Federal Court  Cour fédérale

Date: 20200102

Docket: T-608-17

Citation: 2020 FC 1

Ottawa, Ontario, January 2, 2020

PRESENT: Mr. Justice Sébastien Grammond

BETWEEN:

SEEDLINGS LIFE SCIENCE VENTURES, LLC

Plaintiff/
Defendant by counterclaim

and

PFIZER CANADA ULC

Defendant/
Plaintiff by counterclaim

PUBLIC JUDGMENT AND REASONS

(Confidential Judgment and Reasons issued January 2, 2020)

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[1] Seedlings Life Science Ventures, LLC [Seedlings] is in the business of early-stage health-care related research and product development. It alleges that Pfizer Canada ULC [Pfizer], a major pharmaceutical company, infringes its patent by selling in Canada an auto-injector commonly known as the EpiPen. While, at first sight, the EpiPen and Seedlings's invention do not look alike, Seedlings argues that the EpiPen infringes certain claims of its patent and seeks compensation and an accounting of profits.

[2] Pfizer denies that the EpiPen infringes upon Seedlings's patent. Moreover, by way of counterclaim, it seeks a declaration that the claims of Seedlings's patent asserted in this action are invalid. Pfizer argues that those claims are overly broad, obvious and anticipated by prior art. It also argues that Seedlings has never demonstrated the utility of its invention.

[3] I agree with Pfizer that the claims asserted by Seedlings are invalid, because they are all overly broad, some of them are anticipated and one of them is obvious. Moreover, had those claims been valid, I would have found that they are not infringed by the EpiPen.

[4] In so finding, I am not denying the creative value of Seedlings's work. Indeed, I am invalidating only a subset of the claims of Seedlings's patent. Contrary to Seedlings's assertion, however, this is not a case of two inventors making the same invention independently, with Seedlings being the first in time to file its patent application. Rather, Seedlings's auto-injector and the EpiPen are different inventions. The creative use of language in Seedlings's patent cannot obscure this reality.

[5] Part I of this judgment describes the auto-injectors involved in this case. In Part II, I identify the skilled person to whom the patent is directed and I give my interpretation of certain terms of the patent, the meaning of which is in dispute. Part III is devoted to the analysis of Pfizer's challenge to the validity of the patent's relevant claims. I address the issues of anticipation, obviousness, utility, overbreadth and insufficiency. Even though I conclude that the relevant claims are invalid, I assess, in Part IV, whether the current version of the EpiPen infringes Seedlings's patent. While I conclude that it does not, I also give my opinion, in Part V, as to the compensation that Pfizer would have owed to Seedlings if it had infringed valid claims of Seedlings's patent.

I. Background Facts

[6] The legal issues arising in this case cannot be understood without a general discussion of auto-injectors and a summary of the development of the devices that are at the forefront of the case, namely, the two successive versions of the EpiPen and Seedlings's LifeCard.

A. *Auto-Injectors*

[7] Syringes have been used for decades, if not centuries, to inject medication in the human body. Typically, a syringe is composed of a container to which a needle is attached, as well as a plunger that, when inserted and pushed into the container, compresses the medication and forces it through the needle.

[8] The use of a syringe to inject medication requires a certain degree of dexterity and training. Yet, in certain situations, it is desirable that patients be able to use a syringe themselves.

For that reason, auto-injectors have been developed to facilitate the injection of medication in one's own body. Broadly speaking, an auto-injector is a device that automates most, if not all steps of the injection process. Auto-injectors may be used for a variety of purposes. For example, they may allow users to inject insulin or naloxone, an antidote to opioids.

[9] Most relevant to this case is the use of auto-injectors to provide emergency treatment for anaphylaxis. Anaphylaxis is a severe condition that results from an allergic reaction, for example to certain foods or bee stings. If not treated immediately, severe cases of anaphylaxis may result in death. Thus, persons diagnosed with types of allergies that may lead to anaphylaxis are advised to carry at all times an auto-injector containing epinephrine, a medication that relieves the symptoms of anaphylaxis.

[10] The most well-known brand of epinephrine auto-injector is the EpiPen. It was developed in the 1980s by Survival Technology, Inc. [STI]. In the early 2000s, it was manufactured by Meridian Medical Technologies, Inc. [Meridian] in the United States and distributed by King Pharmaceuticals, Inc. [King], Meridian's parent company, in that country. In Canada, beginning in 2006, the EpiPen was distributed by King Pharmaceuticals Canada Inc. [King Canada], a subsidiary of King. This product was manufactured in essentially the same form from the late 1980s until 2009. As it is no longer on the market, the parties have referred to it as the "EpiPen Legacy," and I will adopt that term in these reasons.

