Team no. 5

IN THE SUPREME MOOT COURT FOR INTELLECTUAL PROPERTY APPEALS

Between:

Filter King Labs, Inc.

(Appellant)

and

AsterixObelix Pharma Inc.

(Respondent)

FACTUM FOR APPELLANT

(The 2013-2014 Harold G. Fox Moot)

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PART I: OVERVIEW

[1] This is an appeal from the judgment of Reanall J.A. invalidating the Appellant's patent for lack of patentable subject matter and lack of proper disclosure. The action is for patent infringement against the Respondent. Findings of infringement have already been made by Stohne J.[1] Only the validity of the patent is at issue.

[2] A purposive construction of the patent is essential and forms the basis for the examination of its validity. In this case, the Court of Appeal misconstrued the patent to be a product patent. An incorrect construction results in the wrong questions being answered with respect to subject matter and sufficient disclosure. On a purposive construction of the claim, the patent is a method patent.

[3] The Appellant's combination of elements forms a diagnostic method. This invention is patentable subject matter for three reasons:

(i) The Appellants claim a limited application of a law of nature, not a monopoly over a mere discovery. The claimed application is limited to human saliva (not other samples) and filtration (not other modes of isolation).

(ii) The invention is a combination of known and new elements. The Appellant claims a method for the detection of a disease via the isolation of a biomarker in human saliva via filtration.

(iii) The invention is a new use for a known process. Jurisprudence relied upon by Reanall J.A. states that a new use for a known process is patentable.

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[1] *Trial Court (TC) Reasons*, at para 1.

[4] The Appellant's patent enables a person skilled in the art to practice the invention using only the specification. This disclosure is sufficient for three reasons:

(i) The patent as a stand-alone document answers the fundamental questions: "What is the invention?" and "How does it work?" Because the Court of Appeal did not apply purposive construction, it misconstrued the invention as a product and therefore mistakenly required a referenced document to form part of the specification.

(ii) Also because the Court of Appeal misconstrued the invention as a product, it held that the Appellant obscured the nature of the invention. Once the claim is purposively construed as a method, nothing was concealed.

(iii) Where the referenced material is not a necessary element of the patent, as in this case, a URL is a footnote. Using a URL does not invalidate a patent.

[5] Because the Appellant's diagnostic method is patentable subject matter and the invention is sufficiently disclosed, the appeal should be allowed.

PART II: STATEMENT OF FACTS

[6] This appeal is based on a patent infringement action in which the Appellant, Filter King Labs, Inc. ("Filter King"), alleges the Respondent, AsterixObelix Pharma Inc. ("Asterix"), has infringed their Canadian Patent No. 5,234,111 ("the 111 Patent"). At trial, the Respondent "frankly admit[ted]"[2] that they infringed the 111 Patent, but raised a defence of patent invalidity. At trial, the Respondent alleged two things: i) the invention was not patentable under section 2 of the *Patent Act* as it was a law of nature, and ii) that the patent did not teach the inventor how to

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[2] *TC Reasons*, at para 1.

use the invention. The patent was determined to be valid at trial, but invalid by the Court of Appeal.

The development of the novel diagnostic method for early-stage chronic kidney disease

[7] Early-stage chronic kidney disease ("eCKD") is the first step in the gradual loss of kidney function over time. The early diagnosis of this disease is crucial for treatment. If not detected early, CKD is potentially lethal and treatment becomes costly and intrusive to the patient.

[8] The Appellant developed a diagnostic method in order to solve the problem that early-stage CKD detection doesn't exist. Four years of hard work and monetary investment led to the conclusion that *Treponema pepsicola* ("*Tp*") bacteria present in human saliva was an indicator (also known as a biomarker) for eCKD. This knowledge alone was useless to the patient. The last step for the Appellant, a start-up company at the time, was to transform this knowledge into something practical to benefit the medical community. At the time the Appellant developed their diagnostic method, "earlier techniques to isolate the bacteria involved lengthy and arduous experimentation and did not involve filtering."[3] Understanding that filtering could be used to filter *Tp* was in itself an inventive step. The 111 Patent was developed as a method patent to cover filtering methods of human saliva to diagnose eCKD.

