

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,248,228 having been rejected under subsection 30(3) of the *Patent Rules*, has consequently been reviewed in accordance with subsection 30(6) of the *Patent Rules* by the Patent Appeal Board and the Commissioner of Patents. The findings of the Board and the decision of the Commissioner are as follows:

Agent for the Applicant

NORTON ROSE CANADA S.E.N.C.R.L.,S.R.L./LLP

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INTRODUCTION

- [1] This recommendation deals with a review by the Commissioner of Patents of patent application no. 2,248,228 entitled AMETHOD OF PRODUCING HYDROCARBON-EXPANDED RIGID POLYURETHANE FOAMS.® The Applicant is BAYER AKTIENGESELLSCHAFT. The inventors are Norbert Eisen, Torsten Heinemann, Dennis McCullough and Walter Klän.
- [2] As the title suggests, this application relates to methods of producing hydrocarbon-expanded rigid polyurethane foams used, for example, as an insulating material in the hollow spaces of domestic refrigerators.
- [3] As described by the Applicant in the present application, such foams can be formed with low boiling point alkanes, particularly cyclic alkanes such as cyclopentane which contribute to forming an expanded material of a described low thermal conductivity. However, the use of cyclopentane brings with it certain disadvantages such as the requirement for a specific quality of polystyrene inner refrigerator container due to the solvent properties of cyclopentane. Cyclopentane also condenses at low temperatures such as those used in domestic refrigerators, leading to reduced pressure in the cells of the material product which must be offset by elevated foam strength or increased density.
- [4] Compared to the use of cyclopentane as a blowing agent, using compounds such as n-pentane and i-pentane avoids the higher

manufacturing costs. As disclosed by the Applicant, these compounds have been used for some time in the polyurethane foam field, however their use brings with it the disadvantage of higher gaseous thermal conductivities, resulting in poorer thermal insulation capacity of the expanded foam.

- [5] It is the focus of the present invention to develop a n-pentane or i-pentane blown rigid foam which avoids the disadvantages associated with the use of cyclopentane and the conventional use of n-pentane and i-pentane as a blowing agent. This focus becomes important later when we look at the utility of the present invention. In particular, as is seen later in these reasons, the debate between the Examiner and the Applicant centres on whether the utility of the invention in relation to two surface tension ranges specified in the claims has been demonstrated or may be soundly predicted.

PROSECUTION HISTORY

- [6] The application was filed on March 3, 1997 and claims priority based on a German patent application filed March 15, 1996. The application was rejected by the Examiner in a Final Action dated February 1, 2011, which identified defects relating to lack of utility under section 2 of the *Patent Act* and sufficiency under subsection 27(3) of the Act, both defects relating to the claimed ranges of surface tension values of n-pentane or i-pentane as a blowing agent with respect to the polyol and polyisocyanate components.
- [7] In its response to the Final Action dated July 28, 2011, the

Applicant did not amend the application and continued to present arguments in favour of compliance with section 2 and subsection 27(3) of the Act.

- [8] The case was forwarded to the Patent Appeal Board (the Board) on November 21, 2011 with a Summary of Reasons (SOR) outlining the outstanding defects. In the SOR the Examiner stated that claims 1-11 lacked utility but no longer put forward a separate issue with respect to sufficiency. Our review is therefore limited to issues relating to utility only.
- [9] In a letter dated May 16, 2012, in response to an offer of a hearing before the Board, the Applicant indicated that they did not wish to attend an oral hearing, nor did they wish to provide further written submissions. From their point of view the record was clear and the Board could proceed with the review based on it.

ISSUES

- [10] The Applicant disputes that it is necessary to make a sound prediction in this case. The Applicant contends that they have demonstrated the utility of the invention by the disclosed examples. Whether or not this is the case becomes the first issue to resolve.
- [11] The Applicant further contends that even if a sound prediction is required to justify the claimed ranges, such a prediction is possible based on the specification and the understanding of surface tension by those skilled in the art. Therefore, if

the utility of the claimed invention has not been demonstrated, our second issue becomes whether or not such a sound prediction is justified.

[12] In light of the above, the Board is faced with two issues:

1) Is this a case of demonstrated utility or predicted utility?

2) If based on predicted utility, are the requirements for a sound prediction met?

