Allergan Inc., Allergan Sales Inc. and Allergan, Inc. (applicants) v. The Minister of Health and Apotex Inc. (respondents)
(T-1560-10; 2012 FC 767)

Indexed As: Allergan Inc. et al. v. Canada (Minister of Health) et al.

Federal Court
Hughes, J.
June 18, 2012.

Summary:

Allergan Inc., Allergan Sales Inc., and Allergan, Inc., applied under the Patented Medicines (Notice of Compliance) Regulations to prohibit the Minister of Health from issuing a Notice of Compliance to Apotex Inc. for a topical ophthalmic product to be known as APO-BRIMONIDINE-TIMOP, a generic version of Allergan's COMBIGAN (an eye drop medicine used to treat glaucoma), until the expiry of Allergan, Inc.'s Canadian Letters Patent No. 2,440,764 (the '764 patent) on April 9, 2023. The basic issue was whether Allergan had discharged its burden of demonstrating that Apotex's allegations of invalidity of the '764 patent were not justified. In determining that matter, there were several discrete issues, including the effect of the previous Federal Court decision in Allergan Inc. et al. v. Canada (Minister of Health) et al.

The Federal Court allowed the application, for reasons of comity. On the evidence, Apotex's allegations as to obviousness were justified. However, serious issues had been raised as to comity. "The somewhat contradictory decisions of the Court of Appeal should be considered by that Court and clear instruction given as to how, in an NOC context, previous decisions of a Court on the same issues respecting the same patent, should be considered. The only practical way to get the matter before the Court of Appeal is for me to grant the Order for prohibition in the likely expectation that Apotex will appeal."

Courts - Topic 82

Stare decisis - Authority of judicial decisions - Prior decisions of same court - Federal Court (incl. judicial comity) - The Federal Court expressed the principle of judicial comity as follows - "Comity comes into consideration when a Court is faced with a decision of the same Court which deals with the same legal issues or factual circumstances. There is a general view that the subsequent Court should respect the decision of the earlier Court unless it is manifestly wrong or the jurisprudence has changed. The earlier decision should be followed unless there is strong reason to the contrary; and, in considering strong reason to the contrary, the Court does not mean a stronger or more persuasive argument of Counsel, but a showing that some jurisprudence has been clearly overlooked or is now changed." - See paragraph 66.

Courts - Topic 82

Stare decisis - Authority of judicial decisions - Prior decisions of same court - Federal Court (incl. judicial comity) - The Federal Court applied the principle of comity in Notice of Compliance (NOC) proceedings in following an earlier decision wherein the same

claims of the patent at issue had been construed by Crampton, J. - "I must respect the decision of Crampton, J., in respect of the various findings that he makes unless I am persuaded that he was 'manifestly wrong' in that he overlooked some relevant statute or authority, or that he misapplied the relevant statute or authority, or that there have been subsequent statutory changes or new authorities that are relevant. Where he makes factual findings on the evidence before him, I am free to make different findings if the evidence before me is different. It is in this latter respect that the jurisprudence that has developed under the NOC Regulations must be examined" - In the result, the court concluded that "[t]he resulting situation is not a good one. A court cannot be 'bound' in NOC proceedings by an earlier decision respecting failed invalidity allegations made by a different generic. ... In proceedings in the United States brought under the Hatch-Waxman Act, endeavours are made to join as many generics as possible in one proceeding so that all may be bound by the result. Canada has no similar provisions." - See paragraphs 68 to 81.

Courts - Topic 82

Stare decisis - Authority of judicial decisions - Prior decisions of same court - Federal Court (incl. judicial comity) - In the context of Notice of Compliance (NOC) proceedings, the Federal Court stated that "what a Court in Canada must do when faced with an earlier decision in NOC proceedings involving failed invalidity allegations raised by a different generic is: do the best it can from the reasons of the Court in the earlier proceeding to discern what the evidence and argument was; compare that evidence and argument with that in the proceedings at hand; determine if there are meaningful differences between the evidence and argument in the earlier case and present case; give respect to the earlier decision but, if there are determinative differences in the evidence, the Court must make its own decision; and if the previous decision contains a critical error of law or if the law has changed the Court must make its own decision as to the law." - See paragraph 82.

