”); *id.* at 396 (Kennedy, J., concurring) (“Both the terms of the Patent Act and the traditional view of injunctive relief accept that the existence of a right to exclude does not dictate the remedy for a violation of that right.”). See generally B.J. Ard, *More Property Rules than Property? The Right to Exclude in Patent and Copyright*, 68 EMORY L.J. 685 (2019); Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783 (2007).

⁴¹ Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After eBay: An Empirical Study*, 101 IOWA L. REV. 1949, 1959-61 (2016) (citing, *inter alia*, *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 425-30 (1908)).

⁴² *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

⁴³ *Id.*, 547 U.S. at 393-94. See also *Monsanto v. Geerson Seed Farms*, 561 U.S. 139, 165 (2010) (“[A]n injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course.”); 7 DONALD S. CHISUM, CHISUM ON PATENTS § 20.04 (Lexis On-line ed. 2020) (“A patent owner prevailing on the merits of a patent infringement claim will usually be granted a permanent injunction against future infringement unless the public interest otherwise dictates.”).

⁴⁴ See, e.g., Gergen *et al.*, *supra* note 20, at 208-09.

⁴⁵ See, e.g., Seaman, *supra* note 41, at 1949 (“*eBay* has effectively created a bifurcated regime for patent remedies, as operating companies who compete against an infringer still obtain permanent injunctions in the vast majority of cases that are successfully litigated to judgment. In contrast, non-competitors and other non-practicing entities are generally denied injunctive relief.”); Gergen *et al.*, *supra* note 20, at 205 (“the four-factor test from *eBay* has, in many federal courts, become the test for whether a permanent injunction should issue, regardless of whether the dispute in question centers on patent law, another form of intellectual property, more conventional government regulation, constitutional law, or state tort or contract law”); RAYMOND T. NIMMER & JEFF DODD, MODERN LICENSING LAW § 11.51 (Westlaw updated Nov. 2019) (“We believe that *eBay* is, at long last, being applied in all cases involving injunctive relief in all federal intellectual property rights cases, not just in patent cases.”).

Box 3: U.S. eBay Standard for Permanent Injunctions

The patent holder “must demonstrate

- (1) that it has suffered an irreparable injury;
- (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury;
- (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
- (4) that the public interest would not be disserved by a permanent injunction.”

The decision to grant or deny an injunction is reviewed for an “abuse of discretion.”

Specifically, the Supreme Court's four-part test in *eBay* places the burden of proving an entitlement to an injunction on the patent holder, requiring the patent holder to demonstrate that each prong of the test is met.⁴⁶ It thereby eliminated any presumption in favor of granting an injunction based on proof of infringement. Instead, a district court's “decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion.”⁴⁷

The “abuse of discretion” appellate review standard is a highly deferential one, as compared to the standards of “de novo” review for questions of law, the bifurcated standard for “mixed questions of law and fact,” and the “clearly erroneous” and “substantial evidence” standards for questions of judicial and jury factfinding.⁴⁸ Notwithstanding this highly deferential standard, one study found that the Federal Circuit affirmed district court denials of injunctions only 53% of the time, whereas it affirmed grants 88% of the time.⁴⁹ This may suggest that appellate judges substitute their views of the equities for those of trial judges.

In theory, the *eBay* standard appears to conflate the first and second requirements of its test, for irreparable injury and inadequacy of monetary damages.⁵⁰ Where such damages are adequate (which at least sometimes may be the case for an ongoing royalty), no irreparable injury should be found. In practice, the *eBay* test generally has been applied to reject injunctive relief when asserted by NPEs (sometimes referred to as, or some of which may be, patent assertion entities or PAEs) or against non-competitors, given that royalty awards would

⁴⁶ See *eBay*, 547 U.S. at 391.

⁴⁷ *Id.* Cf. Edward D. Manzo, *Injunctions in Patent Cases After eBay*, 7 JOHN MARSHALL REV. INTELL. PROP. L. 44, 49-53, 95 (2007) (discussing Federal Circuit cases decided shortly after *eBay* that failed to take a position on whether a presumption of irreparable harm from patent infringement survived the Supreme Court decision, and district court decisions that took conflicting positions on that question; “While courts fall on both sides of the question, the better reasoned view appears to be that the presumption has no continued viability.”).

⁴⁸ See, e.g., Fed. R. Civ. P. 52(a)(6); Kevin Casey, *et al.*, *Standards of Appellate Review in the Federal Circuit: Substance and Semantics*, 11 FED. CIR. B.J. 279, 286 (2001) (“The most lenient standard of review is abuse of discretion. Abuse of discretion may be found when: (1) the tribunal's decision is clearly unreasonable, arbitrary, or fanciful; (2) the decision was based on an erroneous conclusion of law; (3) the tribunal's findings are clearly erroneous; or (4) the record contains no evidence upon which the tribunal rationally could have based its decision.”); U.S. Bank National Assn. ex rel. CW Capital Asset Mgmt. v. Village at Lakeridge, LLC, ___ U.S. ___, 138 S.Ct. 960, 965-68 (2018) (describing bifurcated review of mixed questions of the application of law-to-fact, depending on whether they more resemble questions of law and are thus subject to de novo review or questions of fact and are thus subject to the clear error standard).

⁴⁹ See Holte & Seaman, *supra* note 35, at 186-89. Significant variability existed among the Federal Circuit judges regarding their propensity to favor or disfavor injunctions. See *id.* at 189-90. Further, district courts also may stay their own injunctions, sometimes imposing ongoing royalties during the stay. The Federal Circuit similarly may stay injunctions. The same study found stays to be granted in only 24% of granted injunctions, with district courts granting stays roughly four times as frequently, and PAEs obtaining stays for 75% of granted injunctions. See *id.* at 182-83.

⁵⁰ See, e.g., Gergen *et al.*, *supra* note 20, at 207-08.

generally be considered adequate to remedy the harm that such patent holders incur.⁵¹ Whether and when compensation should be viewed as adequate to remedy the harms incurred by practicing patent holder from infringing competitors is therefore a critical but theoretically unresolved issue, resolution of which may depend on differing views as to the ability to monetize the kinds of harms incurred and as to whether patents should be viewed as a kind of property requiring property remedies or as only requiring liability remedies.⁵²

“[M]any courts have openly recognized *eBay* as disruptive, in particular by requiring the abrogation of previously settled presumptions in favor of an injunction, including presumptions that continuing rights violations entail irreparable injury.”⁵³ Before *eBay*, irreparable injury was “often found when the dispute concern[ed] a unique item, such as a parcel of land or an heirloom, when a Constitutional right such as freedom of speech or the right to vote [we]re abridged, when the defendant ha[d] engaged in repeated acts requiring multiple suits to resolve, or when monetary relief [wa]s either difficult to collect or measure.”⁵⁴ In suits against competitors:

the patentee stands to lose substantial market share, suffer price erosion and lose customer goodwill if the infringing activity is permitted to continue. Other factors supporting a finding of irreparable harm post *eBay* include loss of jobs, the infringer’s inability to pay monetary damages, encouragement of other infringers to enter the market, and a patented product with a short market life.⁵⁵

U.S. district courts therefore often, but not always, find irreparable injury from such competitor injuries, even if economists, the parties, and courts can in fact value such losses to establish ongoing royalty injunctions.⁵⁶

The premise of being able to set an ongoing royalty rate would seem to suggest that monetary relief for these kinds of harms is possible to measure and thus that the harms from patent

⁵¹ See Seaman, *supra* note 41, at 1986-89 (PAEs obtained injunctions in 16% of cases compared to 80% for all other patent holders; of the 16% some were from formerly operating entities that had become PAEs); *id.* at 1990-91 (injunctions awarded against competitors about 84% compared to 21% against non-competitors). Cf. *eBay*, 547 U.S. at 396 (Kennedy, J., concurring) (“In cases now arising trial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases. An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.”); *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1314 (Fed. Cir. 2007) (“Under some circumstances, awarding an ongoing royalty for patent infringement in lieu of an injunction may be appropriate”).

⁵² See, e.g., Holte & Seaman, *supra* note 35, at 190-91 (attributing former Chief Judge Rader’s affirmance rate for grants of injunctions and reversal rate for denials of injunctions to his views of patents as conveying rights of exclusion);

⁵³ *Gergen et al.*, *supra* note 20, at 215-16. See *Robert Bosch, LLC v. Pylon Mfg. Co.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011) (“*eBay* jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief.”). Cf. *Gergen et al.*, *supra* note 20, at 232-37 (discussing various presumptions under real property and contract law relating to findings of irreparable injury or lack thereof).

⁵⁴ Jorge Contreras, *Injunctive Relief in U.S. Patent Cases*, in *INJUNCTIONS IN PATENT LAW 4* (Rafal Sikorski ed. 2018), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2845036 (citing 1 DAN B. DOBBS, *DOBBS LAW OF REMEDIES* 58 (2nd ed., West Publ. 1993)).

⁵⁵ *Id.* at 9.

⁵⁶ Compare, e.g., *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 731 F. App’x 962, 975 (Fed. Cir.), *vacated in part*, 729 F. App’x 936 (Fed. Cir. 2018) (“The district court found that Endo will likely suffer irreparable harm relying on, among other things, its subsidiary findings that: (1) Actavis’s generic version of OPANA[®]ER infringed Endo’s patents; (2) Endo and Actavis are direct competitors in the oxymorphone market; and (3) the introduction of additional generics into the market has led Endo to suffer past harms (losing its market share, cutting its sales force, reducing its promotional expenses, and changing its research and development strategies)—which would continue unabated in the absence of an injunction—and, relatedly, that Endo is also at risk of intangible harms such as ‘reputational, organizational, and administrative.’”) with J. Gregory Sidak, *Ongoing Royalties for Patent Infringement*, 24 TEX. INTELL. PROP. L.J. 161, 165 (2016) (“when determining an ongoing royalty, courts can adopt a modified version of the hypothetical-negotiation framework typically used to calculate the reasonable royalty for past infringement”).

infringement (as opposed to stopping adjudicated or potential infringement of pharmaceutical patents) are never irreparable.⁵⁷ This view appears to be similar to approaches in jurisdictions such as India, where permanent injunctive relief is rarely arrived at (due to delays in concluding patent infringement trials)⁵⁸ and where interim injunctive relief often has been denied when the patent holder had not worked the patent in the jurisdiction (notwithstanding the ability to seek a compulsory license) and where the public's interest in affordable access to pharmaceuticals has been recognized to outweigh the patent holder's interest in precluding potential infringement.⁵⁹ But whether such prospective compensation should be viewed as "adequate remuneration" to recoup research and development investments and to provide adequate incentives is precisely the kind of dispute that faces compulsory licensing.⁶⁰ Accordingly, the issue is highly controversial, and theoretical and political resolution of the differing viewpoints has proved difficult to achieve.⁶¹

Further, *eBay* appears to require, when deciding whether to grant a permanent injunction, that judges must "separately assess[]" all four "prongs" of its test, and that each prong must be established by the patent holder's proofs. In contrast, earlier equity cases required a balancing of various "factors" that could "be weighed with or against one another."⁶² Under *eBay*, public interest concerns therefore need not be weighed against the degree of irreparable harm, the inadequacy of a damages remedy, or the balance of hardships in order to deny such relief.⁶³ As a result, even in competitor suits and even when irreparable injury has been found, permanent injunctions have been frequently denied in the medical device context, based on the balance of hardships or on the public interest in access.⁶⁴

Nevertheless, and counterintuitively given the public's substantial interest in access to medicines, permanent injunctions have to date more routinely been granted for biotechnological and pharmaceutical inventions than for inventions in all other technology sectors.⁶⁵ The public interest factor would seem to suggest a different result based on the need for access, more similar to the need for access to medical devices, even if the costs of pharmaceutical development and regulatory approval may be much greater and even if an

⁵⁷ See, e.g., *Sidak*, *supra* note 56, at 183-211 (discussing in detail a method of calculating a bargaining approach, based on a patent holder's willingness to accept continuing infringement, for calculating ongoing royalties); *Vectura Ltd. v. GlaxoSmithKline, LLC*, Civ. Act. No. Civil Action No. 16-638-RGA, 2019 WL 4346502, at *7 (D.Del. Sept. 12, 2019) ("[T]o determine the ongoing royalty rate, courts have used the *Georgia-Pacific* factors.") (citing *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), *mod. and aff'd*, 446 F.2d 295 (2d Cir. 1971)). Cf. *Innovation Ventures LLC v. Ultimate Lifestyles, LLC*, No. CIV.A 4:08-CV-232, 2009 WL 1490588, at *2 (E.D. Tex. May 27, 2009) ("[D]ifficulty in calculating damages is not enough to show irreparable harm. An injury is 'irreparable' only if it cannot be undone through monetary remedies."). See generally Mark A. Lemley, *The Ongoing Confusion over Ongoing Royalties*, 76 Mo. L. Rev. 695 (2011).

