Commissioner's Decision #1437

Décision du commissaire n^{o} 1437

TOPIC: G00 (Utility), C00 (Adequacy of Deficiency of Description), B00 (Ambiguity or Indefiniteness)

SUJET: G00 (Utilité), C00 (Caractère adéquat ou inadéquat de la description), B00 (Caractère ambigu ou indéfini)

Application No.: 2,454,678

Demande n°: 2 454 678

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,454,678, having been rejected under subsection 30(3) of the *Patent Rules*, has subsequently been reviewed in accordance with paragraph 30(6)(*c*) of the *Patent Rules*. The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application.

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,454,678, which is entitled "Adaptation of Bacteria For Use in Leaching" and owned by Bioheap Limited. The outstanding defects to be addressed are whether the 14 claims on file lack utility according to section 2 of the *Patent Act*; whether the specification fails to comply with subsection 27(3) of the *Patent Act*; and whether claims 1 and 4 on file are unclear and therefore not compliant with subsection 27(4) of the *Patent Act*. A review of the rejected application has been conducted by the Patent Appeal Board pursuant to paragraph 30(6)(*c*) of the *Patent Rules*. As explained in more detail below, our recommendation is that the application be refused.

BACKGROUND

The Application

[2] Patent application 2,454,678 was filed in Canada on July 19, 2002 and laid open for public inspection on February 6, 2003.

[3] The application teaches methods for the adaptation of sulphide mineral oxidizing bacteria for use in the leaching of ores and concentrates in saline environments in which the bacteria would otherwise not be viable. The adaptation is taught to occur via the transfer of a plasmid encoding salt tolerance from saline-tolerant bacteria to sulphide mineral oxidizing bacteria. This would enable the leaching of ore using the adapted bacteria to be performed where access to fresh water is limited and in the presence of high levels of total dissolved solids and chloride ions.

Procedural History

[4] On March 4, 2014, a Final Action ("FA") was issued pursuant to subsection 30(4) of the *Patent Rules*. The FA stated that the application was defective on the grounds that claims 1–14 on file lack utility and do not comply with section 2 of the *Patent Act*, the

specification does not comply with subsection 27(3) of the *Patent Act* and claims 1 and 4 lack clarity under subsection 27(4) of the *Patent Act*.

[5] In a letter dated August 28, 2014, the Applicant provided a response to the Final Action ("R-FA") arguing that the subject-matter of the claims was soundly predictable, that the description fully described and enabled the claimed invention and that the terms identified as causing the lack of clarity were not unclear. Notwithstanding the latter argument, the Applicant proposed claims that incorporated the subject-matter of claim 8 on file, thereby including in claims 1 and 4 the limitation of the minimum chloride concentration the bacteria must be able to tolerate while still being able to oxidize sulphide minerals, to address the lack of clarity defect raised by the Examiner.

[6] Despite the arguments made and the amendments proposed by the Applicant in response to the FA, the Examiner still considered the application to not comply with the *Patent Act*. On December 22, 2015, the application was forwarded to the Patent Appeal Board ("the Board") for review, along with a Summary of Reasons ("SOR") explaining why the application still does not comply. Pursuant to paragraph 30(6)(*b*) of the *Patent Rules*, claims 1–14 that were rejected in the FA are the claims on file and are the basis for this review.

[7] In a letter from the Board dated December 23, 2015, the Applicant was provided a copy of the SOR and was given the opportunity to request a hearing and/or make written submissions.

[8] In a response dated March 30, 2016 ("Letter to the Board"), the Applicant declined participation in a hearing but provided additional written arguments to be taken into consideration by the Board.

[9] The present Panel was formed to review the application under paragraph 30(6)(*c*) of the *Patent Rules* and make a recommendation to the Commissioner as to its disposition. In a letter dated November 23, 2016 (the "Preliminary Review Letter", and henceforth "PR Letter), we set out our preliminary analysis as to why, based on the record before us, the subject-matter of the claims on file does not comply with section 2 of the *Patent Act* but

that the specification complies with subsection 27(3) of the *Patent Act* and that claims 1 and 4 comply with subsection 27(4) of the *Patent Act*.

[10] The Applicant submitted a response to the PR Letter on December 22, 2016, confirming that they did not wish to participate in an oral hearing. They also indicated a desire to submit further written submissions but requested that they be granted until March 23, 2017 to complete and file those submissions. This request was granted in a letter from the Panel dated December 23, 2016.

[11] On March 23, 2017, a letter containing further submissions in response to the PR Letter was received. This letter (the "Reply to the PR Letter") contained arguments to the effect that the common general knowledge differed from the Panel's preliminary observations, along with additional prior art citations in support of this position, and requested reconsideration of what was part of the common general knowledge and thereby our opinion on the soundness of the prediction of utility.

ISSUES

[12] Based on the SOR, three defects remain on record:

1) The claims on file (claims 1–14) do not satisfy the requirements for utility, per section 2 of the *Patent Act;*
2) The specification does not comply with subsection 27(3) of the *Patent Act*; and
3) Claims 1 and 4 are unclear and ambiguous, and thus not compliant with subsection 27(4) of the *Patent Act.*

LEGAL PRINCIPLES AND OFFICE PRACTICE

Purposive Construction

[13] In accordance with *Free World Trust v Électro Santé Inc.*, 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*

Corp v Camco Inc., 2000 SCC 67 at paras. 49(f) and (g) and 52). In accordance with Chapter 13.05 of the *Manual of Patent Office Practice* (revised June 2015), the first step of purposive claim construction is to identify the person skilled 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 disclosed in the application. Essential elements can then be identified as those elements of the claims that are required to achieve the disclosed solution and the meaning of any terms within the claims can be determined.