Courts - Topic 82

Stare decisis - Authority of judicial decisions - Prior decisions of same court - Federal Court (incl. judicial comity) - Allergan applied to prohibit the Minister of Health from issuing a Notice of Compliance to Apotex for a topical ophtalmic product, until the expiry of Allergan's '764 patent - The basic issue was whether Allergan had discharged its burden of demonstrating that Apotex's allegations of invalidity of the '764 patent were not justified - In determining that matter, there were several discrete issues, including the effect of Crampton, J.'s finding in a previous Federal Court decision - Allergan argued that the interpretation of a patent was a legal matter; thus, Crampton, J.'s finding as to what constituted the inventive concept was an interpretation of law and, as a matter of comity, had to be followed - The Federal Court rejected that argument - "The specification is a document drafted by the patentee, not Parliament or the Governor in Council. Interpretation of the specification is like the interpretation of a contract drafted by one or more parties. The level of comity owed by one judge in the interpretation of the same contract by another judge is not as great as the level of comity owed when a statute or regulation has been interpreted." - See paragraphs 148 and 149.

Courts - Topic 82

Stare decisis - Authority of judicial decisions - Prior decisions of same court - Federal Court (incl. judicial comity) - [See second **Patents of Invention - Topic 1589**].

Courts - Topic 103

Stare decisis - Authority of judicial decisions - English, American and Foreign authorities - American decisions - Allergan applied under the Patented Medicines (Notice of Compliance) (NOC) Regulations to prohibit the Minister of Health from issuing a NOC to Apotex for a generic version of Allergan's COMBIGAN, until the expiry of Allergan's '764 patent - The basic issue was whether Allergan had discharged its burden of demonstrating that Apotex's allegations of invalidity of the '764 patent were not justified - In determining that matter, the Federal Court considered the effect of the U.S. District Court decision in Allergan, Inc. v. Sandoz Inc. (2011) (E.D. Tex.) - The decision resulted from proceedings taken by Allergan under the Hatch-Waxman Act, a rough equivalent of proceedings under the NOC Regulations - The proceedings were in respect of four patents similar to the '764 patent, but against different defendants - The defendants attacked the validity of the patents - The judge concluded that the defendants had failed to make out their case - The decision was under appeal - In the end result, the Federal Court held that the decision was not binding upon it - The decision was not a final determination - It involved somewhat different patents, but not very different, with different claims; somewhat different law, but not very different; as well as different evidence - The U.S. decision was "interesting and informative, but it goes no further than that." - See paragraphs 83 to 100.

Food and Drug Control - Topic 1108.2

Drugs - New drugs - Notice of compliance - Prohibition order (incl. compensation by first person) - [See second **Patents of Invention - Topic 1589**].

Patents of Invention - Topic 1026

The specification and claims - Construction of a patent - General - The Federal Court stated that "[c]laim construction can be efficiently conducted by the Court focusing on the issues of contention raised by the parties. This has been characterized as considering where 'the shoe pinches'" - See paragraph 110.

Patents of Invention - Topic 1030

The specification and claims - Construction of a patent - "Person skilled in the art" - What constitutes - The Federal Court stated that "[a]mong the first tasks to which a Court must attend in a patent action is to define the 'person of ordinary skill in the art' (POSITA) or more briefly, 'person skilled in the art'. This is the notional person to whom the patent is addressed, and who takes his or her place in the spectrum of other fictional legal persons, such as the 'reasonable person' in tort law." - In the present case, counsel for the applicant sought to characterize the definition of a person skilled in the art as a legal finding - The court disagreed, stating that "[a]t best, it is a finding of mixed fact and law." - See paragraphs 101 and 107.

Patents of Invention - Topic 1505

Grounds of invalidity - General - Combination patents - [See first **Patents of Invention - Topic 1589**].

Patents of Invention - Topic 1509

Grounds of invalidity - Commercial success - Effect of - [See **Patents of Invention - Topic 1583**].