Decision of the trial judge

[9] In addressing the issue of subject matter, Stohne J. found that the Appellant's invention represented an important medical breakthrough.[4] It was agreed by the parties that the 111 Patent covered a method for isolating a biomarker from a human sample to diagnose a disease. Claim 1 refers to filtration, human saliva, and the relationship between *Tp* and eCKD as parts of the

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[3] *Clarifications to the Moot Problem*, at para 5.
[4] *TC Reasons*, at paras 1, 9.

invention.[5] The Respondent's "SpittingImage" kit was being marketed one month after the 111 Patent was issued and relied on each part of the invention, including the natural relationship.

[10] On disclosure, the trial judge found that using a specific filter to isolate *Tp* was not itself inventive. Paragraph 57 of the 111 Patent is in accordance with Stohne J.'s finding. The specification states the specific filter that isolates *Tp* is "known to one skilled in the art."[6] However, filtration (generally) had never been applied to *Tp*, although its existence was known to researchers before the 111 Patent was granted.[7]

[11] Finally, the use of a URL in the 111 Patent was no cause for concern. This type of reference "aids in the readability of patents."[8]

Decision of the Court of Appeal

[12] Reanall J.A. erred in her construction of the patent. By looking at extrinsic evidence and not applying purposive construction principles, the Court of Appeal confused the Appellant's patent with their commercial product. Its entire validity analysis was premised on the wrong invention. The product on the market (the SpIT kit) is not the invention; the product that went to market and the invention covered by the patent are separate entities.

[13] Reanall J.A. incorrectly found the ceramic micro-filters in the SpIT kit to be essential. Ceramic micro-filters were not mentioned in the patent. They were mentioned in a referenced article, entitled *Advanced Bacterial Filtering* ("ABF"). Because the Court incorrectly thought the filters were essential, it expected the ABF article to form part of the patent. It found "Filter King

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[5] *TC Reasons*, at para 8.
[6] *TC Reasons*, at para 16.
[7] *Clarifications to the Moot Problem*, at para 5.
[8] *TC Reasons*, at para 17.

could have included details about the filtering equipment…in the patent document itself, but chose not to."[9]

[14] With respect, the Appellant did not have to disclose the information about specific filter elements. As the trial judge found, the use of a specific filter to isolate *Tp* "was not inventive, in itself."[10] Thus, contrary to the Court of Appeal's statement,[11] a person of ordinary skill in the art can rely on their knowledge of specific filters because the patent directed them towards using filtration.

[15] The Court of Appeal found that the 111 Patent taught only the relationship between a biomarker and the early stages of a disease. A natural correlation, admittedly, does not warrant the granting of a patent. In the eyes of Reanall J.A., the patented method was the association of *Tp* with eCKD. The Court did not consider the invention to be a combination of a law of nature and two other elements. These two elements are the decision to use human saliva as a sample and filtration as a mode of isolation. Without considering these elements, the court decided that the Appellant's patent was an exclusive right to the relationship between a biomarker and a disease.

PART III: POINTS IN ISSUE

[16] Reanall J.A. referred to the issue of patentable subject matter as "fundamental"[12] but did not examine it first in her decision. While not an error in law, her improper construction followed by an analysis of disclosure likely coloured her examination of patentable subject matter. The Appellant will address the more fundamental issue of patentable subject matter before disclosure.

[17] The Appellant submit that there are three issues in this appeal:

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[9] *Appeal Court (AC) Reasons,*at para 6.
[10] *TC Reasons*, at para 15.
[11] *AC Reasons*, at para 6.
[12] *AC Reasons*, at para 10.

(A) Whether the Court of Appeal erred in its construction of the claim.

(B) Whether the 111 Patent properly claims an innovative method for diagnosing eCKD rather than a scientific discovery.

