Commissioner’s Decision #1383

Décision de la Commissaire #1383

TOPIC: K11, O00

SUJET: K11, O00

Application No: 2,476,327

Demande no: 2,476,327

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,476,327 having been rejected under subsection 30(3) of the *Patent Rules*, has consequently been reviewed in accordance with paragraph 30(6)(c) of the *Patent Rules*.. The recommendation of the Board and the decision are as follows:

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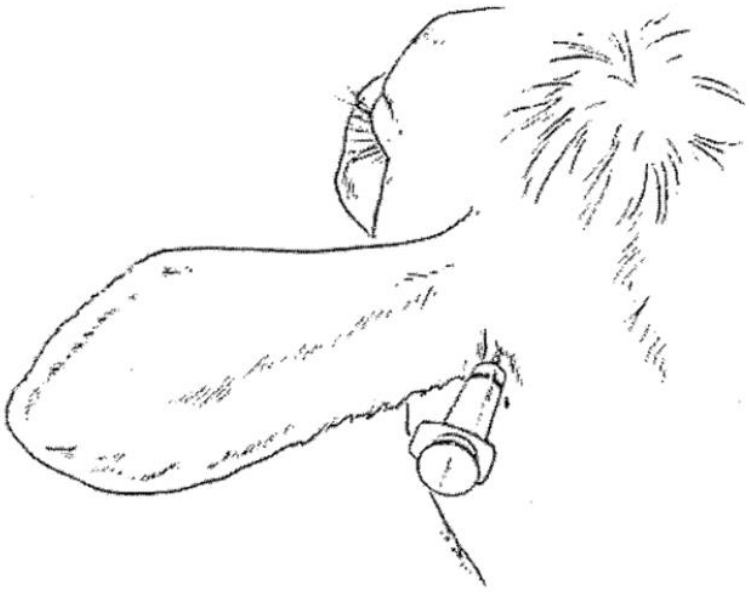
INTRODUCTION

[1] This recommendation deals with a review of the rejection under subsection 30(3) of the *Patent Rules* of patent application no. 2,476,327 entitled "METHOD OF ADMINISTERING AN INJECTABLE ANTIBIOTIC TO THE EAR OF AN ANIMAL", filed on March 19, 2003. The Applicant is ZOETIS P & U LLC and the inventor is Scott A. Brown.

[2] The present application relates to a method of administering a drug, in particular an antibiotic, to an animal in a specific manner at a specific location. The antibiotic is to be administered subcutaneously at the junction of the pinna (ear) with the cranium of the animal, with the injection site being more specifically "caudal to the cervioauricularis muscles and dorsocaudal to the parotid salivary glands." This location is specifically illustrated by Figure 1 of the application, below, which shows injection near the ear of a cow.



[3] For the reasons that follow, we recommend that the application be refused on the basis that the claimed invention is directed to a method of medical treatment, therefore comprising non-statutory subject matter, and that the claimed invention would have been obvious to the person skilled in the art.

PROCEDURAL HISTORY

[4] The present application, filed under the provisions of the Patent Cooperation Treaty, claims priority from a US application filed March 21, 2002, this being the effective claim date for the purpose of assessing obviousness under section 28.3 of the *Patent Act*.

[5] The application was rejected in a Final Action dated February 18, 2013 on the ground that the claims were directed to a method of medical treatment and therefore non-compliant with s. 2 of the *Patent Act,* as not falling within the definition of "art" or "process".

[6] In the response to the Final Action dated August 15, 2013, the Applicant reiterated its previous arguments and set forth its interpretation of the relevant case law in support of its contention that the claims are not directed to a method of medical treatment.

[7] The case was forwarded to the Patent Appeal Board on November 7, 2013 with a Summary of Reasons ("SOR") outlining why the Examiner still considered the claims to be non-compliant with s. 2 of the *Patent Act*. The present panel was formed to perform a review of the application under paragraph 30(6)(*c*) of the *Patent Rules*.