Patents of Invention - Topic 1511

Grounds of invalidity - General - Foreign litigation - [See **Courts - Topic 103**].

Patents of Invention - Topic 1582

Grounds of invalidity - Lack of "inventive ingenuity" (obviousness) - Test for obviousness - Invalidity of the patent-at-issue was alleged on two grounds; namely, anticipation and obviousness - The Federal Court stated that "[t]hese concepts are related, but have important differences. Anticipation arises from the statutory definition of 'invention' in section 2 of the Patent Act in that, in order to be patentable, the invention must be 'new'. Obviousness arises from the concept of invention itself." - See paragraph 116.

Patents of Invention - Topic 1583

Grounds of invalidity - Lack of "inventive ingenuity" (obviousness) - Commercial success - Effect of - The Federal Court stated that commercial success was a secondary factor and had little impact when it came to a consideration of obviousness - See paragraphs 187 and 188.

Patents of Invention - Topic 1589

Grounds of invalidity - Lack of "inventive ingenuity" (obviousness) - Particular patents - Canadian Letters Patent No. 2,440,764 (the '764 patent), entitled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use", were granted to Allergan, Inc. - Allergan applied to prohibit the Minister of Health from issuing a Notice of Compliance (NOC) to Apotex Inc. for a generic version of Allergan's COMBIGAN (a single-dose drug for use in treating glaucoma) until the expiry of the '764 patent - Apotex alleged that the '764 patent was invalid for obviousness - Allergan agreed that the use of the ingredients separately was known, but the "recipe" for combining them into a single dose composition was inventive - The Federal Court found on the evidence that Apotex's allegations as to obviousness were justified - It was more or less self-evident that what was being tried (benzalkonium chloride, a preservative used to prevent microbial contamination) ought to work - In order to arrive at the alleged inventive concept, no more than routine laboratory work was required - There was sufficient motivation provided in the prior art to provide a combination drug for use in treating glaucoma - As to the actual course of conduct that culminated in the invention, no more than routine testing was required - However, the court allowed the application, for reasons of comity - See paragraphs 150 to 188.

Patents of Invention - Topic 1589

Grounds of invalidity - Lack of "inventive ingenuity" (obviousness) - Particular patents - Canadian Letters Patent No. 2,440,764 (the '764 patent), entitled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use", were granted to Allergan, Inc. - Allergan applied to prohibit the Minister of Health from issuing a Notice of Compliance (NOC) to Apotex Inc. for a generic version of Allergan's COMBIGAN until the expiry of the '764 patent - Apotex alleged that the '764 patent was invalid for obviousness - That was a question previously considered by Crampton, J., in Allergan Inc. et al. v. Canada (Minister of Health) et al. - Crampton, J., found that the allegation that the '764 patent was invalid for obviousness was not justified - The Federal Court found differently in this case, but allowed the application, for reasons of comity - On the evidence, Apotex's allegations as to obviousness were justified - However, serious issues had been raised as to comity - "The somewhat contradictory decisions of the Court of Appeal should be considered by that Court and clear instruction given as to how, in an NOC context, previous decisions of a Court on the same issues respecting the same patent, should be considered. The only practical way to get the matter before the Court of Appeal is for me to grant the Order for prohibition in the likely expectation that Apotex will appeal." - See paragraphs 189 to 194.

Cases Noticed:

Allergan Inc. et al. v. Canada (Minister of Health) et al. (2011), 400 F.T.R. 164; 2011 FC 1316, consd. [para. 34].

Allergan Inc. v. Sandoz Inc. (2011), W.L. 3809882 (E.D. Tex)., consd. [para. 37].

GlaxoSmithKline Inc. et al. v. Pharmascience Inc. et al. (2011), 385 F.T.R. 157; 2011 FC 239, refd to. [para. 42].

Sanofi-Synthelabo Canada Inc. et al. v. Apotex Inc. et al., [2008] 3 S.C.R. 265; 381 N.R. 125, refd to. [para. 47].

Glaxo Group Ltd. et al. v. Canada (Minister of National Health and Welfare) et al. (1995), 103 F.T.R. 1; 64 C.P.R.(3d) 65 (T.D.), refd to. [para. 66].