⁵⁸ See, e.g., *Pai*, *supra* note 24, at 25 ("In India, suits rarely reach the stage of a permanent injunction, as it can only be granted after a full completion of trial.").

⁵⁹ See *supra* notes 24-28 and accompanying text.

⁶⁰ See, e.g., David Shore, *Divergence and Convergence of Royalty Determinations between Compulsory Licensing Under the TRIPS Agreement and Ongoing Royalties as an Equitable Remedy*, 46 Am. J. L. & Med. 55, 58 (2020) ("TRIPS compulsory licenses and ongoing royalties arise under independent legal frameworks, but necessarily invoke parallel economic considerations.").

⁶¹ See, e.g., Rosa Castro Bernieri, *Compulsory Licensing and Public Health: TRIPS-Plus Standards in Investment Agreements* 29, 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2101574 ("[F]rom an economic point of view, the result [of an ongoing royalty injunction arguably authorized by Article 44 of the TRIPS Agreement and therefore not subject to Articles 30 or 31] is equivalent to a compulsory license. As a result, one of the most contentious aspect of compulsory licenses remains the appropriate measure of compensation for patentees....").

⁶² *Seaman*, *supra* note 41, at 1990-91.

⁶³ See, e.g., *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) ("Here, the district court concluded that issuing a permanent injunction would disserve the public interest. Despite that finding, the court issued a permanent injunction.... That was in clear violation of *eBay*.").

⁶⁴ See *Seaman*, *supra* note 41, at 1990-91. See also *Holte & Seaman*, *supra* note 35, at 201 (noting Federal Circuit judges' predilections not to enjoin medical device infringement, likely based on the public interest factor).

⁶⁵ See *Seaman*, *supra* note 41, at 1984-85 (injunctions granted 85% of the time for pharmaceuticals and 100% for biotechnology, although the latter was a sample of 4).

ongoing royalty might be viewed as inadequate to address the harms.⁶⁶ This result therefore likely reflects the fact that few cases have arisen in the context of public health emergencies, that cases in the pharmaceutical sector are not normally brought by NPEs, and that to date most U.S. judges have tended to view the harms to such patent holders as irreparable and to prioritize protecting innovation incentives for pharmaceuticals over public health needs.⁶⁷

There are very few cases after *eBay* in which injunctions against continuing infringement have been denied in the U.S. for pharmaceutical or biotechnology patents. Denials of permanent injunctions in the pharmaceutical sector usually occur in the context of related generic drug approval litigation under the “Hatch-Waxman Act.”⁶⁸ That Act provides linkages between the drug regulatory approval system and the patent system. Specifically, the Act provides that a court shall enjoin the Food and Drug Administration (FDA) from approving a generic drug product until after the patent expires or for 30 months (which can be shortened or extended by the court). The 30 month stay applies if the generic applicant seeks earlier approval and certifies a lack of infringement or invalidity, and if the patent holder then sues for infringement within 45 days of receiving a required notice from the generic applicant.⁶⁹ Further, if such a suit is filed by the patent holder, the court “shall order the effective date of any approval of the drug ... involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.”⁷⁰ Because of the 30 month stay provision, preliminary injunctions against potential infringement by generic competitors are not normally needed during litigation on the merits of infringement and invalidity.

Any permanent injunctive relief denials in pharmaceutical cases thus are typically based on the merits of the patent infringement determination or invalidity challenge (although some generic competitors may conditionally admit infringement if the patent is held to be valid). Denials are rarely based on the public’s interest in accessing the commercialized competitive

⁶⁶ See *id.* (injunctions granted for only 65% of the time for medical devices). Cf. *id.* at 2005 (pharmaceutical and biotechnology “industries also have extremely high research and development costs, running into the hundreds of millions of dollars in some cases”). But cf. *Amgen, Inc.*, 872 F.3d at 1381 (“eliminating a choice of drugs is not, by itself, sufficient to disserve the public interest. Under such an approach, courts could never enjoin a drug because doing so would always reduce a choice of drugs.... [A]n accused infringer cannot escape an injunction merely by producing infringing drugs.”). As the reduction of choice of goods is inherent in any permanent injunction, this argument would appear to prove too much, eliminating any consideration of the public’s interest in receiving alternative drugs, particularly at affordable prices.

⁶⁷ See, e.g., *Alcon, Inc. v. Teva Pharms. USA, Inc.*, 2010 WL 3081327, Civ. No. 06–234–SLR, at *3 (D.Del. Aug. 5, 2010) (denying injunction based on lack of irreparable harm; noting that “there is a ‘significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents’”) (quoting *Abbott Labs. v. Sandoz, Inc.* 544 F.3d 1363 (Fed. Cir. 2008)). Cf. *Manzo, supra* note 47, at 95 (“On the public interest factor, district judges have wide discretion and hold varying opinions on whether the public interest is best served by enjoining further infringement, thereby to strengthen the patent system and discourage infringement in general.”). But cf. *Shore, supra* note 60, at 59 (“licenses designed to benefit only underserved sectors of a national market would serve humanitarian ends without disrupting patentees’ established interests... [H]umanitarian purposes should number among the factors considered [for] ongoing royalty determinations in the U.S.”).

⁶⁸ Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417, 98 Stat. 1585 (1984).

⁶⁹ See, e.g., 21 U.S.C. § 355(j)(5)(B)(iii) (2019) (30-month stay of approval, subject to court equitable order to lengthen or shorten that period); *Bayer Pharma AG v. Watson Labs., Inc.*, Civ. Act. No. 12–1726–LPS, Civ. Act. No. 12–1726–(LPS)(CJB), 2016 WL 7468172, at *1–*2 (D. Del. Dec. 28, 2016) (denying an injunction of the competitor and holding that: (1) 35 U.S.C. § 271(e)(4)(A) already required an injunction to the FDA prohibiting generic marketing before expiration of the patent; (2) the patent holder had not provided sufficient evidence that any pre-commercialization activities not excluded from being considered infringement under § 271(e)(1) would result in irreparable harm or that a damage remedy for such infringement – including additional litigation fees if needed – would prove inadequate; (3) the balance of hardships favored an injunction; and (4) the public interest slightly favored an injunction when balancing the slightly earlier launch of a generic against the corresponding loss of patent protection and investment incentive); *Valeant Int’l. (Barbados) SRL v. Watson Pharms., Inc.*, No. 10-20526-CIV-MORENO, at *3 (S.D. Fla. July 9, 2012) (denying injunction given that the court’s earlier declaratory judgment “prohibit[ed] Watson from marketing its proposed bupropion hydrobromide products prior to the expiration of Valeant’s Orange Book patents”). If the patent holder does not file suit within that time frame, the generic may bring a declaratory judgment action. See 35 U.S.C. § 271(e)(5) (2019).

⁷⁰ 35 U.S.C. § 271(e)(4)(A) (2019).

product or on an assessment that the harm is not irreparable (particularly given that the pharmaceutical patent holder is not normally an NPE for which a royalty remedy might more readily be considered adequate). Nevertheless, one district court has held in a pharmaceutical case that the public interest supported denying an injunction against some forms of infringement after reaching the merits of the patent, even though commercialization had been banned under the provisions of the Hatch-Waxman Act, as the effect of such an injunction “would be to deprive the public of the benefit of [the competitor’s earlier] developmental efforts” to bring a generic drug at lower prices to the market at an earlier date after patent expiration.⁷¹

Similarly, in regard to the public’s interest in access, one district court in a non-pharmaceutical, biotechnology case held that the public interest would not be served by granting an injunction against supplying plant-produced omega-3 fatty acids, which provide public health benefits.⁷² This was because “at most 45% of the market demand shortfall for all fish food products could be met if the [infringer] competed.”⁷³ Significantly, the district court noted that the “Proponents [of an injunction] argue that the public interest calls for an injunction to maintain the public confidence in the patent system.... Such an argument overlooks the Proponents’ burden to prove that an injunction is not a disservice to the public’s best interest.”⁷⁴ The need for access would appear to be a particularly relevant concern in the case of supply shortfalls of needed pharmaceuticals, biologics, or medical devices in a public health emergency.⁷⁵

B. Preliminary Injunctions

Unlike permanent injunctions, preliminary injunctions (and *ex parte* temporary restraining orders) are specifically authorized by the Federal Rules of Civil Procedure, Rule 65, as well as being generally authorized under Section 283 of the Patent Act.⁷⁶ As with permanent injunctions, preliminary injunctions in the U.S. are assessed under a four-prong test, each prong of which must be satisfied.⁷⁷ But instead of considering the adequacy of remedies at

⁷¹ *Alcon, Inc.*, 2010 WL 3081327, at *3 (D. Del. Aug. 5, 2010). See *id.* at *1-3 (also finding a lack of proof of irreparable harm, given relief requested under 35 U.S.C. § 271(e)(4)(A), of inadequacy of damages, or of the balance of hardships favoring the injunction).

⁷² *BASF Plant Science, LP v. Commonwealth Scientific and Industrial Research Organization*, C.A. No. 2:17-CV-503-HCM, 2019 WL 8108116 (E.D. Va. Dec. 23, 2019).

⁷³ *Id.* at *20. Further, the district court held that the plaintiff had not shown irreparable harm, inadequacy of damages, or that the balance of hardships would tilt in favor of granting an injunction or an excessive ongoing royalty, given the competitor’s investments. See *id.* at *17-20.

⁷⁴ *Id.* at *20.

⁷⁵ *Cf. Verinata Health, Inc. v. Ariosa Diagnostics, Inc.*, 329 F.Supp.3d 1070, 1122 (N.D. Cal. 2018) (noting in regard to a medical diagnostic invention that “much like the defendants in *Novozymes* who did not practice or license their patent, Illumina does not currently practice the ... patent. Consequently, this Court similarly holds that granting a permanent injunction could disserve the public interest or at the very most is neutral.”) (citing *Novozymes A/S v. Danisco A/S*, No. 10-CV-251-BBC, 2010 WL 3783682 (W.D. Wis. Sept. 24, 2010)), *den. of injunction aff’d* ___ Fed. Appx. ___, 2020 WL 1970571 (Fed. Cir. Apr. 24, 2020); *id.* at 1118-22 (also holding that the licensing patent holder would not be irreparably harmed, that a damage remedy would be adequate, and that the balance of hardships was neutral and did not favor injunction).

