Commissioner’s Decision No. 1508

Décision du commissaire n^{o} 1508

TOPICS: F00 Novelty

O00 Obviousness

B00 Indefiniteness

SUJETS: F00 Nouveauté

O00 Évidence

B00 Caractère indéfini

Application No. 2,576,158

Demande n^{o} 2 576 158

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,576,158, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Rules*), has consequently been reviewed in accordance with paragraph 199(3)(*c*) of the *Patent Rules* (SOR/2019-251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are that the application be allowed only if the necessary amendments are made.

Agent for the Applicant

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,576,158, which is entitled "Adhesive Composition" and is owned by A.V. Topchiev Institute of Petrochemical Synthesis (the Applicant). A review of the rejected application has been conducted by the Patent Appeal Board (the Board) pursuant to paragraph 199(3)(*c*) of the *Patent Rules*.

[2] As explained below, our recommendation is that the Commissioner of Patents inform the Applicant by notice pursuant to subsection 86(11) of the *Patent Rules* that specific amendments are necessary in order to make the application allowable. If these amendments are made the application should be allowed; otherwise, it should be refused.

BACKGROUND

The Application

[3] The application was filed on August 4, 2005 under the provisions of the *Patent Cooperation Treaty* and was laid open to the public on February 16, 2006.

[4] The application relates generally to adhesive compositions that can be used in a variety of products requiring adhesion to a surface of the body, such as wound dressings, blister cushions, transdermal drug delivery devices and products for application to the teeth or oral mucosa. The adhesive compositions combine at least a hydrophilic polymer, a complementary polymer which hydrogen bonds to the hydrophilic polymer, and a phyllosilicate clay.

Prosecution History

[5] On September 25, 2015, a Final Action (FA) was issued pursuant to subsection 30(4) of the former *Rules*. The FA indicated that that application was defective on four grounds: (i) claims 1-8, 11-18, 26-28, 31 and 32 on file are anticipated, contrary to paragraph 28.2(1)(*a*) of the *Patent Act*; (ii) claims 29 and 30 on file are anticipated, contrary to paragraph 28.2(1)(*b*) of the *Patent Act*; (iii) claims 1-32 on file are obvious, contrary to

section 28.3 of the *Patent Act*; and (iv) claim 11 is indefinite, contrary to subsection 27(4) of the *Patent Act*.

[6] The Applicant responded to the FA in a letter dated March 24, 2016 (RFA) by proposing an amended set of claims in order to address all of the defects identified in the FA. No arguments were presented in support of the patentability of the claims on file in the RFA. The Examiner prepared a Summary of Reasons (SOR) which explained that the proposed amendments were considered to remedy the anticipation and indefiniteness defects, but not the obviousness defect. Therefore, pursuant to paragraph 30(6)(*b*) of the former *Rules*, the proposed amendments were not entered and the application was forwarded to the Board for review. On October 11, 2016, the Board forwarded a copy of the SOR to the Applicant. In a response dated January 11, 2017, the Applicant indicated that it would proceed with written submissions only and that an oral hearing was not desired.

[7] This Panel was formed to review the rejected application and make a recommendation to the Commissioner as to its disposition. Following our preliminary review, we sent a letter on July 29, 2019 (PR letter) presenting a preliminary analysis and rationale regarding the patentability of the claims on file in view of the issues raised in the FA, and addressing the claim amendments proposed by the Applicant in the RFA. In accordance with subsection 30(6.1) of the former *Rules*, the PR letter also informed the Applicant of our preliminary view that claims 1 and 9 on file are indefinite, contrary to subsection 27(4) of the *Patent Act*. We invited the Applicant to an oral hearing, in spite of its earlier indication that a hearing was not desired, in case it reconsidered in view of any points raised in the PR letter. The Applicant was further invited to make submissions on all of the issues addressed in the PR letter and any other points it considered as being relevant to the review.

[8] The Applicant responded to the PR letter in a letter dated August 13, 2019 (RPR) by replacing the proposed claims with a new set of proposed claims 1-31 (the proposed claims) to address the outstanding issues identified in the PR letter. Our invitation to attend an oral hearing was declined, and once again no arguments were presented in support of the patentability of the claims on file in the RPR.

[9] As nothing has changed in the record since the PR letter in relation to the claims on file, this review refers to the analysis of those claims that was provided in the PR letter.

ISSUES

[10] There are four issues to be addressed by this review with respect to claims 1-32 on file:

i) whether claims 1-8, 11-18 and 26-28, 31 and 32 on file are anticipated, contrary to paragraph 28.2(1)(*a*) of the *Patent Act*;

ii) whether claims 29 and 30 on file are anticipated, contrary to paragraph 28.2(1)(*b*) of the *Patent Act*;

iii) whether claims 1-32 on file are obvious, contrary to section 28.3 of the *Patent Act*; and

iv) whether claims 1, 9 and 11 on file are indefinite, contrary to subsection 27(4) of the *Patent Act*.

