Commissioner=s Decision # 1309
Décision de la Commissaire # 1309

TOPIC: B00, B20, C00
SUJET: B00, B20, C00

Application No. : 2,285,672
Demande n^{o}. : 2,285,672

Commissioner=s Decision Summary

The present review largely centred on the question of how the inventors might properly claim biochemical preparations having telomerase enzymatic activity that can be obtained by using novel and inventive purification methods.

The subject application was rejected in a Final Action since certain claims were considered indefinite and overly broad.

Indefiniteness

Held: rejection on these grounds reversed.

The terms and expressions used in the claims would be understood by the person skilled in the art. They collectively operate to define the bounds of the claim in such a manner that the skilled person would be able to understand whether or not a given product was within or outside its scope.

Overly Broad Claims

Held: rejection on these grounds affirmed.

The claims are too broad since they are not enabled across the entire scope. They neither indicate an upper limit on the degree of enzymatic purity nor include appropriately limiting terminology.

Certain claim amendments proposed by the Applicant were considered appropriate.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application no. 2,285,672 having been rejected under subsection 30(3) of the *Patent Rules*, has been reviewed in accordance with subsection 30(6) of the *Patent Rules* by the Patent Appeal Board and the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

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INTRODUCTION

[1] Pursuant to subsection 30(6) of the *Patent Rules*, this decision deals with a review of rejected patent application no. 2,285,672.

[2] The Applicant is Geron Corporation and the invention is entitled ÂPURIFIED TELOMERASE.@ The inventors are Scott L. Weinrich, Edward M. Atkinson, Serge P. Lichtsteiner, Alain P. Vasserot, Ronald A. Pruzan, and James T. Kealey.

PROSECUTION HISTORY

[3] The subject application was filed on April 4, 1997 and the Examiner in charge of the application issued a Final Action on December 13, 2004 at which time certain claims were rejected under section 84 of the *Patent Rules* for being too broad. The same claims were also rejected for indefiniteness under subsection 27(4) of the *Patent Act*.

[4] On December 8, 2005, the Applicant replied to the Final Action and submitted a new set of claims. The submission of the new claims resulted in minor claim amendments, the addition of two new claims, and the cancellation of one claim. The Applicant maintained that all the claims now on file are in allowable form.

[5] The rejection was referred to the Board because the Examiner was not convinced that the objections had been overcome. The Applicant provided further written submissions to the Board on April 25, 2008 and requested an oral hearing which was held on August 27, 2008. At the

hearing, the Applicant was represented by Mr. David Schwartz of the firm Smart & Biggar. Dr. Marsha Black, the Examiner in charge of the application, and Mr. Daniel Bégin, Section Head, also appeared at the hearing.

[6] During the hearing the Board posed several questions which the Applicant=s representative was not fully prepared to address at that time. Owing to the technical nature of the questions and the impact the Applicant=s response may have on the outcome of the review, it was agreed that an appropriate course of action would be for the Board to detail its questions in writing and forward them to the Applicant. A letter was therefore prepared and forwarded to the Applicant. A response to the Board=s letter, accompanied with proposed claim amendments, was received on December 16, 2008. This response and the proposed set of claims will be addressed following our analysis of the claims currently on file.

BACKGROUND OF THE INVENTION

[7] Before addressing the questions that the Final Action raises, it is important to understand the nature of the invention and the impetus for its development.

[8] Normally cells have a finite capacity to divide. A cell=s ability to divide is contingent upon the presence of Atelomeres@, or short bits of structural DNA, found on the ends of the cell=s chromosomes which become shorter with each round of chromosomal replication and cell division. After a number of rounds of replication, the telomeres shorten past a critical length and any further rounds of chromosomal replication are halted. At this point the cell enters a senescent state.

[9] At the time of filing the present application it was known that certain cells contain minute amounts of an enzyme, termed Atelomerase@, that is able to replace the bits of telomere DNA that are lost during chromosomal replication. The telomeres therefore never critically shorten and the cell is able to continue dividing. The enzyme was detectable, but its precise make-up, structure, and the identity of all its subcomponents remained unknown.

[10] With the knowledge that many cancer cells express telomerase comes the realization that one might be able to arrest the division of cancer cells if telomerase activity can be inhibited. To find telomerase inhibitors it therefore becomes necessary to develop telomerase inhibition assays. This, in turn, demands that telomerase itself first be available in a practical form in order for such assays to be developed.

[11] Therefore, the problem faced by the inventors was to obtain a suitably pure mammalian telomerase preparation that can be used primarily in telomerase inhibitor screening assays. It was not disputed by the Examiner that this problem was overcome by the inventors since they developed new and inventive purification methods that produce practically useful telomerase preparations.

[12] The present review largely centres on the question of how the inventors might properly claim B beyond the purification methods themselves B telomerase products that can be obtained by using the telomerase purification methods.

THE CLAIMS IN DISPUTE

[13] The independent claims at issue relate to telomerase products claimed in different ways. All include a reference to a minimal level of telomerase purity or concentration:

> 1. A cell extract comprising mammalian telomerase protein that is at least about 2,000-fold more pure (in terms of telomerase activity per weight of protein) than a crude extract of human embryonic kidney 293 cells, which when associated with telomerase RNA component has a molecular weight of 200-2000 kDa.
>
> 5. A composition comprising mammalian telomerase protein in solution in water, which when associated with telomerase RNA component has a specific activity of at least 5 units/Φg protein in a telomere primer elongation assay in which ^{32}P- labeled primer extensions are separated on a gel and detected using a phosphoimager screen.
>
> 9. A composition having telomerase activity, comprising telomerase protein in solution in water at a concentration of at least 3 x 10^{-10} mol L^{-1}.
>
> 10. A composition having telomerase activity, comprising telomerase protein in solution in water at a concentration of at least 2 x 10^{-9} mol L^{-1}.