Utility

[14] The statutory basis for the utility requirement is section 2 of the *Patent Act*, which reads:

> "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;

[15] The utility requirement was described by the Supreme Court of Canada in *Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd*, [1981] 1 SCR 504 at 525 (*Consolboard*):

> There is a helpful discussion in Halsbury's Laws of England, (3rd ed.), vol. 29, at p. 59, on the meaning of 'not useful' in patent law. It means 'that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do'.

[16] In *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC at para. 53 (*AstraZeneca*), the Supreme Court of Canada stated that the "[u]tility will differ based on the subject-matter of the invention as identified by claims construction" and outlined the approach that should be undertaken to determine whether a patent discloses an invention with sufficient utility under section 2 of the *Patent Act*:

> [54] To determine whether a patent discloses an invention with sufficient utility under s. 2, courts should undertake the following analysis. First, courts must identify the subject-matter of the invention as claimed in the patent. Second, courts must ask whether that subject-matter is useful — is it capable of a practical purpose (i.e. an actual result)?
>
> [55] The Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized — a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date (*AZT*, at para. 56).

[17] Therefore, utility must be established either by demonstration or sound prediction as of the Canadian filing date and cannot be supported by evidence and knowledge that only became available after this date (see also *Apotex Inc. v Wellcome Foundation Ltd.*, 2002 SCC 77 at para. 56 (*AZT*), cited in the passage above).

[18] The doctrine of sound prediction allows establishing asserted utility even where that utility had not been fully verified as of the filing date. However, a patent application must provide a "solid teaching" of the claimed invention as opposed to "mere speculation" (*AZT*, at para. 69).

[19] In AZT, it was noted that the soundness of a prediction is a question of fact (para. 71) and at para. 70 the requirements of the doctrine of "sound prediction" were enumerated:

> Firstly … there must be a factual basis for the prediction … Secondly, 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 … Thirdly, there must be proper disclosure.

[20] In *Bell Helicopter Textron Canada Ltée v Eurocopter*, 2013 FCA 219 (*Eurocopter*), the Court clarified that an assessment of the soundness of a prediction is to be performed through the eyes of the skilled person, possessed of the common general knowledge in the art:

> [152] In my opinion, the factual basis, the line of reasoning and the level of disclosure required by the doctrine of sound prediction are to be assessed as a function of the knowledge that the skilled person would have to base that prediction on, and as a function of what that skilled person would understand as a logical line of reasoning leading to the utility of the invention.

[21] The Court went on to note that the part of the factual basis not grounded in scientifically accepted laws or principles, or forming part of the CGK, may need to be disclosed in the specification:

> [153] Where the factual basis can be found in scientifically accepted laws or principles or in information forming part of the common general knowledge of the skilled person, then no disclosure of such factual basis may be required in the specification. On the other hand, where the factual basis is reliant on data which does not form part of the common general knowledge, then disclosure in the specification may indeed be required to support a sound prediction.

[22] Recently, in *Allergan Inc v Apotex Inc*, 2016 FC 344 (*Allergan*), the Federal Court clarified (at para. 57) that, aside from the common general knowledge, the factual basis and sound line of reasoning relied upon for sound predictions must be found in the application:

> In my view, until the Federal Court of Appeal or the Supreme Court of Canada rules otherwise, Canadian jurisprudence is that, with the exception of matters of common general knowledge, the factual basis and the line of reasoning must be included in the patent [*emphasis added*].

Sufficiency

[23] In relevant part, subsection 27(3) of the *Patent Act* reads as follows:

> 27.(3) The specification of an invention must
> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
> (. . .)

[24] As summarized in *Gilead Sciences Inc v Indenix Pharmaceuticals Inc*, 2015 FC 1156 (*Gilead*) at para. 418, the framework for the analysis of sufficiency of disclosure can be put in the form of three questions that must be answered:

> (a) What is your invention?
>
> (b) How does it work?
>
> (c) Having only the specification, can the person of ordinary skill in the art produce the invention using only the instructions contained in the disclosure?

[25] With respect to this third question, "it is necessary that no additional inventive ingenuity be required in order to make the patent work" (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283, at para. 172).

Lack of clarity

[26] Subsection 27(4) of the *Patent Act* reads as follows:

> (4) 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.

[27] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306, 12 CPR 99 at p. 146, the Court emphasized that an Applicant has to make clear in his claims the ambit of the monopoly sought and that the terms used in the claims must 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

Purposive Construction

The person skilled in the art and the CGK of that person

[28] The person skilled in the art was not explicitly described during prosecution. In the Letter to the Board, the Applicant acknowledged this but provided no opinion as to who this person might be.

[29] In the PR Letter, we proposed that the person skilled in the art could be characterized as a microbiologist working in the field of applied microbiology and biotechnology, specifically in the field of bioleaching. The Applicant referred to this characterization in the Reply to the PR Letter and did not appear to disagree with this assessment. As such, this characterization is adopted for the purposes of this review.

[30] In the Letter to the Board, the Applicant did opine on what CGK this person would possess:

> [I]t is submitted that the person skilled in the art would be familiar with molecular biology (including knowledge of plasmids and mechanisms for the transfer of plasmids between bacteria), as well as the use of bacteria in the leaching of ores and concentrates via oxidation, for example in mining applications.

[31] In the PR Letter, we agreed that this would have been part of the CGK the person skilled in the art would have possessed. The Applicant further argued in the Letter to the Board what the CGK would also include:

> At a minimum, it is submitted that the person skilled in the art could reasonably be expected to be aware of or able to easily locate the references discussed in these written submissions, and would be familiar with the general principles represented by these references as part of their common general knowledge.