[11] After addressing these issues, we turn to the question of whether the specific amendments proposed in the RPR qualify as "necessary" amendments under subsection 86(11) of the *Patent Rules*.

LEGAL PRINCIPLES AND OFFICE PRACTICE

Purposive construction

[12] In accordance with *Free World Trust v Électro Santé*, 2000 SCC 66, essential elements are identified through a purposive construction of the claims done by considering the whole of the disclosure, including the specification and drawings (see also *Whirlpool v Camco*, 2000 SCC 67 at paragraphs 49(f) and (g) and 52). In accordance with the *Manual of Patent Office Practice*, (*MOPOP*) at §12.02, revised June 2015 (CIPO*)*, the first step of purposive claim construction is to identify the person of ordinary skill in the art and their relevant common general knowledge (CGK). The next step is to identify the problem addressed by the inventors and the solution put forth in the application. Essential elements can then be identified as those elements of the claims that are required to achieve the disclosed solution.

Anticipation

[13] Subsection 28.2(1) of the *Patent Act* requires claimed subject-matter to be new:

> The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> *(a)* more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
>
> *(b)* before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
>
> …

[14] There are two separate requirements to show that prior art anticipates a claimed invention: there must be a prior disclosure of the claimed subject-matter and the prior disclosure must enable the claimed subject-matter to be practised by a skilled person (*Apotex Inc v Sanofi–Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*] at paras 24–29, 49).

[15] "Prior disclosure" means that the prior art must disclose subject-matter which, if performed, would necessarily result in infringement of the patent. The skilled person looking at the disclosure is "taken to be trying to understand what the author of the description [in the prior patent] meant" (*Sanofi* at para 32). At this stage, there is no room for trial and error or experimentation by the skilled person. The prior art is simply read "for the purposes of understanding it" (*Sanofi* at para 25, citing *Synthon BV v SmithKline Beecham plc*, [2006] 1 All ER 685, [2005] UKHL 59).

[16] "Enablement" means that the person skilled in the art would have been able to perform the invention without undue burden. The person skilled in the art is assumed to be willing to make trial and error experiments to get it to work (*Sanofi* at paras 26–27).

Obviousness

[17] Section 28.3 of the *Patent Act* requires claimed subject matter to not be obvious:

> The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

> *(a)* information disclosed more than one year before the filing date by the Applicant, or by a person who obtained knowledge, directly or indirectly, from the Applicant in such a manner that the information became available to the public in Canada or elsewhere; and
>
> *(b)* information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

[18] In *Sanofi* at para 67, the Supreme Court of Canada stated that it is useful in an obviousness inquiry to follow the following four-step approach:

> (1)(*a*) Identify the notional "person skilled in the art,"
> (*b*) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

Indefiniteness

[19] Subsection 27(4) of the *Patent Act* requires claims to distinctly and explicitly define subject-matter:

> The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

[20] In *Minerals Separation North American Corp v Noranda Mines Ltd,* [1947] Ex CR 306 at 352, 12 CPR 99, the Court emphasized both the obligation of an applicant to make clear in the claims the ambit of the monopoly sought and the requirement that the terms used in the claims be clear and precise:

> By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.

ANALYSIS OF THE CLAIMS ON FILE

Claims construction

The skilled person and the relevant CGK

[21] The skilled person was identified in the PR letter as "a formulation chemist with expertise and full knowledge of medical grade adhesives" and "expertise in the formulation of adhesives that adhere to the skin or other surfaces of the body" (page 5).

[22] On page 6, the PR letter identified the relevant CGK of the skilled person as including:

1) the standard components and typical additives that are commercially available and commonly used in body-contacting adhesive formulations, including the various types of tackifying agents, such as tackifying resins;
2) the common commercial products, including therapeutic products, that adhere to various body surfaces;
3) the general use of clay particles in adhesive compositions for various purposes (e.g., as fillers, absorbents or adhesiveness modulators);
4) the typical particle sizes of pure clays and the units generally used to define particle size, including μm (micrometers, the international standard SI unit) and its quantitative equivalent μ (microns);
5) silicate clay layers are naturally hydrophilic, and intercalation of some polymers between layers (e.g., hydrophobic polymers) may require modification of the clay layers, such as by ion-exchange with quaternary ammonium compounds, to first render the clay layers hydrophobic and organophilic to increase compatibility;
6) a polymer is a large molecule that is made of up smaller repeating subunits, referred to as monomers, that are chemically joined together; and
7) an oligomer is a low molecular weight polymer that has fewer repeating subunits compared to high molecular weight polymers.

Point 3) finds support in the background section of US5300291 (cited as document D2 in the FA) at column 1, line 57-column 3, line 20.