(C) Whether the 111 Patent was sufficiently disclosed.

PART IV: ARGUMENTS IN BRIEF

A: The Court of Appeal erred in its construction of the claim

[18] The Court of Appeal's construction of the patent is at the root of this appeal. Its failure to apply a purposive construction of the claim resulted in an incorrect understanding of the 111 Patent. This misunderstanding of the patent affected the analysis of both subject matter and disclosure.

[19] As required by the Supreme Court of Canada in *Free World Trust* and *Whirlpool*, the patent should be read using a purposive construction of the claims.[13] A purposive construction requires the patent to be read with "a mind willing to understand"[14] the invention and "with a judicial anxiety to support a really useful invention."[15] One should pay close attention to the intent of the patentee. In construing the patent, one must adhere to the claim language; the primacy of claim language has long been acknowledged in jurisprudence.[16] There is a presumption that the patentee`s intent is reflected in the claim language and all elements are essential unless proven otherwise in the specification.[17] Only if the claim is unclear may one look

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[13] *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 31, [2000] 2 SCR 1024 [*Free World Trust*]; *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 49, [2000] 2 SCR 1067 [*Whirlpool*].
[14] See e.g.*Whirlpool*, *ibid* at para 49.
[15] *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 at 521, 122 DLR (3d) 203 [*Consolboard*].
[16] *Free World Trust*, *supra* note 13 at para 33-43.
[17] *Ibid.*

to the specification to understand the claim, but one may not look outside the specification. Binnie J. stressed the point in *Whirlpool* (emphasis added):

> It is … permissible for the trial judge to look at the rest of the specification… to understand what is meant by [a particular word] in the claim, **but not to enlarge or contract the scope of the claim as written and thus understood**.[18]

[20] Furthermore, the patent must be construed through the eyes of a person of ordinary skill in the art ("POSITA"). This hypothetical person is "sufficiently versed in the art to which the patent relates to enable them on a technical level to appreciate the nature and description of the invention."[19] The POSITA in this case is someone possessing a thorough understanding of biomarkers, bacteria, and filters used to isolate various bacteria. He or she also has hands-on experience with the filtration of bacteria in human saliva.

[21] The starting point of the construction is what was agreed upon by the parties at trial. The parties agreed that the invention covers a method of diagnosis for eCKD via the isolation of a biomarker from human saliva. Claim 1, the only claim of the patent, informs us that the isolation occurs via filtration and the biomarker of interest is *Tp*. Incorporating the information of Claim 1, the definition of the invention is construed as a method of diagnosis for eCKD via the isolation of the biomarker *Tp* from human saliva by filtration.

[22] The next step in the validity analysis is to see if every part of the claim is consistent with the specification. In this case, it is. If paragraph 57 is properly and purposively read in relation to claim 1, paragraph 57 exists to define in greater detail the general knowledge of the POSITA. It

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[18] *Whirlpool*, *supra* note 13 at para 52.
[19] *Ibid* at para 53.

tells the reader a POSITA would know the "filtering techniques necessary to isolate the…bacteria from human saliva"[20] once taught to apply filtering methods.

[23] The Court of Appeal referred to extrinsic evidence (the ABF article, which does not form part of the patent) to construe the claim. Not only is extrinsic evidence prohibited,[21] it caused the Court to "contract the scope of the claim as thus written and understood" contrary to *Whirlpool*. There is no mention of a specific mode of filtration in claim 1; there is no reason to disclose what was never meant to be claimed by the 111 Patent. Specific filtering components are in the capacity of the POSITA to determine via regular bench work. Essentially, the error of the Court of Appeal was to construe the invention to include only one filter.

[24] A proper construction, as demonstrated above, would indicate that the Appellant did not patent a product, but rather, patented a method. The invention as defined by the claim and on a purposive construction is the method of diagnosis for eCKD via the isolation of the biomarker *Tp* from human saliva by any mode of filtration. If the Court of Appeal had used this construction, the outcome for both subject matter and disclosure would have favoured the Appellant.