[32] These "references" were submitted with the Letter to the Board. In the PR Letter, we noted that it was our preliminary view that while the person skilled in the art may have been able to locate these references, the "general principles" the Applicant referred to were not a matter of CGK.

[33] Broadly speaking, these "general principles" are: salt-tolerance is plasmid-encoded; plasmids can be transferred between bacteria; and such transfer of plasmid DNA will produce a stable phenotype in the recipient bacteria.

[34] In the Reply to the PR Letter, the Applicant presented further evidence and arguments for each of these being part of the CGK. No other CGK was argued to be relevant, and so the question is whether these three "general principles" were part of the CGK the skilled person would have possessed. This will be determined on the basis of what the references the Applicant has submitted teach as well as whether what was taught met the criteria for being CGK.

[35] Whether a document's disclosure is a matter of CGK can be determined by the factors adopted from UK jurisprudence and enumerated in *Uponor AB v Heatlink Group*, 2016 FC 320 at para. 48 (*Uponor*), citing *Eli Lilly & Co v Apotex Inc*, 2009 FC 991 at para. 97. The

"comprehensive description of common general knowledge" from *Uponor* is as follows, with factor d) being the most relevant to the present case:

> a) The common general knowledge imputed to such an addressee must, of course, be carefully distinguished from what in patent law is regarded as public knowledge;
>
> b) Common general knowledge is a different concept derived from a common sense approach to the practical question of what would in fact be known to an appropriately skilled addressee - the sort of man, good at his job, that could be found in real life;
>
> c) Individual patent specifications and their contents do not normally form part of the relevant common general knowledge, though there may be exceptions.
>
> d) Regarding scientific papers generally:
>
> i. It is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or series of articles, or in a scientific journal, no matter how wide the circulation of that journal may be, in the absence of any evidence that the disclosure is accepted generally by those who are engaged in the art to which the disclosure relates;
>
> ii. A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated;
>
> iii. Such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art; in other words, when it becomes part of their common stock of knowledge relating to the art;
>
> iv. It is difficult to appreciate how the use of something which has in fact never been used in a particular art can ever be held to be common general knowledge in the art.

[36] In the Letter to the Board, the Applicant argued that "plasmids encoding salt tolerant phenotypes exist" was part of the CGK. The Applicant also made reference to the transfer of plasmid DNA between bacterial species and stated that "plasmids encoding a salt-tolerant phenotype exist and can be transferred between different bacterial species." While, at that time, the Applicant did not explicitly argue that these latter two points were known in the CGK, they did so argue in their Reply to the PR Letter.

[37] Factor d) enumerated in *Uponor* defines what makes a "piece of knowledge" as disclosed in a scientific paper part of the CGK. This factor stipulates that "such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art." In the PR Letter, we

noted that there was no evidence to suggest that it was "generally known and accepted without question" that salt tolerance is encoded on plasmid DNA, and so we did not view this as having been part of the CGK. As explained in the PR Letter, none of the references submitted with the Letter to the Board provided persuasive evidence to the contrary. In the Reply to the PR Letter, the Applicant did not further argue for the relevance of those references and instead referred to others.

[38] One of these other references was Ventosa et al. "Biology of Moderately Halophilic Aerobic Bacteria", *Microbiol. Mol. Biol. Rev.*, June 1998, 62(2), 504–544 (Ventosa), arguing that "[b]ecause Ventosa et al. is a review article, it ought to have been known to the person skilled in the art, and can be taken as representative of the common general knowledge in the art at this time."

[39] An additional review article was also referred to in the Reply to the PR Letter: Vreeland, "Mechanisms of Halotolerance in Microorganisms", *CRC Critical Reviews in Microbiology*, 1987, 14, 311–356 (Vreeland). The combination of these two review articles is argued to illustrate the CGK at the time:

> Because both Ventosa et al. and Vreeland are review articles, rather than journal articles detailing the results of a single experiment or series of experiments it is respectfully submitted these references are illustrative of the common general knowledge of the person skilled in the art as of their 1987 and 1998 publication dates. . . . The Board is carefully requested to take these additional references into account as reflecting the state of common general knowledge in the art as of 1987 and 1988.

[40] Further to these documents, the Applicant submitted four others which, they argue, "detail additional experimental examples that support the position that it was within the common general knowledge of the person of ordinary skill in the art that plasmids encoding salt-tolerant phenotypes existed and could be successfully transferred between different bacterial species." These documents are as follows:

- Andresen et al., "Molecular Cloning, Physical Mapping and Expression of the *bet* Genes Governing the Osmoregulatory Choline-Glycine Betaine Pathway of *Escherichia coli*", *J. Gen. Microbiol.*, 1988, 134, 1737–1746 (Andresen).
- Jakowec et al., "Recombinant Plasmid Conferring Proline Overproduction and

Osmotic Tolerance", *Appl. and Envir. Microbiol.*, 1985, 50(2), 441–446 (Jakowec).

- Morishita, "Genetic Regulation on Salt Resistance in Halophilic Bacteria", *Energetics and Structure of Halophilic Microorganisms*, S.R. Caplan and M. Ginzburg, eds., Elsevier/North-Holland Biomedical Press, 1978, 599–606 (Morishita 1).
- Morishita, "Control by Episome on Salt-Resistance in Bacteria", *Origin of Life*, H. Noda, ed., Japan Scientific Societies Press, 1978, 431–439 (Morishita 2).