> Points 4) and 5) find support in the Applicant's description (paras 0072-0073), in the document US2003/0225356 (cited as document D1 in the FA) that is cited in the present description (see D1 paras 0086-0087), and in the following textbook that is also cited in the present description: T.J. Pinnavaia and G.W. Beall, eds, *Polymer-Clay Nanocomposites* (Chichester: John Wiley & Sons Ltd, 2000) at 97-109, 183 and 194.
>
> Points 6) and 7) find support in the following textbook: Malcolm P. Stevens, *Polymer Chemistry: An Introduction*, 2nd ed (New York: Oxford University Press, 1990) at 7-8.

[23] The Applicant did not contest or comment on these characterizations of the skilled person or the CGK.

The problem to be solved and the proposed solution

[24] The problem and solution were identified on page 6 of the PR letter as follows:

> The description at para 007 expresses the problem as a need for self-adhering dressings which provide improved tack, prolonged adhesion, greater fluid handling capability, higher cohesive strength, decreased cold flow, less erosion, controlled active delivery, ease of manufacturability, and translucency. The solution is expressed in terms of the disclosed formulations that provide increased resistance to cold flow, improved tackiness to dry skin and higher moisture uptake without the loss of adhesion. Notably, all of the disclosed formulations combine at least a hydrophilic polymer, a complementary polymer and a phyllosilicate clay. We consider these as reasonable and propose characterizing the problem and solution in these terms.

The claims on file

[25] Independent claims 1 and 29 represent most of the claims on file. The claims read as follows:

> 1. A composition comprising:
> -a hydrophobic polymer;
> -an elastomeric plasticizer;
> -a tackifying resin;
> -a hydrophilic polymer;
> -a complementary polymer which hydrogen bonds to the hydrophilic polymer; and
> -clay particles comprising phyllosilicate.
>
> 29. A composition comprising:

-a hydrophilic polymer selected from poly (N-vinyl lactams), poly(N-vinyl amides), poly(N-vinylacrylamides), poly(N-alkylacrylamides), polyacrylic acids, polymethacrylic acids, polyvinyl alcohol, polyvinylamine, cellulose derivatives, polysaccharides, and copolymers and blends thereof;
-a complementary polymer which hydrogen bonds to the hydrophilic polymer, wherein the complementary polymer is formed of components selected from low molecular weight polyalkylene glycols, low molecular weight polyalcohols, monomeric and oligomeric alkylene glycols, ether alcohols, carbonic diacids, and alkane diols; and
-clay particles comprising phyllosilicate.

[26] The main difference between these claims is that claim 29 only contains hydrophilic components: the first three hydrophobic components defined in claim 1 (i.e., a hydrophobic polymer, an elastomeric plasticizer and a tackifying resin) are omitted. Notably, the description explains that for certain applications, such as a slowly dissolving film, the hydrophobic components can be omitted (paras 0035 and 00102).

[27] We also reproduce independent claim 19 since it more fully defines the three hydrophobic components:

19. A composition comprising:
-a hydrophobic polymer selected from polyisoprenes, butyl rubbers, styrene-isoprene-styrene block copolymers and styrene-butadiene-styrene block copolymers;
-an elastomeric plasticizer selected from styrene-based plasticizers, low molecular weight polyisobutylenes, low molecular weight isoprene rubbers, and combinations thereof;
-a tackifying resin selected from hydrogenated hydrocarbon resins, hydrocarbon resins and synthetic polyterpene resins;
-a hydrophilic polymer selected from poly(N-vinyl lactams), poly(N-vinyl amides), poly(N-vinyl acrylamides), poly(N-alkylacrylamides), polyacrylic acids, polymethacrylic acids, polyvinyl alcohol, polyvinylamine, cellulose derivatives, polysaccharides, and copolymers and blends thereof;
-a complementary polymer which hydrogen bonds to the hydrophilic polymer, wherein the complementary polymer is formed of components selected from low molecular weight polyalkylene glycols, low molecular weight polyalcohols, monomeric alkylene glycols, oligomeric alkylene glycols, ether alcohols, carbonic diacids, and alkane diols; and
-clay particles comprising phyllosilicate particles.

Meaning of Terms

[28] All of the independent claims include "a complementary polymer". As mentioned above, it is CGK that polymers and oligomers are made of up smaller repeating subunits, referred to monomers, which are chemically joined together. However, in contrast to the usual meaning of these terms, the application defines polymers and oligomers as including single unit monomers, like ethylene glycol, that are not joined to anything else (p14, para 0059-0062):

> The complementary polymer can be a polymer, and [*sic*] oligomer, or any low molecular weight substance that is capable of forming hydrogen bonds with the hydrophilic polymer.
>
> Preferably, the complementary polymer is a complementary oligomer.
>
> Generally, the complementary oligomer will have a molecular weight in the range from about 45 to about 800, preferably in the range of about 45 to about 600. The complementary oligomer is preferably a low molecular weight polyalkylene glycol (molecular weight 300-600)…
>
> Other examples of suitable complementary oligomers include, but are not limited to, low molecular weight polyalcohols (e.g., glycerol), monomeric and oligoalkylene glycols such as ethylene glycol and propylene glycol, ether alcohols (e.g., glycol ethers), carbonic diacids, alkane diols from butane diol to octane diol...polyethylene glycols having a molecular weight in the range of about 300 to 600 are optimal complementary oligomers. (emphasis added)