[8] The SOR was forwarded to the Applicant on December 18, 2013 with an accompanying letter offering the Applicant an opportunity to be heard.

[9] In a letter dated March 19, 2014 the Applicant elected to proceed by way of an oral hearing.

[10] In a letter dated November 25, 2014, the panel, in addition to proposing a date for the oral hearing, set out its preliminary view of the construction of the claims that would be used to assess their patentability. The panel also identified a defect in relation to s. 27(4) of the Act with regard to claim 3.

[11] At the Applicant's request, the oral hearing was delayed until April 29, 2015.

[12] Prior to the oral hearing, the Applicant provided written submissions dated April 15, 2015 in which the Applicant submitted proposed claims directed to a "method of administering an antibiotic in an animal …" The Applicant also proposed claims directed to the "use of an antibiotic effective to treat or prevent a bacterial infection in an animal … for the manufacture of a liquid medicament …", a "Swiss" style use claim. It was further proposed that claim 3 be deleted in response to the panel's concern under s. 27(4) of the Act.

[13] In a letter dated April 23, 2015, the panel notified the Applicant that claims of the scope of those proposed in the abovementioned submissions were previously considered during the prosecution before the Examiner and removed in response to the defects identified during prosecution. The panel also notified the Applicant that such a proposal would not be within the scope of what would be considered as "necessary" under s. 30(6.3) of the *Patent Rules*. However, the panel indicated that, for the sake of completeness, the proposed claims would be considered if the claims on file do not comply with the *Patent Act* and *Patent Rules*.

[14] The panel also indicated that the proposed Swiss style use claims had previously been identified as being defective due to obviousness during prosecution. The panel further notified the Applicant that upon a review of the prior art, it was our view that the obviousness defect would equally apply to the claims on file and to the proposed "method of administering …" claims. The panel set out a preliminary construction and patentability analysis of the claims, including those proposed.

[15] Oral submissions were received from the Applicant on April 29, 2015.

ISSUES

[16] The panel will resolve two questions:

- Are the claims on file (and the proposed claims) directed to a method of medical treatment, therefore comprising non-statutory subject matter?
- Would the claims on file (and the proposed claims) have been obvious?

[17] Before the panel proceeds to answer these questions it is first necessary to construe the claims. For the sake of efficiency, we consider all the claims together, both those on file (claims 1-11) and proposed claims 1-19.

LEGAL PRINCIPLES

Claim Construction

[18] Purposive construction identifies those features that are considered to be essential and those that are considered to be non-essential (*Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67 at para. 45). This identification is performed from the point of view of the person skilled in the art, who possesses the common general knowledge of the relevant art (*Free World Trust v. Électro-Santé Inc.*, 2000 SCC 66 at para. 31 ["*Free World Trust"*]).

[19] The skilled person through whose eyes the claims are to be viewed is unimaginative; however, he or she is deemed to be reasonably diligent in keeping up with advances in the field to which the patent relates. This person of ordinary skill in the art is deemed to be sufficiently versed in the art to which the patent relates to enable him or her to appreciate the nature of the invention and is deemed to be aware of those relevant patents and publications that would be discoverable in a reasonable and diligent search (*Newco Tank Corp v Attorney General of Canada*, 2014 FC 287 at para 28).

[20] In order for an element of a claim to be considered non-essential it must be shown either (i) that on a purposive construction of the words of the claim it was clearly not intended to be essential or (ii) that at the date of publication of the patent, the skilled addressee would have appreciated that a particular element could be substituted or omitted without affecting the working of the invention (*Free World Trust* at para. 55).

[21] In Office Patent Notice PN 2013-02 it is specified that elements are to be determined essential or non-essential based on the identified problem and solution, which takes into account the whole of the application.

Methods of Medical Treatment

[22] Section 2 of the *Patent Act* defines invention as:

> 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.