⁷⁶ See Fed. R. Civ. P. 65(a)&(b); 35 U.S.C. § 283 (2019). Temporary restraining orders are normally limited to 14 days, but extensions may be granted, and if granted *ex parte* the preliminary injunction hearing must be set for the earliest possible time, and the adverse party also may seek to dissolve the order. See Fed. R. Civ. P. 65(b)(2),(3)&(4).

⁷⁷ See, e.g., *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1166 (Fed. Cir. 2014) (“a plaintiff must prove each element of the preliminary injunction test to prevail at the district court”). At an earlier time, the Federal Circuit appears to have permitted some balancing of the various factors, rather than requiring proof of each of the various prongs. See, e.g., 7 CHISUM, *supra* note 43, at § 20.04 (“a preliminary injunction decision is ‘a matter of equity’ and requires ‘an evaluation and balancing of’ four factors”) (quoting *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 (Fed. Cir. 1990)); Stephen E. Shapiro, *Preliminary Injunction Motions in Patent Litigation*, 33 IDEA 323, 329 (1993) (“district court must balance each of these factors against the others and against the magnitude of the relief requested”) (citing *Chrysler Motor Corp. v. Auto Body Panels, Inc.*, 908 F.2d 951, 952 (Fed. Cir. 1990)). Further, the Federal Circuit’s standards for preliminary injunction have varied over time; accordingly, reliance on earlier precedents – particularly those preceding *eBay* – is suspect, even though the

law as a separate prong (which as noted above is essentially redundant with considering the existence of irreparable harm, so it gets considered as part of the irreparable harm inquiry), the preliminary injunction standard considers the likelihood that the requestor will prevail on the merits of its infringement claim.

The Supreme Court recently summarized the standard for granting preliminary injunctions, outside of the patent context, in its 2018 decision in *Benisek v. Lamone*.⁷⁸ The Court quoted and reiterated its earlier, 2008 decision in *Winter v. United States*⁷⁹ articulating the four-part standard and the burden on the requestor. In earlier cases, the Court had held that, as with permanent injunctions, the grant or denial of a preliminary injunction is a matter for the equitable discretion of the trial court and is reviewed by the appellate court for an abuse of discretion.⁸⁰ In addition, the Federal Rules of Civil Procedure provide that “in granting or refusing an interlocutory injunction, the district court must ... set forth the findings and conclusions that support its action,” given that the grant or denial of a preliminary injunction normally is immediately appealable.⁸¹ If a preliminary injunction is granted, the patent holder also must post a bond to protect the alleged infringer in case the preliminary injunction was wrongfully granted.⁸²

Box 4: U.S. *Winter* Standard for Preliminary Injunctions Applied to Patents

A preliminary injunction is “an extraordinary remedy never awarded as of right.”

The patent holder must demonstrate

- (1) that it “is likely to suffer irreparable harm in the absence of preliminary relief”;
- (2) “a likelihood of success on the merits” of its infringement claim, considering potential validity and other defenses;
- (3) that, “considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted”; and
- (4) that “an injunction is in the public interest”

The decision to grant or deny a preliminary injunction is reviewed for an “abuse of discretion.”

Federal Circuit’s own rules require that the earliest panel precedent controls in the event of conflict, absent abrogation by en banc decision or superseding Supreme Court precedent. *See, e.g.,* Shapiro, *id.*, at 329 (“Since its institution, the Federal Circuit has taken great steps to lessen the burden of patentees seeking preliminary injunctions.... Attributing the once stricter standard to an unfamiliarity with patent issues and an unfounded belief that the ex parte examination by the Patent and Trademark Office is inherently unreliable, the Federal Circuit has stated that the standards applied in patent cases should be no more stringent than in non-patent cases. In fact, if anything, the standards currently applied in patent cases are less stringent than in non-patent cases and the trial courts have shown an increased willingness to issue preliminary injunctions to stop patent infringement. One trial court recently opined that in patent infringement cases ‘the preliminary injunction carries more importance than in other cases.’”) (citation omitted); *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305, 1316 (Fed. Cir. 2013) (en banc) (earliest panel precedent controls).

⁷⁸ *Benisek v. Lamone*, ___ U.S. ___, 138 S. Ct. 1942 (2018).

⁷⁹ *See Benisek*, 138 S.Ct. at 1943–44 (quoting *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20, 24, 32 (2008)).

⁸⁰ *See, e.g.,* *Ashcroft v. Am. Civ. Liberties Union*, 542 U.S. 656, 664 (2004).

⁸¹ Fed. R. Civ. P. 52(a)(2). *See* 28 U.S.C. § 1292(a)(1) (2019).

⁸² *See* Fed. R. Civ. P. 65(c) (“the movant [must provide a] security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained”).

The Federal Circuit's preliminary injunction standard for patents now generally follows the Supreme Court's *Winter* approach.⁸³ Further, the evidentiary burdens regarding various issues regarding the likelihood of success (on various infringement and validity issues) track those established by Supreme Court and Federal Circuit precedents for patent infringement trials.⁸⁴ As with permanent injunctions, the Federal Circuit's review standard for preliminary injunctions is an abuse of discretion.⁸⁵

Determining likelihood of success in proving infringement and defending against invalidity requires consideration of the many issues that can arise in patent litigation, under the applicable Supreme Court and Federal Circuit precedents. However, because the grant or denial of a preliminary injunction is not specific to patent law, the Federal Circuit in patent cases reviews the non-patent-law-specific district court determinations under the law of the relevant regional Circuit Court of Appeals where the district court is located. Those Courts of Appeals generally follow the same approach to granting preliminary injunctions as does the Federal Circuit. However, their approaches may vary slightly from that of the Federal Circuit in regard to the required strength of the evidentiary showing under each prong of the four-part preliminary injunction test, or in regard to how each prong is framed for analysis as a positive or as a negative showing (e.g., whether the public interest will be served or will not be disserved by the grant).⁸⁶

⁸³ See, e.g., *OrthoAccel Techs., Inc. v. Propel Orthodontics, LLC*, 785 F. App'x 871, 874 (Fed. Cir. 2019) (four-prong test and abuse of discretion review standard) (citing *Winter*, 555 U.S. at 20; *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 629 (Fed. Cir. 2015), and *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1345 (Fed. Cir. 2008)); *Mylan Institutional LLC v. Aurobindo Pharma., Ltd.*, 857 F.3d 858, 865 (Fed. Cir. 2017) (Patent holder "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.") (quoting *Winter*, 555 U.S. at 20). Cf. *Hoffman La-Roche Inc. v. Apotex, Inc.*, 496 Fed. Appx. 46, 50 (2012) (Patent holder "had to establish a right to a preliminary injunction in light of four factors: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if a preliminary injunction is not granted; (3) the balance of hardships tipping in its favor; and (4) the impact of the injunction on the public interest.") (emphasis added). At an earlier time, however, the Federal Circuit imposed more strict standards on parties seeking a preliminary injunction. See, e.g., 7 CHISUM, *supra* note 43, at § 20.04 ("The patent owner must establish (1) a strong probability of success on the merits at the final hearing, and (2) irreparable injury. In patent cases, the courts require a particularly strong showing of probable success. Many decisions required the plaintiff to establish the elements of validity and infringement 'beyond question.' (More recently, the Federal Circuit has ruled that the appropriate standard is that of a 'clear showing,' not of 'beyond question.'") (citations omitted).

⁸⁴ See, e.g., *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1375 (Fed. Cir. 2018) ("the evidentiary burdens at the preliminary injunction stage track the burdens at trial"); *Hoffman La-Roche*, 496 Fed. Appx. 46 at 50 (patent holder bears the "burden to show, in light of the burdens and presumptions that will inure at trial, that it will likely prove infringement and that it will likely withstand any invalidity challenge to the patent"). Some cases place the burden on an alleged infringer to "raise a substantial question of invalidity." *Sciele Pharma. Inc. v. Lupin, Ltd.*, 684 F.3d 1253, 1261 (Fed. Cir. 2012) (emphasis added) (finding abuse of discretion in granting injunction based on district court's improper determination that alleged infringer had failed to raise a substantial question of invalidity). However, in theory, that may only be a burden of production and not a burden of persuasion, and may not require a heightened showing beyond a likelihood of invalidity, given that the preliminary injunction claimant has the burden of showing likelihood of success on the merits. Cf., e.g., PATRICK J. FLINN, HANDBOOK OF INTELL. PROP. CLAIMS & REMEDIES § 6.03 (Westlaw 2020-2 Supp.) ("In making the 'clear showing' of success on validity, the claimant must be prepared to demonstrate both clear infringement--consistent with the traditional burden of proof--as well as a showing that any attacks on validity are likely to fail."). See generally Joshua D. Sarnoff, *Bilcare, KSR, Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Cases*, 25 CARDOZO ARTS & ENT. L.J. 995, 1003-07 (2008) (discussing presumptions shifting burdens of production and of proof).

⁸⁵ See, e.g., *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 629 (Fed. Cir. 2015) ("We review a denial of a preliminary injunction for abuse of discretion."); *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1352 (Fed. Cir. 2012) ("The grant of a preliminary injunction can be overturned 'by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.'") (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed.Cir.1997)).

⁸⁶ See, e.g., *Trebco Mfg.*, 748 F.3d at 1165-66 (citing 9th Circuit cases); *Myco Indus., Inc. v. BlephEx, LLC*, 955 F.3d 1, at *10 (Fed. Cir. Apr. 3 2020) (citing 6th Circuit cases that require consideration of "[w]hether the movant has a strong likelihood of success on the merits" and "[w]hether the issuance of the injunction would cause substantial harm to other") (emphasis added); *Am. Parking Meter Advertising, Inc. v. Visual Media, Inc.*, 848 F.2d

As a matter of litigation practice, preliminary injunctions often precede the detailed development of needed information to assess infringement or invalidity contentions.⁸⁷ However, trial on the merits may be accelerated on issues and combined with hearings on the preliminary injunction.⁸⁸ Particularly in light of the complexities of patent litigation, and given that preliminary injunctions are an extraordinary remedy, district courts may be somewhat more reluctant to grant preliminary relief than to grant permanent injunctions that follow determinations of infringement and lack of invalidity. This is true even when there has been a showing of likelihood of success on the merits for a later trial.⁸⁹ And given that preliminary injunctions are immediately appealable and that errors of analysis of the likelihood of success on the merits will result in the case being returned to the district court for trial,⁹⁰ district courts may be reluctant to grant preliminary injunctions for fear of later appellate reversal.⁹¹ However, as denials of preliminary injunctions also are appealable, parties may seek an interlocutory appeal from either grant or denial so as to obtain case-dispositive determinations on critical issues such as patent claim construction.⁹²

1244, *1 (Fed. Cir. May 3, 1988) (patentee must show “reasonable likelihood of success on the merits” and that the “issuance of the injunction will not *disserve* the public”) (citing *T.J. Smith & Nephew Ltd. v. Consolidated Medical Equip., Inc.*, 821 F.2d 646, 646-47 (Fed. Cir. 1987)) (emphasis added).