[29] On pages 8-9 of the PR letter, we expressed the view that, based on the above definitions, which include specific small molecules and compounds having molecular weights as low as 45 g/mol, the skilled person would understand that in claim 1 "complementary polymer" encompasses single unit monomers, oligomers and polymers. By contrast, claims 19 and 29 further limit the complementary polymer by specifying that it is "formed of components selected from low molecular weight polyalkylene glycols, low molecular weight polyalcohols, monomeric alkylene glycols, oligomeric alkylene glycols, ether alcohols, carbonic diacids, and alkane diols". In our view, the expression *formed of components* would indicate to the skilled person that the complementary polymer is made of up of a plurality of monomer units chemically joined together, and would therefore not include single unit monomers. In other words, "complementary polymer" is restricted to

polymers and oligomers in claims 19 and 29, but also includes single unit monomers in claim 1.

Essential elements that contribute to the proposed solution

[30] In the PR letter, we addressed the essential elements as follows (page 9):

> In our view, the skilled person would consider all of the composition components defined in independent claims 1, 19 and 29 to be essential elements contributing to the proposed solution.
>
> Independent claims 26-28, 31 and 32 are for specific products that use the composition of claim l for adhering to a body surface. Specifically, the claims are directed to an adhesive cushion (claim 26), a wound dressing (claim 27), a transdermal drug delivery device (claim 28) and an oral care product for application to the teeth or oral mucosa (claims 31 and 32). As above, our view is that the skilled person would consider all of the elements of these claims as essential.
>
> Dependent claims 2-18, 20-25 and 30 provide further limitations relating to the six components of the composition and their relative amounts (claims 2-14 and 20-25), or provide further actives or additives (claims 15-18 and 30). In our view, the skilled person would consider these claims as further characterizing or limiting the essential elements of the independent claims.

Anticipation

[31] The FA identified two documents:

D1: US2003/0225356	Kulichikhin et al.	Published: December 4, 2003
D2: US5300291	Sablotsky et al.	Published: April 5, 1994

Document D1

[32] The FA considered that D1 was relevant to claims 1-8, 11-18, 26-28, 31 and 32. D1 was characterized on pages 9-10 of the PR letter as follows:

> D1 discloses body-surface adhesive compositions useful for a variety of applications including adhesive cushions, wound dressings and transdermal drug delivery devices (see the claims, for example). The adhesive compositions have a hydrophilic phase comprising three components i) a high molecular weight cellulose derived polymer, ii) a low molecular weight cellulose derived polymer or naturally occurring polysaccharide, and iii) clay particles (see paras 0012, 0025, 0042, 0066 and 0086-

> 0087). The FA points specifically to formulations 9-13 of example 6, each of which contains components i) and ii) above along with Cloisite Na^+ (a phyllosilicate clay). Formulations 9-13 further comprise a hydrophobic styrene-isoprene-styrene block copolymer, an elastomeric polyisoprene or styrene-based plasticizer, a hydrocarbon tackifying resin, an adhesive agent and an antioxidant. D1 also discloses active agents, permeation enhancers and the relative amounts of each component of the adhesive compositions (see paras 0088-0089, 00101, 00115, and the claims).

[33] On page 10 of the PR letter, we noted that the definitions of the "hydrophilic polymer" and the "complementary polymer" in claim 1 on file are each broad enough to encompass high and low molecular weight cellulose derivatives and polysaccharides. The FA appears to indicate on page 2 that the high molecular weight cellulose derivative in part i) corresponds to the claimed "complementary polymer", and the polysaccharide and low molecular weight cellulose in part ii) correspond to the "hydrophilic polymer". We expressed our view that the reverse case would also be true. In any case, our view was that the analysis of the claims on file would be the same either way.

[34] On page 10 of the PR letter, we addressed earlier arguments concerning D1 that were made by the Applicant in the letter of October 11, 2013:

> The Applicant had contended that the hydrogen bonding that is defined in the claims as taking place between the two polymers is not inherently present in the compositions of D1: since the hydroxyl groups of the cellulose derivatives of D1 have been partially or fully reacted, leaving few or no hydroxyl groups free to participate in hydrogen bonding, the polymers in D1 would not necessarily and always allow hydrogen bonding. In response, the FA (page 2) contended that a single hydrogen bond between the two polymers would anticipate the claims on file, and that given the abundance of free hydroxyl groups in each of the polymers in example 6, hydrogen bonding would occur.
>
> In our view, the skilled person reading D1 would recognize that the polymers of i) and ii) would each have at least some free hydroxyl groups capable of hydrogen bonding, and that hydrogen bonding would take place between the polymers via those groups. The claims on file do not specify the degree or extent of hydrogen bonding that takes place between the hydrophilic polymer and the complementary polymer, and so the claims cannot be distinguished from D1 on that basis. Although it is not explicit in D1, our preliminary view is that hydrogen bonding between the polymers of i) and ii) would necessarily take place, and is thus inherent.

