Federal Court of Appeal | Cour d'appel fédérale

Date: 20210728

Docket: A-44-20

Citation: 2021 FCA 154

CORAM: **GLEASON J.A.**
LASKIN J.A.
LOCKE J.A.

BETWEEN:

SEEDLINGS LIFE SCIENCE VENTURES, LLC

Appellant

and

PFIZER CANADA ULC / PFIZER CANADA SRI

Respondents

Heard by online video conference hosted by the registry, on May 6, 2021.

Judgment delivered at Ottawa, Ontario, on July 28, 2021.

REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: GLEASON J.A.
LASKIN J.A.

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REASONS FOR JUDGMENT

LOCKE J.A.

I. Background

[1] On May 6, 2021, this Court heard the present appeal (Court File No. A-44-20), as well as a related appeal (Court File No. A-431-19). The related appeal is addressed in a separate decision.

[2] The present appeal arose following a three-week trial in which the appellant, Seedlings Life Science Ventures, LLC (Seedlings), claimed that the respondent, Pfizer Canada ULC (Pfizer), infringed certain claims of its Canadian Patent No. 2,486,935 (the 935 Patent), and Pfizer counterclaimed that the claims in issue of the 935 Patent are invalid.

[3] The 935 Patent in suit is entitled "Apparatus and Method for Rapid Auto-Injection of Medication," and Pfizer's allegedly infringing product is its auto-injector called EpiPen. Because the design of the EpiPen has evolved since it was introduced to the market in the 1980s, the allegedly infringing product is referred to as the Next Generation Auto-injector EpiPen or NGA EpiPen.

[4] The Federal Court (per Justice Sébastien Grammond, 2020 FC 1) concluded that Pfizer had not infringed the 935 Patent, and that the claims in issue were indeed invalid. The claims that remain in issue are claims 40, 44-47, 57-60 and 62. The Federal Court found that all of these claims are invalid for overbreadth, that claims 44-47 and 57 are also invalid for anticipation, and that claim 58 is also invalid for obviousness. Aside from the invalidity issues, the Federal Court found that none of the claims in issue was infringed. Despite its conclusions that the 935 Patent was neither valid nor infringed, the Federal Court also considered issues related to remedies in the event that those conclusions should be reversed.

[5] The related appeal concerns a decision made during trial to admit into evidence certain documents produced by Pfizer during examination for discovery concerning business plans. In light of the Federal Court's comment at paragraph 235 of its reasons for the trial decision

(Reasons) that it did not need to rely on those documents, I conclude that the decision on the related appeal will not affect the present appeal.

[6] Seedlings argues that all of the claims in issue should have been found valid and infringed. The sole exception is claim 40, in respect of which Seedlings does not dispute the finding of non-infringement, though it still disputes the finding of invalidity. Pfizer argues that that the Federal Court was right to find all of the claims in issue invalid and not infringed. For the reasons discussed below, it is my view that the present appeal should be dismissed and that the Federal Court's conclusion that the claims in issue are invalid and not infringed should be affirmed.

II. The 935 Patent

[7] Prior to discussing the issues in dispute, I will provide some details concerning the 935 Patent. The Background section notes two key shortcomings of prior art auto-injectors that would be addressed: (i) the tubular shape, which made them bulky and made instructions printed thereon difficult to read, and (ii) the fact that the needle remained exposed after deployment.

[8] The solution provided in the 935 Patent is a relatively flat device having three phases. The first is a *retracted storage position* in which the needle is ready for use (see Figure 17 from the 935 Patent reproduced in Appendix A hereto). Here, a reverse syringe containing medication is held in place within the device housing by a syringe carrier at its rear end. The needle extends from the forward end of the reverse syringe, but remains covered by a needle shield. The needle

shield is located at the forward end of the device, but includes arms extending rearward on either side of the reverse syringe to the rear of the device where they engage the syringe carrier to hold it in place. A compressed spring lies between the rear of the syringe carrier and the rear of the housing. The needle shield and its arms are held in place by a latch locking mechanism using fingers fixed to the housing on both sides that project into slots in the arms.

[9] Once a safety cover is removed from the needle shield, the device may be moved to an *injection position* by pressing its forward end against the area of the body that is to receive the injection. This forces the needle shield and the needle rearward relative to the rest of the device (see Figure 18 from the 935 Patent in Appendix A). At a certain point, the rearward arms of the needle shield release the syringe carrier. This allows the spring behind the syringe carrier to push the reverse syringe and needle forward and into the body (see Figure 19 from the 935 Patent in Appendix A), and then compress the reverse syringe to force the medication through the needle and into the body (see Figure 21 from the 935 Patent in Appendix A).

[10] After injection, two other springs (located on either side of the device) urge the needle shield forward to cover the needle as it is withdrawn from the body (see Figure 22 from the 935 Patent in Appendix A). The operation of the device thus concludes in an *extended position* (also called a post-injection position). In this position, the needle shield is locked in place by another latch locking mechanism, using the same fingers as the first locking mechanism, this time projecting into different slots in the arms of the needle shield.

III. Issues

[11] The analysis below addresses the following issues in dispute:

A. Standard of review

B. Claim construction

i. “Rearwardly”

ii. “Actuation assembly”

iii. “Coupled to”

iv. “Movably mounted”

C. Validity

v. Anticipation and obviousness

vi. Overbreadth and insufficiency

D. Infringement

E. Remedies

[12] Because of my conclusion on some of these issues, I have found it unnecessary to address others.

IV. Analysis

A. *Standard of Review*

[13] The parties both argue correctly that the standard of review in the present appeal is as described in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 (*Housen*). The standard of correctness applies to questions of law (see *Housen* at para. 8), but findings of fact or of mixed

fact and law, absent an extricable question of law, are set aside only where the Federal Court has made a palpable and overriding error (see *Housen* at paras. 10 and 36).

[14] The standard of review on questions of construction of patent claims is complicated. Seedlings argues that claim construction is a matter of law (see *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, at para. 61 (*Whirlpool*)), and that the standard of review should be correctness. However, the issue is not that simple. Claims are construed from the point of view of the person skilled in the art to which the patent pertains at the date of its publication, and that point of view is typically determined with reference to expert evidence. The appreciation of such expert evidence is a question of fact reviewable on a palpable and overriding error standard: *Tearlab Corporation v. I-MED Pharma Inc.*, 2019 FCA 179, 166 C.P.R. (4th) 367, at para. 29.

B. *Claim construction*

[15] Seedlings takes issue with the Federal Court's construction of several terms in the claims in issue.