[23] Not every "process" is a patentable "invention". Processes directed to methods of medical treatment or surgical treatment have been considered by the courts to be unpatentable (see *Tennessee Eastman Co v Commissioner of Patents* [1974] SCR 111 at 119 ("*Tennessee Eastman*"), *Imperial Chemical Industries Ltd v Commissioner of Patents* (1986), 9 CPR (3d) 289 at 296 (FCA) ("*ICI*"), *Janssen Inc v Mylan Pharmaceuticals*, 2010 FC 1123 at para. 53, *Manual of Patent Office Practice* (*MOPOP*) 12.05.02 and 17.02.03).

Obviousness

[24] Section 28.3 of the *Patent Act* sets out the conditions under which a claim may be found to be obvious:

> **28.3** 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.

[25] In *Sanofi* the Supreme Court of Canada put forward a four-step approach to performing the obviousness assessment:

> (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?

ANALYSIS

Claim Construction

[26] In our letters of November 25, 2014 and April 23, 2015 we set out our preliminary view as to the construction of the claims, including claims 1-11 on file and proposed claims 1-19.

[27] The Applicant has not taken issue with these views and so we use them in our assessment below.

The person skilled in the art

[28] As set out in our letter of November 25, 2014, the panel characterizes the skilled person as "a person skilled in the art of methods of drug administration to animals, such as a veterinarian or farmer."

The relevant common general knowledge

[29] As set out in our letter of November 25, 2014, the panel takes the following to have been part of the relevant common general knowledge (with references to the prior art discussions in the present application):

- Injection of antibiotics produces irritation and potentially illegal drug residues at injection sites of food producing animals (page 1, lines 9-10)
- The trend at the filing date of moving away from intramuscular injection to the more preferable subcutaneous injection to avoid drug residue in edible meat (page 1, lines 10-13)
- There is still a problem with subcutaneous injection since injection site irritation and drug residue can be present on carcass itself (which is also edible) (page 1, lines 17-19)
- USDA requires a "target tissue" for residue monitoring (e.g. kidney, liver, muscle, fat) (page 1, lines 20-23), injection in edible tissue fails criteria for a target tissue (page 1, lines 24-26), surrogate target tissues are used when antibiotics have injection site residues (page 2, lines 1-3) and residue levels in surrogate tissues must be lower than those normally acceptable for such a site due to use as a surrogate (page 2, lines 7-10)
- CCFA-SS as a known sustained release antibiotic used as a single injection treatment of bacterial diseases in animals (page 2, lines 11-13)
- All such sustained release injectable compounds have the same problem in that the use of a surrogate tissue is impossible since the injection site contains highest concentration of drug residue for longest period of time (page 2, lines 13-19)
- Injection of antibiotics subcutaneously into posterior of ear
- Injection of CCFA-SS subcutaneously in neck, flank, posterior of ear or other subcutaneous sites on the edible tissue portions of carcass, for treatment of bacterial disease (page 3, lines 3-7)
- Subcutaneous aural (i.e., ear) administration of hormones as solid dose implants (page 3, lines 7-8)
- Implants of antibiotics, but they are typically administered intramuscularly (page 3, lines 8-10)

- Small volume vaccines have been administered successfully intradermally in the ear of dogs and swine (page 3, lines 10-11)
- In swine, diagnostic allergens and a vaccine in small volumes have been administered subcutaneously in the dorsal part or posterior side of ear (page 3, lines 11-13)
- Injection of CCFA-SS in posterior of ear (page 3, lines 13-14).

The problem to be solved and the solution provided by the invention

[30] In our letter of November 25, 2014, the panel set out the problem to be solved in light of the discussion in the background portion of the application as follows:

> to provide a method of injecting antibiotics into an animal in a manner that avoids drug residues remaining in the edible portions of the carcass.