[11] The EpiPen Legacy has a generally cylindrical form, measuring approximately 15 centimeters in length and 2.5 centimeters in diameter. After taking it out of its carrying case and

removing a safety pin, the user activates the EpiPen Legacy by pressing its front end against the injection site. A needle then sticks out of the front end and injects the medication. A picture of the EpiPen Legacy is reproduced below.

[12] There were several concerns with the EpiPen Legacy. After operation, the needle remained exposed. This created a safety concern, especially as people became more aware of the risk of transmission of blood-borne diseases, in particular HIV/AIDS and hepatitis C. The EpiPen Legacy was also considered to be somewhat bulky, which discouraged users from carrying it at all times. Moreover, the instructions printed on the cylinder were not easy to read.

B. *Seedlings's LifeCard Project*

[13] Dr. Keith Rubin is the founder and CEO of Seedlings. He is a medical doctor by training. In the 1990s, he was practicing in New York City. A significant portion of his patients were diagnosed with HIV/AIDS or hepatitis C. As a result, Dr. Rubin was acutely aware of the risks associated with the handling of needles.

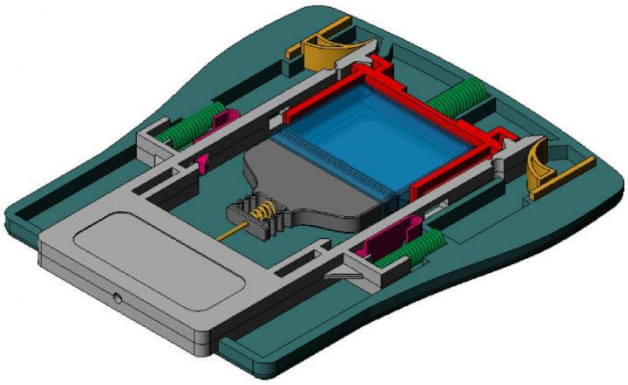
[14] One day, Dr. Rubin had a traumatic experience. As a result of eating nougat that, unbeknownst to him, contained hazelnuts, he had an anaphylactic shock. He had to be transported to the emergency room. The treatment he received saved his life.

[15] Dr. Rubin thus began to carry an EpiPen Legacy. While recognizing that the device could save his life, or that of other persons subject to the same condition, he became conscious of its shortcomings. Given the nature of his medical practice, he was keenly aware of the risks associated with the exposed needle. He also thought that people would be more inclined to carry an auto-injector if it were smaller. Thus, he decided that he could make a contribution to public health by designing a new auto-injector that would overcome those limitations.

[16] Dr. Rubin knew that this endeavour would require teamwork. He enlisted the help of Eclipse Product Development Corp. [Eclipse], a company specializing in the design and testing of medical devices. He explained his idea to Mr. Jim Sellers, Eclipse's CEO, and Mr. Haydn Taylor, its senior designer. He founded Seedlings in February 2002. Soon afterwards, Seedlings and Eclipse signed a product design agreement. A schedule to that agreement contained the ideal specification for the auto-injector, including maximal dimensions, ease of use and needle protection. Under that agreement, any intellectual property deriving from the project would belong to Seedlings. The project became known as the LifeCard.

[17] The development of the LifeCard began in earnest in early 2002. Eclipse proposed a number of potential concepts. It was eventually decided that the needle shield would also serve as the actuator. Thus, the user would not need to press any button to operate the device. Eclipse designed an actuator assembly that included a needle shield that, after triggering the injection of medication, would automatically deploy over the needle and then lock in that position. At that stage, the LifeCard was designed with computer-assisted design [CAD] software that allowed, among other things, simulation of the movement of the components of the device.

[18] The following view of the device with the upper portion of the cover removed gives a general idea of the arrangement of the internal components.



[19] The following video, created by Mr. Taylor in March 2002 using CAD software, illustrates the intended functioning of the LifeCard. It highlights a latch mechanism, located towards the rear end of the device, by which pressure on the needle shield unlocks the power source – a spring – and triggers the injection process. It also shows the double-latch mechanism – also called shield latch – that permits the needle shield to move forward once the injection is complete and then locks it in its extended position. [See Video 1 (2657)]

[20] It will be noted that, in this video, the medication is contained in a collapsible bellows, made of plastic. Seedlings and Eclipse realized that epinephrine could only be kept in a glass container, which, obviously, cannot be collapsible. Thus, Eclipse designed what the parties referred to as a flat "reverse syringe," that is, a syringe in which the needle is attached to the plunger. To operate it, one must press the container against the plunger and needle. The container (or vial) of the syringe is made of glass instead of plastic. The following video shows the intended operation of this version of the LifeCard. [See Video 2 (2684)].

[21] On May 23, 2002, Seedlings filed US patent application no. 10/154,202.