(1) Legal principles

[16] Though Seedlings does not specifically criticize the Federal Court's summary of the legal principles applicable to claim construction, it does highlight two principles: (i) the primacy of the language of the claims, not the disclosure, in defining the subject matter of an invention; and (ii) claims are not to be read in a literal or result-oriented manner.

[17] Pfizer does not take issue with the principles that Seedlings highlights. Neither do I. Pfizer adds correctly that construction is done once and for all purposes (i.e. for assessing both validity and infringement): *Whirlpool* at para. 49(b).

(2) Rearwardly

[18] The word "rearwardly" appears in claim 48 as part of the phrase, "[…] the syringe body and needle being disposed and maintained rearwardly within the housing in a retracted, storage position in readiness for use." The word rearwardly is the only substantial difference from the similar phrase in claim 47. Though claim 48 is not one of the claims in issue, claims 57-60 and 62, which are in issue, all depend indirectly from claim 48, and therefore contain all of the elements thereof, including "rearwardly".

[19] The Federal Court found that the addition of the word "rearwardly" in claim 48 was intended to distinguish from well-known prior art devices in which the syringe and body were located in the front half (see Reasons at paragraph 82). By contrast, the syringe and needle of the device described in the 935 Patent extends over most of its length. Therefore, by comparison to the prior art, the syringe and needle are disposed and maintained rearwardly.

[20] Seedlings takes issue with this construction of the term "rearwardly". It notes that construction of this term was not in dispute at trial, and that no expert evidence supports the Federal Court's construction. Seedlings also takes issue with the Federal Court's application of the principle of claim differentiation to compare two claims that are not otherwise identical. Further, Seedlings argues that the Federal Court's construction is absurd because the preferred

embodiment of the invention shows the needle and syringe located closer to the front of the device than the rear. Finally, Seedlings argues that the Federal Court erroneously construed the term "rearwardly" with an eye on the prior art. Seedlings argues that the word "rearwardly" should have been construed to refer simply to the direction in which the syringe and needle are restrained before deployment. Seedlings argues that, but for the Federal Court's error in this regard, it would have found that Pfizer's NGA EpiPen infringes claims 58-60 and 62 of the 935 Patent.

[21] I must reject all of Seedlings' arguments concerning construction of the term "rearwardly". The absence of a dispute between the parties as to the meaning of "rearwardly" could not prevent the Federal Court from construing the term to mean something. In addition, I see no error in applying the principle of claim differentiation to compare similar clauses in two claims, even if those two claims have other differences. While other differences might limit the application of this principle in some circumstances, that will not always be the case. The aim of claim construction is to determine what the person skilled in the art would think the inventor intended. Other differences between two claims may or may not affect the skilled person's understanding.

[22] Though it may be difficult to recognize that a syringe and needle could be disposed and maintained rearwardly within the housing when they are actually located as close to the front end as is possible, in my view this does not amount to absurdity. The Federal Court explained its view that "rearwardly" was intended to distinguish from the prior art, and to define a syringe and needle that extended further to the rear of the device. Though the Federal Court made reference

to the prior art in construing the term, this did not amount to impermissibly construing the term with an eye on the prior art. Courts are restrained from construing claims based on whether their construction will result in invalidity or infringement. However, there is no error in considering the common general knowledge that was available to the inventor when the patent was prepared. The Federal Court's reference to the prior art when determining what the inventor intended was permissible.

[23] Seedlings' proposed construction of "rearwardly" is reasonable, but that is not the test. The Federal Court's construction was supported by the expert evidence that it was entitled to prefer. I see no error in this regard. Moreover, even if I were to accept Seedlings' position, it would be far from establishing infringement of claims 57-60 and 62. Claim 57 was found invalid for both overbreadth and anticipation. Claim 58 was found invalid for both overbreadth and obviousness. Finally, claims 59, 60 and 62 were found invalid for overbreadth and not infringed for another reason (to infringe, the needle shield had to be "coupled" to the power source, not merely "operatively associated" therewith. All of these additional issues are discussed later in these reasons).

(3) Actuation assembly

[24] The term "actuation assembly" appears in claim 59 in the phrase "an actuation assembly that includes the needle shield and by which the needle shield is coupled to the power source." This term is included in claims 60 and 62 by dependency.

[25] The Federal Court concluded that this term refers to “one complex part or several parts attached together, either fixedly or movably” (see Reasons at paragraph 93). The Federal Court continued, “[c]onversely, separate parts do not constitute an assembly if they are merely touching without being attached.” The Federal Court explained that, “[i]t is difficult to think of an assembly when the parts are not attached together” (see Reasons at paragraph 91). Seedlings takes issue with the requirement that the parts be attached together. I address its several submissions in this regard in the paragraphs below.

[26] Seedlings submits that the Federal Court’s construction is internally incompatible because, before concluding that parts of an assembly could be attached movably, it stated that they do not move relative to one another. This submission lacks merit. It relies on a passage in paragraph 89 of the Reasons in which the Federal Court was describing the opinion of one of the expert witnesses. The Federal Court did not adopt that opinion.

[27] Seedlings asserts another contradiction by the Federal Court, noting that Schedule A of the Reasons, which describes the working of Pfizer’s NGA EpiPen, includes a description of “the Power Pak Inner / Collet / Power Pak Spring” as an assembly, even though the collet is not attached to the Power Pak Inner. I do not accept this as an inconsistency in the Reasons. Schedule A is described in paragraph 35 of the Reasons as a series of diagrams prepared by Meridian Medical Technologies, Inc. (the company that developed the NGA EpiPen) showing the main steps in the operation of the NGA EpiPen. Therefore, the use of the term “assembly” therein is Meridian’s, not the Federal Court’s. The mere fact that the word “assembly” was used

in a different manner in Meridian's document does not make the construction adopted by the trial judge inconsistent or inappropriate.

[28] Seedlings also points to a prototype made by the inventors of the 935 Patent that was relied upon to establish utility. Seedlings argues that the "actuation assembly" in this prototype was not attached together, but was found nevertheless to fall within the scope of the claims. However, paragraphs 158 and 159 of the Reasons, which were cited by Seedlings in support of this finding, appear to be based principally on the fact that there was no dispute between the experts as to whether the prototype fell within the scope of the claims. Accordingly, I am not prepared to accept that this finding is an inconsistency in the Reasons that amounts to either an error of law or a palpable and overriding error on question of fact or of mixed fact and law.

[29] Finally, Seedlings criticizes the Federal Court's reasoning that "if it is enough that parts be touching directly or indirectly for them to constitute an assembly, all the parts of each of the auto-injectors under consideration would constitute a single assembly, which deprives the term of any useful meaning." Seedlings notes the Federal Court's failure to recognize evidence of whole auto-injectors being described as assemblies. In my view, this observation is insufficient to prompt this Court to intervene. The Federal Court was not obliged to apply terminology used in relation to other auto-injectors, and I see no error in its silence in this regard.