[31] In the same letter, the solution provided by the invention was set out as follows:

> to inject the antibiotic (the purpose of which is to treat or prevent bacterial infection) at a specific location on the animal, namely "at the junction of a pinna with the cranium of the animal, wherein the injection is caudal to the cervioauricularis muscles and dorsocaudal to the parotid salivary gland." Most, if not all, of this region is discarded at slaughter, thereby avoiding contamination of the edible portions.

[32] The Applicant did not take issue with the above statements.

The essential elements of the claims

[33] Claim 1 of the claims on file (the only independent claim) is as follows:

> 1. A method for treating or preventing a bacterial infection in an animal selected from the group consisting of cattle, swine, sheep and goats comprising injection of an effective amount of an antibiotic subcutaneously at the junction of a pinna with the cranium of the animal, wherein the injection is caudal to the cervioauricularis muscles and dorsocaudal to the parotid salivary gland.

[34] As set out in our letter of November 25, 2014, in light of the solution provided by the invention, it is our view that the skilled person would consider the step of injecting the

antibiotic in an animal at the particular location specified in the claims to be essential to the method of treating or preventing the bacterial infection. As claim 1 is the only independent claim, this feature is common to all the claims on file. The other claims (other than claim 3, which was proposed to be deleted) set out details of the antibiotic to be injected and the type of bacterial infection to be treated as part of the method, which elements we take to be essential to those claims.

[35] Independent claim 1 of proposed claims 1-19 submitted on April 15, 2015 is as follows:

> 1. A method of administering an antibiotic in an animal selected from the group consisting of cattle, swine, sheep and goats comprising injection of the antibiotic subcutaneously at the junction of a pinna with the cranium of the animal wherein the injection is caudal to the cervioauricularis muscles and dorsocaudal to the parotid salivary gland.

[36] As set out in our letter of April 23, 2015, although proposed claim 1 is directed to a method of "administering" a drug, it is our view that the skilled person would understand, in light of the specification as a whole, that the result of administration is still the treatment or prevention of a pathological condition (i.e., a bacterial infection such as bovine respiratory disease or swine respiratory disease). This view was not contested by the Applicant. Proposed claims 2-10 are similar in scope to the dependent claims on file.

[37] Independent claim 11 of proposed claim 1-19 is set out below:

> 11. Use of an antibiotic effective to treat or prevent a bacterial infection in an animal selected from the group consisting of cattle, swine, sheep and goats for the manufacture of a liquid medicament for injection of the antibiotic subcutaneously at the junction of a pinna with the cranium of the animal wherein the injection is caudal to the cervioauricularis muscles and dorsocaudal to the parotid salivary gland.

[38] Proposed claim 11 is directed to a Swiss style use claim where the use is focused on the manufacture of a medicament, rather than the use for treatment or prevention itself. Although the claim is ostensibly directed to a use and not a method, the claim still specifies the injection at the same location as claim 1 on file. In line with the solution

proposed by the application, it is our view that, in this case, the skilled person would understand that injection at the specific location is essential to this claim as well. As was done in *Novartis Pharmaceuticals Canada Inc v Cobalt Pharmaceuticals Company*, 2013 FC 985 at para. 101, we "disregard the artificial nature of a Swiss claim and look at what is the real subject matter of the claim."

[39] In this case the focus is on a method of administering the drug (i.e., at a particular location), the purpose of which is to treat or prevent bacterial infection. Therefore, in accordance with our view set out in the letter of April 23, 2015, despite the form of the claim, the skilled person would consider that proposed claim 11 is directed to a method of treatment as well. Dependent claims 12-19 are similar in scope to the dependent claims on file.

[40] In light of the above, the claims on file and proposed claims 11-19 are directed to a method of treating or preventing a bacterial infection in an animal, comprising injection of an antibiotic at the particular location specified in the claims.

Are the claims on file (and the proposed claims) directed to a method of medical treatment, therefore comprising non-statutory subject matter?