⁸⁷ For this reason, judges and academics sometimes propose a rule of minimizing error costs of irreparable harm to the parties in case the preliminary decision turns out to be wrong. See, e.g., Siebrasse *et al.*, *supra* note 11, at 220 (citing *Films Rover Int’l Ltd. v. Cannon Film Sales Ltd.* 780-81 (Ch 1986) (UK) (Lord Hoffmann, J.); *Am. Hosp. Supply Corp. v. Hosp. Prods. Ltd.*, ___ F.2d 508 (7th Cir. 1986) (Posner, J.); and DOUGLAS LAYCOCK, *THE DEATH OF THE IRREPARABLE INJURY RULE* 118-23, 273 (Oxford University Press 1991)).

⁸⁸ See Fed. R. Civ. P. 65(a)(2). It bears noting that validity issues and infringement issues are not bifurcated to separate courts or agencies in the United States, although invalidity may be administratively adjudicated in various post-grant PTO proceedings. See, e.g., 35 U.S.C. § 302 (ex parte reexamination) (2019); 35 U.S.C. § 311 (inter partes review) (2019); 35 U.S.C. § 321 (post-grant review) (2019).

⁸⁹ See, e.g., Seaman, *supra* note 41, at 1976 n.175 (“grants of preliminary injunctions appear to be significantly less frequent than permanent injunctions”) (citing Colleen V. Chien & Mark A. Lemley, *Patent Holdup, the ITC, and the Public Interest*, 98 CORNELL L. REV. 1, 2 (2012)); Contreras, *supra* note 54, at 19 (“[C]ourts have recently begun to deny preliminary injunctive relief when substantial questions have been raised regarding whether a patent claims patentable subject matter... [P]atentable subject matter has become an increasingly important avenue for challenging patents...”). Cf. *id.* at 20 (“[T]he Court’s abolition in *eBay* of the presumption of irreparable harm in patent cases appears to be applicable to preliminary, as well as permanent, injunctions.”); NIMMER & DODD, *MODERN LICENSING LAW*, *supra* note 45, at § 11.52 (After *eBay*, “we cannot fathom why the Supreme Court would be any more tolerant of allowing the finger of presumption to be placed on the equitable scales in preliminary injunction cases than it was in permanent injunction cases. In fact, we think that allowing a presumption of harm in a preliminary injunction context may be even less satisfactory than in the context of a permanent injunction, for while the showing of infringement may be strong, the merits themselves have not been fully adjudicated.”).

⁹⁰ See, e.g., *Indivior v. Dr. Reddy’s Labs., SA*, 752 Fed. Appx. 1024, 1027-35 (Fed. Cir. 2018) (vacating injunction based on erroneous claim construction that had led district court to improper view of likely success on the merits, without considering any other preliminary injunction factors, and remanding for further proceedings).

⁹¹ In contrast, courts may need to invest less effort in denying preliminary injunctions, as the patent holder’s failure on any of the four prongs should terminate further analysis. See, e.g., JOHN GLADSTONE MILLS III ET AL., *PATENT LAW BASICS* § 20.90 (Westlaw Nov. 2019 Update) (“a more limited analysis may support a trial court’s denial of a motion for a preliminary injunction”). Further, courts may be wary of placing burdens on defendants at early stages of litigation, parties may be more reluctant to seek preliminary injunctions given the need to post bonds, and defendants have a lower burden of proof in contesting validity (given the “substantial question” standard as opposed to the “clear and convincing” proof standard at trial). See Contreras, *supra* note 54, at 21-22; *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 95 (2011) (“We consider whether [35 U.S.C.] § 282 [creating a presumption of validity for issued patents] requires an invalidity defense to be proved by clear and convincing evidence. We hold that it does.”). *But cf.* *KSR Intern. Co. v. Teleflex, Inc.*, 550 U.S. 398, 426 (2007) (“We need not reach the question whether the failure to disclose Asano during the prosecution of Engelgau voids the presumption of validity given to issued patents, for claim 4 is obvious despite the presumption. We nevertheless think it appropriate to note that the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished here.”); Sarnoff, *supra* note 84, at 1009 (“It would ... make little sense to require a higher burden of production to rebut the presumption than the burden ultimately established to persuade the factfinder. But whether the clear and convincing burdens of production and proof are warranted is highly debatable.”).

⁹² See, e.g., MILLS III ET AL., *supra* note 91, at § 17.9 (WL On-line ed. Nov. 2019 Update).

As with permanent injunctions, the *eBay* decision changed judicial views about the circumstances that would warrant granting preliminary injunctions. The *eBay* decision thus has affected the frequency of granting and of seeking preliminary injunctive relief. As one study found, in the six years prior to *eBay* preliminary injunction motions were granted by the district courts 23% of the time, and in the six years after *eBay* only 19% of the time.⁹³ As the same study indicated, both permanent and preliminary injunctions were sought in substantially fewer cases following *eBay*.⁹⁴ This likely reflects the recognition by lawyers of the change to the legal standard affected by *eBay*,⁹⁵ and therefore patent holders seek such extraordinary remedies only where they can make stronger showings under the relevant factors. Finally, in regard to irreparable harm, some decisions have required proof of a causal nexus between the harm alleged and the alleged infringing conduct.⁹⁶

In particular regard to irreparable harm from alleged infringement, some cases have held that irreparable harm is not demonstrated by various factors that typically are argued by patent holders as a basis for why compensation would be difficult to measure or inadequate. For example, in *Altana Pharma AG v. Teva Pharms. USA, Inc.*,⁹⁷ the district court had denied a preliminary injunction where the patent holder had claimed “irreparable harm from price erosion, loss of market share, loss of profits, loss of research opportunities and possible layoffs.”⁹⁸ The district court rejected that the claimed losses were irreparable, given that the patent holder and its exclusive licensee had known for over three years that Hatch-Waxman stays of generic competition would be expiring and that the companies must have had a business plan in place to address that result.⁹⁹ Further, and of greater relevance, the district court held that:

a movant does not establish irreparable harm by arguing loss of revenue and loss of research and development opportunities where money damages are calculable and the defendants have the ability to pay any damages award.... “If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make that same claim and thus be equally entitled to a preliminary injunctive relief. Such a rule would convert the ‘extraordinary’ relief of a preliminary injunction into a standard remedy available whenever the plaintiff has shown a likelihood of success on the merits.”... “[N]either the difficulty of calculating losses in market share, nor

⁹³ See Contreras, *supra* note 54, at 48 (citing Kirti Gupta & Jay P. Kesan, *Studying the Impact of eBay on Injunctive Relief in Patent Cases* (Working Paper No. 17-03, July 10, 2015)).

⁹⁴ Kirti Gupta & Jay P. Kesan, *Studying the Impact of eBay on Injunctive Relief in Patent Cases*, at 14-16 (Hoover IP² Working Paper No. 17004 version, Jan. 10, 2017), at <https://hooverip2.org/wp-content/uploads/ip2-wp17004-paper.pdf>.

⁹⁵ *Cf. id.* at 16 (“[W]e conclude that the overall rate of preliminary and permanent injunctions, measured as a percentage of the total number of cases filed has decreased post- *eBay*, and that this drop has primarily resulted from fewer plaintiffs seeking an injunction in the first place.”).

⁹⁶ See, e.g., *Mylan Institutional LLC v. Aurobindo Pharma. Ltd.*, 857 F.3d 858, 872-73 (Fed. Cir. 2017) (affirming preliminary injunction and holding district court’s finding of a causal nexus not to be “clear error”).

⁹⁷ 566 F.3d 999 (Fed. Cir. 2009).

⁹⁸ *Id.* at 1010. *Cf. Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (finding irreparable harm notwithstanding third-party price erosion, citing cases finding irreparable harm from price erosion, loss of market position, loss of revenue, goodwill, and research and development support, and loss of market opportunities).

⁹⁹ See *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 532 F. Supp. 2d 666, 683 (D.N.J. 2007) (quoting *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996), and *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991)), *aff’d*, 566 F.3d 999 (Fed. Cir. 2009). See *id.*, 566 F.3d at 1005 (“An appellant carries a heavier burden when seeking to reverse the denial of a preliminary injunction than seeking to reverse the grant of a preliminary injunction.”); *id.* at 1011 (“Here, we find no error in the district court’s findings that these harms are not irreparable to Altana.... The manner in which the district court addressed the credibility of Altana’s argument regarding the impact of generic versions entering the market on Altana’s business was not clearly erroneous.”).

speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial.”¹⁰⁰

The Federal Circuit on appeal in *Altana Pharma AG* found no error in the district court’s holding on irreparable harm, and affirmed the denial of a preliminary injunction.¹⁰¹

In summary, given the early stage of litigation and the burdens of proving both likelihood of success as well as a provisional need for an injunction under the *Winter* standard (given the potential later to seek a permanent injunction if infringement is proven and validity is sustained), and particularly after *eBay*, preliminary injunctions are sought less frequently by patent holders and are awarded less frequently than permanent injunctions. And *eBay* established both for permanent and preliminary injunction decisions that actual or potential infringement of a patent does not create a presumption of irreparable harm to justify the grant of an injunction. Rather, the facts of each case must be carefully scrutinized, and the potential for interim compensation or an ongoing royalty must be considered in order to determine whether any harm would be irreparable. Further, each of the *Winter* or *eBay* factors must be proven by the patent holder seeking a preliminary or permanent injunction, including the public’s interest in access to alternative or lower-cost competing products¹⁰² or to non-competing products.

Nevertheless, to date preliminary injunctions are still frequently granted in pharmaceutical cases (when injunctions granting automatic stays of generic drug regulatory approval would not resolve the issues or are expiring). And permanent injunctions also are normally granted in pharmaceutical cases even though *eBay* eliminated any presumption of an entitlement to the extraordinary remedy of an injunction. Because such issues are committed to the trial judge’s discretion, in theory the *trial judges’* views regarding irreparable harm, the balance of hardships, and the relative importance to the public interest of innovation incentives for and access to patented pharmaceuticals are likely to be dispositive of these preliminary and permanent injunctive relief decisions.¹⁰³ However, in practice *appellate judges* may impose

¹⁰⁰ *Id.* at 683-84 (citations omitted).

¹⁰¹ *Altana Pharma AG*, 566 F.3d at 1011. See *id.* (“the law cited by the district court highlights this court’s deference to a district court’s determination whether a movant has sufficiently shown irreparable harm.”).

¹⁰² *Compare, e.g.,* *Sanho Corp. v. KaiJet Tech. Int’l Ltd., Inc.*, No. 1:18-CV-05385-SDG, 2020 WL 1800372, at *5 (N.D. Ga. Jan. 22, 2020) (“The public interest is further served by the promotion of robust competition in the marketplace.”) (citing *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990), and *Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc.*, 99 F. Supp. 3d 461, 507 (D.N.J. 2015)). with *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) (rejecting public interest argument favoring denial of preliminary injunction based on making low-cost drugs available through competition; “[S]elling a lower priced product does not justify infringing a patent.” And while the statutory framework under which Ranbaxy filed its ANDA does seek to make low cost generic drugs available to the public, it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents.”) (citation omitted).