[41] In the Reply to the PR Letter, the Applicant explains that it was CGK that plasmids encoding salt-tolerant phenotypes existed and could be successfully transferred between different bacterial species by reference to these cited documents:

> While the Applicant accepts that a single journal article my [*sic*] not be sufficient to establish that something is common general knowledge, where there are several different unrelated articles that describe the same subject matter (i.e. plasmids encoding genes conferring a salt-tolerant phenotype, and the successful transfer of such plasmids between different species), the inference that a particular fact is within the common general knowledge of the skilled person becomes much stronger than if there is only a single journal article describing a particular result.

[42] The Applicant's position therefore appears to be that these additional documents show that it was CGK that salt tolerance is a plasmid-encoded phenotype and that such plasmids can transfer between different species when they argue that "those skilled in the art were generally aware even as of 1987 that genes carried on plasmids played a role in establishing a salt-tolerant phenotype." We disagree with this assessment, as discussed below.

First "general principle": salt tolerance is plasmid-encoded

[43] In the Reply to the PR letter, the Applicant pointed to a passage from page 535 of Ventosa, which states that, "[a]t least in certain bacteria, halotolerance may be linked to the presence of certain plasmids." The reference supporting this statement is the review by Vreeland (reference 351 in Ventosa), which concluded that a study involving *H. elongata* showed "that when the organism's single plasmid is cured, it loses its ability to grow in high salt." The context of this quotation comes from page 352 of Vreeland, which reads:

> Recently, Martin and his colleagues[126] have found that *H. elongata* contains a single plasmid. Their preliminary studies have indicated that when the plasmid is cured, *H. elongate* loses its ability to grow in 3.4 M NaCl. This will be, if it proves to be true, of tremendous value. [*Emphasis added*].

[44] The conclusions from this Martin document are somewhat tempered by the characterization of this study as "preliminary" and the citation (number 126 of the Vreeland endnotes) as being a "personal communication" with apparently none of the data being published. Vreeland also expresses a reservation about drawing any conclusions on even this one species when it states that "if it proves to be true, [it will be] of tremendous value."

[45] We note that the entire passage from which the quotation at para. [43] was drawn shows that there were questions surrounding the mechanism of salt tolerance and that genetic studies were lacking:

> Another euryhaline research area which is wide open at present involves genetic and molecular biology studies. These areas impinge of course on biological technology and potential commercial value of the euryhaline bacteria and algae. At present, there have been no genetic studies performed on euryhaline microbes. We have no knowledge of the genetic controls of these organisms yet we have indications (described in this review) that some of the biosynthetic functions and their physiology are Na^+-induced. A question which comes to mind here is how important are these Na^+-induced genes to salt tolerance? Another genetic question would involve the presence of plasmids in these organisms and the involvement of the plasmids in salt tolerance. Recently Martin and his colleagues[126] have found that *H. elongata* contains a single plasmid. Their preliminary studies have indicated that when the plasmid is cured, *H. elongata* loses its ability to grow in 3.4 *M* NaCl. This will be, if it proves to be true, of tremendous value. Agriculture the world over is threatened with loss of arable land because of saline pollution. In addition, many underdeveloped countries are unable to grow sufficient food because of a lack of fresh water. Development of salt-tolerant plants has been terribly hampered by a lack of genes conferring salt tolerance. Euryhaline microorganisms possess these genes but they need to be identified, isolated, and tested. We need to know about the molecular structures of these gene products and ultimately how they might interact with other cell components in order to confer salt tolerance. [*Emphasis added*]

[46] We consider that this passage would have suggested to the skilled person that while there were "indications" that some of the biosynthetic functions of the physiology of these bacteria are Na^+-induced, the exact mechanism(s) of salt tolerance and the identity of the genes involved were still an open question requiring further study.

[47] The final paragraph of the Vreeland review further illustrates this lack of understanding around bacterial salt tolerance:

> Numerous investigators have tried to train bacteria to grow in higher or lower salts, and have met with failure. It seems that marine bacteria do not have the ability to grow in high salts and extreme halophiles can't be trained to accept lower salts. In addition, most mutations have resulted in bacteria with less, not more, salt tolerance [citation omitted]. Is it possible in view of the presence of salt tolerance in diverse bacterial groups that extreme salt tolerance is an ancient trait simply maintained along much the same lines as the unique molecular structure of tRNA molecules . . .?

[48] With respect to the Andresen, Jakowec, Morishita 1 and Morishita 2 documents, the Applicant presented these, in the Reply to the PR Letter, as detailing "additional experimental examples that support the position that it was within the common general knowledge of the person of ordinary skill in the art that plasmids encoding salt-tolerant phenotypes existed and could be successfully transferred between different bacterial species."

[49] The Applicant noted that the Andresen document "shows the use of a vector plasmid to clone a salt tolerance gene from *E. coli* [into a different species] . . . can induce a halotolerant phenotype." While the reference does mention that a vector plasmid encoding halotolerance can induce a halotolerant phenotype in *E. coli*, the gene encoding the salt tolerance was derived from the chromosomal DNA of the host bacteria, which was then cloned into the *E. coli* plasmid. This was therefore not a naturally-occurring plasmid-derived salt tolerance transfer between species, but rather a laboratory experiment that shows how such might be done with significant human intervention. Further, the results showing that the *E. coli* salt tolerance genes involved in this particular mechanism of protection against osmotic stress (i.e., the choline-glycine betaine pathway) originate from genomic DNA contradict, or at least do not support, the position that plasmid-encoded salt tolerance is a "general principle".