[41] The Applicant has submitted, both in its oral submissions and in its written submissions dated April 15, 2015 and October 12, 2011 that the prohibition on the patenting of methods of medical treatment was comprised of two branches, the first being related to former s. 41 of the *Patent Act* (since repealed). The second related to a common law branch, illustrated by a reference by the Supreme Court in *Tennessee Eastman* to a decision of the UK Patents Appeal Tribunal in *Re Schering A.G.'s Application* [1971] RPC 337 (Patents Appeal Tribunal) at 345 ("*Schering*").

[42] In the passage quoted by the Supreme Court of Canada from the *Schering* case, the Court emphasized the portion that stated "*patents for medical treatment in the strict sense must be excluded*." The Applicant contends that "*in the strict sense*" should be interpreted

narrowly to mean that methods of medical treatment are only prohibited when the skill and judgment of a medical professional such as a physician are required to practice the invention (see Applicant's written submissions dated April 15, 2015 at pages 5-6). In our view, this position is not consistent with that of our courts.

[43] In the present case, in accordance with our identification of the person skilled in the art, although the invention may also be addressed to a medical professional (e.g., veterinarian), it may be addressed to non-medical professionals, e.g., a farmer.

[44] In accordance with the *Manual of Patent Office Practice* ("*MOPOP"*) at 12.05.02 and 17.02.03, a method "which provides a practical therapeutic benefit to a subject is considered to be a method of medical treatment and is therefore not patentable." The method should "cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity such as by physiotherapy or surgery."

[45] The above statements are made with reference to *Tennessee Eastman* and *ICI* (both of which have been addressed in the Applicant's oral and written submissions). In *ICI* the invention related to a method of cleaning teeth by applying to the teeth an oral hygiene composition. The Federal Court of Appeal reviewed *Tennessee Eastman* and concluded that the Supreme Court, at page 207 of their decision, made:

> a clear and unequivocal statement that "methods of medical treatment are not contemplated in the definition of 'invention' as a kind of 'process'…"

[46] On this basis, and the fact that a "leading function of the invention was medical", the Court concluded that the method of cleaning teeth was unpatentable, despite the fact that the method need not be practiced by a physician.

[47] The panel has also reviewed the *Schering* case, referenced by the Supreme Court of Canada and used by the Applicant to support the contention that only methods of medical treatment that require the skill and judgement of a physician are prohibited.

[48] The *Schering* case related to a method of contraception and in finding such a method patentable the Tribunal contrasted methods of medical treatment in the strict sense (unpatentable) with methods of medical treatment in a broader sense (patentable):

> Unless any treatment of the human body, as opposed to medical treatment to cure or prevent disease, is to be considered as being outside the scope of patent protection, there seems to be no reason why such a claim should not be allowed. [emphasis added]

[49] As in ICI there is no qualification that a method of medical treatment, in order to be precluded from patentability, need be practiced by a physician. It need only "cure or prevent disease".

Conclusions

[50] In light of the above, as the claims have been construed to include an essential administration or treatment step, the purpose of which is to treat or prevent bacterial infection (a pathological condition), the claims are directed to a method of medical treatment, and therefore non-compliant with s. 2 of the *Patent Act*.

Would the claims on file (and the proposed claims) have been obvious?

[51] In our letter dated April 23, 2015, the panel set out its preliminary analysis of the claims (both claims 1-11 on file and proposed claims 1-19) using the *Sanofi* approach. The Applicant, neither in its written submissions dated April 27, 2015, nor in its oral submissions, took issue with the panel's view with respect to steps 1-3 of the approach, which we use in our analysis below.

(1)(a) Identify the notional "person skilled in the art"

[52] The person skilled in the art was set out at paragraph [28].

(1)(b) Identify the relevant common general knowledge of that person

[53] The relevant common general knowledge was set out at paragraph [29].

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

[54] As stated in our letter of April 23, 2015, the panel considered claims 1-11 on file to relate to details of the antibiotic to be injected and to the site of administration, in accordance with the solution identified above under claim construction. As such, we take the features of the claims on file to be essential in light of the solution and to be reflective of their respective inventive concepts. Likewise, we take the features of proposed claims 1-19 to be reflective of their inventive concepts as well.