[14] Claims 39 and 40 are independent claims directed to assay methods useful for identifying modulators of telomerase activity. These claims rely on a telomerase product as defined in any one of claims 1 to 4 (in the case of claim 39) or as defined in any one of claims 5 to 13 (in the case of claim 40). Therefore, by virtue of their reference to the rejected claims, these claims are also implicated in the rejection.

THE ISSUES

[15] The present review raises two questions:

(1) Are claims 1 to 13, 39 and 40 indefinite and therefore not compliant with subsection 27(4) of the *Patent Act*?

(2) Are the same claims too broad and therefore not compliant with section 84 of the *Patent Rules*?

ARE CLAIMS 1 TO 13, 39 AND 40 INDEFINITE?

The Final Action

[16] The Examiner found the rejected claims indefinite for the following reasons:

- The claims are directed to products which, by virtue of the terminology used, implicitly suggest the presence of more than a single component whereas the claims merely refer to a single Atelomerase protein@ component and lack an explicit indication of the presence of any other components.

- The claims inappropriately rely on non-technical features to define the purity of the telomerase protein found in the claimed products.

- The claims do not adequately distinguish the invention from the prior art since the telomerase protein was previously known.

[20] In order to address these concerns, the Final Action indicated that the claims ought to define the products in terms of the method by which they can be prepared, i.e. in product-by-process format.

The Position of the Applicant

[21] The Applicant submitted the following in response to the indefiniteness rejection:

- The requirement that a claim to a composition explicitly recite at least two ingredients is based on a misunderstanding of the decision in *Rohm & Haas Co. v. Commissioner of Patents* (1959), 30 C.P.R. 113 (Ex. Ct.)[*Rohm & Haas*].

- Claim 1, which is directed to a cell extract, is implicitly understood to comprise other products of cells and claims 5, 9 and 10 explicitly recite the presence of two ingredients.

- The claims are definite if a person of skill in the art can understand the scope of the claims.

- The discussion in the Final Action concerning what was known about telomerase preparations is not relevant to the question of definiteness.

- In view of the decision in *Re University of Strathclyde Patent Application* (1996), 77 C.P.R. (3d) 328, Commissioner=s Decision No. 1212 [*Strathclyde*] purity levels of a component in a claimed product, not drafted in product-by-process form, can distinguish over old products that were merely known to contain the same component but in less pure form.

- In the present case, the Applicant developed separation methods that yield highly pure

telomerase preparations and is therefore, in accordance with *Strathclyde*, entitled to coverage for the purified telomerase as a composition of matter irrespective of the method by which it is obtained.

[28] The Applicant also provided additional lengthy written submissions to the Board and further submitted that:

- There is no absolute requirement, in the case of a claim to a composition, that such a claim define a minimum of two components and that such a requirement is based on a misinterpretation of *Rohm & Haas* that case being concerned with double-patenting and decided based on an older version of subsection 27(4) which had an additional or different requirement that an applicant state the things or combinations *which the applicant regards as new.*

- The Applicant=s invention is different from the invention at issue in *Rohm & Haas* since what is new, non-obvious, and useful is providing telomerase at a level of purity previously unattainable.

- Purified products are patentable in principle and that, absent Canadian jurisprudence, guidance may be taken from decisions in the United States.

- The Commissioner=s Decision in *Strathclyde* continues to be a relevant authority since it is analogous to the present situation.

- Recent court decisions in *Sanofi-Synthelabo Inc. v. Apotex Inc.* (2005), 39 C.P.R. (4th) 202 (F.C.); aff=d (2006) 59 C.P.R. (4th) 46 (F.C.A.) and *Janssen-Ortho Inc. v. Novopharm Ltd.* (2006), 57 C.P.R. (4th) 58 (F.C.); aff=d (2007), 59 C.P.R. (4th) 116 (F.C.A.) concerning the purification and separation of chemical enantiomers from racemic mixtures, like the *Strathclyde* case, are guiding.

- Since the pending claim set includes claims in product-by-process format that were found to be acceptable by the Examiner, and since products that are already known may not be claimed anew by making them dependent on a new process (*Hoffman-LaRoche v. Commissioner of Patents* (1955), 23 C.P.R. 1 (S.C.C.)[*Hoffman-LaRoche*], the Examiner has implicitly acknowledged that the rejected claims, which are not drafted inproduct-by-process format, are also novel and inventive.

Definiteness: Legal Principles

[35] Subsection 27(4) of the Act states the following:

> 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.

[36] Definiteness can be assessed based on the guidance in *Minerals Separation North American Corp. v. Noranda Mines Ltd.*, [1947] Ex.C.R. 306 at 352 wherein Thorson P. stated:

> 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

Claim 1

[37] Independent claim 1 reads:

> 1. A cell extract comprising mammalian telomerase protein that is at least about 2,000-fold more pure (in terms of telomerase activity per weight of protein) than a crude extract of human embryonic kidney 293 cells, which when associated with telomerase RNA component has a molecular weight of 200-2000 kDa.

[38] The terms and expressions found in claim 1 that require consideration with respect to the requirement for definiteness are the following:

- $Acell extract@
- $Amammalian telomerase protein@
- $Aat least about 2,000-fold more pure (in terms of telomerase activity per weight of protein) than a crude extract of human embryonic kidney 293 cells@
- $Atelomerase RNA component@
- $Awhen associated with telomerase RNA component has a molecular weight of 200-2000 kDa@

ACell extract@

[44] The term Acell extract@ is not explicitly defined in the description but the description generally indicates on page 17, lines 19 to 20 that:

> [p]urification of telomerase begins with an impure source composition, such as a nuclear extract or crude cell extract, preferably rich in telomerase activity

[45] Taking this passage into account, and in view of the general knowledge expected of a person of skill in the art, the term Acell extract@ would be understood by that person to mean a fluid, or lysate, obtained by breaking open a cell containing telomerase activity. Cell extracts are

understood to be heterogeneous and include many types of intracellular biomolecules in varying amounts. Claim 1 would therefore be understood by the skilled person to qualify as a composition of at least two components.