(4) Coupled to

[30] As with “actuation assembly”, the term “coupled to” appears in claim 59, and is included in claims 60 and 62 by dependency. The relevant phrase, already quoted in paragraph 24 above, concerns an actuation assembly in which “the needle shield is coupled to the power source.”

[31] The Federal Court found that components are coupled if they are connected (touching), directly or indirectly, in a manner that will transmit a force or a movement (see Reasons at paragraphs 97 and 98). The Federal Court also noted the distinction between the term “coupled to” in claim 59 and the term “operatively associated with” in claim 58, and found that components that do not touch one another, directly or indirectly, may be operatively associated but are not coupled.

[32] Seedlings criticizes the Federal Court’s requirement for touching in the term “coupled to” based on differentiation from the term “operatively associated with” in claim 58. It makes an argument concerning the principle of claim differentiation similar to that made in relation to the term “rearwardly”. In this regard, I maintain the view I expressed in paragraph 21 above that claim differentiation may apply even with claims that have several differences. Moreover, the Federal Court’s view that the use of the term “coupled to” in claim 59 defines the relationship between the needle shield and the power source more restrictively than the term “operatively associated with” in claim 58 was entirely open to it.

[33] Seedlings also argues that the Federal Court’s construction of “coupled to” is absurd because the preferred embodiment described in the 935 Patent falls outside the claim. I disagree. While the needle shield and the power source described in the preferred embodiment at Figure 8

are not in *direct* contact, they do touch indirectly (as contemplated by the Federal Court's construction) via the syringe carrier. Accordingly, the preferred embodiment falls within the claim.

[34] Finally, Seedlings submits that there is an inconsistency in the Reasons where, in addressing the issue of infringement of claims 59, 60 and 62 (at paragraph 211 of the Reasons), the Federal Court added the requirement that coupled components be in contact "at all times", a requirement that had not previously been mentioned. I do not see this as an inconsistency. I see it rather as a more detailed explanation of the definition of "coupled to" already provided. This detail also fits with the example already provided by the Federal Court at paragraph 98 of the Reasons, namely that "if I press a button with my finger, my finger may be 'operatively associated' with the button, but not 'coupled' to the button." Specifically, the additional explanation appears to clarify that the contact must be constant, i.e. it must be present prior to deployment (as shown in Figure 8), and not only when deployed (as is the case with the NGA EpiPen). The Federal Court appears to accept that the contact present in the NGA EpiPen satisfies the definition of "operatively associated with", but not "coupled to".

(5) Movably mounted

[35] The Federal Court noted several instances in the claims in issue in which the term "movably mounted" or "disposed and maintained within" or "movably disposed within" is used. Of relevance to the present appeal is the Federal Court's conclusion that "movably mounted" requires that the components in issue be in *direct* contact, while "disposed and maintained within" and "movably disposed within" do not.

[36] Seedlings argues that “movably mounted” should also include indirect contact. Seedlings argues that the 935 Patent does not suggest a requirement for direct contact, and indirect contact instead has no material effect on the way the invention works. It notes that this disputed construction was the sole basis for finding non-infringement of claims 44 to 47.

[37] Firstly, I note that the Federal Court also found claims 44 to 47 invalid for both overbreadth and anticipation. Therefore, this analysis is meaningless unless Seedlings is successful in setting aside both of those grounds of invalidity.

[38] In any case, the Federal Court’s claim construction was based on the expert evidence that it favoured after having considered both sides of the debate. As part of its reasoning, the Federal Court distinguished “movably mounted” from the “more general expression” “disposed and maintained within”, which does not require direct contact. In my view, there was no error in the Federal Court’s conclusion in this regard. Seedlings refers to a hypothetical case in which direct contact would be prevented by placing a sheet of paper between two components that would otherwise be in direct contact. However, in my view, such a hypothetical is insufficient to override the Federal Court’s weighing of the expert evidence, and to characterize its construction as erroneous.

[39] Finally, I disagree with Seedlings’ assertion that the Federal Court drew a distinction between “movably mounted to” and “movably mounted in” or “movably mounted within”. As I have indicated, the distinction that the Federal Court drew was between “movably mounted” and “disposed and maintained within” or “movably disposed within”.

C. *Validity*

(1) Anticipation and obviousness

[40] As indicated above, the Federal Court found that claims 44-47 and 57 are invalid for anticipation, and that claim 58 is invalid for obviousness. Anticipation of claims 44 to 47 is based on U.S. Patent No. 5,295,965 (the US 965 Patent) and the common general knowledge of the person skilled in the art at the relevant time. Anticipation of claim 57 and obviousness of claim 58 are based on U.S. Patent No. 6,210,369 and the common general knowledge.

[41] Seedlings takes issue with the Federal Court's findings on anticipation and obviousness, citing two principal grounds. First, Seedlings argues that the Federal Court misunderstood the doctrine of approbation and reprobation. This doctrine addresses situations in which a party takes a position at trial that is inconsistent with a position that it took earlier, i.e. where a party attempts to "have its cake and eat it, too" (see *Apotex Inc. v. Astrazeneca Canada Inc.*, 2012 FC 559, 410 F.T.R. 168, at paras. 137-138).

[42] Seedlings argues that Pfizer (or its predecessor) approbated when it filed and prosecuted a U.S. patent application in relation to the NGA EpiPen that it said was novel over the US 965 Patent. Seedlings argues that Pfizer then reprobated by taking a position at trial that the US 965 Patent falls within the scope of claim 1 of the patent that issued from that U.S. patent application (and hence anticipates said claim 1).

[43] I agree with the Federal Court and Pfizer that the doctrine of approbation and reprobation does not apply in this case. I do not accept that Pfizer took the position at trial that the US 965 Patent falls within the scope of claim 1 of its U.S. patent. The evidence that Seedlings relies on arose during its cross-examination of one of Pfizer's fact witnesses. Seedlings cites nothing to indicate that Pfizer has adopted the view expressed by the witness. In addition, I see no reason to disagree with the Federal Court that the hypothetical construct presented by Pfizer's expert Neil Sheehan involving an additional outer sleeve on the device described in the US 965 Patent is insufficient to establish a reprobation.

[44] The second basis for Seedlings' criticism of the findings on anticipation and obviousness is that the Federal Court erred by engaging in a tortured reading of the US 965 Patent to find that it describes the three needle shield positions defined in claims 44 to 47 of the 935 Patent. Seedlings argues that the US 965 Patent describes only two positions for the needle shield, and that there were palpable and overriding errors in the Federal Court's conclusion. Seedlings argues that the passage from column 10 of the US 965 Patent cited by the Federal Court could not support the hypothetical construct mentioned in the previous paragraph, which the Federal Court accepted in reaching its conclusion.

