

**D. The motion in the Federal Court**

[11] Teva renewed its motion, this time adding particulars such as the names of the inventors whose evidence it relies upon and offering more details on the misrepresentation. Its motion came before the Federal Court (*per* Barnes J., who is the designated trial judge).

[12] Before the Federal Court, Teva submitted that the allegations it wanted to add to its claim were based on evidence obtained during discovery.

[13] According to Teva, the '619 Patent claims a vast number of prodrugs of phosphonate nucleotide analogues. By the filing date of the patent, Gilead had made only a small number of these compounds. Teva said that on discovery, the inventors and the representative of Gilead admitted that they had not made and did not believe they could make any predictions of utility across the broad class of compounds claimed in the '619 Patent.

[14] In light of this, Teva took the view that Gilead has committed a material misrepresentation by filing the '619 Patent without a factual foundation to prove or to soundly predict utility. So Teva sought to amend its statement of claim to add this allegation, along with the material facts supporting it.

[15] By order dated November 3, 2014, the Federal Court dismissed Teva's motion. Its reasons for doing so shall be analyzed in more detail below. But, in short, the Federal Court

found that the amendments improperly added allegations tantamount to fraud without sufficient evidence. Further, the allegations had no reasonable prospect of success.

**E. The second motion in the Federal Court**

[16] Within two weeks of the Federal Court's order on the first motion, Teva brought a second motion seeking leave to amend its pleadings. Teva relied on certain discovery evidence to assert that only a very small number of the compounds claimed in the '619 Patent had been made and that the inventors did not and could not predict the efficacy of those compounds. Teva noted that the '619 Patent nevertheless claims these compounds.

[17] From this, Teva sought to plead that the '619 Patent is invalid because what is disclosed in the specification is not the invention "as contemplated by the inventor," as required by subsection 27(3) of the *Patent Act*.

[18] The second motion came before the Federal Court (again *per* Barnes J., who is the designated trial judge). By order dated January 19, 2015, the Federal Court dismissed the motion.

[19] Again, the Federal Court's reasons for dismissing the motion will be considered further below. But for present purposes, the Federal Court found that the proposed amendments were not supported by the discovery evidence. The amendments lacked a reasonable prospect of success.

And, in the Federal Court's view, Teva's second motion should have been brought with its first motion; it was essentially the same motion brought on the same basis.

**F. The standard of review on appeal to this Court**

[20] In their memoranda of fact and law, the parties disagreed concerning the standard of review that this Court should apply in these appeals. However, by the time of the hearing in this Court, this Court had released new jurisprudence on the standard of review.

[21] In its memorandum, Teva suggested that the issues associated with its pleadings amendment are vital to the final issues in the case and so this Court should perform a *de novo* review. But that is the standard of review applied in a Rule 51 appeal from a Prothonotary. Here, Teva's motions were decided on their merits by a judge of the Federal Court acting on the merits at first instance, not as a Rule 51 appeal court.

[22] In its memorandum, Gilead submitted that the Federal Court's decision is one of discretion. Therefore, it can be set aside only if there was an error of law, a misapprehension of the facts or a wrongful exercise of discretion in that no weight or no sufficient weight was given to relevant considerations, or consideration was given to irrelevant factors.

[23] But, in recent jurisprudence, this Court has altered that formulation of the standard of review of orders such as the ones in this appeal in an effort to homogenize the law on standard of review concerning all appeals of orders. See *Imperial Manufacturing Group Inc. v. Decor Grates*

*Incorporated*, 2015 FCA 100, [2016] 1 F.C.R. 246 rev'g *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588 at p. 594, 58 C.P.R. (3d) 209 at p. 213 (C.A.); see also, more recently, *Turmel v. Canada*, 2016 FCA 9. In accordance with those recent authorities, the standard of review for the orders before us is the usual appellate standard set out in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235.

[24] Therefore, according to that recent jurisprudence, to succeed in this appeal Teva must persuade us that the Federal Court erred on a pure question of law or on a legal principle that can be extracted from a question of mixed fact and law. Absent that sort of legal error, Teva can succeed only if it demonstrates palpable and overriding error. A palpable and overriding error is one that is both obvious and determinative in the sense that it undermines the outcome reached below. See generally *Canada v. South Yukon Forest Corporation*, 2012 FCA 165, 431 N.R. 286 at paragraph 46.

[25] However, as will be seen, regardless of how one enunciates the standard of review, the standard of review is deferential. And as will be explained below, under that deferential standard Teva has failed to persuade us that we should interfere with the Federal Court's orders.

**G. Analysis of the order made on the first motion: the November 3, 2014 order**

[26] Motions for leave to amend are governed by Rule 75 of the *Federal Courts Rules*, SOR/98-106. Amendments should be allowed "for the purpose of determining the real questions in controversy between the parties" as long as they "would serve the interests of justice" and they