[35] On pages 10-11 of the PR letter, we expressed the view that all of the elements defined within claims 1-7, 11-18 and 26-28 on file are disclosed in D1, and that the compositions and steps in example 6 constitute a disclosure of subject-matter which, if performed, would necessarily infringe those claims. With respect to enablement, we expressed the view that D1 discloses the compositions sufficiently for a skilled person to produce them.

[36] By contrast, the hydrophilic polymer defined in claim 8 does not encompass high or low molecular weight cellulose derivatives or polysaccharides. On that basis, the PR letter stated on page 11 that we did not consider the subject-matter of claim 8 as being disclosed within D1. Likewise, D1 does not mention oral care products, and so the view expressed in the PR letter was that we did not consider the subject-matter of claims 31 and 32 as being disclosed within D1.

[37] In response, the Applicant did not contest or comment on any of the views expressed in the PR letter. Our conclusion is therefore that claims 1-7, 11-18 and 26-28 on file are anticipated by D1.

Document D2

[38] The FA considered that D2 was relevant to claims 29 and 30. D2 was characterized on page 11 of the PR letter as follows:

> D2 discloses skin-adhesive compositions for applications including transdermal drug delivery which comprise an acrylic polymer and a clay, and optionally an alkylene glycol as a solvent or permeation enhancer (see col 10, lines 24-43, col 11, lines 41-44, and the examples). The FA points specifically to the compositions that are exemplified in columns 17-20 which include a methacrylic polymer (the hydrophilic polymer), Korthix H-NF (the phyllosilicate clay) and propylene glycol, dipropylene glycol and/or butylene glycol (the complementary polymer). The acrylic polymer can be a homopolymer or copolymer of various acrylic acids, including methacrylic acids (see col 7, line 62 to col 8, line 25). D2 also discloses a variety of natural and synthetic elastomeric rubber polymers, such as polyisoprene, styrene/butadiene polymers, styrene-isoprene-styrene and polyisobutylene, and tackifying resins such as aliphatic and aromatic hydrocarbon resins, terpene resins and rosin ester resins (see col 6, lines 33-36, col 9, lines 1-17, col 13, lines 50-54, col 14, lines 19-45, and the examples). While D2 discloses using tackifying resins in the adhesive compositions, and a number of commercially available resins are identified in the examples section in column 13-14, no tackifying resins are included in the example compositions of columns 17-20.

[39] In the PR letter we pointed out on page 11 that, insofar as the independent claims were concerned, the FA only considered D2 as being relevant to claim 29 because it is the only independent claim that does not explicitly include a tackifying resin. Recall that, unlike the other independent claims, claim 29 defines only three components: the hydrophilic polymer, the complementary polymer, and clay particles comprising phyllosilicate.

[40] The FA on page 2 only considered propylene glycol in the examples of columns 17-20 in D2 to correspond to the complementary polymer, however we expressed the view in the PR letter that dipropylene and butylene glycol—which are also monomeric alkylene glycols—would correspond to the complementary polymer as well.

[41] As discussed above, unlike the more broadly defined "complementary polymer" of claim 1, the "complementary polymer" of claim 29 is limited to polymers and oligomers. On page 11 of the PR letter, we expressed the view that since the composition in claim 29 does not include single unit monomers such as those in the examples of columns 17-20, D2 does not disclose the subject-matter of claim 29. Further, since claim 30 is dependent on claim 29 and shares the same definition of "complementary polymer", we did not consider the subject-matter of claim 30 as being disclosed in D2 either. Our conclusion is therefore that claims 29 and 30 comply with paragraph 28.2(1)(*b*) of the *Patent Act*.

Conclusion on Anticipation

[42] We conclude that the subject-matter of claims 1-7, 11-18 and 26-28 is anticipated by D1, contrary to paragraph 28.2(1)(*a*) of the *Patent Act*.

[43] We further conclude that the subject-matter of claims 29 and 30 on file is not disclosed by D2, and so these claims comply with paragraph 28.2(1)(*b*) of the *Patent Act*.

Obviousness

(1) Identify the notional person skilled in the art and the relevant common general knowledge of that person

[44] The skilled person has already been identified above. The relevant CGK identified above is considered to be valid as of the claim date and is therefore applicable for the purpose of assessing obviousness.