[22] Eclipse then proceeded to make prototypes of the LifeCard. The first prototypes were "look-like" prototypes, intended to show the proposed shape and visual appearance of the device. It then designed "works-like" prototypes, that is, prototypes that would simulate the actual operation of the device. The "works-like" prototype was designed in the fall of 2002 and its components were made over the winter of 2003.

[23] The LifeCard prototype was first successfully fired on April 1, 2003. It was fired again a few days later, but on the third attempt, the glass of the syringe vial broke. There is an issue as to the evidence of the dates of those tests. I will address it when I discuss the utility of the patent.

[24] On May 9, 2003, Seedlings filed a Canadian patent application, claiming priority to the US application filed in May 2002. It was laid open for public inspection on December 4, 2003.

[25] Eclipse continued testing the LifeCard prototype. It was able to successfully inject ink into a chicken breast, as shown on a video that was played at trial. The testing program, however, was not free from difficulties. The mechanism often suffered from "racking," and there were many instances where the glass vial broke when the device was triggered. I will return to the testing program later in these reasons, when I discuss the utility of the patent.

[26] Seedlings then sought to find partners for the commercialization of the LifeCard. Dr. Rubin realized that the commercial success of the LifeCard would depend on a larger

organization that would provide, among other things, the requisite manufacturing, distribution and marketing capacities, which Seedlings did not possess. He thus sought meetings with various pharmaceutical companies. While some of them were impressed with the concept and initially showed interest, ultimately no one pursued the matter. In particular, Dr. Rubin had discussions with Pfizer, Inc. [Pfizer US], which was not involved in making or marketing the EpiPen at that time, and Meridian. Pfizer US was initially interested in testing prototypes of the LifeCard, but its interest dwindled after an internal reorganization. With respect to Meridian, Dr. Rubin testified that he had a single meeting with Mr. Steven Natsch, Meridian's director of operations, in May 2004. On that occasion, he informed Mr. Natsch of the development of the LifeCard and Seedlings's patent application. He described the conversation as "high-level" (October 22, 2019, pp. 31-32). There were no further discussions with Meridian.

[27] Seedlings was granted US patent no. 6,979,316 on December 27, 2005.

[28] In 2007, Seedlings entered into a licence agreement with [redacted]. Pursuant to this agreement, [redacted] was granted a non-exclusive licence to use Seedlings's US and Canadian patents. Subsequently, [redacted] concluded an agreement with [redacted] for the commercialization of epinephrine auto-injectors known as [redacted]. The internal functioning of those devices has not been put in evidence before me. The extent to which they use the technology developed by Seedlings remains unclear.

[29] The processing of Seedlings's Canadian patent application took some time. In 2011 and 2012, there were discussions between the Patent Office and Seedlings's Canadian patent agents, which resulted in certain claims being withdrawn, certain claims being amended and new claims being added. I will return to those interactions when discussing claims construction. On March 18, 2014, Seedlings was granted patent no. 2,486,935, which I will call "the '935 patent" or "Seedlings's patent."

C. *The NGA EpiPen*

[30] In the early 2000s, Meridian decided to enhance its EpiPen. Mr. John Wilmot, who testified at trial, led this project on behalf of Meridian. He explained that Meridian embarked upon that project for a number of reasons. It was aware of the possibility that the regulations concerning sharps protection for products used in hospitals or by medical personnel could one day be extended to consumer products such as auto-injectors. It also wanted to improve usability of the device, in light of the potential entry of competitors on the market.

[31] During the year 2002, various concepts were assessed, including a push-button-activated device and several forms of sharps protection. It is only toward the end of that year that a new way of locking the needle shield after activation was found. The development process continued in 2003 and a substantially final design was achieved in early 2004. Starting in August 2004, Meridian filed patent applications that led to the granting of US patent no. 7,794,394 in September 2010. The device became known as the "Next Generation Auto-Injector" or "NGA." I will use that acronym to describe this new version of the EpiPen, in contrast to the EpiPen Legacy.

[32] Mr. Wilmot testified that, while designing the NGA EpiPen, he was not aware of Seedlings's patent application and did not rely in any way on Seedlings's design (October 29, 2019, pp. 34–35).

[33] The dimensions of the NGA EpiPen are similar to those of the EpiPen Legacy. However, while the Legacy is cylindrical, the NGA has an oval shape. This facilitates its handling and the reading of the instructions label and prevents it from rolling if it is left on a slightly inclined surface. A picture of an NGA EpiPen is reproduced below.

[34] The user of the NGA EpiPen must first remove the device from its carrying case and remove the blue safety pin found on the top of the device. The orange end of the device must then be firmly pressed on the injection site. A needle will then extend outside of the orange part and inject the medication. Once the injection is completed, the device may be pulled from the injection site. The orange cover will then extend and cover the needle, thus ensuring protection from needlestick.