AMammalian telomerase protein@ and Atelomerase RNA component@

[46] The description (page 12, lines 3 to 8) indicates that telomerase exists as a complex of a protein component and an RNA component:

> ATelomerase protein component@ refers to a protein component of the telomerase core enzyme.
>
> ATelomerase core enzyme@ refers to the assembled collection of telomerase components, both the RNA and protein components, sufficient for telomerase activity *in vitro*.

[47] The use of the terms Amammalian telomerase protein@ and Atelomerase RNA component@ in claim 1 therefore accurately reflects this knowledge.

AAt least about 2,000-fold more pure (in terms of telomerase activity per weight of protein) than a crude extract of human embryonic kidney 293 cells@

[48] The expression Aat least about 2,000-fold more pure (in terms of telomerase activity per weight of protein) than a crude extract of human embryonic kidney 293 cells@ indicates that, to be within the claim, a product must exceed the threshold stated. This aspect of the claim relates to a biochemical property (purity expressed in terms of specific activity) and, as a measurable parameter, is a valid technical characteristic that can be used to define the invention. Indeed, purity and specific activity are terms that are often used to describe products that have enzymatic activity. A person of skill in the art B having regard to the methods disclosed which may be used to test specific activity (see page 12, lines 14 to 25) B would be able to assess this parameter when determining whether a given cell extract is within or outside the scope of the claim.

[49] We note at this point that there is no defined upper limit to the increase in telomerase activity per unit weight of protein. However, this relates to the question of possible over breadth of the claim B a question that will be dealt with subsequently B but not to the definiteness of the claim.

Awhen associated with telomerase RNA component has a molecular weight of 200-2000 kDa@

[50] The expression Awhen associated with telomerase RNA component has a molecular weight of 200-2000 kDa@ relates to the apparent molecular weight of the Amammalian telomerase protein@ when it is associated with a telomerase RNA component, i.e. the apparent molecular weight of the complete telomerase complex. We are satisfied that this expression would be understood by a person of skill in the art. It is an approximation that could be determined using methods suitable for estimating the molecular weights of protein-RNA complexes, e.g. gel filtration chromatography (see page 22, lines 3 to 14; and page 56, lines 8 to 16 which gives

technical details and results of a typical analysis).

[51] Based on the foregoing, we conclude that the terms and expressions used in the claim would be understood by the person skilled in the art. They collectively operate to define the bounds of the claim in such a manner that the skilled person would be able to understand whether or not a given cell extract was within or outside its scope.

[52] Since dependent claims 2 to 4 recite further limitations, which themselves do not obscure the scope of claim 1, these claims are also definite.

Claim 5

[53] Independent claim 5 reads:

5. A composition comprising mammalian telomerase protein in solution in water, which when associated with telomerase RNA component has a specific activity of at least 5 units/Φg protein in a telomere primer elongation assay in which ^{32}P- labeled primer extensions are separated on a gel and detected using a phosphoimager screen.

[54] This claim refers to a composition comprising telomerase protein in water and it satisfies the basic definition of a Acomposition@ since it calls for two ingredients: a protein and its aqueous solvent (water) B the two together forming a Acomposition.@

[55] Claim 5 also recites a Amammalian telomerase protein@ and a minimum specific activity. Features such as these have been dealt with in respect of claim 1 and we find no lack of clarity when used in claim 5.

[56] From this we conclude that claim 5 is definite. Since dependent claims 6 to 8 recite further limitations, which themselves do not obscure the scope of their parent claims, these claims are also definite.

Claims 9 and 10

[57] Independent claims 9 and 10 read:

9. A composition having telomerase activity, comprising telomerase protein in solution in water at a concentration of at least 3 x 10^{-10} mol L^{-1}.

10. A composition having telomerase activity, comprising telomerase protein in solution in water at a concentration of at least 2 x 10^{-9} mol L^{-1}.

[58] Concerning the allegation that these claims are indefinite for not properly defining the Acomposition@, the same reasoning applied above in respect of claim 5 also applies in the case of claims 9 and 10 since these claims refer to a Acomposition@ comprising a protein component

and a water component.

[59] Claims 9 and 10 define the presence of telomerase protein in terms of molar concentration. Molarity is a well-known manner of indicating the absolute number of molecules of a compound found in a volume of solution. It is expressed as Amoles per litre@ and abbreviated Amol L^{-1}.@ Molar concentrations of telomerase can be estimated by determining the molar concentration of the RNA component. A stoichiometric association of the RNA component and the protein component allows one to then extrapolate the protein concentration (see page 54, lines 31-32).

[60] Since dependent claims 11 to 13 recite further limitations, which themselves do not obscure the scope of their parent claims, these claims are also definite.

[61] Having dealt with the first question facing us, we now turn to the question of support and whether the claims are compliant with section 84 of the *Patent Rules*. But before doing so we would take the opportunity to clarify a point of contention that arose during prosecution.