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it

[45] We addressed the inventive concepts of the claims on pages 12-14 of our PR letter as follows:

> In the FA at page 3, the inventive concept of the claims on file was characterized as follows:
>
> > According to the description, the invention pertains to adhesive compositions which are suitable for use in dermal medical applications such as wound dressings and transdermal drug delivery. The adhesive compositions comprise a hydrophobic polymer, an elastomeric plasticizer, a tackifying resin, a hydrophilic polymer, a complementary polymer which hydrogen bonds to the hydrophilic polymer and a phyllosilicate clay.
>
> The Applicant did not contest the inventive concept. In our view, this inventive concept is generally consistent with claim 1, but does not capture the embodiments of the other claims. As mentioned above, our view is that the skilled person would consider all of the elements in the claims to be essential, and so they should be reflected in the inventive concepts of the claims.
>
> Also relevant to all of the inventive concepts, page 3 of the FA adds:
>
> > It also appears that when the "complementary polymer" is an oligomer or small molecule, such as those defined in instant claim 9, that hydrogen bonding occurs between the hydrophilic polymer and oligomer or small molecule which leads to a temporary network which allows for intercalation of the oligomer and phyllosilicate clay. This narrower embodiment appears to give rise to additional properties that may not have been expected to occur in compositions which comprise a "complementary polymer" which is <u>larger than the aforementioned oligomers or small molecules</u>. (emphasis added)
>
> In other words the FA did not take into account any "additional properties" resulting from intercalation for any claims defining the complementary polymer as being larger than an oligomer or small molecule. We understand this statement as implying that large polymers would not intercalate between the layers of the phyllosilicate clay, or that there is an insufficient basis supporting that intercalation would take place with a large polymer. This was not contested in the RFA, however this is inconsistent with the CGK and the teachings of the description (paras 0072, 00116, Ex 1 and 2). According to the description, the hydrogen bonding that takes place between the hydrophilic polymer and complementary polymer leads to the formation of "a rather rare physical

network" that prevents fast dissolution and "permits the intercalation process to occur" (para 00146, Ex 2). The skilled person would be aware of the ability of polymers to intercalate between clay layers in the same way as oligomers and small molecules: this was well known and had been demonstrated in multiple fields for a variety of polymers of different polarities. As such, our preliminary view is that the skilled person would consider the improved properties associated with the combination of the hydrophilic polymer, complementary polymer and phyllosilicate clay (i.e., improved cold flow, tackiness and moisture uptake) to be part of the inventive concept of all the claims, including claim 1.

In our view, the skilled person would consider the inventive concept of claim 19 to be the same as claim 1 except for its more narrowly defined components:

- a hydrophobic polymer selected from polyisoprenes, butyl rubbers, styrene-isoprene-styrene block copolymers and styrene-butadiene-styrene block copolymers;
- an elastomeric plasticizer selected from styrene-based plasticizers, low molecular weight polyisobutylenes, low molecular weight isoprene rubbers, and combinations thereof;
- a tackifying resin selected from hydrogenated hydrocarbon resins, hydrocarbon resins and synthetic polyterpene resins;
- a hydrophilic polymer selected from poly(N-vinyl lactams), poly(N-vinyl amides), poly(N-vinyl acrylamides), poly(N-alkylacrylamides), polyacrylic acids, polymethacrylic acids, polyvinyl alcohol, polyvinylamine, cellulose derivatives, polysaccharides, and copolymers and blends thereof;
- a complementary polymer which hydrogen bonds to the hydrophilic polymer, wherein the complementary polymer is formed of components selected from low molecular weight polyalkylene glycols, low molecular weight polyalcohols, monomeric alkylene glycols, oligomeric alkylene glycols, ether alcohols, carbonic diacids, and alkane diols; and
- clay particles comprising phyllosilicate particles.

The inventive concept of independent claim 29 is the same as claim 19 except for the omission of the hydrophobic components (i.e., the hydrophobic polymer, the elastomeric plasticizer and the tackifying resin).

Independent claims 26-28, 31 and 32 define specific products using the adhesives of claim 1: an adhesive cushion (claim 26), a wound dressing (claim 27), a transdermal drug delivery device (claim 28), an oral care product for application to the teeth (claim 31) and an oral care product for application to the oral mucosa (claim 32). In our view, the skilled person would consider these limitations as part of the inventive concepts of these claims.

> Dependent claims 2-18, 20-25 and 30 further limit the six components of the compositions and their relative amounts (claims 2-14 and 20-25), or provide further actives or additives (claims 15-18 and 30). In our view, the skilled person would consider these limitations as part of the inventive concepts of these claims.

(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed

[46] The FA considered D2 as relevant to the assessment of the obviousness. As mentioned above during the discussion of anticipation, all the components of the composition of claim 1, including alkylene glycols, are found within the examples in columns 17-20 of D2 except for the tackifying resin. The use of tackifying resins in the adhesive compositions is taught elsewhere within D2, however.