[50] As mentioned in the Reply to the PR Letter, Jakowec is cited at page 1745 of Andresen and is characterized by the Applicant as teaching experimental work whereby "the conjugal transfer of a plasmid to different strains of enteric bacteria [results] . . . in proline

overproduction and osmotolerance". We note that, once again, the transfer involved genes that originate from genomic DNA and was not without laboratory intervention.

[51] Morishita 1 and Morishita 2 both date from 1978 and were cited some twenty years later in Ventosa (see references 216 and 217) where they were summarized (at page 535) as concluding that "salt tolerance in this organism [*Spirillium luteum*] is probably controlled by a plasmid." (*Emphasis added*.) Although Ventosa and Vreeland reviews are illustrative of various elements of the CGK, we consider that the skilled person would not have appreciated from the quotation, and the context within which Morishita documents were cited, that plasmid-encoded salt tolerance was generally known and accepted in the field.

[52] Amongst all of the documents submitted with the Reply to the PR Letter, there is an expression of uncertainty whether salt tolerance is a plasmid-encoded trait, even in the species being studied, much less in halophilic bacteria in general. We also note that Ventosa and Vreeland the Applicant referred to in the Reply to the PR Letter as being "review articles, rather than journal articles detailing the results of a single experiment or series of experiments" ultimately rely on the "personal communication" of Martin, which appears to have not been published, and the two Morishita documents that Ventosa concludes teach that in one bacterial species, salt tolerance is *probably* controlled by a plasmid.

[53] Although the review documents contain a few anecdotal reports of salt-tolerance being possibly encoded by a plasmid, we consider that they more convincingly describe the state of uncertainty that surrounded the exact mechanism(s) of salt-tolerance in halotolerant bacteria. Accordingly, our view is that it would not have been "generally known and accepted without question by the bulk of those who are engaged in the particular art" that mechanism(s) of salt-tolerance had been elucidated or identified with any degree of certainty, let alone widely accepted that such mechanisms are plasmid-encoded.

[54] We find it even more evident that plasmid-encoded salt tolerance in bacteria was not CGK as a "general principle" when the prior art cited by the Examiner during prosecution is considered. D1 (Oren, "Chapter 10: Genetics and Genomics of Halophilic Archaea and

Bacteria", *Halophilic Microorganisms and their Environments*, Volume 5, 2003, pp. 323–355) is an excerpt from a textbook about halophilic bacteria; that is, a textbook on the subject of salt-tolerant and salt-requiring bacteria, published in 2003, which is closer to (though after) the claim date of the present application (July 23, 2001). We consider that the information contained in D1 is therefore more representative of the relevant CGK than, for example, the Ventosa or Vreeland review articles, which were published about 13 and 24 years before the claim date, respectively.

[55] As noted in at least the FA, D1 reports that although plasmids had been found in many or most halophilic bacteria investigated, there was only a single report of plasmid-encoded salt tolerance in 1978. This salt tolerance was noted to have "never been confirmed, and its mechanism has not been clarified" (D1, page 344). This disclosure corresponds to the Morishita 1 and Morishita 2 documents. We note that no mention is made of the Martin results in D1, consistent with our understanding that this study was not published.

[56] Given the level of uncertainty surrounding the disclosure of the journal articles cited in the review documents and that a more recent textbook did not suggest that saline tolerance was generally known to be plasmid-encoded, we consider that the totality of the evidence favours the conclusion that plasmid-encoded salt tolerance in bacteria as a general mechanism of salt tolerance was not CGK at the time of filing.

Second "general principle": Plasmids can be transferred between bacteria

[57] The next "general principle" is whether plasmid-encoded genes would be transferred to other bacterial species and stably expressed.

[58] Lorenz et al., "Bacterial Gene Transfer by Natural Genetic Transformation in the Environment", *Microbiological Reviews*, vol. 58, 1994, pp. 563–602 (D2) was cited in the FA for teaching that "[m]ixed strain experiments suggest that interspecies transformation is highly unpredictable in bacteria". D2 is a document reviewing gene transfer with a focus on occurrences within natural environments. This review of the state of the art at the time (published in 1994) indicated that genetic transfer between bacterial species is possible but that there are "barriers" to such transformations, such as species divergence (D2

pages 588–590 and quoted in the FA). The Applicant argued, in the Letter to the Board, that the Examiner read D2 too narrowly, pointing to passages indicating that, while there are barriers to such genetic transfer between bacterial species, this is a relatively commonplace occurrence, leading to what is known as "horizontal gene transfer". We address this argument in para. [60].

Third "general principle": Transfer of plasmid DNA will produce a stable phenotype in recipient bacteria

[59] Further to the more specific question of whether transfer of salt tolerance from salt-tolerant bacteria to other bacteria would have been commonly known to produce a stable phenotype, we note that in the Hasnain 1996 reference submitted by the Applicant during prosecution (Hasnain and Thomas, "Two related circle replication plasmids from salt-tolerant bacteria", *Plasmid*, 36(3), 1996, 191–199) it was reported that although salt tolerance was conferred, "the phenotype was unstable, with the loss of salt tolerance apparently being correlated with structural instability of the plasmid DNA" (abstract). In the Letter to the Board, the Applicant acknowledged this but argued that it nevertheless shows "the inter-species transfer of a salt-tolerant phenotype on a plasmid". The fact that one of the few documents on record showing salt tolerance being transferred via plasmid DNA resulted in an unstable phenotype in the recipient bacteria casts further doubt on whether it would have been CGK that a stable phenotype would necessarily result from plasmid gene transfer. This was noted in the PR Letter but not addressed further by the Applicant.