¹⁰³ See, e.g., *Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 410 (D. Del. 2019) (citation omitted), *aff’d*, 778 F. App’x 135 (3d Cir. 2019) (“No doubt there are important public interests on both sides of the scale here. The public has a strong interest in protecting valid patent rights, particularly as ‘the patent system provides incentive to the innovative drug companies to continue costly development efforts.’... Yet the public also has a strong interest in enforcing contractual rights and encouraging the widespread distribution of life-saving pharmaceuticals to patients in need of them, an interest fostered by careful adherence to the laws permitting approval and marketing of less expensive generic versions of drugs.”) (citation omitted). Cf. Rathod, *supra* note 21, at 3 (discussing the concern for the public interest in access to life-saving drugs in *F. Hoffmann-La Roche Ltd. v. Cipla*, [FAO (OS) 188/2008], which denied an interim injunction); *F. Hoffmann-La Roche, supra*, ¶¶ 72-84 (affirming denial of interim injunction and rejecting argument that the three-year exclusivity period for granting compulsory licenses should preclude denials of injunctive relief) (citing *Novartis AG v. Mehar Pharma*, 2005 (30) PTC 160 (Bom.)); *id.*, ¶¶ 81-83 (“[I]n a country like India where question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for.... [W]hile it may be possible to distinguish the judgment of the US Supreme Court in *E Bay* as relating to a case of permanent and not temporary injunction, the traditional four factor test identified in the said judgment does assume relevance even at the stage of grant of an interim injunction. Given the nature of the drug, in the instant case, which admittedly is a life saving one, the

their own views thereof, or trial judges may conform their views to those of appellate judges so as to avoid potential reversal, notwithstanding the deferential abuse of discretion standard.¹⁰⁴

fourth test identified in E Bay that the grant of an injunction should not result in the public interest being "disserved" would be relevant.... Whether indeed the public interest in the availability of the drug to the public at large is outweighed by the need to encourage research in the invention, would obviously differ from case to case and depend on a host of factors.").

¹⁰⁴ *Cf., e.g., Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) ("[W]e agree with the district court that the public is best served by enforcing patents that are likely valid and infringed.").

SECTION 3: CANADA

Box 5: Canadian Patent Act Section 57(1)

In any action for infringement of a patent, the court, or any judge thereof, may, on the application of the plaintiff or defendant, make such order as the court or judge sees fit, (a) restraining or enjoining the opposite party from further use, manufacture or sale of the subject-matter of the patent, and for his punishment in the event of disobedience of that order, or (b) for and respecting inspection or account, and generally, respecting the proceedings in the action.

Unlike in the U.S., the Canadian patent system provides for exclusive jurisdiction over the validity of patents in a separate court system (the Federal Court of Canada) from the provincial superior courts that can hear infringement actions. However, infringement jurisdiction is concurrent between the Federal Court and the provincial superior courts, and the provisional courts can hold patents invalid as between the parties.¹⁰⁵ Most cases, however, are brought in the Federal Court, and “it is largely the case law of the Federal Court which governs the grant of injunctive relief in patent cases, subject to the guidance of the Supreme Court of Canada.”¹⁰⁶

Section 57(1) of the Patent Act provides for injunctions in patent infringement actions, authorizing any judge to “make such order as the court sees fit), (a) restraining or enjoining” another party from “further use, manufacture or sale” or (b) for an “inspection or account.”¹⁰⁷ As in the United States, injunctive relief is governed by principles of equity originally derived from England, but subsequently articulated by Canadian judicial precedents.

As a former colony of the United Kingdom, Canada has based its legal system on the English common law, and the grant of injunctive relief is based on the English legal tradition of equitable remedies. The discretionary nature of equitable remedies is consistent with the permissive mandate of the statute.¹⁰⁸

¹⁰⁵ See Patent Act, § 54(1)&(2) (R.S.C. 1985, c. P-4) (patent infringement actions “may be brought in that court of record that, in the province in which the infringement is said to have occurred, has jurisdiction, pecuniarily, to the amount of the damages claimed and that, with relation to the other courts of the province, holds its sittings nearest to the place of residence or of business of the defendant,” without impairing the jurisdiction of the Federal Court under Federal Courts Act § 20); Federal Courts Act, § 20(1)(b)&(2) (R.S.C. 1985, c. F-7) (exclusive jurisdiction of the Federal Court over actions “in which it is sought to impeach or annul any patent of invention,” and concurrent jurisdiction with provisional courts over Acts of Parliament or matters “at law or in equity respecting any patent of invention” and other industrial or literary property); Steven Garland, *et al.*, Patent Litigation in Canada: Overview (June 1, 2020), at [https://content.next.westlaw.com/5-621-1843?transitionType=Default&contextData=\(sc.Default\)&firstPage=true&bhcp=1](https://content.next.westlaw.com/5-621-1843?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1) (“The provincial superior courts can also declare a patent or any claim in a patent invalid, but only as between the parties to the litigation”). Appeals from the Federal Court run to the Federal Court of Appeal, and then discretionarily to the Canadian Supreme Court. Federal Courts Act, § 27(1)(a)&(c) (jurisdiction over appeals from final and interlocutory judgments of the Federal Court); Supreme Court Act, § 35 (R.S.C. 1985, c. S-26) (Supreme Court jurisdiction for appeals from Federal Court of Appeal and provisional courts). Supreme Court review requires leave to appeal in patent cases. See *id.* §§ 37, 40(1); 3 STEVEN GARLAND ET AL., THE PATENT LITIGATION LAW REVIEW, CANADA (Nov. 2019), available at <https://thelawreviews.co.uk/edition/the-patent-litigation-law-review-edition-3/1210571/canada>.

¹⁰⁶ Norman Siebrasse, *Flexibility and Tailoring in Canadian Patent Law*, in INJUNCTIONS IN PATENT LAW: TRANS-ATLANTIC DIALOGUE ON FLEXIBILITY AND TAILORING *1 (draft) (Martin Husovec & Jorge Contreras eds. forthcoming).

¹⁰⁷ Patent Act, § 57(1).

¹⁰⁸ Siebrasse, *supra* note 106, at *2.

As with the U.S. Patent Act Section 283, Section 57(1) of the Canadian Patent Act authorizes permanent, interlocutory, and interim (*ex parte*) injunctions. Such injunctions also are authorized under the relevant court's rules.¹⁰⁹ However, judicial precedents establish the principles of equity for when such injunctions are or are not justified.¹¹⁰ Section 57(2) authorizes appeals from injunctions in the same manner as from other judgments or orders of the provincial courts or the Federal Court.¹¹¹

Like in the United States, appellate review of the grant or denial of injunctions is deferential in theory, based on review of the Federal Court's exercise of discretion in considering all of the relevant factors.¹¹² However, the Federal Court of Appeal may substitute its own judgment when the Federal Court has failed to properly "weigh[] relevant factors" or has misunderstood the applicable "principle of law," or has "seriously misapprehended the facts," or if the decision would result in "obvious injustice."¹¹³ In looking at the legal, factual, and mixed-question application of law-to-fact determinations underlying an injunction decision, the reviewing court may look to the "correctness" of the legal standard applied and whether the factual findings or mixed-question applications reflect a "palpable and overriding error."¹¹⁴

Finally, as in the United States under the Hatch-Waxman Act,¹¹⁵ in Canada there are linkages between the drug regulatory approval system and the patent system. This linkage, created by Food and Drug Regulations adopted under the Food and Drug Act, temporarily prohibits

¹⁰⁹ See Patent Act, § 57(1) (authorizing injunctions); Federal Courts Act, § 44 (authorizing injunctions); Federal Court Rules, SOR/98-106, r. 373(1) (June 2, 2020) ("On motion, a judge may grant an interlocutory injunction."); *id.*, r. 374(1)&(2) (authorizing interim injunctions "in a case of urgency, [where] no notice is possible" or where "to give notice would defeat the purpose of the motion" and limiting grants of interim injunctions to 14 days, subject to one further 14-day extension). See also *id.*, r.373(2) (requiring party seeking injunction to abide by any order addressing damages from granting or extending an injunction).

¹¹⁰ See Siebrasse, *supra* note 106, at *3.

¹¹¹ Patent Act, § 57(1).

¹¹² See, e.g., *Merck & Co. v. Apotex Inc.*, 2006 FCA 323, ¶ 68 ("The decision to award an injunction is a discretionary one entitled to considerable deference by this Court. I do not think [the infringer] has succeeded in showing that the Judge's exercise of that discretion warrants our interference. [The alleged infringer] has provided little guidance as to the factors that should have been considered. Moreover, while [the trial judge] does not specifically explain his reasons for awarding an injunction in great detail, the care with which he outlined the remedies section of his reasons militates against a finding that he did not adequately *consider all relevant factors* in awarding the injunction. In particular, the fact that he granted [the infringer] a thirty day grace period before the injunction would take effect shows *he did not award the injunction automatically* and without considerable thought.) (emphasis added); Siebrasse, *supra* note 106, at *2 ("[I]t is perfectly clear, both on the basis of the Act and the traditional equitable nature of injunctive relief, that the grant of injunctive relief to a successful patentee is a matter of discretion, and not a matter of right, and the discretionary nature of injunctive relief is regularly acknowledged by the courts."). Cf. *supra* notes 47-48 and accompanying text (discussing U.S. "abuse of discretion" appellate review standard).

¹¹³ See, e.g., *Apotex Inc. v. Canada (Governor in Council)*, 2007 FCA 374, ¶ 15 ("When the lower court judge has made a discretionary decision, it will usually be afforded deference by the appellate court. However, the latter will be entitled to substitute the lower court judge's discretion for its own if the appellate court clearly determines that the lower court judge has given insufficient weight to relevant factors or proceeded on a wrong principle of law.... This Court may also overturn a discretionary decision of a lower court where it is satisfied that the judge has seriously misapprehended the facts, or where an obvious injustice would otherwise result.") (citing *Elders Grain Co. v. "M/V Ralph Misener" (The)*, 2005 FCA 139, ¶ 13; *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.*, 2005 FCA 50, ¶ 9.)).

¹¹⁴ See *Housen v. Nikolaisen*, 2002 SCC 33, ¶¶ 8, 10, 23, 32-33 ("On a pure question of law, the basic rule with respect to the review of a trial judge's findings is that an appellate court is free to replace the opinion of the trial judge with its own. Thus the standard of review on a question of law is that of correctness.... The standard of review for findings of fact is that such findings are not to be reversed unless it can be established that the trial judge made a 'palpable and overriding error'.... it is only where the *inference-drawing process itself* is palpably in error that an appellate court can interfere with the factual conclusion.... the numerous policy reasons which support a deferential stance to the trial judge's inferences of fact, also, to a certain extent, support showing deference to the trial judge's inferences of mixed fact and law.... Where, however, an erroneous finding of the trial judge can be traced to an error in his or her characterization of the legal standard, then this encroaches on the law-making role of an appellate court, and less deference is required, consistent with a 'correctness' standard of review.)).