THE CLAIMS

[13] In the present case there are 11 claims with claim 1 being the only independent claim. The remaining dependent claims 2-11 relate to refinements of the polyethers or polyesters of component A and the polyisocyanates of component B, which refinements do not relate to the surface tension ranges in dispute. Therefore it is sufficient for the purpose of this review to deal with claim 1, which contains the disputed surface tension ranges common to all the claims. If claim 1 falls, all claims will fall. If claim 1 is allowable, all claims will be allowable. Claim 1 is reproduced below:

1. A process for preparing polyurethane rigid foams from polyols and polyisocyanates as well as blowing agents and optionally foam auxiliary agents, characterised in that the polyurethane rigid foam is obtained by reacting
 - A) a polyol component comprising at least 3 isocyanate-reactive hydrogens and containing

1. 60 to 100% of polyethers and/or polyesters with a molecular weight of 250 to 1,500 and at least 2 hydroxyl groups, which have a surface tension of 6 to 14 mN/m with respect to i-pentane and/or n-pentane as blowing agent, wherein the polyethers are obtained by the polyaddition of 70 to 100 wt. % of ethylene oxide and 0 to 30 wt. % of propylene oxide to starter compounds,
 2. i-pentane and/or n-pentane as blowing agent,
 3. water and
 4. optionally auxiliary agents and additives with
- B) a polyisocyanate with an NCO-content of 20 to 48 wt. % which has a surface tension of 4.0 to 8 mN/m with respect to i-pentane or n-pentane as blowing agent.

[14] In the present case there were no arguments concerning the essentiality of claimed elements and so we take the claims as is with all elements being essential. The focus of the dispute is on a specific portion of the claims, namely the ranges of surface tension values.

ISSUE #1: DEMONSTRATED UTILITY OR PREDICTED UTILITY?

Legal Principles

[15] The requirement that an invention be useful is found in section 2 of the *Patent Act* (emphasis added):

"invention" means any new and useful art,
process, machine,
manufacture or
composition of matter,

or any new and useful
improvement in any art,
process, machine,
manufacture or
composition of matter.

[16] To meet the utility requirement of section 2 of the Act, the invention described in the patent must do what the patent says it will do (i.e., that the promise of the invention be fulfilled, see *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60 at para. 38 [*Teva* (SCC)]).

[17] As of the relevant date (the filing date of March 3, 1997) the utility of the invention must either be demonstrated or based on a sound prediction (*Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197 at para. 74; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 at para. 46 [*AZT*]).

[18] In relation to a situation of demonstrated utility, the Federal Court of Appeal has recently stated that (*Novopharm Limited v. Pfizer Canada Inc.*, 2010 FCA 242 at para. 82):

there is no requirement for a patent to demonstrate utility in the patent disclosure, so long as the trier of fact finds it to be proven upon a legal challenge.

[19] When an invention's utility cannot actually be demonstrated by way of tests or experiments it becomes necessary to base utility on a sound prediction@ (*Teva* (SCC), *supra* at para. 37).

Analysis

[20] As noted at paragraph [16] above, utility is to be assessed

against the promise of the invention. As such, in the following section we perform a brief analysis to clearly point out the promised utility. As is shown below, the promised utility, when considered based on the intrinsic evidence of the specification as a whole, is consistent with the comments of the Examiner and Applicant during prosecution.

The Promised Utility

[21] The Applicant=s views with respect to the promise of the invention are reflected in the response of July 28, 2011 to the Final Action:

Applicants are claiming a process for the production of a rigid polyurethane foam. In the claimed process, an isocyanate satisfying specified criteria, a polyol satisfying specified criteria, water and a blowing agent selected from i-pentane and/or n-pentane are reacted to produce a rigid polyurethane foam.

These foams overcome disadvantages of prior [foams] employing i-pentane and/or n[-]pentane as blowing agent, in particular the rigid foams of the invention are of low thermal conductivity thereby providing thermal insulation. The prior foams had high thermal conductivity (see page 1 of the Disclosure).

[22] In the SOR the Examiner similarly speaks of the Apromised rigid polyurethane foams with improved thermal conductivity@. The Final Action speaks of Apromised [κ]-value benefits@ as well.