[60] While it did appear to be CGK that plasmids may transfer between bacterial species and it may be the case that this can result in an expressed phenotype (e.g. such as what occurs from the transformation of antibiotic resistance from one bacterial species to another), it does not appear to have been CGK that this DNA will inevitably be expressed in the recipient bacteria in the form of a stable phenotype. We consider that it was CGK that a stable phenotype <u>may</u> be expressed from transformed plasmid DNA. However, even if salt tolerance were plasmid-encoded, we are not persuaded that it was CGK that it could be transferred and stably expressed; we consider the art too uncertain on this point to

conclude that it was "generally known and accepted without question". But even allowing for this as a possibility, this point is moot given our previous conclusion that it would not have been CGK that bacterial salt tolerance is plasmid-encoded.

Conclusions on the CGK

[61] In sum, we are of the view that the relevant CGK of the person skilled in the art would have comprised:

- familiarity with applied microbiology and molecular biology, including knowledge of plasmid transfer;
- knowledge that plasmids can encode genes that are responsible for tolerance to certain environmental stressors (e.g. antibiotic resistance) and can be transferred among bacteria of different species but that there are "boundaries" to this, and it is not necessarily the case that a stable phenotype will result; and
- the use of bacteria in leaching of ores and concentrates.

[62] To be clear, we consider that saline tolerance was not generally known or believed to be plasmid-encoded in halotolerant bacteria. At best, we consider that the person skilled in the art would have been aware of the few cited anecdotal and/or uncorroborated reports of possible plasmid-encoded salt tolerance, arguably because they were briefly described in review articles. However, we consider that the disclosure of such isolated reports was made in a context of general uncertainty regarding the mechanism(s) of salt-tolerance within which plasmid-encoded salt-tolerance was cautiously presented as a hypothesis to further explore.

Problem to be solved and the solution proposed

[63] The problem and proposed solution were outlined in the PR Letter and no arguments were raised by the Applicant against our assessment. Therefore, we maintain our view that the problem to be solved is that the sulphide mineral oxidizing bacteria used in leaching processes are unsuitable for use where a sufficient supply of "good quality" (e.g. low salinity) process water is unavailable.

[64] The proposed solution to this problem is to adapt known sulphide mineral oxidizing bacteria to saline conditions by growing a culture of said bacteria with one of salt-tolerant bacteria, where this adaptation is accomplished by the transformation of plasmid-encoded salt-tolerance from the latter to the former.

Determine the meaning of terms used in the claims

[65] In the PR Letter, we also identified the essential elements of the claims, which first required us to determine the meaning of certain terms in the claims. Since the Applicant did not appear to take issue with our preliminary opinion, we adopt the same reasoning for the purposes of our present analysis both in determining the meaning of expressions in the claims and in the essential elements identification.

"Exhibiting salt tolerance"

[66] We are of the view that the person skilled in the art would construe "bacteria exhibiting salt tolerance" to refer to bacteria that are able to survive in conditions that would be viewed as providing a useful adaptation. In this case, the adaptation is the tolerance to salinity levels comparable to what is found in the process water the sulphide mineral oxidizing bacteria would be exposed to.

"*Ability to oxidise sulphide minerals"*

[67] We understand "stock bacterial bacteria known to have the ability to oxidise sulphide materials" to be the equivalent of "capable of oxidising sulphide minerals", (e.g. description page 5, line 18); "sulphide mineral oxidizing bacteria" (e.g. description, page 4, line 2); and "proprietary bacterial culture" (Figure 1). From the context of the specification as a whole, our view is that this refers to bacteria that may be useful in bacterial leaching operations by virtue of their ability to oxidize sulphide-containing minerals, and that such bacteria would be known to the person skilled in the art.

Essential elements of the claims

[68] Claims 1, 4, 13 and 14 are the four independent claims on file. We view the essential elements of claim 1 to be the steps of:

1) Obtaining samples of bacteria exhibiting salt tolerance;
2) Combining said bacteria with a stock culture of sulphide mineral oxidizing bacteria; and
3) Growing the combination in a saline environment, such that the cultured stock sulphide mineral oxidizing bacteria become adapted to be salt tolerant.

[69] Dependent claims 2 and 3 respectively introduce the elements that the salt-tolerant bacteria samples are obtained with water, which is used to prepare nutrient solutions for the stock bacterial culture, and where the salt-tolerant bacteria are obtained from two different locations, combined and grown, before being combined with the stock bacterial culture.

[70] The essential elements of claim 4 are similar to claim 1:

1) Obtaining samples of bacteria exhibiting salt tolerance from a number of sources;
2) Combining the samples and growing them;
3) Combining said bacteria with a stock culture of sulphide mineral oxidizing bacteria; and
4) Growing the combination in an environment and gradually increasing salinity, such that the cultured stock sulphide mineral oxidizing bacteria become adapted to be salt tolerant.

[71] Claims 5–12 depend from claim 4. These claims introduce the elements of:

- The water from obtaining the bacteria is used to prepare a nutrient solution for the stock culture prior to combining the culture with the salt-tolerant bacteria;
- The water sample with the lowest chloride concentration is used to prepare the nutrient solution;
- The lowest chloride concentration is defined to be about 13 g/L;
- The chloride concentration is increased to levels of 40 g/L;
- The chloride concentration is increased over a period of eight months;
- The total dissolved solids is increased to at least about 80,000 ppm; and
- The total dissolved solids is increased to at least about 200,000 ppm.

[72] The sole essential element of claims 13 and 14 is viewed to be:

1) Using the bacterial culture made by the method of claim 1 or claim 4, respectively, in the manner known by the person skilled in the art.