(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

[55] As set out in the letter of April 23, 2015, the panel identified the defect under obviousness in relation to the Applicant's own earlier US Patent no. 6,074,657 ("the '657 Patent") , issued June 13, 2000. Further, in relation to all the claims on file and proposed claims 1-19, the panel identified only one difference between the inventive concepts of the claims and the state of the art represented by the '657 Patent, namely the exact injection location specified in the claims:

> injection of an effective amount of an antibiotic subcutaneously <u>at the junction of a pinna with the cranium of the animal, wherein the injection is caudal to the cervioauricularis muscles and dorsocaudal to the parotid salivary gland</u>. [emphasis added]

(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?

[56] The ‘657 Patent discloses the subcutaneous administration of an injectable antibiotic (ceftiofur crystalline free acid sterile oil suspension – CCFA-SS – the same drug preferred in the present application) into the posterior of the ear of an animal such as cattle, swine, sheep and goats. The ‘657 Patent particularly discloses injection sites such as the midline of the ear, in approximately the middle third of the ear (see col. 8, lines 5-12 and Figure 1). In a preferred method the ear is folded in half along its long axis and injection takes place approximately midway from the base of the ear to the tip of the ear and approximately ½ to 1 inch from the top edge of the ear (see col. 8, lines 23-34 and Figure 2). Despite the above specifically exemplified embodiments, the posterior of the ear is generally described as a desired injection point, as the ear portion is not edible, and therefore the introduction of sustained release antibiotics such as CCFA-SS will not be a human food safety concern (see col. 9, lines 1-4).

[57] As set out in step (1)(b), it was part of the common general knowledge to avoid injection of, e.g., antibiotics, into the edible portions of animals. It was also part of the common general knowledge to inject antibiotics into the posterior of the ear. Further, a commonly known problem with sustained-release antibiotics was that the injection site would contain the highest concentration of drug residue for the longest period of time.

[58] The ‘657 Patent sought to address the concerns with respect to contamination of the edible portions by moving away from the conventional injection of a sustained-release antimicrobial sterile suspensions formulation (e.g., CCFA-SS) subcutaneously into the neck, flank, or other subcutaneous sites on the animal carcass and, instead, injecting the antibiotic subcutaneously into the posterior of the ear. In this way, with the removal of the ear upon slaughter, contamination of the edible portion is avoided.

[59] The same concerns are addressed by the present application (see page 4, lines 13-14). Although the point of injection is more specifically at the junction of the pinna and cranium, as well as caudal to the cervioauricularis muscles and dorsocaudal to the parotid salivary gland, this location (as reflected in Figures 1 and 2 of the present application) is adjacent to the posterior region of the ear. Since the skilled person knows that the

antibiotic concentration is highest for the longest period of time at the injection site, this would support the view that the skilled person would have expected that as the injection site moves closer to the carcass, the potential for contamination of the edible portions increases.

[60] The ‘657 Patent also suggests broadly that anywhere on the posterior of the ear is preferable to an injection on the carcass itself (see col. 6, lines 6-11). This suggests that a point at or very close to the joint of the pinna and cranium is contemplated as a possible injection site. The specification in the present application that the injection be “at the junction” of the pinna and cranium is a very slight change in location. This would support the view that the skilled person would have taken this location to be an obvious possibility, but would have also realized the risk of contamination in moving closer to the carcass.

Advantages associated with the injection location

[61] There are two references (see pages 4, lines 15-19 and 5, lines 24-30 of the present application) in the application relating to an advantage that may be realized by the claimed injection location, namely, that the animal’s head may not need to be restrained during injection. The injection may take place in a pasture with the hand not holding the needle being used to grip the ear and stabilize the head.