The Prior Art

[62] The Final Action indicates that the claimed products ought to be defined in terms of their method of production (product-by-process format). It suggests that, since a mammalian telomerase protein was previously known, and since a higher level of purity is not a distinguishing technical feature, there is something amiss with the claims:

> In the absence of defining how the extract and composition are obtained, or defining said extract and composition by any new, inventive and useful components, these claims are essentially directed to a mammalian telomerase which is allegedly more pure than the previously obtained telomerase. The product per se is known, as acknowledged by applicant on page 11 of the description and as indicated by the References of Interest, above. The only difference between the telomerase disclosed in Greider et al. and Villeponteau et al. (References of Interest, above) and that of the instant application is in the level of purity, specific activity, or concentration of telomerase. As indicated in the last Office Action, simply preparing an old and known telomerase preparation so that it is allegedly more pure than another telomerase preparation does not render it novel. Comparative purity, activity and concentration are not technical features that can be used to distinguish the claimed preparations from known telomerase preparations.

[63] These allegations presuppose that features of the claims, such as purity and specific activity, can be disregarded such that the prior art forcefully comes into play.

[64] The Federal Court has recently indicated in *AstraZenaca v. Apotex Inc.*, 2010 FC 714 that, in the context of anticipation, purity is a technical feature that can distinguish a claim directed to a chemical compound over the prior art if it has been established that the prior art would only occasionally enable the skilled person to reach the threshold level of purity recited in the claim.

However, that same decision also indicated that where a fair mosaic of prior art references provides the means and the motivation to obtain the threshold indicated, the same claim can be found obvious.

[65] In the present case, mammalian telomerase protein was previously known to exist in cells (see for example the References of Interest cited in the Final Action). But a practically useful telomerase product was not previously available. Importantly, it has been established by way of expert declaration submitted by the Applicant during prosecution that the prior art did not disclose telomerase products within the bounds of the claims and that the prior art would not have enabled the skilled person to prepare such products. Absent this information it may not have been unreasonable to presume otherwise. However, in light of this information, we do not see how the test for anticipation has been satisfied. The prior art must disclose something falling within the scope of the claims, and it must also do so in an enabling manner: *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*., 2008 SCC 61, [2008] 3 S.C.R. 265, at paras 23-28 [*Sanofi*]. The claimed products are distinguished over the art on the basis of a combination of meaningful features and testable parameters. Therefore an argument that informally brings into play the question of novelty cannot succeed.

[66] The same is true of any question of obviousness because it has been conceded that inventive effort would have been required to develop the Applicant=s purification methods and thereby, for the first time, arrive at something falling within the scope of the claims.

ARE CLAIMS 1 TO 13, 39 AND 40 TOO BROAD?

The Final Action

[67] From the arguments presented in the Final Action we gather that the claims are seen as too broad for the following reasons:

- What has been invented is a purification method with specific application to a human telomerase, and an allegedly novel extract produced by that method.

- The product claims exceed the invention made and disclosed since they fail to recite the new and inventive method.

- No other methods of obtaining the products have been disclosed.

- Human telomerase is a known protein and therefore cannot be claimed simply in a more pure form.

[72] The Final Action concludes by indicating that the allegedly novel or improved telomerase products would be considered patentable if drafted in product-by-process format.

The Position of the Applicant

[73] From the response to the Final Action and the Applicant=s submissions to the Board we understand the Applicant=s position to be the following:

- The rejection demands not only consideration of section 84 of the Rules but also of subsection 27(3) of the Act.

- There is no relevant judicial authority supporting the proposition that a product must be claimed in product-by-process form.

- The claimed products themselves, when considered apart from the claimed methods, do not exceed the invention made and disclosed.

- The decision in *Farbwerke Hoechst Akteingesellschaft vormals Mesiter Lucius & Bruning v. Commissioner of Patents,* [1966] Ex. C.R. 91; aff=d (1966), 50 C.P.R. 220 (S.C.C.) [*Farbwerke Hoechst*] is not proper authority for the rejection.

- Under the Act as it currently reads there is no longer any statutory authority whatsoever for requiring a product-by-process format, even in respect of claims to products intended for food or medicine.

- There is no requirement under subsection 27(3) of the Act for the specification to disclose every way to make the invention. The disclosure of one way is enough.

[80] With respect to the last point, there was discussion by the Board and the Applicant at the hearing that the minimal requirement for subsection 27(3) to provide Aone way@ of making the invention really meant Aat least one way.@ It was also clarified that the claims must be enabled across their breadth.

Support and Claim Scope: General Legal Principles

[81] The claims have been rejected under section 84 of the *Patent Rules* which states:

> The claims shall be clear and concise and shall be fully supported by the description independently of any document referred to in the description.

[82] Canadian courts have provided little judicial interpretation of Section 84 of the Rules or any of its preceding equivalents. However in *Re Application of Ciba* (1974), Commissioner's Decision No. 208, the Board stated B after noting that it may be possible for a single sentence in the disclosure to provide sufficient support to warrant claims to some inventions B that the overriding principle was that an inventor may not validly claim what he has not described (citing *Radio Corporation of America v. Raytheon Manufacturing Co.* (1957), [1956-1960] Ex. C.R. 98

para 28, 27 C.P.R. 1). The Board then went on to consider whether the invention had been sufficiently described as required by the statute [then section 35 of the *Patent Act*; subsection 27(3) for today=s purposes] and as expressed by the case law.

[83] Since section 84 of the Rules is a subordinate form of legislation that cannot operate outside its enabling statute it should be read in conjunction with subsection 27(3) of the Act, the relevant portions of which read:

> 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 likely connected, to make, construct, compound or use it; . . .