B: The Appellant's invention constitutes patentable subject matter

[25] The Appellant has patented a diagnostic method; this type of invention is allowed in Canada. It is true that the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) allows member states to exclude diagnostic methods from patentability.[22] Although

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[20] *TC Reasons*, at para 16.
[21] *Free World Trust*, *supra* note 13 at paras 61-67.
[22] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299.

Canadian courts have expressly prohibited patents for certain types of inventions, there is no exclusion of diagnostic methods from patentable subject matter.[23]

1. The Appellant does not claim an exclusive right to a mere law of nature

[26] The Court of Appeal, in concluding that the Appellant claimed a law of nature, relied on a distinguishable case from a foreign jurisdiction. In *Mayo Collaborative Services v Prometheus Labs*, the invalid patent monopolized a correlation between a metabolite and the human body's response to a drug. The flaw of Prometheus's patent was that it was not confined to "particular applications of [a law of nature]."[24] Prometheus Labs sought to prevent others from using <u>any means</u> of determining the metabolite concentrations in the blood stream. For this reason, the American Court invalidated the patent.

[27] The Appellant, unlike Prometheus Labs, did not patent all applications of a law of nature. Instead, the Appellant only seeks <u>what is explicitly allowed</u> by *Prometheus,* namely to "foreclose from others the use of [a law of nature] in conjunction with <u>all of the other steps</u> in their claim" (emphasis added).[25] Protecting a limited application of a law of nature does not invalidate a patent. The 111 Patent applies two functional limitations to the diagnosis of eCKD via *Tp*. The first limitation restricts the analysis to human saliva. Secondly, the Appellant selected filtration, and only filtration, to isolate the biomarker. Where a limitation is inventive and not "obvious, already in use, or purely conventional" a patent should be granted. [26]

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[23] See especially *Tennessee Eastman Corp v Canada (Commissioner of Patents)*, [1974] SCR 111, 8 CPR (2d) 202. (A surgical method is not patentable subject matter).
[24] *Mayo Collaborative Services v Prometheus Laboratories*, 566 U. S. ____ (2012) at 13, 132 S Ct 1289 [*Prometheus*].
[25] *Ibid* at 12.
[26] *Ibid*.

[28] Filtering human saliva for *Tp* was not obvious, already in use, or conventional at the date of filing. Filtering generally was inventive. The 111 Patent met *Prometheus'* requirement that there is a more than routine application of the law of nature and properly restricts the claim to a specific application.

[29] The 111 Patent leaves room for other applications of the same law of nature without infringing the patent. For example, relying on other samples (e.g. DNA, blood, or urine) or any form of isolation other than filtration are non-infringing applications of a law of nature. Relying on methods other than filtration to isolate *Tp* would not infringe the 111 Patent. And finally, filtering *Tp* for a purpose other than the diagnosis of eCKD is allowable.

[30] Diagnostic methods that are very similar to the 111 Patent are regularly granted in the United States despite the decision in *Prometheus*. A recent study categorized U.S. diagnostic method patents. 23% of the patents in the sample involve an analytic procedure (like filtration) that identifies a particular biomarker, "where the mere presence of the biomarker is indicative of disease."[27] This is a significant percentage of patents which rely on the same underlying principle as the 111 Patent. A method that applies filtration of a specific sample to detect a biomarker for the purpose of diagnosis is patentable.

2. The invention is a new and useful combination of known and new elements

[31] An invention is patentable if the sum of its components is greater than their individual parts. It is established law in Canada that a combination of known and uninventive elements can

[27] Matthew D Snow, "A Dreadful Prognosis: Patentability of Diagnostic and Personalized Medical Procedures in the Wake of *In re Bilski*" (2010) 2:2 Hastings Science & Technology Law Journal 301 at 321.

still be patentable if the combination has a useful result that cannot be achieved by its individual elements.