[62] However, the method of administration disclosed by the ‘657 Patent also does not require that the animal’s head be restrained (see col. 8, lines 2-4), although it may be the case. The particular method of administration disclosed at col. 8, lines 23-62 of the ‘657 Patent includes gripping the ear not holding the needle and folding it in half along the long axis prior to injection. In any case, since the teaching of the ‘657 Patent is not restricted to the middle of the posterior of the ear, this would support the view that the skilled person would expect that as the injection moves closer to the cranium, more of the ear may be gripped to stabilize the animal during injection.

The declarations submitted on April 27, 2015

[63] Prior to the hearing, the Applicant submitted three declarations in support of the inventive ingenuity of the claims, these declarations having been submitted during the prosecution of the corresponding US Patent.

The declaration of Merlyn J. Lucas

[64] The first is from Merlyn J. Lucas, a veterinarian and Director, Pharmaceutical Clinical Development, Pfizer Animal Health. Having reviewed Mr. Lucas' declaration, although he fits within our identification of the person skilled in the art, we do not find that it weighs in favor of the nonobviousness of the claims.

[65] In relation to the '657 Patent, Mr. Lucas contends that the differences between this document and the claimed invention are (1) "the location of the injection sites" and (2) "the unexpected safety profile from an injection site tolerance standpoint when larger volumes of antibiotics are injected at the junction of a pinna with the cranium of the animal, particularly when the antibiotic is ceftiofur crystalline free acid" (Lucas declaration at page 3).

[66] With respect to the first difference, Mr. Lucas contends that the '657 Patent teaches injection in the middle third of the ear, whereas the application teaches injection at the base of the ear. In this regard, Mr. Lucas' declaration provides no reasoning as to why the different location is not obvious beyond his assertion that it is a difference.

[67] With respect to the second difference, Mr. Lucas speaks of an unexpected safety profile associated with the exact location of injection as specified in the claims and points to Exhibit B to his declaration for support. Exhibit B is a report dated June 2, 2006 associated with a US "SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION" related to antibiotic injection in lactating dairy cattle. While the document does indicate that injection at the base of the ear is safe and better tolerated than the middle third of the

ear (see page 18 of Exhibit B), this result was in respect of a specific group of animals (i.e., lactating dairy cows which require higher volumes of antibiotic). We note that the injection volumes ranged from 15 to 30 mL per cow, with the volumes of problematic cases for middle third of the ear injections being greater than 19.5 mL (see page 18 of Exhibit B). However, the present application contemplates lower injection volumes (i.e., 1-15 mL) at a similar concentration (6.6 mg CE/kg BW). Therefore, while the document points to advantages with respect to the problems associated with the injection volumes required by lactating dairy cows, it does not support advantages associated with lower injection volumes such as those contemplated by the present application.

[68] We further note that these results are associated with a study conducted between January 2004 and April 2004, which post-dates the present application. They would therefore be "subsequently recognized advantages." We do not consider the present case to be a "most extraordinary case" in the manner considered in *Novopharm Ltd. v. Janssen-Ortho Inc.*, 2007 FCA 217 at para. 26 and therefore give them no weight.

[69] Other portions of Mr. Lucas' declaration discuss why the combination of the '657 Patent (also cited in the US) and a document by Forg *et al.* relating to DNA vaccination would not render the claims obvious. As the Forg *et al.* document has not been cited against the present application, arguments in relation to this reference are not relevant.

The declaration of Rodney K. Frank

[70] Mr. Frank is a Research Fellow in Safety Sciences in Veterinary Medicine Research and Development, Zoetis LLC and a veterinarian, in line with our identification of the skilled person. Having reviewed Mr. Frank's declaration, we conclude that it does not weigh in favor of the nonobviousness of the claims.