[84] The equivalent of subsection 27(3) has been interpreted in *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.R. 504 para 27, 6 C.P.R. (2d) 146:

> Section 36(1) seeks an answer to the questions: "What is your invention?" How does it work?" With respect to each question the description must be correct and full in order that, as Thorson P. said in *Minerals Separation North American Corporation v. Noranda Mines, Limited* :
>
> > ...when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application. [at p. 316]

[85] Compliance with subsections 27(3)(a) and (b) therefore requires that the specification provide a correct and full written description of the invention and must disclose how the invention actually was, or at least how it can be, put into practice: it must be enabling. In respect of each requirement it is understood that there must be a correct and full compliance. What may validly be claimed is thus constrained by what the remainder of the specification, the description, teaches. In this respect we note that the Final Action states that the rejected claims are too broad and that both the Final Action and the submissions from the Applicant refer to *Farbwerke Hoechst* (*supra*):

> There are two fundamental limitations on the extent of the monopoly which the inventor must validly claim. One is that it must not exceed the invention which he has made, the other is that it must not exceed the invention he has described in his specification.

[86] *Farbwerke Hoechst* has been discussed in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FC 11 para 46, 69 C.P.R. (4th) 191 wherein, in relation to the Atwo fundamental limitations@, Hughes J. stated:

> The first limitation is a question of fact, what is the invention that the inventor(s) have made. The second is a question of construction of the disclosure of the patent to determine what it says. In both cases a comparison must then be made of the claims at issue to determine if the Abreadth@ of the claim exceeds either what the inventor(s) actually did or what the disclosure actually says. In the event that evidence from the inventor(s) is not available and secondary evidence such as notebooks, memoranda and evidence of colleagues is unavailable or unsatisfactory, it is reasonable to assume that the disclosure of the patent coincides with that which the inventor(s) invented.

[87] In the present case, neither evidence from the inventor nor secondary evidence is available. We will therefore proceed on the assumption that the specification coincides with the invention made. What remains is to determine whether the claims comport with the description.

Analysis

[88] *Farbewerke Hoechst* has been discussed in both the Final Action and in the Applicant=s submissions. In *Farbewerke Hoechst* (a reissue case) questions arose as to the appropriateness of very broad product-by-process claims that encompassed a vast range of purportedly therapeutically useful compounds. A new specification was sought and the petition for reissue included claims that were found to relate to a different, more specific, invention. Since the new claims were not considered to be directed to the Asame invention@ as that originally filed, a new specification could therefore not be properly reissued.

[89] At the time of the *Farbewerke Hoechst* decision there was also a statutory requirement to draft claims to products intended for food or medicine in product-by-process format.

[90] In the present case we are not concerned with products intended to be used as medicines and there is no statutory requirement to present the claims in product-by-process format. There has been no allegation made that the claims are too broad for the reason that the invention now claimed is different than that originally described in the specification and no allegation has been made that they encompass subject matter that cannot possibly be useful. The present case is therefore factually distinguishable from *Farbewerke Hoechst.*

[91] Nonetheless, we are still guided by the general principles of *Farbewerke Hoechst*. It is not disputed that the Applicant can rightfully claim telomerase products. Although the Final Action asserts that the product-by-process claim format is required, the principal question, in our view, is whether the claims as drafted are too broad in light of the description.

[92] The Final Action appears to derive from *Farbewerke Hoechst* the notion that the claims are too broad because Athe invention@ is a purification method. Since the claimed products are not explicitly tied, in product-by-process format, to that inventive method they are considered too broad. The Final Action in effect appears to say that Athe invention@ defined in the method claims must also explicitly appear in the product claims.

[93] It is not disputed that the methods used to obtain the telomerase products are new and inventive. In that respect, the present case is factually similar to the situation in *Strathclyde* as well as a host of other decisions involving the use of new and inventive methods for resolving enantiomeric mixtures of chemical compounds: see *Sanofi*, and *Lundbeck Canada Inc. v. Canada (Minister of Health)*, 2009 FC 146, aff=d 2010 FCA 320 [*Lundbeck*]. In all of these Aenantiomer cases,@ the development of a new and inventive method for separating chemical enantiomers from one another did not preclude the legitimate claiming of one of the enantiomeric forms in a manner independent of the method for its separation.

[94] In *Lundbeck* at para 144 it was argued before the Federal Court that claims to a chemical enantiomer B which were not drafted in product-by-process format B were broader than the invention made, and that if there was any invention, it should have been limited to the specific methods used to obtain the enantiomer. This argument was rejected by the trial judge in favour of the reasoning expressed in *Generics (UK) Ltd & Ors v H Lundbeck A/S*, [2008] EWCA Civ 311 at paras 26-27, aff=d [2009] UKHL 12 [*Generics (UK)*] B a case involving the equivalent European patent. The appellant court in *Generics (UK)* explained that, in the case of an ordinary product claim, the product is the invention and that providing one method for its production is sufficient:

> The judge held that claim 1 and claim 3 (which is dependent on claim 1) were insufficient. His reasoning was that claim 1, being a claim to the (+) enantiomer as a product, was a claim to a monopoly of that product however made: see section 60(1)(a) of the 1977 Act. But Lundbeck's inventive idea was not to discover that the enantiomer existed and had a medicinal effect. Everyone knew that the two enantiomers existed and that one or other or both had a medicinal effect. What Lundbeck discovered was one way of making it. But that did not entitle them to a monopoly of every way of making it.
>
> I can understand and sympathise with the judge's instinctive reaction to the inherent breadth of a product claim. Indeed, as I shall in due course show, he is not the first to have registered such a protest. But in my opinion his reasoning is not justified either by the statute or the authorities. In an ordinary product claim, the product is the invention. It is sufficiently enabled if the specification and common general knowledge enables the skilled person to make it. One method is enough. [emphasis added]

[95] Therefore, there is no general principle in law which demands that a claim to a product be tied to a method that was used to obtain it, even if the invention of the method was first required before the product itself could be legitimately claimed. This holds even where a claim is directed to a product that was previously known to exist and its features could be envisaged, e.g. as in the enantiomer cases which involved claims to substantially pure, structurally defined, chemical species that were previously known to exist in racemic mixtures.