Utility

[73] The claims on file were rejected for lacking utility. Based on the FA, the SOR and the Applicant's correspondence, we understand this to be a question of whether the utility has been established by a sound prediction. In the Reply to the PR Letter, the Applicant did not argue that there was demonstration, but instead that the CGK should be reconsidered in support of the sound prediction of utility, thereby confirming this understanding.

[74] Claims 1 and 4 assert the utility to be the production of "an adapted stock bacterial culture that expresses salt tolerance in addition to its ability to oxidise sulphide minerals." We are of the view that the person skilled in the art would understand this to mean that the defined methods will result in an adapted stock bacterial culture that is both "salt tolerant" and able to oxidize sulphide minerals.

[75] A valid claim based on a prediction of utility requires a factual basis, a sound line of reasoning and a proper disclosure (*Wellcome* at para. 70). The soundness of the prediction underlying the claims will be considered with this in mind and from the perspective of the person skilled in the art.

Factual basis

[76] The FA suggests that there is no factual basis that "saline tolerant bacteria have plasmids conferring the ability to survive in saline environments". The FA continues with: "there is no factual basis for a sound prediction that DNA transfer between bacteria would confer an adaptation allowing bacteria with the ability to oxidise sulphide minerals to express salt tolerance."

[77] As mentioned above, the factual basis can comprise information provided in the description, including data and information referred to in the prior art, as well as the CGK of the person skilled in the art (*Eurocopter* at paras. 152 and 153).

[78] We note that there are no references disclosed in the description that are particularly relevant to the factual basis supporting the prediction. Although a textbook is mentioned at page 1 of the description (Freifelder, *Essentials of Molecular Biology*, Jones and Bartlett

Publishers, USA, 1985), and this textbook is described as being relevant to the concept of genes within plasmids being essential for the growth of bacteria in certain extreme environments, no particular passage was cited. In the next paragraph (page 1, lines 28–30), the description does not suggest that this book provided any particular support for saline tolerance being plasmid-encoded when it states that "[i]t is possible that any bacteria living in saline environments may contain plasmids allowing them to do so" (emphasis added). Therefore, the factual basis this reference contributes is understood to be that plasmid genes may be essential for the growth of some bacteria in certain extreme environments, however, salinity is not necessarily one of these environments.

[79] In their Letter to the Board, the Applicant referred to a passage of the description as being "the factual basis and the articulable and sound line of reasoning from which the desired result can be inferred", which they summarized as being that:

> (a) bacteria living in saline environments may contain plasmids that confer salt tolerance on such bacteria; and
> (b) plasmids are known to be transferred frequently and rapidly amongst bacteria, and so plasmids from bacteria that live in saline environments may be transferred naturally into sulphide oxidizing bacteria. [*Emphasis added*].

[80] We disagree that this constitutes a factual basis. Pointing to what may be the case is more indicative of something that is to be predicted, rather than ground upon which to base predictions.

[81] The description includes a single example, which the Applicant has not argued during prosecution (nor in the Reply to the PR Letter) to be part of the factual basis. For completeness, we will consider whether it contributes to the factual basis for the prediction. At page 4, the description teaches that "[t]he method of the present invention will now be described with reference to an example and Figure 1." In the example, samples of saline tolerant bacteria were obtained from "black smokers", which are sulphide deposits found on the ocean floor. Samples were also obtained from puddles of process water from around sulphide mines, as well as from other saline environments. Samples of these "salt tolerant bacteria" were grown in the lab.

[82] In parallel, a "'stock' bacterial culture capable of oxidizing sulphide minerals was adjusted slowly to saline waters." No details are provided about the stock culture beyond it having the ability to oxidize sulphide minerals, but we consider it to be equivalent to the "proprietary bacterial culture" in Figure 1. We understand this culture to have been, at this point in the process, relatively salt intolerant compared to the "salt tolerant bacteria" samples from the saline environments.

[83] According to page 5, lines 18–27 and Figure 1, this stock culture was slowly adjusted to saline waters and a sample of this culture was combined with the salt tolerant bacteria:

> The transfer of genetic material from one bacterial species to another may take some time. However, the resulting bacterial culture is capable of both growing in saline environments and oxidising sulphide minerals.

[84] However, no mention is made of any direct evidence of a transfer of DNA, only that the "resulting bacterial culture" is capable of growing in saline environments of undefined salt concentration while retaining the ability to oxidize sulphide minerals. Considering that the stock bacterial culture was known to have this ability and was adjusted to saline waters before being combined with salt tolerant bacteria from indigenous saline environments, the person skilled in the art would expect that the stock bacterial culture would possess these properties even without combining it with the salt tolerant bacteria by selecting for the more salt-tolerant bacteria. We do not see any evidence of genetic transfer having taken place.

[85] In view of the above, we consider that any factual basis in this case would derive wholly from the CGK, as presented in para. [61], above.

Line of reasoning

[86] As we understand it, the line of reasoning holding that the recited methods would produce an adapted stock bacterial culture that expresses salt tolerance in addition to its ability to oxidise sulphide minerals is primarily based on the premise that the salt tolerance may be passed on to the stock bacterial culture via the natural transfer of a plasmid encoding the tolerance (see para. [79] above).

[87] Given our view, expressed below, that there is not an adequate factual basis to establish that salt tolerance would be plasmid-encoded in these bacteria, we are of the view that the person skilled in the art would not consider such a line of reasoning to be sound. Therefore, we will not consider the soundness of the line of reasoning further.