[32] One example of a combination that is inventive is provided in *Canada v American Optical*. In this case, eye-glasses with arms that connected at above the mid-point of the glass frame and eye-glasses with low nose pads had already been invented. The inventor claimed the combination of these two elements in a patent. The court found the patent valid, stating "it is not necessary to the validity of a combination invention that its elements should be new…all of them may be old." [28] The two known elements only produced an advantage when combined and the same result could not be produced by each part individually. It followed that there was an inventive step in putting the known elements together.

[33] An example of a combination that is a mere aggregation is given in *Lester v Canada*. In this case, the inventor sought a patent for a toy pistol that doubled as a whistle. The judge found that "the pistol and the whistle are not combined to produce a common result. Each part performs its function independently."[29] The function of the whistle was not enhanced by the toy pistol and vice versa.

[34] Applying the law to the facts of this case, the invention of the Appellant consists of three elements: using human saliva as a sample, isolating the biomarker via filtration, and the relationship between *Tp* and eCKD. The three elements of the invention will only result in a useful diagnosis when combined. The discovery of the correlation between *Tp* and eCKD is useless to medical professionals by itself. It does not give them a solution to a problem on its own; it is merely knowledge. The use of filters themselves is also not useful without the

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[28] *Canada (Attorney General) v American Optical Co*, [1950] Ex C R 344 at para 22, 13 CPR (1st) 87 [*American Optical*].
[29] *Lester v Commissioner of Patents*, [1946] ExCR 603 at para 2, 6 CPR 2 [*Lester*].

discovery. Filtration can be used to isolate hundreds of different biomarkers in the human body. One could filter for any number of markers but not be able to identify them or correlate them to any disease. Filters, on their own, have a broad application. Similarly, a human saliva sample without knowledge of what to isolate from that sample is useless on its own. One could swab a desk and isolate the bacteria that is present on the desk, but that does not produce any useful information.

[35] The method in the 111 Patent creates a unitary, simple, and useful result (the diagnosis of eCKD) that is not attributable to any of the three elements but flows from the combination itself and would not be possible without it.

[36] Based on the incorrect patent construction of Reanall J.A., it is not surprising she interpreted the Appellant's invention to be invalid. She committed two errors. Firstly, in failing to use purposive construction, she construed the patent as a product that deceptively claimed a monopoly over the entire law of nature. Secondly, Reanall J.A. began at paragraph 10 of her decision to assess the inventiveness of each constituent part, rather than as a whole. For example, paragraph 11 of her decision amounted to a novelty analysis on one element of the product. Neither novelty nor the product was at issue. Further, she stated that "there is no new bacteria-isolating technique or equipment per se that is sought to be patented by Filter King."[30] She also said that the only element that was new was the "recognition that a particular bio-marker is connected to a kidney disease."[31] This is all true; but it is irrelevant. The law in Canada is that a combination of known and uninventive elements can still be – and in this case, is – inventive.

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[30] *AC Reasons*, at para 13.
[31] *AC Reasons*, at para 12.

3. A new use for the known process of filtration is patentable

[37] The Appellant found a new use for filtration, even though it was a known process. As the Federal Court of Appeal acknowledged in *Calgon Carbon Corp v North Bay*,[32] an invention that is a new use for a known process is patentable. This case was cited in the court below for the proposition that a mere discovery is not patentable. However, the Court of Appeal ignored the context and the remainder of the decision.

[38] In *Calgon*, a method for preventing the replication of protozoa eggs (bacteria that when fully grown can cause infection from drinking water) using low levels of UV light to irradiate water was invented. Low level light had already been used before in water treatment for the killing of bacteria and viruses, but not specifically for the killing of protozoa. Prior to the patentee's invention, it was thought high doses of UV light were required to destroy protozoa eggs. Thus the inventive step of the patent was that it was only necessary to use a low level of light to prevent replication and disease. In *Calgon*, the trial judge found that the low-level UV light method had been known to eliminate bacteria, and all that had changed is the application of the old method to protozoa. He found the use of the old method to prevent disease was a mere discovery and not a patentable invention. He was overturned by the Court of Appeal.