¹¹⁵ See *supra* notes 68-70 and accompanying text.

generic market entry and thus functions to make interlocutory injunctions unnecessary in most cases. Specifically, under the current Canadian Patented Medicines Notice of Compliance (PM(NOC)) regime, a generic pharmaceutical producer cannot gain marketing approval unless it first challenges patents listed for the reference product. If the reference product patentee responds, that action then triggers an automatic 24 month stay of such approval.¹¹⁶ Thus, there are relatively few cases regarding the standards for interlocutory injunctions in pharmaceutical cases.¹¹⁷

A. *Permanent Injunctions*

The actual standard for granting permanent injunctions, particularly in patent cases, is somewhat uncertain under Canadian law. Although it is clear that permanent injunctions are a matter of equitable discretion, there is no clear synthesis of the manner in which such discretion is to be exercised in Canadian Supreme Court or Federal Court of Appeal precedents. Nor is it clear that permanent injunctions are subject to a balancing test of multiple factors or to a multi-prong test, each of the prongs of which must be met by the party seeking the injunction. The cases on permanent injunctions seeking to prohibit conduct also do not clearly establish the criteria for establishing that such an injunction is warranted. However, one frequently cited case, *1711811 Ontario Ltd. (Adline) v. Buckley Insurance Brokers Ltd.*, requires the requestor to “establish its legal rights” and for a court to then “determine whether an injunction is an appropriate remedy.”¹¹⁸

Box 6: Canadian 1711811 Ontario, Ltd. (Adline) Standard for Permanent Injunctions

“In order to obtain final injunctive relief, a party is required to establish its legal rights. The court must then determine whether an injunction is an appropriate remedy.”

In most cases, the patent holder is permitted to elect an equitable accounting and to obtain a permanent injunction. Unlike in the U.S., in Canada an equitable accounting of profits is an available remedy and a successful patentee will normally be entitled to elect between an

¹¹⁶ Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.

¹¹⁷ Prior to September 21, 2017, the PM (NOC) Regulations required the patentee to seek an order prohibiting market authorization of the generic, which generic might then seek a stay pending appeal of that order. The prohibition order was routinely granted. The judicial stay request would apply the same legal standard as the standard for interlocutory injunctive relief pending appeal. See, e.g., *Janssen Inc. v. AbbVie Corp.*, 2014 FCA 176, ¶ 18 (a request to stay an order of another body attracts the “tougher” *RJR-MacDonald* test for interlocutory injunctions) (citing *Astrazeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FCA 312; *Epicept Corp. v. Canada (Minister of Health)*, 2011 FCA 209, ¶ 14; *Korea Data Systems (USA) Inc. v. Amazing Technologies Inc.*, 2012 ONCA 756 (Ont. C.A. [In Chambers]), ¶¶ 17-19). As discussed later, the *RJR-MacDonald* test is that applied to interim and interlocutory injunctions. Accordingly, determinations in such earlier linkage cases are relevant to the standards for interim and interlocutory injunctive relief. See Siebrasse, *supra* note 106, at *4 n.16 (citing SOR/2017-166, § 7). However, grant of stays of prohibition orders under the old rules, like grants of interlocutory injunctions, were rare given the difficulty of establishing irreparable harm in the temporary prohibition context.

¹¹⁸ *1711811 Ontario Ltd. (Adline) v. Buckley Insurance Brokers Ltd.*, 2014 ONCA 125, ¶ 79. See *id.* (“In order to obtain final injunctive relief, a party is required to establish its legal rights. The court must then determine whether an injunction is an appropriate remedy. Irreparable harm and balance of convenience are not, per se, relevant to the granting of a final injunction, though some of the evidence that a court would use to evaluate those issues on an interlocutory injunction application might also be considered in evaluating whether the court ought to exercise its discretion to grant final injunctive relief.”); Marie-Andrée Vermette, WeirFoulds LLP, Primer on Permanent, Mandatory, and Interlocutory Injunctions (Sept. 21, 2017), at <http://www.weirfoulds.com/Primer-on-Permanent-Mandatory-and-Interlocutory-Injunctions> (“a party is required to establish: (1) its legal rights; and (2) that an injunction is an appropriate remedy.”) (citing *1711 Ontario Ltd.*, 2014 ONCA 125, ¶¶ 77-80; *Cambie Surgeries Corp. v. British Columbia (Medical Services Commission)*, 2010 BCCA 396 ¶¶ 27-28).

accounting of an infringer's profits and damages.¹¹⁹ These cases do not appear to require the patent holder to establish its entitlement to the equitable remedy of a permanent injunction, having first established that its legal rights have been infringed.¹²⁰ Rather, as with the United States district courts under the Federal Circuit prior to *eBay*, the Canadian federal courts have routinely granted permanent injunctions in patent cases following a determination of infringement and lack of invalidity.¹²¹

The routine granting of permanent injunctions by Federal Court judges occurs even though the legal doctrine recognizes that granting permanent injunctions is a matter of equitable discretion in regard to the specific facts of each case.

While permanent injunctions are routinely granted as a remedy for [patent] infringement, it is clear that they are discretionary in principle, and may be modified or denied entirely.... the Canadian courts are of the view that an injunction will normally follow a finding that a valid patent has been infringed, and a permanent injunction will be refused only in "rare circumstances" with the caveat that an injunction will not normally be granted if there is no realistic prospect of future infringement.¹²²

Nevertheless, a permanent injunction has been refused in at least one patent case based on public interest concerns (although that case is frequently cited before being distinguished, and thus its approach to the public interest has not been followed).¹²³ In *Unilever, PLC v. Proctor & Gamble, Inc.*, the Federal Court refused to award a permanent injunction in light of the court's willingness to grant an ongoing royalty injunction (rather than an accounting of profits, and at a rate higher than the granted reasonable royalty damages for pre-trial infringement). The Federal Court described its ongoing royalty award as "a generous, but non-confiscatory, rate of royalty."¹²⁴ Further, the Court in *Unilever* rejected a prohibitory injunction based in part on public interest considerations.

The fact of the plaintiffs' never having practised the patented invention in Canada, the hardship which an injunction would inflict on the infringing defendants, and also, and especially, on their innocent employees in these hard economic times which still appear to be a full blown recession (*pace* Statistics Canada) in which unemployment insurance benefits payable and the level of unemployment do not need to be expanded, and by contrast, the

¹¹⁹ See, e.g., Siebrasse, *supra* note 106, at *12 ("an accounting of profits is commonly awarded as a remedy for patent infringement."). Although Patent Act Section 57(1) uses "or" in separating what courts may order as equitable remedies, both injunctive relief and an accounting are available.

¹²⁰ See, e.g., Siebrasse, *supra* note 106, at *2; *id.* at *12 & n.66 (citing *Monsanto v. Schmeiser* (SCC 2004, ¶ 104); *Apotex v. ADIR* (FCA 2017, ¶¶ 24-30)). For one case placing the burden of establishing an entitlement to an equitable remedy, see *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234, ¶ 131 ("It is ... necessary for a party seeking an equitable remedy, such as profits, to show some basis for the exercise of equity.").

¹²¹ See, e.g., *Eurocopter v. Bell Helicopter Textron Canada Ltée*, [2006] FC 113, ¶ 397 ("Section 57 of the Act provides the Court with the discretionary power to issue an injunction, which will be commonly granted for an infringement or threatened infringement, unless there is some equitable reason not to do so, such as acquiescence, long delay, lack of clean hands, unconscionability, or triviality. Moreover, the granting of injunctive relief is not only to the benefit of a successful party but it is issued by the Court in the public interest to ensure the enforceability of the Canadian patent system"); *Janssen-Ortho Inc.*, [2006] FC 1234, ¶ 132 ("As to an injunction that remedy normally follows a finding that a valid patent has been infringed.").

¹²² Siebrasse, *supra* note 106, at *2 (quoting *Valence v. Phostech*, [2011] FC 174, ¶240, and citing, *inter alia*, *Merck v. Apotex (lisinopril infringement)*, [2006] Federal Court of Appeal, ¶ 68).

¹²³ See Siebrasse, *supra* note 106, at *11, 24 & n.138.

¹²⁴ *Unilever, PLC v. Proctor & Gamble, Inc.*, 1993 CarswellNat 355, [1993] F.C.J. No. 1005, ¶ 186; See *id.*, ¶¶ 174-86; Siebrasse, *supra* note 106, at *12 ("The Court of Appeal held that in awarding damages in lieu of an injunction, the trial judge "chose a middle ground," between an accounting and a reasonable royalty and he was entitled to do so. Thus, the enhanced damages were awarded essentially as a middle ground between a reasonable royalty, and the other two remedies, an accounting or an injunction, which a successful patentee might normally expect.").

absence of a competing workforce engaged by Lever, are all factors *inter alia* in the exercise of the Court's discretion. No permanent injunction is awarded.¹²⁵

In contrast, only a partial injunction was sought in at least one pharmaceutical patent case (possibly based on public interest concerns). In *AbbVie Corp. v. Janssen, Inc.*, permanent injunctive relief regarding a patented medicine was granted but was limited at the patent holder's request.¹²⁶ The patent holders likely recognized that the Federal Court would not have granted a prohibition in its entirety, although the Court rejected the infringer's request to refuse the injunction pending appeal of the infringement and validity holdings.¹²⁷ The partial exclusion from the injunction avoided preventing continuing sales of a biologic by the infringer to existing and some new patients, where the patent holder did not supply the market with a product that practiced the patent (but rather supplied only competitive products) and where some patients did not respond adequately to the patent holder's product.¹²⁸

Although these cases might suggest that permanent injunctions *should be* refused, particularly if there is a strong public interest, if the patent's term has a limited duration, or if the trial court believes that the harm from continuing infringement can be quantified, to date the courts have continued to grant permanent injunctions in patent cases. Whether Canadian judges in the future will continue to routinely grant permanent injunctions in pharmaceutical patent cases may depend (as discussed in regard to the U.S. history) on whether they continue to view the patent as creating a right to a property-rule remedy, on its views of the competing public interests, and on the ability to adequately measure damages from continuing infringement. Canada has historically been much more willing than the U.S. to legislatively authorize the grant of compulsory licenses.¹²⁹ Particularly after the COVID-19 pandemic, it is possible that the Canadian courts may seek to follow the *eBay* precedent and to find more frequently that permanent prohibitory injunctions should be denied and ongoing compensation granted.¹³⁰ In contrast to the context of permanent injunctions, as discussed below in the context of interlocutory injunctions there is some increasing recognition in Canadian and the United

¹²⁵ *Unilever*, 1993 CarswellNat 355, [1993] F.C.J. No. 1005, ¶ 185.

¹²⁶ *AbbVie Corp. v. Janssen, Inc.*, [2014] FC 489, ¶ 41 ("The Plaintiffs are prepared to allow, as an exception, the continued use of STELARA by existing patients, and the use by new patients in particular circumstances.").

¹²⁷ See *id.*, ¶ 44. Cf. Siebrasse, *supra* note 106, at *21 ("this seems like a compelling case in which a carve-out should be granted and, given the court's concern over the details of the carve-out, it seems likely that a request for a broad injunction without a carve-out would have been refused.").

¹²⁸ See *AbbVie Corp. v. Janssen, Inc.*, [2014] FC 489, ¶¶ 44-53; Siebrasse, *supra* note 106, at *10-*12, *20-*21. Cf. *AstraZeneca AB v. Emcure Pharms. Ltd.*, CS(COMM) 561/2019 (High Court of Delhi) (Jan. 15, 2020), ¶ 50 (denying grant of interim injunction after the patent at issue had expired, while requiring preservation of records up to that date).