[96] There is also no strict requirement to disclose all possible ways of obtaining a claimed product. Nonetheless, while the disclosure of a single method of obtaining claimed products can be sufficient, it should be remembered that the full breadth of the invention as claimed must be enabled (see also subsection 9.02.05 of the *Manual of Patent Office Practice*, December 2010).

[97] Although clearly relevant, the factual circumstances considered in the various enantiomer cases do not illustrate a complete picture. All of those cases concerned claims to substantially pure chemical compounds that could be considered enabled across their scope, i.e. up to the limits of purity indicated. To develop a fuller picture we have also considered the decisions from the United States that the Applicant has cited in support of the proposition that products which are more pure can be claimed. These decisions are not binding, but can be guiding, especially given that the United States Act has similar statutory provisions. Most importantly, they serve as a reminder that it is critical to consider the scope of the claims and the facts.

[98] We need not discuss them all, but certain United States decisions are helpful since they concern open-ended claims to more pure, complex biochemical products. As such, they are more like the products claimed in the present application than the enantiomers claimed in *Strathclyde*, *Sanofi*, *Lundbeck* or *Generics (UK)*.

[99] The *Scripps* decision cited by the Applicant relates to a purified proteinaceous blood clotting factor claimed through reissue in product-by-process format as well as in simple product format alone: see *Scripps Clinic & Research Foundation v. Genentech, Inc*., 18 U.S.P.Q. 2d 1001 (C.A.Fed.(Cal.), 1991. Generally speaking, if there is anything from the law in the United States that we would take B which is still consistent with the enantiomer case law discussed above B it is the points that are summarized at page 1006 of *Scripps*:

$ Open-ended claims are not inherently improper.

$ Their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art.

$ Such claims may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit.

$ Open-ended claims are unpatentable for lack of enablement if they encompass future compositions having potencies far in excess of those obtainable from the teachings of the specification plus ordinary skill.

[104] These points are best appreciated by further considering the situation *In re Fisher*, 427 F.2d 833, 166 U.S.PQ. 18 (C.C.P.A. 1970) [*Fisher*] B a decision that was also discussed in *Scripps*.

[105] In *Fisher*, the disputed claims were directed to adrenocorticotrophic (ACTH) hormone preparations that were more pure than previously known preparations and which were obtained through the use of a novel extraction method. The claims were open-ended since they minimally called for preparations having a lower threshold of potency. The court stated:

> [The claim] has a lower limit but no upper limit. As previously mentioned, the specification

> discloses products having potencies from 111% to 230% of standard, which we understand to mean from 1.11 to 2.30 International Units of ACTH activity per milligram. The issue thus presented is whether an inventor who is the first to achieve a potency of greater than 1.0 for certain types of compositions, which potency was long desired because of its beneficial effect on humans, should be allowed to dominate all such compositions having potencies greater than 1.0, including future compositions having potencies far in excess of those obtainable from his teachings plus ordinary skill.
>
> . . .
>
> In the present case we must conclude, on the record before us, that appellant has not enabled the preparation of ACTHs having potencies much greater than 2.3, and the claim recitations of potency of Aat least 1@ render the claims insufficiently supported under the first paragraph of 35 U.S.C. 112.[emphasis added]

[106] Thus *Fisher* stands for the proposition that, where a composition is claimed as having a potency of Aat least@ a particular value, it can be the case that the claim is not commensurate in scope with the specification if compositions having considerably higher potencies are not enabled. The fact that an applicant was the first to achieve a composition with a potency beyond a particular lower threshold does not necessarily entitle one to claim any composition that exceeds the lower threshold.

[107] *Fisher* also acknowledged a distinction between claims to impure hormone preparations with limited potency and claims to substantially pure chemical compositions:

> Our conclusion is in no way opposed to the principles of the cases cited by appellant in support of his contention that he is entitled to coverage of the breadth now sought. *Farbenfabriken of Elberfeld Co. v. Kuehmsted* (& ldquo; Athe aspirin case@), 171 F. 887 (N.D. Ill. 1909), affd. 179 F. 701 (7th Cir. 1910), *In re Williams*, 36 CCPA 756, 171 F.2d 319, 80 USPQ 150 (1948), and *Parke, Davis & Co. v. Mulford & Co.*, 196 F. 496 (2d Cir. 1912), each involved claims to substantially pure compositions. Such claims do not present the same breadth problem as here, because in those cases the possible range of further purification was either small or non-existent. Such claims have an inherent upper limit of 100% purity, whereas in the present case it would appear theoretically possible to achieve potencies far greater than those obtained by appellant. [emphasis added]

[108] This leads us to now consider the scope of the claims in relation to the question of enablement.

[109] In the present case, we are confronted with open-ended claims directed to a biochemical preparation, which encompass products purified to an inherent upper limit that approaches 100%. The Applicant has argued in the written submissions to the Board that Athe claims do not recite telomerase *per se* (i.e. absolutely pure telomerase), but rather a cell extract (claim 1) or a composition comprising telomerase protein in water (claims 5, 9 and 10), at a defined level of purity@ (page 8, second paragraph). However, claim 5 neither places an upper limit on the degree of purity (as expressed in terms of specific activity) nor does it indicate the presence of impurities. Thus the composition of claim 5 can encompass a mammalian telomerase protein in water, provided that the composition has the defined minimal level of specific activity. The same is true of claims 9 and 10. Claim 1 is somewhat more restrictive than claim 5 in that it suggests

the presence of impurities through the use of the term Acell extract.@ Nonetheless claim 1 is open-ended and does not place an upper limit on the degree of purity.