[23] In our earlier introduction to the present case we pointed to the prior art problems spoken of by the Applicant in the present application. The application states, subsequent to the prior art discussion:

The object of the present invention was to develop a n-pentane or i-pentane blown rigid foam in which the disadvantages mentioned above are overcome and in particular in which low thermal conductivities are produced.

Surprisingly, it has now been found that polyol formulations based on specific polyethers and/or polyesters and polyisocyanates, which have a specific surface tension with respect to n-pentane or i-pentane as blowing agent, produce expanded materials with particularly low thermal conductivities.

[24] The application goes on to state at page 3 that the invention provides a process for preparing polyurethane rigid foams from polyols and ...@, which statement includes the particular surface tension ranges specified in the claims as well. Although at later points in the description the invention is characterized as preferably@ having these surface tension values, the Applicant provides comparison examples in the description illustrating the importance of particular surface tension values in producing the desired low thermal conductivities.

[25] We note that although recent jurisprudence has cautioned against construing an object clause, such as the one quoted above from the application, as a promise on its own (see e.g., *Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc.*, 2012 FCA 109 at para. 26), in the present case the rest of the specification, including the comparison examples and the claims, is consistent with the objectives set forth therein.

[26] The promised utility is therefore, as stated by the Applicant in the response to the Final Action and as noted in the application itself, overcoming the disadvantages of the prior

art foams employing n-pentane or i-pentane as a blowing agent, to produce a rigid foam of low thermal conductivity.

[27] We now turn to whether the promised utility is demonstrated over the range of surface tension values or whether it must be based on a sound prediction.

Is the Utility Demonstrated?

[28] In the response to the Final Action the Applicant stated:

Applicants have demonstrated in their Examples that materials within the scope of their claimed invention do indeed produce rigid foams.

The Examples also demonstrate that the rigid foams of the invention have low thermal conductivity.

Applicants have also demonstrated in their Examples that the use of materials outside the scope of the claimed invention produce rigid foams which have high thermal conductivity (Example 1 and 3).

[29] Similar statements are made in the previous letter of July 21, 2008:

Examples 4 and 5 are more than adequate to support the claimed range of 4.0 to 8 mN/m for the surface tension, and there is no requirement that the specification include an example to demonstrate the utility of every possible surface tension characteristic within this narrow range.

Indeed, as explained previously in the prosecution, the value of 4.0 represents only a variation of about 20% from the value of 5 in Example 4, and the value of 8 represents only a variation of about 20% in the value of 6.4 in Example 5.

As to the polyol component, Examples 4 and 5 illustrate a value for the surface tension of about 12.4 and this is adequate to support the range of 6 to 14 mN/m.

[30] No reason is given by the Applicant in the above passages as to why Examples 4 and 5 are Amore than adequate@ or Adequate@

to support the claimed range. The Applicant does specify that the claimed endpoints for the isocyanate represent only a 20% variation from the values of 5 and 6.4 from Examples 4 and 5, but no basis has been established to confirm that a 20% variation would still give the promised results.

[31] As noted in the Final Action and SOR, the Examples only demonstrate the utility of the claimed invention at practically one point (12.4 and 12.38 (wherein component A is 80 parts by wt. of a polyether with a surface tension of 12.4 and 20 parts by wt. of a polyether-ester with a surface tension of 12.3 in Example 5)) in the claimed range for the polyol component, in combination with two points (5 and 6.4) in the claimed range for the isocyanate component. The utility of the invention at the upper and lower limits of the claimed ranges has not been demonstrated. In fact lack of utility has been demonstrated at values just below the lower end of the claimed ranges (4.4 for the polyols and 3.3 for the isocyanates), which indicates that the lower limit of the operable range lies somewhere between 4.4 and 12.3 for the polyols and 3.3 and 5 for the isocyanates. Where such an operable lower limit lies must be based on a prediction, based on the lack of demonstrated results.

[32] In the letter of July 21, 2008 the Applicant also contended that the issue of sound prediction Amore properly belongs to situations in which there is no showing of utility at all.@ We cannot agree with such a principle. In the Final Action at page 6 the Examiner made reference to a case similar to the present one, namely *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC

235, in which the Court was faced with a situation where, for a claimed range, two data points were provided, one well outside the range and one well inside the range. The Court stated (emphasis added):

[107] A single point cannot define a range. There is no data at or near the limits of the range nor is there provided data as to a number of points within the stated range so as to establish that in the range there is surprising consistency. A single point within the range does not demonstrate consistency throughout the range.