Pfizer Canada Inc. et al. v. Canada (Minister of Health) et al. (2007), 12 F.T.R. 100; 59 C.P.R.(4th) 166; 2007 FC 446, refd to. [para. 67].

Toronto (City) et al. v. Canadian Union of Public Employees, Local 79 et al., [2003] 3 S.C.R. 77; 311 N.R. 201; 179 O.A.C. 291, refd to. [para. 70].

Pfizer Canada Inc. et al. v. Canada (Minister of Health) et al., [2008] 1 F.C.R. 672; 312 F.T.R. 100 (F.C.), refd to. [para. 71].

Sanofi-Aventis Canada Inc. v. Novopharm Ltd. et al. (2007), 364 N.R. 325; 2007 FCA 163, refd to. [para. 72].

Janssen-Ortho Inc. et al. v. Apotex Inc. et al. (2009), 392 N.R. 71; 2009 FCA 212, refd to. [para. 74].

Pfizer Canada Inc. et al. v. Canada (Minister of Health) et al. (2009), 354 F.T.R. 280; 2009 FC 1165, refd to. [para. 75].

Pfizer Canada Inc. et al. v. Canada (Minister of Health) et al. (2008), 326 F.T.R. 88; 2008 FC 500, refd to. [para. 76].

Pfizer Canada Inc. et al. v. Canada (Minister of Health) et al. (2008), 322 F.T.R. 86; 2008 FC 11, refd to. [para. 77].

Eli Lilly Canada Inc. v. Novopharm Ltd. et al., [2007] F.T.R. Uned. 828; 2007 FC 596, refd to. [para. 78].

Apotex Inc. v. Pfizer Ireland Pharmaceuticals (2011), 419 N.R. 189; 93 C.P.R.(4th) 42; 2011 FCA 77, refd to. [para. 79].

Merck & Co. et al. v. Pharmascience Inc. et al. (2010), 368 F.T.R. 1; 2010 FC 510, refd to. [para. 109].

Shire Biochem Inc. et al. v. Canada (Minister of Health) et al. (2008), 328 F.T.R. 123; 2008 FC 538, refd to. [para. 110].

Eli Lilly Canada Inc. v. Apotex Inc. et al. (2008), 323 F.T.R. 56; 2008 FC 142, refd to. [para. 117].

Rothmans, Benson & Hedges Inc. et al. v. Imperial Tobacco Ltd. (1993), 152 N.R. 292; 47 C.P.R.(3d) 188 (F.C.A.), refd to. [para. 117].

Eli Lilly Canada Inc. et al. v. Novopharm Ltd. (2010), 405 N.R. 1; 2010 FCA 197, refd to. [para. 119].

Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59 (Eng. C.A.), refd to. [para. 129].

Janssen-Ortho Inc. et al. v. Novopharm Ltd. (2007), 366 N.R. 290; 2007 FCA 217, refd to. [para. 130].

Actavis v. Novartis, [2010] F.S.R. 18 (U.K.C.A.), refd to. [para. 131].

Poszzoli SPA v. BDMO SA, [2007] EWCA Civ. 588, refd to. [para. 132].

Sanofi-Synthelabo Canada Inc. et al. v. Apotex Inc. et al. (2008), 381 N.R. 125; 2008 SCC 61, refd to. [para. 132].

Pfizer Canada Inc. et al. v. Apotex Inc. et al. (2009), 385 N.R. 148; 2009 FCA 8, refd to. [para. 133].

Conor v. Angiotech, [2008] R.P.C. 716, refd to. [para. 137].

Laboratoires Servier et al. v. Apotex Inc. et al. (2009), 392 N.R. 96; 2009 FCA 222, refd to. [para. 138].

Novo Nordisk Canada Inc. et al. v. Cobalt Pharmaceuticals Inc. et al. (2010), 376 F.T.R. 104; 2010 FC 746, refd to. [para. 139].

Whirlpool Corp. et al. v. Camco Inc. et al., [2000] 2 S.C.R. 1067; 263 N.R. 88, refd to. [para. 149].