[110] Ultimately, in contrast to the situations in *Strathclyde*, *Sanofi*, *Lundbeck*, *Generics (UK)*, and *Scripps*, the independent claims at issue in the present case relate to a wide range of embodiments rather than to a single, practically homogeneous, compound. Some embodiments covered by the claims read as telomerase protein in water above a defined minimal level of purity or activity. Other possible embodiments include more complex mixtures or extracts *B* the critical limitation again being a minimal level of purity or activity.

[111] Turning to the description, we note that all the embodiments actually obtained were obtained by taking an enriched telomerase fraction and then subjecting it to affinity purification using telomerase-specific oligonucleotides. There are no indications that the Applicant has actually prepared a mammalian telomerase well beyond the minimal levels stated in the claims so as to approach the theoretical limits of molecular purity. The purification methods actually undertaken indicate that telomerase was purified, at best, to a level not much greater than about 60,000-fold (see page 27, lines 19 to 22 for example). At a purification level of 100,000-fold, the inventors estimate that about 6% of the proteins present in a purified sample would be telomerase (page 12, line 32 to page 13, line 1). This means that, although considerably more pure than extracts previously known, the best telomerase preparations actually prepared still comprise telomerase in a relatively very minor amount. Not surprisingly, samples of the best preparations actually made were found to be heterogeneous and, when analyzed by SDS-PAGE gel electrophoresis (a commonly accepted analytic technique used to determine protein purity), they were found to contain about 50 visible protein bands. This would indicate to the skilled person that further purification of telomerase is possible and that the theoretical limits of purification have not been approached or achieved by the inventors. If the specification had disclosed substantially pure telomerase, the skilled person would expect SDS-PAGE analysis to reveal the presence of many fewer protein bands.

[112] The description at page 3, lines 28 to 30 and page 27, lines 22 to 23 indicates that telomerase products prepared according to the methods actually performed can be taken and further manipulated to produce a substantially pure telomerase protein or preparations that are greater than 1,000,000-fold pure. However, the further manipulations rely on isolating bands from an electrophoretic gel and there is nothing in the description that identifies which of the 50 bands (evidently found in the most pure preparations that were actually made) corresponds to telomerase. To achieve these levels of purity the skilled person would be required to perform an extensive series of experiments involving the excision and testing of multiple bands and/or combinations of bands without the benefit of specific guidance. We see this not as routine, non-inventive work, but rather as an undue burden placed on the skilled person.

[113] Further purification beyond about 60,000-fold would appear to require separation of telomerase from co-purifying contaminating materials based on a technique(s) that exploits some other property that could be used to differentially separate telomerase and contaminants.

The only other such technique adequately disclosed that could plausibly raise the purification level to 500,000-fold is a second type of affinity purification that is mentioned on page 3, lines 26-27 and page 27, lines 9-12. That second method relies on immunopurification techniques to purify two particular, defined, molecules that are associated with telomerase. Through non-covalent molecular interaction, telomerase could thereby be co-purified to a higher degree.

[114] To return to the language of claims 5, 9 and 10, we do not see how the claimed products can be aptly termed Acompositions@, in their broadest sense, without extending beyond what the description enables. This is because the term Acomposition@ is very broad and covers embodiments that have not been enabled. For example, the claims encompass a product minimally having two components , i.e. something consisting essentially of molecularly pure telomerase protein plus water. To fully enable the composition claims, the description must allow the skilled person to make or obtain telomerase products minimally comprising telomerase protein and water. The presence of the latter component, being well-known, would not present any problem to the skilled person. However, the same cannot be said of the principal component of the claimed compositions: the telomerase protein. As explained above, the description neither identifies what constitutes molecularly pure telomerase nor does it teach the skilled person how to obtain it. Instead the description teaches products that are much more heterogeneous than the claimed, minimally defined, compositions.

[115] The products described and enabled are therefore all more aptly termed cell extracts.

[116] Lastly, the use of the term Atelomerase protein@ when used in conjunction with the expression Awhen associated with telomerase RNA component@ (in the case of claims 1-8) or when used alone (in the case of claims 9-13) indicates that the claims encompass products in which the RNA component is absent. In our view this again renders the scope of the claims broader than what is taught in the description. All of the teachings in the description relate to telomerase products prepared through extraction of cells. This necessarily results in the concomitant purification of the telomerase RNA component through molecular association with the protein component(s). Therefore, suggesting that the RNA component can be absent from the claimed products results in overly broad claims which fail to indicate the presence of a feature understood from the description to be present.

[117] For all these reasons we conclude that the independent claims are too broad. Since the rejected dependent claims suffer from one or more of the defects outlined above, they too are not considered compliant.

POST-HEARING SUBMISSIONS AND PROPOSED CLAIMS

[118] We have reviewed the Applicant=s letter of December 16, 2008 and have considered the Applicant=s proposed amendments to claims 1 through 13 provided therein.

[119] That same letter proposes amendments to other claims that were not rejected in the Final

Action and does so for the purpose of consistent use of expressions throughout the claims. The letter also proposes to delete claim 31 and insert a new claim. Even if proposed in good faith, a review of the nature, purpose, and effect of these further amendments is outside the scope of the present review since they pertain to claims not indicated to be rejected in the Final Action and for which we cannot clearly perceive an issue that would render them non-compliant with the Act and Rules. As such, the Commissioner does not have authority under Rule 31(*c*) for requiring that these additional amendments be made.

[120] The three proposed independent claims that correspond to rejected claims 5, 9 and 10 do not fully address the concerns outlined above and will therefore not be considered any further.