[108] Therefore the question becomes whether there is sufficient information provided in the =191 patent to enable a person skilled in the art to Asoundly predict@ consistency within the range.

[33] We also point to *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.*, 2010 FC 230 at paras. 71-72 as a further example of a situation where the utility of a claimed range had been only partially demonstrated, the full extent of the claim then requiring a sound prediction.

[34] The Applicant also referred to the decision of the Supreme Court of Canada in *Burton Parsons Chemicals Inc. et al. v. Hewlett-Packard (Canada) Ltd. et al.* (1974), 17 C.P.R. (2d) 97 for the point that Aan applicant must be permitted to adequately claim his invention otherwise his Patent will be useless@ (see letter of July 21, 2008 at page 4). The Applicant also contends that ARequiring restriction of claims to specific working examples which is essentially what is being required in the Requisition would make the Patent worthless.@ We agree that a claimed invention need not be limited to specific working examples. However, as noted above, the jurisprudence requires that if the utility of an invention has not been demonstrated

over the scope of a claim, then it must be based on a sound prediction, which, as is seen later in this recommendation, requires a line of reasoning in order to justify the generalization from the specific demonstration of utility.

[35] In light of the above factual considerations and the related jurisprudence, the answer to our first question is that the claimed ranges of surface tension values must be based on a sound prediction. The utility is not demonstrated.

ISSUE #2: ARE THE REQUIREMENTS FOR A SOUND PREDICTION MET?

Legal Principles

[36] As set forth in *AZT, supra*, an invention that must rely on a sound prediction of utility to justify its scope must satisfy three criteria:

- (1) there must be a factual basis for the prediction
- (2) the inventor must have at the date of the patent application an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis; and
- (3) there must be proper disclosure.

[37] A sound prediction, as noted by the Applicant in the response of July 21, 2008, does not mean a certainty. It does not exclude all risk that some of the area covered may prove devoid of utility. There are two reasons for rejecting claims based on a sound prediction: (1) there is evidence of lack of utility in respect of some of the area covered; or (2) it is not a sound prediction (*Monsanto Co. v. Canada (Commissioner of Patents)*,

(1979) 42 C.P.R. (2d) 161 at 176 (SCC))

Analysis

(1) The Factual Basis

[38] The only factual basis given is that of the examples shown in the description. As noted earlier, they indicate that the promised utility is achieved at a point where the surface tension of the polyol is 12.4 mN/m and the surface tension of the polyisocyanate is 5 mN/m (Example 4), and at a point where the surface tension of the polyol is also 12.4 (rounded off taking into account that 20 parts by wt. of the polyol has a surface tension of 12.3 mN/m and 80 parts by wt. has a surface tension of 12.4 mN/m) and the surface tension of the polyisocyanate is 6.4 mN/m (Example 5). The Table on page 14 of the description presents the product thermal conductivity values showing that Examples 1-3 failed to achieve the promised utility (the structure in Example 2 having collapsed).

(2) and (3) The Line of Reasoning and Its Disclosure

[39] In the letter of July 21, 2008 the Applicant stated:

The line of reasoning and the soundness of the prediction must be as of the filing date. The inventors were aware of results achieved with different surface tension characteristics in the reactants including surface tensions which produced a desired result, and surface tensions which were less successful. These results are included in the specification. The inventors and indeed persons in the art had an understanding of surface tension, and that surface tension effects play a part in foam formation. The data in the specification shows that at low surface tension, [poorer] results are achieved. The art also had an understanding of the effect of

unitary change in surface tension. The inventors reasoned the variations or adjustments in surface tension of the components that would still provide acceptable foams and they set this out in their specification. As indicated, in the *Apotex v. Wellcome* decision [reliance] on *Acertainty*® is not required. Furthermore, an Applicant may take a conservative approach and frame his claims more narrowly than necessary in defining the invention.

[40] We note that the reasoning given in the above passage is not part of the present patent specification.