¹²⁹ See, e.g., Daphne Lainson & Nancy Pei, *Compulsory licensing in Canada – revisited*, LIFE SCI. INTELL. PROP. REV. (Apr. 21, 2020), available at <https://www.lifesciencesipreview.com/article/compulsory-licensing-in-canada-revisited> ("The Canadian Patent Act has permitted the grant of compulsory licences in four broad circumstances: (i) for a pharmaceutical patent, on application and payment of a nominal royalty (repealed in 1993); (ii) where there has been abuse of patent rights; (iii) for use by the government; and (iv) use for export of pharmaceutical products for humanitarian reasons. The COVID-19 Emergency Response Act grants the Commissioner of Patents the power to authorise use of a patented invention to the extent necessary to respond to a public health emergency. This form of compulsory licensing builds on the existing framework that has allowed government use of a patented invention."). However, as a result of the North American Free Trade Agreement, Canada now requires its government to seek a compulsory license rather than being immune from injunctive relief while requiring payment of compensation. See Patent Act, § 19; Siebrasse, *supra* note 106, at *23.

¹³⁰ Cf. Siebrasse, *supra* note 106, at *3 ("this historical pattern does not necessarily imply that Canadian courts would be unwilling to refuse a permanent injunction in appropriate circumstances. Cases which present the strongest argument for refusing injunctive relief, such as those involving patent assertion entities (PAEs), as in *eBay v. MercExchange* (U.S. 2008), have seldom been litigated to judgment in Canadian courts."); Berryman, *supra* note 17, at 159 ("The U.S. Supreme Court has restored the discretionary nature of the inquiry to grant a permanent injunction in intellectual property disputes, and requires the plaintiff to demonstrate that monetary remedies are inadequate. While there is no similar and definitive statement from Canadian courts, I argue that Canadian law largely mirrors the approach now adopted in the U.S. This approach is to be preferred as the best way to match appropriate remedy to the complex policy choices engaged in regulating intellectual property. It is also an approach to remedies endorsed in other areas of law by the Supreme Court of Canada.").

Kingdom's precedents of the ability to measure the harms from continuing (albeit temporary) infringements, which thus may be remedied by adequate compensation without such harms being viewed as irreparable. However, a similar change of views in regard to permanent injunctions would likely require Canadian judges to change their fundamental attitudes toward the balance of protecting patent holders' innovation incentives and the public's interest in affordable access to medicines.¹³¹ It would also require the courts to be more involved in the supervision of injunctions requiring the payment of ongoing royalty awards.¹³²

B. Preliminary Injunctions

In contrast to the standard for permanent injunctions, the standard for grant or denial of interlocutory injunctions in patent cases in Canada is clear and well-established in the Canadian judicial precedents. As in the United States, the patent holder in Canada must establish its entitlement to an interlocutory injunction against patent infringement prior to trial, and must show that each prong of the test is met.¹³³ In 1994 in *RJR-McDonald, Inc. v. Canada (Attorney General)*, the Supreme Court of Canada established a three-prong, general test for interlocutory injunctions and for judicial stays pending appeal (based on an earlier precedent that adopted the approach of the United Kingdom's House of Lords in *American Cyanamid Co. v. Ethicon, Ltd.*).¹³⁴ Under this test, the court must consider: (1) the merits to determine if there is a "serious question to be tried"; (2) "whether the applicant would suffer irreparable harm"; and (3) the burden of hardships from grant or denial prior to "a decision on the merits."¹³⁵ The *RJR-McDonald* decision further specified that "[a]ny alleged harm to the public interest should also be considered at th[e] final stage."¹³⁶

¹³¹ *Compare, e.g.,* Dableh v. Ontario Hydro, [1996] 3 FC 751, ¶ 51 ("The grant of an injunction after trial to protect a right confirmed by the court is not subject to the same strict criteria as the grant of an interlocutory injunction.") with *Imperial Chemical Industries PLC v. Apotex Inc.*, 1989 CarswellNat 545, [1989] FCA 950, ¶ 13 ("In this Court the grant of an interlocutory injunction in a patent infringement action is not a common occurrence in most instances, the result of an application for an interlocutory injunction, where infringement and validity are in issue, is that the defendant gives a satisfactory undertaking to keep an account and upon that being done the application is dismissed with costs in the cause.... The principal reason for this practice is, in my opinion, the fact that in most instances the nature of the patent rights involved is such that damages (provided there is some reasonably accurate way of measuring them) will be an adequate remedy for such infringement of the rights as may occur pending the trial and because when the matter turns on the balance of convenience if the defendant undertakes to keep an account and there is no reason to believe that he will be unable to pay such damages as may be awarded, the balance will generally be in favour of refusing the injunction. It is always necessary to bear in mind that the damages that can be caused to a defendant in being restrained, for a period that may run into several years, from doing what, if he succeeds, he was, but for the injunction, entitled to do in the meantime, may have consequences that are as serious for him as any that his infringement, if he does not succeed, may have for the patentee.") (quoting *Cutter Ltd. v. Baxter Travenol Laboratories of Can. Ltd.*, [1980] FCA, ¶¶ 53, 55-56).

¹³² *Cf. Siebrasse, supra* note 106, at *22 ("One disadvantage of the carve-out is the need for detailed judicial supervision of the terms of access") (discussing *AbbVie Corp. v. Janssen, Inc.*, [2014] FC 489).

¹³³ *See id.* at *3-4 ("It is a three-part test [based on a U.K. precedent], requiring the applicant to establish that: (1) there is a serious question to be tried on the merits; (2) the applicant would suffer irreparable harm if the application were refused; and (3) the balance of convenience favours granting the injunction.") (citing *American Cyanamid Co. v. Ethicon, Ltd.*, [1975] A.C. 396 (U.K.)); *RJR — MacDonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311, ¶ 41 ("The applicants are only entitled to this relief if they can satisfy the test..."). *But cf. id.*, ¶ 42 ("A careful balancing process must be undertaken.").

¹³⁴ *RJR — MacDonald*, ¶¶ 46, 48-49 ("Generally, the same principles should be applied by a court whether the remedy sought is an injunction or a stay... *Metropolitan Stores* adopted a three-stage test for courts to apply when considering an application for either a stay or an interlocutory injunction.") (citing *Manitoba (Attorney General) v. Metropolitan Stores (MTS) Ltd.*, [1987] 1 S.C.R. 110, adopting the approach in *American Cyanamid Co.*, and rejecting the earlier approach of requiring a "strong *prima facie* case" on the merits). *See American Cyanamid Co.*, [1975] A.C. at 407 ("The court no doubt must be satisfied that the claim is not frivolous or vexatious, in other words that there is a serious question to be tried.").

¹³⁵ *RJR — MacDonald*, [1994] 1 S.C.R. 311, ¶ 48.

¹³⁶ *Id.*, ¶ 62. *See id.*, ¶ 71 ("[E]ither the applicant or the respondent may tip the scales of convenience in its favour by demonstrating to the court a compelling public interest in the granting or refusal of the relief sought. 'Public interest' includes both the concerns of society generally and the particular interests of identifiable groups.").

Box 7: Canadian *RJR-McDonald* Standard for Preliminary Injunctions

“First, a preliminary assessment must be made of the merits of the case to ensure that there is a serious question to be tried.

Secondly, it must be determined whether the applicant would suffer irreparable harm if the application were refused.

Finally, an assessment must be made as to which of the parties would suffer greater harm from the granting or refusal of the remedy pending a decision on the merits....

Any alleged harm to the public interest should also be considered at th[e final] stage.”

Thus, the three-part Canadian test looks remarkably similar to the four-part test for a preliminary injunction in the United States.¹³⁷ The *RJR-McDonald* test has been applied in various patent cases seeking interlocutory injunctions (or a prohibition on generic marketing approvals), pending trial on the merits of infringement and validity.¹³⁸ Unlike in the United States, in Canada under the *RJR-McDonald* standard “[p]reliminary injunctions are essentially never granted.”¹³⁹ Given that “[i]n Federal Court, the hurdle at the second stage, irreparable harm, is very high ... [and a]s almost all patent actions are brought in Federal Court, this means that interlocutory injunctions are almost never granted in patent cases.”¹⁴⁰ However, in generic pharmaceutical cases, the automatic 24-month stay on issuing a notice of compliance has the same effect as a preliminary injunction against market entry and commercialization for the duration of that stay (which usually is sufficient time to reach a judgment on the merits).

Nevertheless, some denials of interlocutory injunctions in the pharmaceutical context are highly instructive regarding the kinds of harms that should *not be* considered irreparable, either for interlocutory or for permanent injunctions, given that these decisions indicate that such harms *can be* quantified.¹⁴¹ Although these cases focus on denials to a generic competitor of a modification of an injunction and to a patent holder’s interim challenge to a notice of compliance, the same considerations would seem to apply if a patent holder were to seek a

¹³⁷ Compare *id.*, ¶¶ 63-64, 67 (“the only issue to be decided [under the second prong] is whether a refusal to grant relief could so adversely affect the applicants’ own interests that the harm could not be remedied if the eventual decision on the merits does not accord with the result of the interlocutory application. ‘Irreparable’ refers to the nature of the harm suffered rather than its magnitude. It is harm which either cannot be quantified in monetary terms or which cannot be cured, usually because one party cannot collect damages from the other.... The third test to be applied in an application for interlocutory relief was described by Beetz J. in *Metropolitan Stores* at p. 129 as: “a determination of which of the two parties will suffer the greater harm from the granting or refusal of an interlocutory injunction, pending a decision on the merits”. In light of the relatively low threshold of the first test and the difficulties in applying the test of irreparable harm ... many interlocutory proceedings will be determined at this stage.”), with *supra* notes 79-83 and accompanying text (discussing the *Winter* test).

¹³⁸ See, e.g., *Aventis Pharma S.A. v. Novopharm, Ltd.*, [2005] FC 815, ¶ 52 (citing *RJR-McDonald* when denying an interim injunction against a granted Notice of Compliance for lack of proof of irreparable harm, without reaching the balance of hardships), *aff’d*, 2005 FCA 390.

¹³⁹ Siebrasse, *supra* note 106, at *1.

¹⁴⁰ *Id.* at *4. See *id.* at *22 (“[P]atentees in all fields are routinely denied interlocutory injunctions.... [I]t is entirely possible that the courts would find that the circumstances typically attending the assertion of patent rights by a PAE would justify refusing injunctive relief on the basis of traditional principles”). Cf. *Janssen Inc. v. AbbVie Corp.*, 2014 FCA 176 ¶ 55 (“But an injunction cannot be suspended just because it creates usual or normal burdens, uncertainties or risks. Otherwise, injunctions that, as here, are intended to take immediate effect would almost always be suspended as a matter of course. That would conflict with the consistent thread running through the *RJR-MacDonald* test for a stay — the need to engage in a careful, case-by-case, fact-specific balance between fairness and the principle of legality A moving party seeking to suspend an injunction pending appeal must adduce evidence showing *unusual or abnormal burdens*, uncertainties and risks. Here, that evidence is missing.”) (citation omitted) (emphasis added).