[45] Seedlings made similar submissions before the Federal Court, which considered them and rejected them with reasons. It noted the parties' competing views as to the meaning of the passage at column 10, and concluded that Seedlings' interpretation was too narrow, and that the needle shield on a device modified in the manner contemplated in the passage would have three

positions. In my view, this conclusion was open to the Federal Court. Seedlings has not convinced me that there was any palpable and overriding error in this conclusion.

(2) Overbreadth and insufficiency

[46] As indicated above, the Federal Court found all of the claims in issue to be invalid for overbreadth (where the claim is broader in scope than the invention made or the invention described in the disclosure). On the other hand, the Federal Court rejected Pfizer's allegations of insufficiency (where the patent specification fails to describe the claimed invention in sufficient detail to permit a person skilled in the art to put it into practice without the exercise of ingenuity or undue experimentation). As discussed in the previous section, some of the claims in issue were also found to be invalid for anticipation or obviousness, and these findings survive scrutiny. However, those findings did not apply to claims 40, 59, 60 and 62. These claims were found invalid based only on overbreadth, and are therefore of particular interest on this issue.

[47] Seedlings asserts two grounds for its challenge to the Federal Court's finding of overbreadth. First, it argues that overbreadth is not a proper ground for invalidity. Second, it argues that, even if overbreadth is a proper ground of invalidity, the Federal Court erred in applying it in this case.

[48] Pfizer takes issue with Seedlings' arguments. It also argues that, regardless of this Court's conclusion on the issue of overbreadth, the claims in issue should have been found invalid for insufficiency.

(a) *Whether overbreadth is a proper ground for invalidity*

[49] Seedlings argues that there is no statutory basis for overbreadth as a ground of invalidity. It notes that that the requirements for a valid patent are set out in the *Patent Act*, R.S.C. 1985, c. P-4, and that nothing therein relates to overbreadth. Seedlings also notes that there is only one other case in which a Canadian patent claim has been held invalid for the sole reason of overbreadth: *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* (1986), 72 N.R. 290, 12 C.P.R. (3d) 193 (F.C.A.) (*Amfac*). It argues that *Amfac* was wrongly decided. It also argues that the Federal Court's finding of overbreadth in the present case represents an improper re-emergence of the promise doctrine, which was rejected by the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943 (*AstraZeneca*). The promise doctrine held that a patent was invalid for lack of utility if the specification promised more than it could provide. The Supreme Court rejected it on the basis that such an interpretation of the utility requirement was not congruent with the *Patent Act*.

[50] In my view, overbreadth remains a proper ground of invalidity. I recently commented on the issue of overbreadth, albeit in a case in which the existence of overbreadth as a ground of invalidity was not put into question: *Western Oilfield Equipment Rentals Ltd. v. M-I LLC*, 2021 FCA 24, 2021 CarswellNat 234 (*Western Oilfield*). Despite having considered Seedlings' submissions, I have not changed my views as stated in paragraphs 128 to 130 thereof:

> [128] There are two ways that a patent claim can fail for overbreadth (or overclaiming): it can be broader than the invention disclosed in the specification, or it can be broader than the invention made by the inventor: *Pfizer Canada Inc. v. Canada (Health)*, 2007 FCA 209, 60 C.P.R. (4th) 81 at para. 115.
>
> [129] The concept of claim invalidity for overbreadth (or overclaiming) arises from the combination of the requirements that a patent specification (i) correctly

> and fully describe the invention (see subsection 27(3) of the *Patent Act*), and (ii) include "claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed" (see subsection 27(4)). One may also consider overclaiming as a natural consequence of the bargain theory of patent law as described in *Free World Trust* [*v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024] at para. 13: "[i]n return for disclosure of the invention to the public, the inventor acquires for a limited time the exclusive right to exploit it." If a patent claims more than it describes, or more than the inventor has made, it gives the patentee more than the bargain entitles them to. Such a claim violates the bargain and is therefore invalid.
>
> [130] Overbreadth often overlaps with other grounds of invalidity. For example, a claim that is invalid for anticipation because it encompasses embodiments that are described in the prior art may also be considered overbroad for claiming more than the inventor has truly invented. In addition, overbreadth might be considered the other side of the coin of insufficiency. Where a claim is broader than the description, it may fail for overbreadth, but it may also fail because the description does not adequately describe how to put it into practice. Despite this possibility of overlap, overbreadth is a distinct ground of invalidity that must be considered separately.

[51] These paragraphs address Seedlings' argument concerning the statutory basis for overbreadth. The last paragraph also addresses another argument by Seedlings that overbreadth, as a ground of invalidity, is redundant. I maintain my view that overbreadth as a ground of invalidity is supported by the combination of subsections 27(3) and 27(4) of the *Patent Act*. The invention must be described in full, and the claims define a subset of the described invention that the inventor seeks as exclusive property. It follows that the scope of the claims cannot exceed the disclosure.

[52] I acknowledge that the overlap with other grounds of invalidity makes it difficult to define circumstances in which a patent claim would be invalid for overbreadth but not also invalid on other grounds. In this regard, it may be helpful to consider *Amfac*. There, this Court affirmed a trial decision that found that claims of a patent on a device for cutting potatoes into

french fries were invalid for overbreadth because they omitted a feature of the device that was essential to the working of the invention as described. The awkward aspect of *Amfac*, and of the present case, is that determining that a feature is essential had to be done by reference to the disclosure, not the claims. This is awkward because it is the claims that define the scope of the monopoly that the inventor asserts, and it is they that are typically reviewed to determine the essential features of the invention for the purpose of claim construction: *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024, at para. 31 (*Free World Trust*). Recourse to the disclosure to construe the claims is appropriate only in certain situations: *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc.*, 2016 FCA 119, [2017] 2 F.C.R. 280, at para. 39. Accordingly, one might reasonably ask how a feature can be found to be essential when it is absent from the claim.

[53] Generally, the purpose of the disclosure is to describe the art, process, machine, manufacture or composition of matter (the invention) that the inventor has made, and the purpose of the claims is to define what part of the disclosure is inventive. When an inventor drafts and files a patent application, they describe how to make and use their invention, but they do not necessarily know the scope of the invention they have made because they are not necessarily familiar with all of the prior art. It is not uncommon for the focus of the claims to evolve during prosecution of the patent application as prior art is revealed. In addition, a patent application often describes more than one invention. During prosecution, such applications are commonly divided, whereby the original application is limited to claims to only one invention, and a new divisional application is filed containing only claims to another. In both of the foregoing situations, it can be expected that the claims of a patent that issues from the application in

question may omit some elements that might have been considered important to the invention when the application was published (publication being the relevant date for interpreting the patent: *Free World Trust* at paras. 52-54). Clearly, overbreadth should not apply to invalidate claims in these circumstances.