[41] The Federal Court of Appeal in *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 (pointed to by the Examiner in the Final Action) dealt with a situation related to the present one where the information necessary to make a sound prediction (the Hong Kong study which provided a factual basis for the prediction) was not part of the patent specification. The Court commented on the disclosure requirements for both the factual basis and the line of reasoning (emphasis added):

[14] The decision of the Supreme Court in *AZT* is particularly significant to the disposition of this appeal. According to *AZT*, the requirements of sound prediction are three-fold: there must be a factual basis for the prediction; the inventor must have at the date of the patent application an articulable and sound line of reasoning from which the derived result can be inferred from the factual basis; and third, there must be proper disclosure (*AZT*, supra, at paragraph 70). As was said in that case (para. 70): At the sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly®. In sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction.

[15] In my respectful view, the Federal Court Judge proceeded on proper principle when he held, relying on *AZT*, that when a patent is based on a sound prediction, the disclosure must include the prediction. As the prediction was made sound by the Hong Kong study, this study had to be disclosed.

[42] This line of reasoning has been followed in *Eli Lilly & Co. v.*

Teva Canada Ltd., 2011 FCA 220:

[47] Lilly submits that neither the Patent Act nor the Supreme Court=s jurisprudence requires disclosure of this kind in the patent as a condition precedent to successfully invoking sound prediction as the basis of the utility of the claimed invention. However, while Justice Binnie may not have definitively decided this question in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 70, it has been held in the Federal Court, and affirmed by this Court, that a patentee must disclose in the patent a study that provides the factual basis of the sound prediction: *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, *aff=d.* 2009 FCA 97, 78 C.P.R. (4th) 388 (*Eli Lilly Canada*).

[43] In the present case, there is also no evidence on file in the form of, for example, an affidavit, that this logic was part of the common general knowledge of the person skilled in the art, which knowledge might bridge the gap between the factual basis and a sound prediction (see *Teva Canada Limited v. Novartis AG*, 2013 FC 141 at para. 326). We therefore have no evidence before us as to what persons skilled in the art would have reasoned based on the factual data presented in the application.

[44] Although the Aenhanced@ or Aheightened@ disclosure requirement in relation to sound predictions was noted in *Teva* (SCC), *supra*, it was not an issue in that case and was therefore not addressed (see *Teva* (SCC), *supra* at para. 43). We therefore apply the principles set out by the Courts above (in paras. [41] to [43]) in relation to disclosure of the factual basis and the line of reasoning.

[45] The Applicant contends in the letter of July 21, 2008 that they may take a Aconservative approach@ in defining the invention

in light of the examples and that the claimed surface tension ranges represent a Amodest variation of the successful surface tension parameters of Examples 4 and 5, taking account of the comparison examples.@ While the panel agrees that in light of the factual basis, some variation would be possible while still providing the promised utility, without a line of reasoning we find that the person skilled in the art would have no way of knowing what is a soundly predictable variation from the demonstrated parameters of Examples 4 and 5.

[46] In the present case, even if what the Applicant contended to be a sound line of reasoning in their submissions was sufficient, it is not disclosed as part of the application, nor did the Applicant file any evidence that it was part of the common general knowledge of the skilled person. Therefore such reasoning cannot justify the necessary prediction based on the examples given in the description.

[47] Specifically, we find that the person skilled in the art would not be able to predict if the full scope of the claimed surface tension ranges of 6 to 14 mN/m for the polyol component in combination with 4.0 to 8 mN/m for the polyisocyanate component would provide the promised utility.

RECOMMENDATION OF THE BOARD

[48] In view of the above findings, the Board recommends that the application be refused for the utility of the claimed subject matter being neither demonstrated nor soundly predicted, the application therefore being non-compliant with section 2 of the

Patent Act.

Stephen MacNeil
Member

Paul Fitzner
Member

Christine Teixeira
Member

DECISION OF THE COMMISSIONER

[49] I concur with the Patent Appeal Board=s findings and its recommendation that the application be refused for the utility of the claimed subject matter being neither demonstrated nor soundly predicted, the application therefore being non-compliant with section 2 of the *Patent Act*.

[50] Accordingly, I refuse to grant a patent on this application. Under section 41 of the *Patent Act*, the Applicant has six months within which to appeal my decision to the Federal Court of Canada.

Sylvain Laporte
Commissioner of Patents

Dated at Gatineau, Quebec,
this 28th day of March, 2013