[39] Rothstein J.A., as he then was, succinctly stated the law. In examining the *Patent Act*'s definition of invention, Rothstein J.A. defined 'new' as "a contribution to knowledge, something

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[32] *Calgon Carbon Corp v North Bay (City)*, 2005 FCA 410, 45 CPR (4th) 241 [*Calgon*] (appeal of a motion for summary judgment).

that was not known before."[33] Furthermore, he adopted *Shell Oil* which said "the discovery of a new use for an old invention which is capable of practical application is an invention."[34]

[40] Rothstein further adopted the Supreme Court of Canada's analysis in *Shell Oil*, where they consider U.K. jurisprudence:

> "… once the idea was formed, no further inventive ingenuity was required in order to put it into effect… When once the idea of applying some well-known thing for a special and new purpose is stated, it may be very obvious how to give effect to that idea, and yet none the less is that a good subject-matter for a Patent."[35]

[41] The principle in *Calgon* and *Shell Oil* applies to the case before this Court as the facts are analogous. In this case, filters were well-known and had previously been used to filter bacteria, but had not been used to specifically filter *Tp* from saliva. Prior to the Appellant's invention, isolating *Tp* required arduous experimentation and work. This work did not involve filtering. Thus the inventive step of the 111 Patent was that filtering could be applied to saliva to isolate *Tp.* Filtering *Tp* was not known in the art. The invention applies a technique that was well-known for the new purpose of diagnosing eCKD. This is allowed by jurisprudence.

[42] In summary, the 111 Patent meets the statutory requirement of subject matter in the *Patent Act*. The Appellant did not patent a mere law of nature and is an allowable method of diagnosis according the recent American jurisprudence. The method is an inventive combination of old and new elements, namely the use of a human sample, a means of isolation, and a discovery. Furthermore, the invention is a new use for the known process of filtration. Never before has the filtration of bacteria in human saliva led to a method of diagnosing eCKD. Using a filtration to isolate *Tp* was not well known or part of the common general knowledge. However,

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[33] *Ibid* at para 10.
[34] *Ibid* at para 13.
[35] *Ibid* at para 15.

once the idea of applying the technique for a new and special purpose was created, it did not require inventive ingenuity to select a specific arrangement of filters.

C: The 111 Patent provides sufficient disclosure of the invention

[43] Disclosure is sufficient if the patent enables a POSITA to practice the invention. Based on the purposive construction of the claim above in Issue A, does the 111 Patent sufficiently disclose a method of diagnosis of eCKD via the isolation of *Tp* by filtration of human saliva? The Appellant respectfully submits that it does.

1. The 111 Patent meets the disclosure requirements of s. 27(3) of the *Patent Act*

[44] Canadian courts have applied the disclosure requirement of s. 27(3) of the *Patent Act,* through a two-part test. The first question, "What is the invention?" and subsequently, "How does it work?" are considered by the Supreme Court of Canada when disclosure is at issue. [36] In answering the second question, the underlying principle is whether a POSITA, having only the specification, could make the same use of the invention as the inventor.[37] If the 111 Patent answers these two questions, the disclosure is sufficient.

[45] The contents of the ABF article did not have to form part of the patent; the article was merely a publically available reference. To demand inclusion of the ABF article as part of the specification is to incorrectly construe the 111 Patent. Requiring this heightened level of disclosure is only appropriate in sound prediction cases.[38]

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[36] *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at para 70, [2012] 3 SCR 625 [*Sildenafil*].
[37] *Consolboard, supra* note 13 at para 27.
[38] *Eli Lilly Canada v Apotex*, 2009 FCA 97, 78 CPR (4th) 388.

(a). What is the invention?

[46] The answer to this question depends on the construction of the patent as contemplated under Issue A. Based on a purposive construction, the invention is the method of isolating *Tp* from human saliva by any means of filtration to diagnose eCKD.