[54] It is apparent that determining that a feature of an invention is essential is a distinct exercise for the purpose of overbreadth than for the purpose of claim construction. For overbreadth, the focus is not whether omitting or changing the feature avoids the claim (as it is for claim construction), but rather whether that feature is so key to the invention described in the disclosure that a claim that omits it encompasses embodiments that were not contemplated in the disclosure. There is little helpful discussion in the jurisprudence as to how a feature should be assessed for essentiality for the purposes of overbreadth. However, uncertainty as to how to apply overbreadth is not a sufficient reason to set aside a principle of patent law that has been widely accepted for many decades: see *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)* (1965), [1966] Ex. C.R. 91 at 106, 50 C.P.R. 220 at 222, aff'd [1966] S.C.R. 604; Harold G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969) at pp. 199-201. I am not prepared to accept that an element that is described in the disclosure of a patent but not claimed could never be considered an essential element that goes to the core of the invention.

[55] I close this section by noting that the Supreme Court itself, in *AstraZeneca* at para. 46, recently indicated that "[a]n overly broad claim may be declared invalid."

(b) *Whether the Federal Court erred in finding the claims in issue invalid for overbreadth*

[56] The basis for the Federal Court's finding of overbreadth was three elements that are described in the disclosure of the 935 Patent, but which do not appear in the claims in issue: (i) the syringe carrier, (ii) the flat reverse syringe (or collapsible bellows, which is described in another embodiment), and (iii) the shared latch locking mechanism (the Omitted Elements). See my description at paragraph 8 above. The Federal Court found that these Omitted Elements were essential to the invention, and that their absence from the claims in issue made them invalid for overbreadth.

[57] The Federal Court cited three reasons for concluding that the Omitted Elements were essential:

A. They are shown in all of the embodiments disclosed in the 935 Patent, and there is no teaching as to how to make the invention without these elements.

B. They interact with one another and are at the core of the mechanism of the device; the device would work differently if they were replaced; and replacing them would be beyond the ability of the skilled person (in other words, replacing them would require inventive ingenuity).

C. They and their arrangement are entirely original.

[58] In my view, and with respect, the first and third reasons cited by the Federal Court would, without more, be inadequate. The first reason effectively limits the scope of valid claims to the embodiments described in the disclosure; claims beyond the described embodiments being overbroad. That is incorrect. The purpose of a patent disclosure is to comply with the requirement of subsection 27(3) of the *Patent Act* to "correctly and fully describe the invention

and its operation or use as contemplated by the inventor." Generally speaking, and in the present case, a patent describes preferred (or exemplary) embodiments, but does not attempt to describe all possible embodiments of the invention.

[59] The third reason provided by the Federal Court to support its conclusion of overbreadth is problematic because it suggests that a patent cannot describe an invention without claiming it – that any original invention must be claimed. This is clearly incorrect, as demonstrated by the well-known practice of filing divisional applications when a patent application describes more than one invention (see discussion at paragraph 53 above). An inventor is well-advised to claim any invention that is described in a patent disclosure, but is not obliged to do so. Likewise, the mere fact that certain elements or their arrangement are original does not mean that they must necessarily be claimed.

[60] The second reason cited by the Federal Court better reflects the principle behind overbreadth – a claim is overbroad if it omits one or more elements that, based on the description, are essential to the art, process, machine, manufacture or composition of matter that the inventor has made. Arguably, the difficulty of replacing the Omitted Elements is relevant to whether they should be considered essential, though it is not clear to me that it is necessary to consider whether an invention so modified would work differently. Differences in how an invention works may be relevant to determining which elements are essential for the purposes of claim construction (*Free World Trust* at para. 55), but determining that an element is essential to an invention such that it goes to the core of the described invention is a different exercise (see paragraph 54 above). The challenge in the present appeal is in determining which elements go to

the core of the invention such that their absence from the claims results in invalidity for overbreadth.

[61] This issue turns on whether the facts support the Federal Court's conclusion, which is a question of mixed fact and law. Therefore, and as discussed above, this Court will not interfere with the Federal Court's conclusion on overbreadth in the absence of a palpable and overriding error.

[62] So, do the Omitted Elements go to the core of the invention described in the 935 Patent? I mentioned at paragraph 7 above that the 935 Patent describes two shortcomings of the prior art: bulkiness and the needle exposure after deployment. The proposed solutions to these shortcomings are good indicators of what the inventor considered to be the core of the invention. The first shortcoming was solved by having a flat housing. That quality of flatness is not really in issue here, though I note that, among the claims of particular interest for overbreadth (claims 40, 59, 60 and 62), flatness is incorporated only in claim 40. It is the second shortcoming that is addressed by the Omitted Elements.

[63] The fact that the Omitted Elements are described in all of the embodiments of the 935 Patent is not enough, without more, to require that they be included in the claims in issue. However, a key pair of additional findings by the Federal Court is that the 935 Patent does not describe how to make the invention without the Omitted Elements (see paragraph 176 of the Reasons), and an uninventive skilled person would not know how to do so (see paragraph 177 of the Reasons).

[64] These findings would seem to lead more readily to a conclusion of insufficiency than overbreadth (insufficiency is discussed in the next section). However, the fact that claims may be invalid for insufficiency does not prevent a finding of overbreadth.

[65] In the end, I am not convinced that the Federal Court made any palpable and overriding error in its application of the law to the facts in relation to overbreadth. Though the Federal Court made errors concerning some aspects of the law applicable to overbreadth, and considered some irrelevant factors, it also considered the correct legal principles. Moreover, I see no misunderstanding of, or failure to consider, the evidence. Accordingly, I would not interfere with the Federal Court's conclusion on overbreadth.

(c) *Insufficiency*

[66] As indicated above, the Federal Court rejected Pfizer's allegations of insufficiency. The Federal Court found that its expert's admission that a skilled person could make the preferred embodiments based on the disclosure was sufficient to meet the requirement for sufficiency. In this respect, the Federal Court erred.

[67] Seedlings argues that, since Pfizer filed no cross-appeal, it is not entitled to challenge the Federal Court's finding that the claims in issue are not invalid for insufficiency. I disagree. Pfizer was entirely successful in the decision under appeal, and therefore it is not seeking any change to the Federal Court's judgment that could be addressed in a cross-appeal. However, there is no impediment in the present appeal to Pfizer arguing that, in addition to the grounds of invalidity

that the Federal Court found to apply, the claims in issue should also have been found invalid on additional grounds.