[121] Of the four independent product claims proposed, only claim 1 (and by extension dependent claims 2 to 4) addresses all of the concerns outlined above. It reads:

> A cell extract comprising human telomerase that is between about 2,000-fold and about 500,00 fold more pure (in terms of telomerase activity per weight of protein) than a crude extract of human embryonic kidney 293 (HEK) cells, wherein the human telomerase has a molecular weight of 200-2000 kDa. [markups removed]

[122] Proposed claim 1 recites an upper limit on the degree of purification: up to Aabout 500,000-fold.@ The proposed amendment also substitutes the term Atelomerase@ for the term Atelomerase protein@ B an amendment that would address the over breadth of the claim in relation to the failure to indicate the presence of the RNA component since the term Atelomerase,@ as opposed to the term Atelomerase protein,@ means a complex of both the protein and RNA components (see, for example, the last paragraph of page 11). Lastly, the claim is limited to a cell extract as opposed to a composition.

[123] We note that proposed claim 1, now more narrowly refers to Ahuman@ telomerase as opposed to a Amammalian@ telomerase. Since this amendment does not seem to be required to address a defect under the Act or Rules, as explained above, we do not see that the Commissioner has authority under Rule 31(*c*) for requiring it. For greater certainty, we should not be taken to say that the claim may be broadened through the deletion of the term Amammalian.@

PROPOSED CLAIM LANGUAGE AND CLAIM FORMAT

[124] Since the issues to be resolved were better clarified at the hearing, we would also take this opportunity to add the following comments on the product-by-process claim format, the language used in proposed claim 1 and how that language might be considered to relate to desired properties (i.e. activity or purity) of the claimed subject matter.

[125] When considering the patentability, or not, of a claim drafted in product-by-process format, the focus remains on the product. Even though the process referred to in such claims may be novel, it does not necessarily follow that the resultant product *per se* is also new and therefore patentable: see *Hoffman-LaRoche* (*supra*), and subsection 17.05.03 of the *Manual of Patent*

Office Practice. Thus, the principal reason for the need to refer to a process in a product-by-process claim is found in the requirement to distinguish any purportedly novel product from all others. Yet in this case there are ways other than by process terminology through which the claims can be distinguished over the art. In the present case, the products in proposed claim 1 are defined on the basis of meaningful, definite terms and testable biochemical properties that befit the nature of the invention. These features are sufficient, as evidenced by way of expert declaration, to distinguish the claimed products from the prior art. As such, we are not convinced in this case that there is a need to further include process terminology.

[126] The present case may bring to mind comments made by Binnie J. in *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024 at para 32:

> As stated, the ingenuity of the patent lies not in the identification of a desirable result but in teaching one particular means to achieve it. The claims cannot be stretched to allow the patentee to monopolize anything that achieves the desirable result. It is not legitimate, for example, to obtain a patent for a particular method that grows hair on bald men and thereafter claim that anything that grows hair on bald men infringes. [emphasis added]

[127] Although the principle expressed above applies in the present case, it is understood that the inventors have actually achieved what might be considered desirable results and the proposed claims have not been stretched to improperly cover any telomerase product (e.g. essentially pure human telomerase protein) that is practically useful, but rather have appropriately claimed cell extract products.

[128] The inventors= new and inventive method results in the manufacture of products that are themselves new, unobvious, and useful. Proposed claim 1 includes a lower limit that is required to distinguish the product from known, practically useless crude products and an upper limit that reflects the level of purity enabled by the Applicant=s methods. The proposed claim would be considered to be properly defined since it distinguishes the claimed subject matter over the prior art and since it allows the person skilled in the art to determine whether a product that he manufactures falls within the scope of the claim. The claim would also be properly supported across its width.

SUMMARY

[129] Based on the foregoing analyses, we conclude:

- that claims 1 to 13, 39 and 40 are definite and compliant with subsection 27(4) of the *Patent Act*; and

- that claims 1 to 13, 39 and 40 are too broad and not compliant with section 84 of the *Patent Rules*.

[130] The Applicant=s proposed claim amendments to claims 1 to 4 would properly constrain their

scope and would therefore be considered to satisfactorily address all outstanding issues relating to these claims. These proposed claim amendments would also be considered to address all outstanding issues relating to claim 39 since it refers exclusively to claims 1 to 4. Further constraining the scope of claims 1 to 4 through the proposed limitation of the Amammalian@ telomerase to Ahuman@ telomerase is not permissible.

[131] Since claim 40 exclusively refers to claims 5 to 13, which must be deleted in view of our findings above, it too must be deleted.

RECOMMENDATION

[132] We recommend that, in accordance with paragraph 31(*c*) of the *Patent Rules*, the Commissioner inform the Applicant that the following amendments are required for compliance with the Act and Rules:

- deletion of currently pending claims 5 to 13 and 40;
- amendment of claims 1 to 4, save for the limitation of the Amammalian@ telomerase to a Ahuman@ telomerase, in accordance with proposed claims 1 to 4 submitted with the Applicant=s correspondence dated December 16, 2008; and
- adjustment of claim numbering and dependencies of the remaining claims accordingly.

Ed MacLaurin — Member

Stephen MacNeil — Member

Paul Fitzner — Member

COMMISSIONER=S DECISION

[133] I concur with the findings and recommendation of the Patent Appeal Board. In accordance with paragraph 31(*c*) of the *Patent Rules*, I hereby inform the Applicant that the following amendments are required for compliance with the Act and Rules:

- deletion of currently pending claims 5 to 13 and 40;
- amendment of claims 1 to 4, save for the limitation of the Amammalian@ telomerase to a Ahuman@ telomerase, in accordance with proposed claims 1 to 4 submitted with the Applicant=s correspondence dated December 16, 2008; and
- adjustment of claim numbering and dependencies of the remaining claims accordingly.

[134] I invite the Applicant to make the above amendments, and only the above amendments,

within three months from the date of this decision, failing which I intend to refuse the application. If the above amendments, and only the above amendments, are made within three months from the date of this decision I will consider the outstanding issues to have been addressed.

Mary Carman
Commissioner of Patents

Dated at Gatineau, Quebec
this 18th day of January, 2011