(b). How does it work?

[47] A person skilled in the art would understand how the invention works by reading the 111 Patent as a stand-alone document, without the contents of the ABF article. In the case of a "new combination of old elements" the patent must disclose "the elements…of [the invention]…and their mode of operation."[39] At the heart of this dispute is the disclosure of a mode of operation for the isolation of *Tp*.

[48] The mode of operation for isolating *Tp* from human saliva is filtration; it is not a single type of filter. Since the Appellant did not seek to patent a filter, they were not required to disclose a filter in their specification: "It is only if the applicant desires to claim invention for a subordinate element…that it is necessary for him to claim the element."[40]

[49] No Canadian court has overturned the statement that "a skilled worker can practice the invention, even if routine trials and experiments not amounting to invention might be necessary to arrive at the desired result."[41] Selecting a filter that isolates *Tp* may require trial and error, but it would not require inventive ingenuity.

[50] The 111 Patent as properly construed teaches the reader the inventive step: to apply filtration as a method of isolation. Earlier attempts to isolate *Tp* involved arduous and lengthy

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[39] *Consolboard, supra* note 15 at 520-521
[40] *Ibid*.
[41] *Cabot Corp v 318602 Ontario Ltd.* (1988), 17 FTR 54 at 115, 20 CPR (3d) 132.

experimentation. By informing the POSITA to accomplish the isolation via filtration, the reader of the 111 Patent does not have to be inventive in order to put the Appellant's patented method into practice.

[51] It is within the POSITA's common general knowledge to use routine trials to find a working filter. *Tp* was a known bacterium prior to the patent. The description in the patent is supplemented by the common general knowledge of the POSITA. It is not necessary for the common knowledge to be disclosed.[42] The level of bench work involved in selecting a filter to isolate bacteria is normal in the complex field of medical diagnostics.

[52] The case at bar is analogous to *Merck & Co Inc. v Apotex Inc*[43] where Apotex argued that the patent failed to disclose the methods for determining which strains of the genus *Aspergillus* would produce the desired compounds. In the same vein, the Respondent argues the Appellant is required to disclose a specific filter to isolate *Tp*. The Federal Court found that the person of ordinary skill could screen a large number of isolates of strains of *Aspergillus terreus* without inventiveness or excessive benchwork. Similarly, the POSITA could screen a large number of filters to determine those effective in filtering *Tp.* Just as the *Merck* patent directed the POSITA to a particular genus of *Aspergillus,* the 111 Patent directs the reader to a particular mode of isolation—filtration.

[53] The Appellant successfully disclosed what the invention was, as well as how the invention functions. The Court of Appeal, however, did not purposively construe the invention. As a result, Reanall J.A. expected a disclosure of the SpIT kit when it was not required.

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[42] *Burton Parsons Chemical Inc v Hewlett-Packard (Canada) Ltd*, [1976] 1 SCR 555 at 563-565, 17 CPR (2nd) 97.
[43] *Merck & Co Inc v Apotex Inc*, 2010 FC 1265 at paras 531-532, 91 CPR (4th) 1.

Requiring an inventor to guide the reader through non-inventive steps, such as how to select a filter, is not a part of the patent bargain.

2. The Appellant does not obscure the nature of the invention

[54] The error committed in the Court of Appeal's application of *Sildenafil* stems again from the incorrect construction of the claim. Firstly, it misconstrued the invention to be the SpIT kit. Therefore it incorrectly believed the filter elements to be essential and thus concluded the Appellant obscured the invention hiding the filter elements in the ABF article, separate from the patent. The Appellant concedes that, if the SpIT kit had been patented, the specific filter elements needed to be disclosed. However, based on the purposive construction in Issue A, the SpIT kit was not disclosed. The ABF article was merely a reference.