[71] It is Mr. Frank's opinion that the method of administration of the present application is "counter-intuitive" in light of the '657 Patent, since in his view the '657 Patent taught the skilled person to move the injection site away from the edible tissues, to ensure their

removal at slaughter (Frank declaration at para. 14 and 15). In particular, the '657 Patent taught injection at the middle of the ear on the posterior side. It is Mr. Frank's opinion that there would have been a "clear prejudice" against moving the injection site closer to the carcass (Frank declaration at para. 18).

[72] In our view, as noted above, the skilled person would not interpret the'657 Patent as being limited to a teaching of injection at the middle posterior portion of the ear. While this location is described as a particularly preferred injection location, the '657 Patent broadly suggests the posterior portion of the ear as a suitable injection location, in order to prevent contamination of the edible carcass portion by removal of the ears at slaughter. In our view, the effect of movement of the injection location (in particular, towards the carcass), within the scope of the broad teaching of the '657 Patent, would have been evident to the skilled person (e.g., the increased potential for drug residue on the edible portions

The declaration of Duncan Mwangi

[73] Mr. Mwangi is an Associate Research Fellow in Veterinary Medicine R&D Technology at Zoetis LLC and also a veterinarian, in line with our identification of the skilled person. Having reviewed Mr. Mwangi's declaration, we conclude that it does not weigh in favor of the nonobviousness of the claims.

[74] For the most part, Mr. Mwangi's declaration is based on his opinion that the skilled person would not have read the '657 Patent and the Forg *et al.* document (cited by the US Patent Office) in combination to arrive at the claimed invention. With respect to arguments in relation to the applicability of the Forg *et al.* document, since the Forg *et al.* document (or a document comparable to Forg *et al.*) has not been cited against the present application, such arguments are not relevant.

[75] Mr. Mwangi does at one point, in comparing the claimed invention with the '657 Patent, make reference to the "lack of tissue residues following injection of an antibiotic at this

site" (the one claimed in the present application) and provides his opinion that this is "an unexpected result" (Mwangi declaration at para. 14) and that it is "surprising and unexpected that there is minimal distribution of the antibiotic into the surrounding edible tissues" (Mwangi declaration at para. 16). As we have already stated, in our view, in light of the teachings of the '657 Patent and the common general knowledge, the skilled person would have expected less tissue residue in the carcass using the injection site of the present invention when compared with intramuscular injection into, e.g., the neck, as in the prior art. We also note that this expected result is consistent with the Applicant's own findings of average residue concentration in the edible tissue (see present application at page 9, lines 14-19).

Conclusions

[76] Having considered the prior art of record, the common general knowledge of the skilled person and the Applicant's submissions (including the declarations submitted in support of the nonobviousness of the claims, we conclude that claims 1-11 on file and proposed claims 1-19 would have been obvious and are therefore non-compliant with s. 28.3 of the *Patent Act*.

RECOMMENDATION OF THE BOARD

[77] The panel recommends that the application be refused because the claims on file, namely claims 1-11:

- are directed to a method of medical treatment and therefore non-compliant with s. 2 of the *Patent Act*; and
- would have been obvious and are therefore non-compliant with s. 28.3 of the *Patent Act*.

[78] Further, proposed claims 1-19 suffer from the same defects and therefore are not considered "necessary" under s. 30(6.3) of the *Patent Rules*.

Stephen MacNeil	Paul Fitzner	Paul Sabharwal
Member	Member	Member

DECISION

[79] I concur with the conclusions and recommendation of the Patent Appeal Board that the application be refused because the claims on file, namely claims 1-11:

- are directed to a method of medical treatment and therefore non-compliant with s. 2 of the *Patent Act*; and
- would have been obvious and are therefore non-compliant with s. 28.3 of the *Patent Act*.

[80] The proposed amendments do not overcome these defects and are therefore not considered "necessary" under s. 30(6.3) of the *Patent Rules*.

[81] Therefore, in accordance with section 40 of the *Patent Act*, 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

Agnès Lajoie
Assistant Commissioner of Patents

Dated at Gatineau, Quebec,
this 16th day of July, 2015