[47] In the PR letter, the differences were identified as follows:

> D2 does not mention the improved properties associated with the combination of a hydrophilic polymer, complementary polymer and the phyllosilicate clay (i.e., improved cold flow, tackiness and moisture uptake). However, the compositions disclosed in the examples of columns 17-20 contain that same combination, and so the properties in question would have necessarily been present for those compositions. The only difference between the inventive concept of claim 1 and the compositions in columns 17-20 is therefore that those compositions do not contain a tackifying resin.
>
> The additional features of claims 2-7, 12, 15-18, 20-22, 25 and 28 are taught within D2, and so these are not further differences.
>
> A difference between D2 and the inventive concepts of claims 8 and 23 is that these claims effectively exclude acrylic polymers by defining the hydrophilic polymer as poly(N-vinyl lactams), poly(N-vinyl amides), poly(N-vinyl acrylamides), and copolymers and blends thereof.
>
> A difference between D2 and the inventive concepts of claims 9, 10, 19, 24 and 29 is that these claims do not include propylene glycol, dipropylene glycol and butylene glycol (used in the examples of columns 17-20) since, as discussed above, the complementary polymer in these claims would be construed by the skilled person as being restricted to polymers and oligomers.
>
> Finally, further differences are that claims 11, 13, 14, 26, 27 and 30-32 define the clay particle size (claim 11), the relative amounts of the components (claims 13 and 14), products other than transdermal delivery devices that adhere to body surfaces (claims

26, 27, 31 and 32) and the addition of a water-swellable water-insoluble polymer (claim 30), which are not disclosed in D2.

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[48] We addressed each of these differences in the PR letter, as follows:

> The adhesive compositions disclosed in the examples of columns 17-20 do not include a tackifying resin. However, adding a tackifying resin to adhesive compositions is CGK, and is specifically taught within D2, and so adding a tackifying resin to the compositions of columns 17-20 would not constitute a step that would require any degree of invention on the part of the skilled person. In our view, claim 1 on file would have been obvious to the skilled person in view of D2.
>
> Since there are no differences between D2 and the inventive concepts of claims 2-7, 12, 15-18, 20-22, 25 and 28, there are no further steps that would have required any degree of invention. In our view, these claims would also have been obvious to the skilled person for the same reasons as claim 1.
>
> Claims 8 and 23 do not include acrylic polymers as the hydrophilic polymer. While there are other hydrophilic polymers taught within D2, there is no mention of the polymers specified in claims 8 and 23. In our view, the step of substituting the polymers in the D2 combination with the polymers defined in claims 8 and 23 to achieve the resulting properties of improved cold flow, tackiness and moisture uptake would constitute a step requiring a degree of invention. It is therefore our preliminary view that claims 8 and 23 would not have been obvious to the skilled person.
>
> Claims 9, 10, 19, 24 and 29 do not include monomeric alkylene glycols as the complementary polymer. D2 teaches that the monomeric alkylene glycols used in columns 17-20 are solvents or permeation enhancers. In our view, the step of substituting the solvents or permeation enhancers in the D2 combination with a complementary polymer as defined in these claims to achieve the resulting properties of improved cold flow, tackiness and moisture uptake would require a degree of invention. Our preliminary view is that claims 9, 10, 19, 24 and 29 would not have been obvious to the skilled person.
>
> The particular clay particle size, the relative amounts of the components and the addition of a water-swellable, water insoluble polymer in claims 11, 13, 14 and 30 are all features that fall within the CGK of the skilled person. In our view, the skilled person would not consider these as requiring any degree of invention. It is therefore our preliminary view that these claims would have been obvious to the skilled person.

> Finally, with respect to the products defined in claims 26, 27, 31 and 32, our view is that it would have been obvious to use the dermal adhesive taught in D2 in other commonly known products that adhere to a surface of the body, and doing so would not require any degree of invention. It is therefore our preliminary view that using the adhesive composition in D2 in the products disclosed in claims 26, 27, 30 and 31 would have been obvious to the skilled person.

[49] In response, the Applicant did not contest or comment on any of the preliminary views expressed in the PR letter. Our conclusion is therefore that 1-7, 11-18, 20-22, 25-28 and 30-32 would have been obvious in view of D2.

Conclusion on obviousness

[50] Our conclusion is that the subject-matter of claims 1-7, 11-18, 20-22, 25-28 and 30-32 would have would have been obvious to the skilled person in view of D2, considered in light of their CGK, contrary to subsection 28.3(*b*) of the *Patent Act*.

Indefiniteness

Claim 11

[51] The FA on page 4 states that claim 11 on file does not comply with subsection 27(4) of the *Patent Act* because the average diameter of the clay particles is expressed in microns (μ) instead of micrometers (μm). On page 16 of the PR letter, we explained that because the skilled person's CGK includes the units conventionally used to express the diameter of such particles, the skilled person would be aware that microns and micrometers are equivalent and can be used interchangeably. While SI units are the international standard, the micron remains a commonly used and accepted unit of measure. We therefore did not consider that the use of microns in claim 11 would be indefinite, ambiguous or otherwise confusing to the skilled person. Our conclusion is that claim 11 is definite and complies with subsection 27(4) of the *Patent Act*.