[68] With regard to the Federal Court's basis for dismissing the insufficiency allegation, it is not enough for the disclosure to teach how to make the preferred embodiment. The disclosure must teach the skilled person to put into practice all embodiments of the invention, and without exercising inventive ingenuity or undue experimentation. In *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 at 520, 56 C.P.R. (2d) 145 at 157, the Supreme Court of Canada stated:

> Section 36(1) [now subsection 27(3)] 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*[, [1947] Ex. C.R. 306 at 316, 12 C.P.R. 99 at 102, rev'd [1950] S.C.R. 36, 12 C.P.R. 99, aff'd 15 C.P.R. 133, 12 Fox Pat. C. 123 (P.C.)]:
>
> > […] when the period of the 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.

[69] This same passage was quoted again by the Supreme Court of Canada in *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625, at para. 50.

[70] It may be helpful to consider the bargain theory of patent law mentioned in paragraph 50 above in the quote from *Western Oilfield*. As described in *Free World Trust* at para. 13, this is the theory that, "[i]n return for disclosure of the invention to the public, the inventor acquires for a limited time the exclusive right to exploit it." If an inventor could validly limit the disclosure of the invention to one or two particular aspects, but claim further aspects thereof that are not

described and which a skilled person would not be able to make, then the inventor would be getting exclusive rights to aspects of the invention that are not taught to the public. This would give the inventor more than the bargain permits, in the sense that, after expiration of the patent, the public would not be able "to make the same successful use of the invention as the inventor could at the time of his application."

[71] In the present case, Seedlings' claims in issue encompass devices that do not include the Omitted Elements. As a result, these claims are broader than the embodiments described in the disclosure. For claims of this scope to be valid, subsection 27(3) requires that the disclosure teach a skilled person how to make such devices. Based on the Federal Court's finding at paragraph 177 of the Reasons that a skilled person would not know how to make a device without the Omitted Elements, it follows that the 935 Patent does not meet this requirement.

[72] In my view, the Federal Court should have concluded that the claims in issue are invalid for insufficiency.

(d) *Conclusion on overbreadth and insufficiency*

[73] For the reasons discussed above, I would affirm the Federal Court's conclusion that the claims in issue are invalid for overbreadth. Regardless of this view, I would also find that the claims in issue are invalid for insufficiency.

D. *Infringement*

[74] Based on my conclusions on invalidity of the claims in issue, it is not necessary to address the question of infringement. An invalid claim cannot be infringed.

E. *Remedies*

[75] My conclusions on invalidity of the claims in issue also make it unnecessary to address the question of remedies. However, I do wish to take this opportunity to make a few comments concerning the Federal Court's discussion of the question of election of an accounting of profits as a remedy for patent infringement.

[76] While a patentee is entitled to damages for patent infringement, it may be granted the right to elect an accounting of the infringer's profits instead. The right to elect is within the discretion of the trial court.

[77] In the present case, the Federal Court concluded that, even if infringement had been found, an accounting of profits would have been inappropriate. One reason cited by the Federal Court for this conclusion was that Seedlings does not practise the invention, and never had any intention to do so. Instead, it intended to license its invention to another entity. At paragraph 252 of the Reasons, the Federal Court cited several decisions over many decades in support of the statement that "if the patentee made its profits by selling licenses, it should not be entitled to compensation beyond a reasonable royalty." In response to the concern that denying it the right to elect would ignore the deterrent purpose of an accounting of profits, the Federal Court noted the absence of jurisprudence in which such an argument overcame the fact that the patentee did not practise the invention.

[78] With regard to the cases cited at paragraph 252 of the Reasons, I note that three of them concern damages, not accounting for profits, and are therefore not helpful in the present context: *Colonial Fastener Co. Ltd. v. Lightning Fastener Co. Ltd.* (1936), [1937] S.C.R. 36, [1937] 1 D.L.R. 21, at 45; *Alliedsignal Inc. v. du Pont Canada Inc*. (1998), 142 F.T.R. 241, 78 C.P.R. (3d) 1 , at paras. 21–22 (F.C.T.D.), aff'd 235 N.R. 185, 86 C.P.R. (3d) 324 (F.C.A.); and *Jay-Lor International Inc. v. Penta Farm Systems Ltd.*, 2007 FC 358, 313 F.T.R. 1 at para. 119. The other cases focus on the fact that the patentee was not practising the invention, and not necessarily on whether it made profits from licensing. In my view, none of the cited decisions provides firm support for the broad principle that a patentee that makes (or intended to make) profits by selling licences to its patent should not be entitled to elect an accounting of profits.

[79] I am particularly concerned about the potential effect of such a broadly defined principle on inventors who recognize that their specialty lies in inventing, and that production and marketing of their inventions are better left to different specialists. Such inventors will seek to license third parties to take their inventions to market as a matter of business efficiency. The broadly defined principle would force such inventors to choose between business efficiency and retaining a potential remedy for infringement of their patent rights. The value of a patent would therefore be reduced for specialist inventors. I see no reason to force such a choice. In my view, business efficiency should be encouraged.

[80] At paragraph 253, the Federal Court stated that "it is difficult to say that Seedlings was entitled to profits that it would never have made in any scenario." The Federal Court went on to express concern that an award of profits would give Seedlings a tremendous windfall. However,

this concern fails to take account of the purpose of an accounting of profits, and seems more relevant to the question of compensatory damages. An accounting of profits is not aimed at compensating the patentee for its losses. Rather, it is aimed at denying the infringer the fruits of its wrongful activities: *Nova Chemicals Corporation v. Dow Chemicals Company*, 2020 FCA 141, 452 D.L.R. (4th) 318, at para. 20. It is intended as a deterrent. Accordingly, concern for overcompensation of the patentee should not be a determinative factor.

[81] Certainly, a patentee's decision to license its invention may be a factor for a court to weigh when considering whether to permit a patentee to elect an accounting of profits. However, I disagree that such a decision should necessarily deny a patentee the right to elect.

V. Conclusion

[82] For the reasons set out above, I would dismiss the present appeal with costs.

"George R. Locke"
J.A.