[55] Secondly, after erroneously believing the 111 Patent to be a product patent, the Court of Appeal erred in its interpretation of *Sildenafil* by applying what amounts to a best mode requirement. A best mode requirement, however, exists only for machine inventions.[44] The Appellant has not patented a machine, and even so, there is no evidence that the Appellant knew which filter was most effective at filing. The subject matter of the 111 Patent is a method. The patented process was described in claim 1 as "isolating a biomarker from human saliva…to determine" eCKD. [45]

[56] Jurisprudence interpreting *Sildenafil* has held that the Supreme Court of Canada's interpretation of the disclosure requirement does not amount to a best mode requirement. Snider J., speaking for the Federal Court stated "There is no requirement in s. 27(3) that 'best mode'

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[44] *Sanofi Aventis Canada v Apotex*, 2009 FC 676 at para 329, [2009] 77 CPR (4th) 99.
[45] *TC Reasons*, at para 8.

must be disclosed in inventions that are not machines."[46] In *Teva Canada Ltd v Novartis AG*, the patent claimed a broad genus. In addition to imatinib – the compound that was eventually Novartis' marketed product – there were six individually claimed compounds in the same group as imatinib. Teva claimed that imatinib had to be disclosed as sildenafil had to be disclosed in *Sildenafil,* just like how the Respondent argues here that the set of filters used in the first product by the Appellant must be disclosed to satisfy s. 27(3) of the *Patent Act.* Justice Snider however found imatinib to be distinguished from Viagra, as there was no evidence that the inventor knew at the time of filing that imatinib was superior. She upheld the patent. Likewise, in the case at bar, the Respondent has advanced no evidence that the Appellant knew the filters disclosed in the ABF filters were the best filters. Thus, there was no need for them to disclose those filters to satisfy sufficient disclosure.

3. The use of a URL should not invalidate the 111 Patent

[57] The ABF article did not have to form part of the 111 Patent, and the fact it was referenced via URL should not invalidate the patent. If the Court or Respondent has issue with the use of a hyperlink in the body of the specification, the proper remedy would have been to bring an administrative review of the Commissioner's decision, as stated in the Manual of Patent Office Practice ("MOPOP"):

> "Examiners will object to the identification of a document by way of a URL where it is not clear that the URL refers to a **reliable, publically available source**."[47]

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[46] *Teva Canada Ltd v Novartis AG*, 2013 FC 141 at para 376, 109 CPR (4th) 1 [*Imatinib*].
[47] *Manual of Patent Office Practice*, Chapter 9, online: Canadian Intellectual Property Office <http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03150.html>.

This is echoed in the *Patent Rules.*[48] There was no objection by the examiner as to the presence of the URL.

[58] The Appellant concedes that a website is different, in some respects, from a book on a shelf. Once published, a book is a tangible and static reference. A webpage is dynamic and susceptible to change by the owner. However, the integrity of the ABF article is not an issue in the case at bar. There was no evidence that the Appellant blocked access or attempted to alter the content of the article. The court shouldn't invalidate an entire patent based on hypothetical facts.

[59] In the case before this Court, the mere presence of a URL should not invalidate the 111 Patent. The URL is analogous to a footnote reference to a book. The applicant, in this respect, included the name of the article, its web address and the purpose of the reference; the article was properly identified. Furthermore, the document was available to the public. Firstly, the fact the Respondent's admitted no trouble accessing the article is evidence of the availability of the article. Secondly, a resource locked behind a pay-wall (such as newspaper articles or journal articles) is less publically available than a resource than can be obtained for free and by the click of a button. A resource that only exists on a library shelf is also less publically available than one that can be viewed on any screen anywhere in the world.

PART V: ORDER REQUESTED

[60] The Appellant respectfully requests that this appeal be allowed and the findings of infringement by the lower court reinstated.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

Dated this 13th day of January 2014.

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[48] *Patent Rules*, SOR/96-423, r 81.

PART VI: TABLE OF AUTHORITIES

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Manual of Patent Office Practice, Chapter 9, online: Canadian Intellectual Property Office <http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03150.html>.	

PART VII: APPENDICES

None.