¹⁴¹ Cf. Berryman, *supra* note 17, at 177 (“Many of the cases considered above do not confront that problem [of fluctuating losses from changed usage or changed market conditions] because there is only limited life remaining under the intellectual property right, or its effective economic value has already been lost. The difficulty over quantifying prospective losses is not a new issue for the law.”).

preliminary or permanent injunction for infringement. For example, in the 2014 *AbbVie v. Janssen* case, the Federal Court held that:

the non-monetary burdens associated with complying with the injunction — training personnel, changing communications, *etc.* — are the sorts of administrative inconvenience that, without more, cannot support suspending the injunction.... Further, although non-monetary on the surface, the burdens identified here may well be quantifiable in monetary terms.... Janssen is concerned about its reputation with doctors who prescribe Stelara. I am not persuaded on this record that these doctors will think less of Janssen or Stelara because of this intellectual property dispute. In accordance with the terms of the injunction, Janssen remains free to explain to physicians the dispute.... Accordingly, Janssen's long term reputation as a reliable supplier of good pharmaceutical products will not be hurt.... Janssen's related concern that it will lose market share is unpersuasive. On this record, it appears that treating physicians in this area know Stelara well and, as mentioned in the preceding paragraph, they will continue to prescribe it.... Against this concrete backdrop, the evidence only shows general and speculative assertions about loss of market share, unsupported by particularity. Further, like Justice Rothstein in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2000 CarswellNat 4299 (Fed. C.A.) at paragraph 13, I suspect that, despite the *obiter* statement of the Supreme Court in *RJR-MacDonald* to the contrary, any such loss nevertheless might be quantifiable in monetary terms."¹⁴²

Similarly, in the 2005 *Aventis v. Novopharm* case, the Federal Court held that:

The injunction was granted in *Allergan* notwithstanding the observation by the Court that "Recent jurisprudence would indicate that the grant of an interlocutory injunction is not a common occurrence in patent cases, the main reason being that in most instances damages will be an adequate remedy."... In the present case, I have indicated that although I acknowledge and accept the Plaintiffs' argument that the respective strength of the parties' case is a factor that the Court should take into account, I have also indicated that, on the present facts, the principal difficulty for the Plaintiffs is establishing irreparable harm and overcoming what appears to be accepted in the jurisprudence that damages are an adequate remedy in most instances of patent infringement.... A review of the allegations and evidence put forward by the Plaintiffs for irreparable harm suggests that there is insufficient clear evidence that irreparable harm will occur if the injunction is not issued. For the most, the suggestions as to how irreparable harm could occur lack elucidation and remain unsubstantiated, speculative and theoretical. In face of the information that the Plaintiffs have chosen not to provide, and their general approach to problematizing the damages issue rather than providing clear evidence of unquantifiable harm and loss, Ms. Loomer asserts that none of the categories of loss claimed by the Plaintiffs are beyond the realm of quantification "or are other than ordinary components of the standard exercise undertaken by the Courts." Consequently, there is no adequate basis to warrant an injunction.¹⁴³

¹⁴² *AbbVie Corp.*, 2014 FCA 176 ¶¶ 25-27. See also *id.*, ¶ 24 ("Legal and other expenses without "abnormal, harsh consequences beyond the norm" do not qualify as irreparable harm, as these can be quantified in damages: *Canada (Superintendent of Bankruptcy) v. MacLeod*, 2010 FCA 84 (F.C.A.) at paragraph 21.").

¹⁴³ *Aventis Pharma S.A. v. Novopharm Ltd.*, 2005 FC 815, ¶ 109-10, 113 (citing *Allergan Pharmaceuticals Inc. v. Bausch & Lomb Inc.*, [1985] 7 C.P.R. (3d) 209 (Fed. T.D.), at ¶ 214). See *id.* at ¶¶ 59-112 (discussing allegations of permanent loss of market share and ability to increase it in the retail, hospital, related product, and U.S. markets; price reductions; loss of knowledgeable employees; and damage to goodwill and reputation).

A recent case in the United Kingdom also may reflect changing views in that jurisdiction regarding irreparable harm, in light of the ability to calculate economic damage.¹⁴⁴ In *Neurim Pharmaceuticals (1991) Ltd. v. Generics UK Ltd.*, the patent holder sought an interim injunction, the generic company agreed to delay market entry until the interim injunction could be resolved (but not until expedited trial), and the court denied the interim injunction on the basis of the *American Cyanamid* factors.¹⁴⁵ Specifically, the court noted the allegations of irreparable harm that generic entry would result in price reductions (that would extend beyond any permanent injunction that might issue at trial until the expiration of the patent) and in loss of market share (including further generic entry). The court found that the defendant could pay a damage remedy and that the asserted price reductions were likely to occur (although limited during direct competition to about six months until a final judgment might be reached, Period 1, and for some uncertain time thereafter until patent expiry, Period 2).¹⁴⁶ Nevertheless, in regard to the adequacy of damages for the claimed price reductions and market share losses, the Court stated that:

Generally speaking, damages are an adequate remedy for a tort, including an infringement of a patent....

...

In the present case, I can see no reason why Neurim and/or Flynn's [the exclusive licensee's] losses during both Period 1 and Period 2 cannot properly be calculated, whether it is necessary to calculate lost revenues by reference to all three Medical Uses [some of which were off-label and not covered by the patent] or individually by reference to each particular Medical Use. Clearly, Neurim and Flynn will have records of their sales to date of Circadin and Slenyto, and they will continue to keep such records. Equally, there is no difficulty in Mylan maintaining and (for the purposes of trial) providing to Neurim and Flynn records of its sales of the Generic Product, differentiating as far as can be done between Medical Use, and providing information as to the price at which the Generic Product sold....

It may be that during Period 1, but for the intervention into the market of Mylan, Neurim and Flynn were anticipating an increase in the volume of sales and/or an increase in the price of individual units sold. I can see no reason why evidence on such points cannot be adduced, and why such increases cannot inform the losses that Neurim and Flynn claim.

All of these losses can – in my judgment – be calculated by reference to information that is or will be in the hands of Neurim and Flynn. But, as I say, it

¹⁴⁴ See, e.g., Brian Cordery & Rachel Mumby (Bristows), A wake up call for patentees?, Kluwer Patent Blog (June 10, 2020), at http://patentblog.kluweriplaw.com/2020/06/10/a-wake-up-call-for-patentees/?doing_wp_cron=1592813667.3568000793457031250000 (“the Court has generally been willing to accept that in the pharmaceutical field premature generic entry may lead to unquantifiable and irreparable harm to the patent holder which outweighs that to the potential infringer. Nevertheless, in a judgment dated 3 June 2020, Marcus Smith J refused to grant an interim injunction to Neurim against the leading generics company Mylan. It remains to be seen if this decision will mark the start of a new direction from the English Patents Court....”).

¹⁴⁵ See *Neurim Pharms. (1991) Ltd. v. Generics UK Ltd.*, ¶¶ 15-17, 27-28 (discussing the *American Cyanamid* factors and noting, when holding that a “serious issue to be tried” existed, that that question should not authorize a “trial within a trial” requiring evaluation of competing evidence) (citation omitted), aff’d, [2020] EWCA Civ 793; Léon Dijkman, *Neurim v. Mylan: UK Court of Appeal denies interim injunction in face of a launch-at-risk, but are damages really adequate?*, The IPKat (June 26, 2020), at <http://ipkitten.blogspot.com/2020/06/neurim-v-mylan-uk-court-of-appeal.html> (although the Court of Appeals decision in *Neurim Pharms.* “called the case one with ‘extremely unusual’ facts, not one deciding ‘any principle of general application’.... **the facts of this case do not seem that far out of the ordinary: it will always be possible to calculate lost sales and price drops within a limited period of time.** True, an increased likelihood of market entry by other generics, coupled with a longer time to trial, may make damages (much) more difficult to calculate in future cases. However, the recognition that price erosion will not automatically take place in case of generic entry, and is not by definition incapable of being redressed with damages, is an important one and [the author] expects it will invoked often in cases to come.”) (emphasis in original).

¹⁴⁶ See *id.*, ¶¶ 18-19, 38-49.

would be appropriate to ensure that proper figures were maintained and disclosed by Mylan for the purposes of the trial of these proceedings. If, therefore, the avoidance of irretrievable harm to the market position of a patent-holder was the test for an interim injunction, this would be an appropriate case for the granting of such an injunction. But that is not the test. The question is whether that irretrievable harm to market position cannot be compensated for in damages. I can see no reason why the process of quantification of loss for Period 2 will not be very similar to that for Period 1. Indeed, the process of quantification of loss for Period 2 will be an extension of or extrapolation from the process undertaken in relation to Period 1.¹⁴⁷

In summary, in Canada to date, permanent injunctions are normally granted to patent holders (including pharmaceutical patent holders) following a determination of infringement and lack of invalidity, notwithstanding the uncertain standard for granting such injunctions and the equitable discretion possessed by the courts. In contrast, interlocutory injunctions to prohibit infringement pending trial are subject to a clear, three-prong (plus public interest) standard that is extremely difficult to meet, particularly in regard to proving “irreparable harm.” Such injunctions normally are not sought by pharmaceutical patent holders, given the automatic 24-month stay of generic marketing approval, and the difficulty of proving irreparable harm. Finally, the reasoning of some courts in the context of interlocutory injunction decisions suggests that the harms to patent holders from continuing infringement in both preliminary and permanent injunction contexts may be calculable and not irreparable, and thus that interim compensation or ongoing royalty injunctions should be issued.¹⁴⁸ Finally, although the public interest in affordable access to patented medicines could be more explicitly taken into account, and may sometimes factor into decisions not to seek permanent or interlocutory injunctive relief against all competitive sales and uses, the Federal Court has yet to explicitly apply public interest concerns to deny injunctions in pharmaceutical patent cases, even when public interest considerations would justify granting a compulsory license.

¹⁴⁷ *Id.*, ¶¶ 69, 71(2)-(6) (emphasis added).

¹⁴⁸ Conversely, the routine grant of permanent injunctions may suggest that the irreparable harm analysis in the preliminary injunction context is askew.

CONCLUSION

As can be seen from the comparative analyses above, the approaches to and standards for permanent and preliminary injunctive relief in regard to pharmaceuticals, medical devices, and other needed medical products may vary dramatically among developed country (and developing country) common-law jurisdictions. Although such relief is historically based in equity, the standards for the exercise of a trial judge's equitable discretion have changed over time. These standards for judicial discretion may change further in response to the public's need for affordable access to patented products in emergencies, such as the COVID-19 pandemic, just as have legislative views on the appropriateness of granting compulsory licenses. Some judges in these jurisdictions (and others) already may be developing new norms of equity for denying permanent and preliminary injunctions that would prohibit the infringement of pharmaceutical patents, while awarding the patent holders ongoing or temporary royalties.

In contrast, further legislative action may be needed in the U.S., Canada, and other jurisdictions that provide linkages between their regulatory marketing approval systems and their patent systems. Where those linkages provide for (effectively) automatic stays of generic or other regulatory approvals based on patents, those stays may render it unnecessary for a patent holder to request a preliminary injunction from infringement. The linkages thus may prevent prompt responses from unlicensed producers to supply shortfalls in emergencies, by precluding judges from denying preliminary injunctions when it would be equitable to do so in order to assure public access to needed medicines. However, enacting such legislation would require developing a new normative consensus regarding an appropriate balancing of innovation incentives and investment rewards for patent holders with affordability and access to needed medicines by the public. We will have to wait to see whether such norms for patent linkage can reach legislative consensus.

Nevertheless, both developed and developing countries may choose to exercise TRIPS flexibilities to more routinely deny preliminary and permanent injunctive relief in regard to pharmaceutical patents. Developing countries also may choose to resist international trade pressures and to avoid linking their patent system to their drug regulatory approval system, permitting generic drug approvals and normal equitable consideration of whether to issue prohibitory preliminary injunctions. In these ways, they may avoid paradoxically ending up imposing more stringent levels of protection through remedies law than is imposed in more developed jurisdictions or than is required by international IP treaties.

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Chemin du Champ-d'Anier 17
PO Box 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
<http://www.southcentre.int>

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