"I agree.
Mary J.L. Gleason"

"I agree.
J.B. Laskin"

APPENDIX A

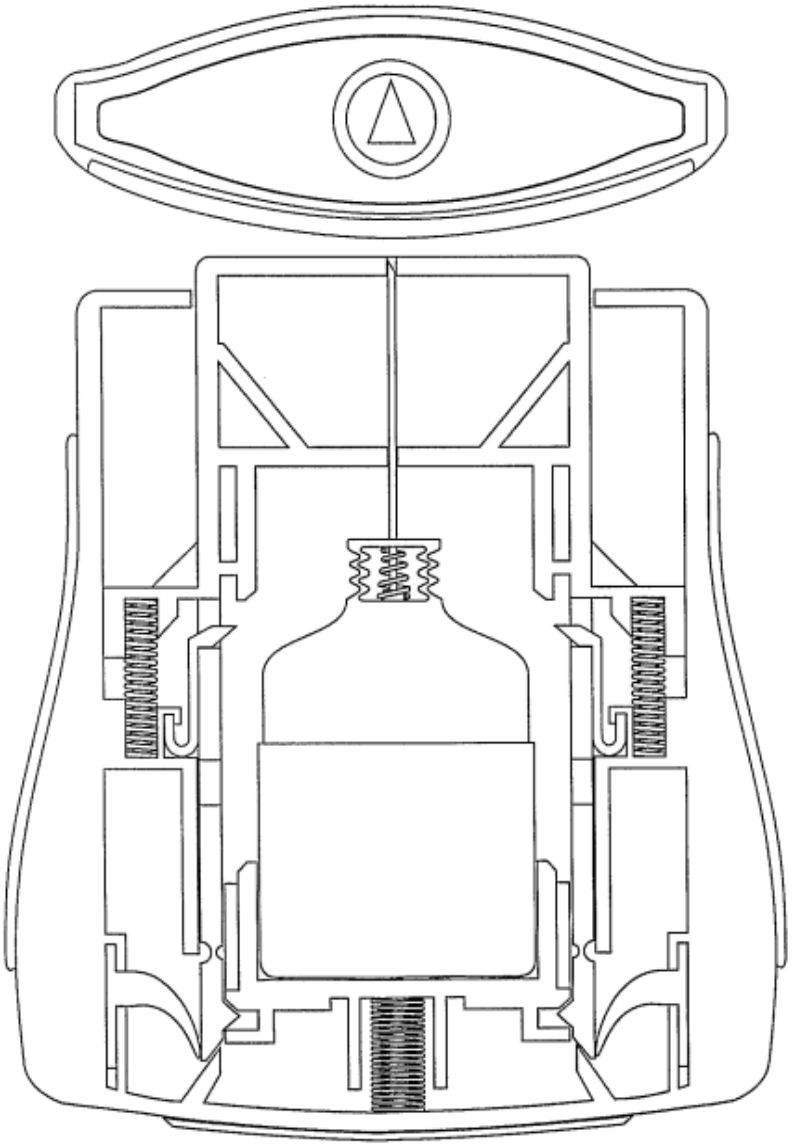

Fig. 17

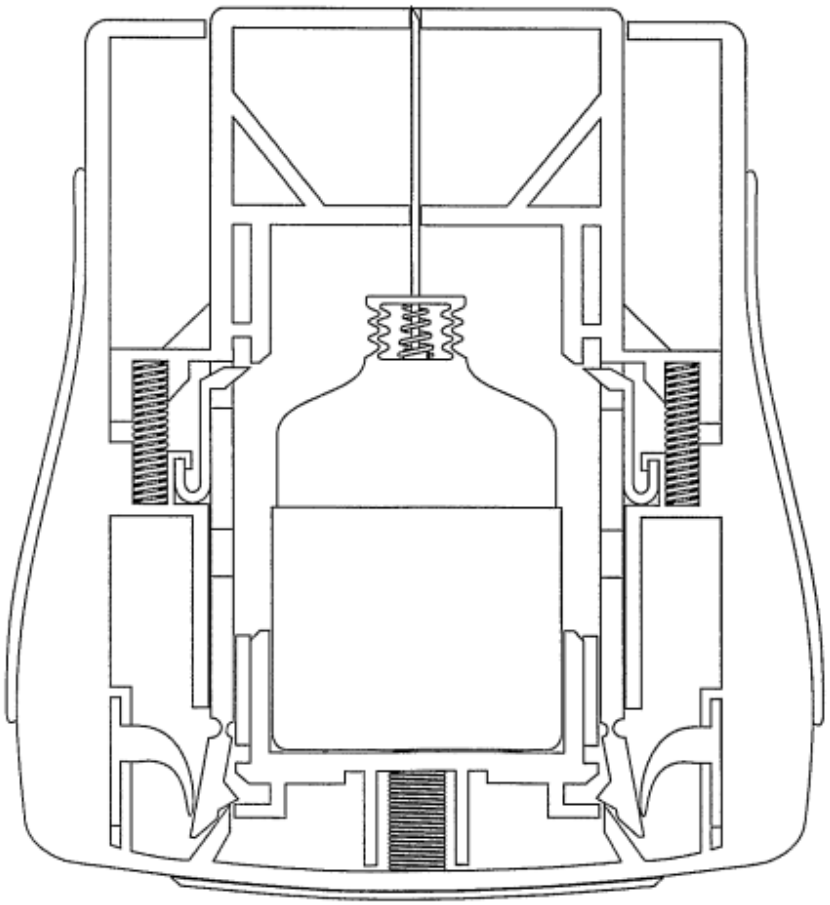

Fig. 18

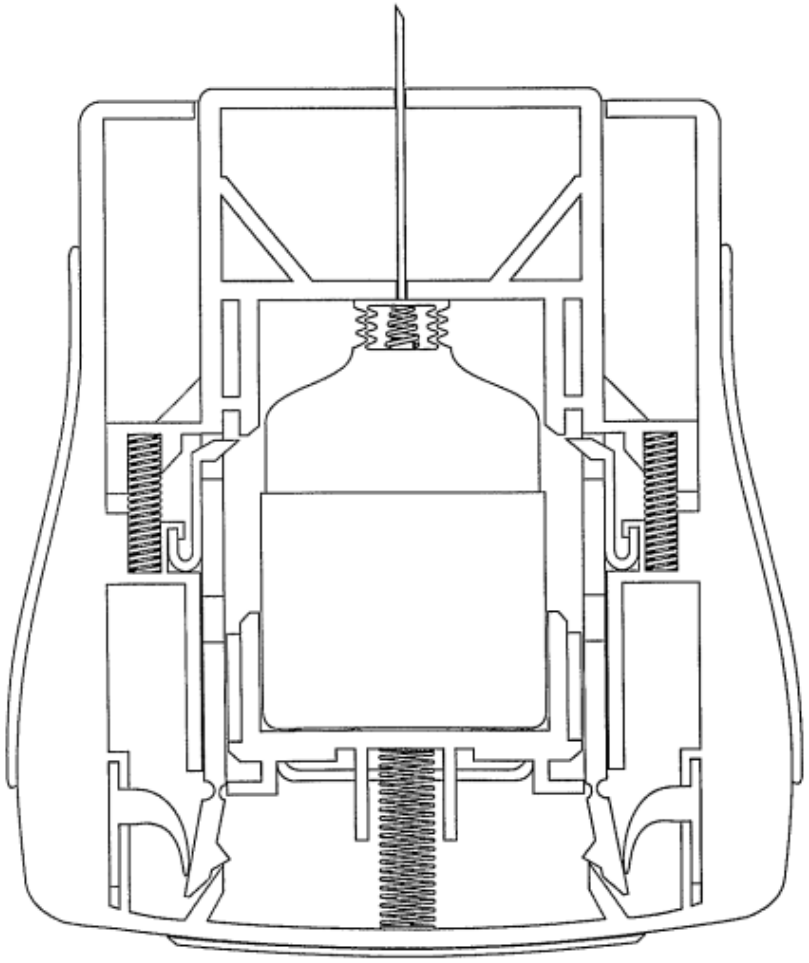

Fig. 19

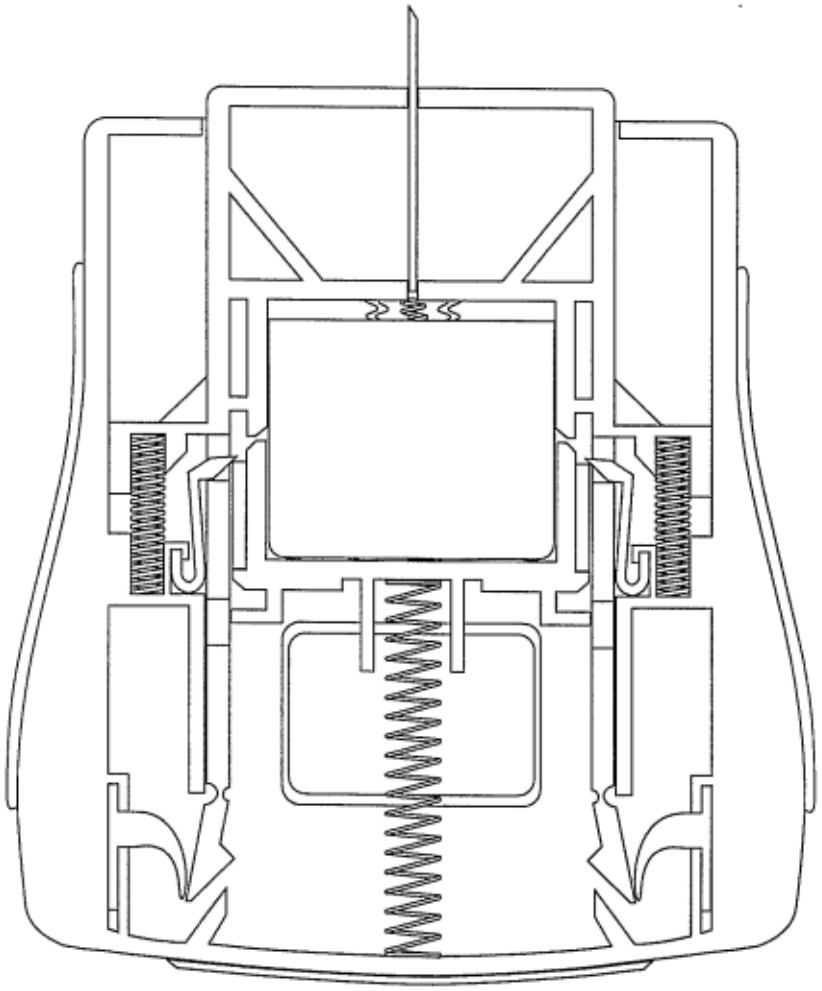

Fig. 21

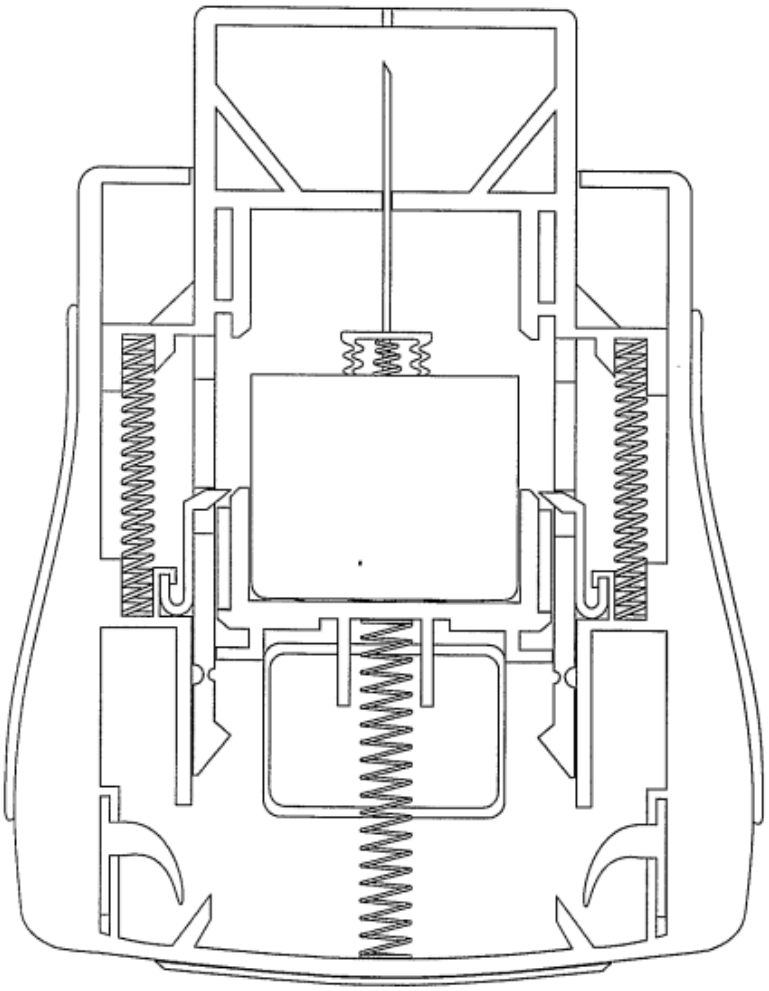

Fig. 22

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-44-20
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DATED:	JULY 28, 2021

APPEARANCES:

Christopher C. Van Barr Michael Crichton William Boyer Benjamin Pearson Charlotte Dong	FOR THE APPELLANT
Peter Wilcox Stephanie Anderson Benjamin Reingold Michael Schwartz	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

GOWLING WLG (CANADA) LLP Ottawa, Ontario	FOR THE APPELLANT
BELMORE NEIDRAUER LLP Toronto, Ontario	FOR THE RESPONDENTS