Claims 1 and 9

[52] We addressed claim 1 on pages 16-17 of the PR letter:

> As mentioned above, the description defines the "complementary polymer" as encompassing monomers and small molecules which is at odds with the plain and ordinary meaning of "polymer" in the art. The Applicant is entitled to act as their own lexicographer, however when doing so creates a definition that is contrary to the usual meaning ascribed to a term in the art, that is liable to cause confusion or avoidable ambiguity. The terms used in a claim should be clear, precise and free from avoidable ambiguity.

[53] The Applicant did not contest or comment on this characterization. Instead, the Applicant opted to address this defect with a proposed amendment. Our conclusion is therefore that defining "a complementary polymer" as encompassing single unit monomers renders claim 1 ambiguous, contrary to subsection 27(4) of the *Patent Act*.

[54] We further addressed claim 9 on page 17 of the PR letter, expressing a general concern that defining a product "as an oligomer that is "formed of components" that are themselves oligomers" introduces confusion or ambiguity.

[55] In response, the Applicant did not contest or comment on this characterization, nor were any amendments proposed to address this concern. However, upon further consideration we are not satisfied that this wording, insofar as it relates to polyalkylene glycol (PAG), would be unclear or confusing to the skilled person. The product in claim 9 is clearly and explicitly limited to oligomers, and the skilled person would know that lower molecular weight PAGs can be used as starting material to produce larger PAGs that would still be considered as oligomers by the skilled person. Our conclusion is therefore that claim 9 on file complies with subsection 27(4) of the *Patent Act*.

Conclusion on Indefiniteness

[56] Our conclusion is that claim 1 is ambiguous, contrary to subsection 27(4) of the *Patent Act*.

Conclusions for the claims on file

[57] We have concluded that:

- the subject-matter of claims 1-7, 11-18 and 26-28 on file is disclosed and enabled by D1, contrary to paragraph 28.2(1)(*a*) of the *Patent Act*;

- the subject-matter of claims 29 and 30 on file is not disclosed by D2, and so these claims comply with paragraph 28.2(1)(*b*) of the *Patent Act*;
- the subject-matter of claims 1-7, 11-18, 20-22, 25-28 and 30-32 would have been obvious to the skilled person in view of D2, contrary to subsection 28.3(*b*) of the *Patent Act*; and
- the subject-matter of claim 1 is ambiguous, contrary to subsection 27(4) of the *Patent Act*.

ANALYSIS OF THE PROPOSED CLAIMS

[58] We note that there is a clear correspondence between the proposed claims and the claims on file, that the proposed changes find support in the originally filed specification, and that the subject-matter of proposed claims would not necessitate another prior art search. Accordingly, we considered the proposed claims.

[59] The proposed independent claims all define the composition as comprising:

> a complementary oligomer which hydrogen bonds to the hydrophilic polymer, wherein the complementary oligomer is formed of low molecular weight polyalkylene glycols, low molecular weight polyalcohols, alkylene glycols, ether alcohols, carbonic diacids, or alkane diols (…)

[60] Defining an oligomer in this manner would no longer include the polysaccharide or celluloses of D1, and so our view is that this amendment would render the claims compliant with paragraph 28.2(1)(*a*) of the *Patent Act*. Also, since this definition would no longer include the monomers of D2, or monomers of any kind, our view is that this amendment would overcome the defects identified under both subsection 28.3(*b*) of the *Patent Act* and subsection 27(4) of the *Patent Act*.

[61] Our conclusion is therefore that proposed claims, and the corresponding amendments to pages 3b and 3c of the description that would provide literal support for the proposed claims, qualify as amendments that are necessary in order to make the application allowable under subsection 86(11) of the *Patent Rules.*

RECOMMENDATION OF THE BOARD

[62] We recommend that the Applicant be informed by notice pursuant to subsection 86(11) of the *Patent Rules* that the deletion of claims 1-32 and page 3b on file in the application and the insertion of claims 1-31 and pages 3b and 3c proposed in the Applicant's letter of August 13, 2019 are amendments that are necessary for compliance with the *Patent Act* and *Patent Rules*.

Cara Weir Member	Marcel Brisebois Member	Ed MacLaurin Member

DECISION

[63] I concur with the conclusions and recommendation of the Board. In accordance with subsection 86(11) of the *Patent Rules*, I hereby notify the Applicant that the above amendments must be made within three (3) months of the date of this decision, failing which I will refuse to grant a patent for this application.

[64] In accordance with subsection 200(*b*) of the *Patent Rules*, the following amendments, and only these amendments, may be made to the application:

i) delete claims 1-32 and page 3b on file; and

ii) insert claims 1-31 and pages 3b and 3c proposed in the Applicant's letter of August 13, 2019.

Johanne Bélisle
Commissioner of Patents

Dated at Gatineau, Quebec,

this 27th day of December, 2019.