Proper Disclosure

[88] As noted (para. [22]), *Allergan* held that the factual basis and the line of reasoning must be included in the patent (application). With respect to the factual basis, the references cited by the Applicant during prosecution were not disclosed in the application so only that parts which relates to the CGK can be relied upon as part of the factual basis.

Analysis

[89] Our view is that the factual basis would not have allowed the person skilled in the art to soundly predict that the methods of claims 1 and 4 would result in the transfer of salt-tolerance so as to provide adapted stock bacterial culture that expresses salt tolerance while being capable of oxidizing sulphide minerals. In light of the uncertainty regarding the mechanism(s) for conferring salt tolerance to halotolerant bacteria and without a factual basis establishing that salt tolerance is plasmid-encoded in halotolerant bacteria, we consider that the person skilled in the art would not have been able to soundly predict that this tolerance could be naturally transferred to other bacterial species, much less be stably expressed to produce adapted stock bacterial culture that expresses salt tolerance in addition to its ability to oxidise sulphide minerals.

[90] As detailed above, we did not consider the teaching of the few isolated reports of salt tolerance being plasmid-encoded as being part of the CGK. If we had, however, we would nevertheless have come to the same conclusion regarding the soundness of the utility prediction. These teachings would have been counterbalanced by the context of general uncertainty they expressed regarding the mechanism(s) of salt-tolerance to the extent that the person skilled in the art would not have been in a position to make a "*prima facie*" reasonable inference that salt-tolerance in the halotolerant bacteria is generally plasmid-encoded.

[91] As such, we are of the view that these claims do not comply with section 2 of the *Patent Act*, as the utility of the claimed subject-matter was not established by demonstration or sound prediction. Dependent claims 2, 3 and 5–12 do not add any limitations that would affect this conclusion. Claims 13 and 14 relate to the use of adapted bacteria obtained from the method of claim 1 or claim 4 but, since our opinion is that there is no sound prediction that these methods would provide the required adapted bacteria, these claims are also considered to lack utility.

Sufficiency

[92] The second ground for the rejection in the FA was that the specification does not comply with subsection 27(3) of the *Patent Act*. The first reason given was the lack of disclosure of the factual basis relied upon for the sound prediction. The second reason was that the specification does not correctly and fully describe the invention and its operation or use so as to enable any person skilled in the art to practice the invention.

[93] As we noted in the PR Letter, our view is that the specification complies with subsection 27(3) of the *Patent Act*. The lack of disclosure of the factual basis was addressed in our utility analysis and we consider the description to fully describe the invention in a manner that would enable a person skilled in the art to practice it, notwithstanding our conclusions that utility of the claimed subject-matter was not established by demonstration or sound prediction.

Clarity of claims 1 and 4

[94] In the FA, claims 1 and 4 were rejected on the ground that the claimed methods are not clear, arguing that "capable of oxidizing sulphide minerals" and "exhibiting salt tolerance" are used to define the bacteria functionally, i.e. "merely by the desired activity . . . rather than in clear and explicit terms" and the concept of "salt tolerance" does not clearly define what level of sensitivity to chloride ions the bacteria must possess to exhibit salt tolerance. These factors were considered in the FA to render the claimed methods unclear: "Without provision of clear detail as to the bacteria used, the methods are not defined distinctly and in explicit terms".

[95] We addressed "capable of oxidizing sulphide minerals" and "exhibiting salt tolerance" in the PR Letter, where we concluded that the person skilled in the art would understand what was meant. This understanding is also reflected in our construction of the claims (see para. [66]).

[96] We therefore are of the view that claims 1 and 4 comply with subsection 27(4) of the *Patent Act*.

Claims submitted in response to the Final Action

[97] Proposed claims 1–13 were submitted by the Applicant in R-FA (the "proposed claims"). In accordance with paragraph 30(6)(*b*) of the *Patent Rules*, they have not been entered as an amendment as the Examiner did not consider them to overcome the outstanding defects. However, in accordance with subsection 30(6.3) of the *Patent Rules*, if after review of a rejected application, the Commissioner determines that an application does not comply with the *Patent Act* or the *Patent Rules*, but that the specific amendments set out in the proposed claims are necessary, the Commissioner shall notify the Applicant to make these amendments.

[98] The proposed claims only address the clarity defect raised in the FA. Since our opinion is that the claims on file comply with subsection 27(4) of the *Patent Act* and the proposed claims do not overcome the lack of utility defect, these claims do not meet the requirements of a "necessary" amendment under subsection 30(6.3) of the *Patent Rules.*

CONCLUSIONS

[99] For the reasons above, it is our view that the subject-matter defined by the claims on file does not comply with section 2 of the *Patent Act*. Further, it is our view that the specification meets the requirements of subsection 27(3) of the *Patent Act* and claims 1 and 4 comply with subsection 27(4) of the *Patent Act*.

[100] We consider that proposed claims 1-13 do not overcome the lack of utility of the claims on file.

RECOMMENDATION OF THE BOARD

[101] In view of the above, we recommend that the application be refused on the basis that the claims on file are not compliant with section 2 of the *Patent Act*.

[102] Further, the proposed claims do not overcome this defect and therefore do not constitute specific amendments that are "necessary" under subsection 30(6.3) of the *Patent Rules*.

Ryan Jaecques	Marcel Brisebois	Paul Fitzner
Member	Member	Member

COMMISSIONER'S DECISION

[103] I concur with the findings and the recommendation of the Board and its recommendation that the application should be refused because the claims on file do not comply with section 2 of the *Patent Act*.

[104] 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.

Johanne Bélisle
Commissioner of Patents
Dated at Gatineau, Quebec,
this 27th day of December, 2017