Apotex Inc. and Novopharm Ltd. v. Wellcome Foundation Ltd. (2002), 296 N.R. 130; 2002 SCC 77, refd to. [para. 173].

Teva UK Ltd. v. Merck & Co., [2009] E.W.H.C. 2952 (Pat.), refd to. [para. 175].

Merck & Co. et al. v. Canada (Minister of Health) et al. (2010), 375 F.T.R. 121; 2010 FC 1042, refd to. [para. 189].

Authors and Works Noticed:

Hayhurst, W.K., The Distinction between Letters Patent and Patent Specification, How Did We Get Where We Are? (2007), 57 C.P.R.(4th) 161, [para. 149].

Moy, R. Carl, Moy's Walker on Patents (4th Ed. 2003) (Looseleaf Update), generally [para. 117].

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Andrew Brodkin and Richard Naiberg, for the respondent, Apotex Inc.

Solicitors of Record:

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Goodmans LLP, Toronto, Ontario, for the respondent, Apotex Inc;
Myles J. Kirvan, Deputy Attorney General of Canada, Toronto, Ontario, for the respondent, the Minister of Health.

This application was heard on at Toronto, Ontario, on May 22 to 24, 2012, before Hughes, J., of the Federal Court, who delivered the following reasons for judgment and judgment, dated June 18, 2012.

Application allowed.

Editor: E. Joanne Oley

Courts - Topic 82

Stare decisis - Authority of judicial decisions - Prior decisions of same court - Federal Court (incl. judicial comity) - Canadian Letters Patent No. 2,440,764 (the '764 patent), entitled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use", were granted to Allergan, Inc. - Allergan applied to prohibit the Minister of Health from issuing a Notice of Compliance (NOC) to Apotex Inc. for a generic version of Allergan's COMBIGAN until the expiry of the '764 patent - Apotex alleged that the '764 patent was invalid for obviousness - That was a question previously considered by Crampton, J., in Allergan Inc. et al. v. Canada (Minister of Health) et al. - Crampton, J., found that the allegation that the '764 patent was invalid for obviousness was not justified - The Federal Court found differently in this case, but allowed the application, for reasons of comity - On the evidence, Apotex's allegations as to obviousness were justified - However, serious issues had been raised as to comity - "The somewhat contradictory decisions of the Court of Appeal should be considered by that Court and clear instruction given as to how, in an NOC context, previous decisions of a Court on the same issues respecting the same patent, should be considered. The only practical way to get the matter before the Court of Appeal is for me to grant the Order for prohibition in the likely expectation that Apotex will appeal." - See paragraphs 189 to 194.

Food and Drug Control - Topic 1108.2

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Patents of Invention - Topic 1505

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Patents of Invention - Topic 1509

Grounds of invalidity - Commercial success - Effect of - The Federal Court stated that commercial success was a secondary factor and had little impact when it came to a consideration of obviousness - See paragraphs 187 and 188.

Patents of Invention - Topic 1511

Grounds of invalidity - General - Foreign litigation - Allergan applied under the Patented Medicines (Notice of Compliance) (NOC) Regulations to prohibit the Minister of Health from issuing a NOC to Apotex for a generic version of Allergan's COMBIGAN, until the expiry of Allergan's '764 patent - The basic issue was whether Allergan had discharged its burden of demonstrating that Apotex's allegations of invalidity of the '764 patent were not justified - In determining that matter, the Federal Court considered the effect of the U.S. District Court decision in Allergan, Inc. v. Sandoz Inc. (2011) (E.D. Tex.) - The decision resulted from proceedings taken by Allergan under the Hatch-Waxman Act, a rough equivalent of proceedings under the NOC Regulations - The proceedings were in respect of four patents similar to the '764 patent, but against different defendants - The defendants attacked the validity of the patents - The judge concluded that the defendants had failed to make out their case - The decision was under appeal - In the end result, the Federal Court held that the decision was not binding upon it - The decision was not a final determination - It involved somewhat different patents, but not very different, with different claims; somewhat different law, but not very different; as well as different evidence - The U.S. decision was "interesting and informative, but it goes no further than

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