[35] To illustrate the internal functioning of the NGA EpiPen, I have reproduced, in Schedule A to this judgment, diagrams prepared by Meridian in 2004 showing the main steps of the operation of the device.

[36] Meridian began manufacturing the NGA EpiPen in 2009. The first shipments to Canada were in February 2010 and the first Canadian sales were made in the first quarter of 2010.

[37] In 2011, Pfizer US acquired King. Because of the ensuing corporate reorganization, Pfizer Canada Inc., now known as Pfizer Canada ULC, the defendant in this case [Pfizer or Pfizer Canada], continued the business of King Canada, in particular with respect to the distribution of the NGA EpiPen in Canada. Pfizer Canada is a subsidiary of Pfizer US. At the same time, Meridian also became a subsidiary of Pfizer US.

D. *The Present Proceedings*

[38] When Dr. Rubin first became aware of the NGA EpiPen, in late 2009 or early 2010, he quickly formed the opinion that it incorporated two of the important features of the LifeCard, namely, a flatter housing and a needle shield that is the actuator and that locks in place to protect the needle after the device has been used. As he said, "they LifeCarded the EpiPen."

[39] Seedlings then investigated enforcement options. In June 2012, Seedlings wrote a letter to Pfizer US to inform it that the NGA EpiPen was infringing Seedlings's patent. Dr. Rubin testified that he asked Seedlings's attorneys to send the letter to Pfizer US. Although a copy of the letter was filed in evidence, there is no direct evidence that it was sent to Pfizer US and no evidence that Pfizer US received it. Pfizer Canada, the defendant in this action, says that it has no knowledge of what its parent company may have received. In any event, there was no follow-up by either Seedlings or Pfizer US.

[40] Seedlings began this action against Pfizer Canada in April 2017.

II. Preliminary Issues

[41] Before analyzing the issues of invalidity and infringement that are at the heart of this case, it is necessary to address certain preliminary issues: the identity of the "skilled person" to whom the patent is addressed, the definition of the "common general knowledge" possessed by the skilled person, the proper construction (or interpretation) of certain expressions found in the asserted claims of Seedlings's patent and the identification of the essential elements of those claims.

[42] Dealing with those issues at the outset, as is customary in patent infringement cases, affords certain benefits. It ensures consistency in the analysis. For example, one should not construe a claim in one way for the purposes of validity, and in a different way for the purposes of infringement: *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paragraph 49(b), [2000] 2 SCR 1067 [*Whirlpool*]. Identifying the skilled person and common general knowledge at an early stage of the analysis also provides a basis for determining what, in the relevant field of activity, will be considered as inventive. Moreover, addressing issues of claim construction before analyzing validity or infringement prevents claims construction from becoming a "results-oriented" exercise: *Whirlpool*, at paragraph 49(a).

[43] This is not to say that these preliminary issues must be determined in total isolation from the actual issues in dispute. It would be impossible to identify the skilled person without knowing the subject matter of the relevant patent. It would be highly impractical to construe the

claims without knowing what specific terms or phrases give rise to interpretive difficulties. In this case, these difficulties were brought to the forefront because Seedlings "blinded" its experts and asked them to provide their opinion on those preliminary issues with little knowledge of the actual dispute and without telling them which party was retaining them. Whatever the merits of blinding in other respects, I must say that it is not particularly helpful with respect to the skilled person, common general knowledge and claims construction.

[44] More generally, I do not agree that Seedlings's experts' opinions must be preferred because they were blinded. Most of what is called "expert opinion" is in fact argument, and often argument about the interpretation of legal documents. When courts assess arguments, they focus on the validity of the reasoning, not on the credibility of the person who puts the argument forward. Thus, when assessing expert testimony, the logical character of their reasoning is much more important than the fact that some of them were blinded. Moreover, I did not find that experts who were blinded in the early phases of the preparation of their reports were more neutral or more objective in later phases of the preparation of their reports or when testifying at trial. I thus share the skepticism of certain of my colleagues with respect to blinding: *Shire Canada Inc v Apotex Inc*, 2016 FC 382 at paragraphs 42–48; *Janssen Inc v Apotex Inc*, 2019 FC 1355 at paragraphs 57–59.

A. *Defining the Person Skilled in the Art*

[45] It is generally accepted that patents are not meant to be read by ordinary persons, but rather a "person skilled in the art or science to which it pertains" (see sections 27(3)(b) and 28.3

of the *Patent Act*, RSC 1985, c P-4) or, in short, the skilled person: *Burton Parsons Chemicals, Inc v Hewlett-Packard (Canada) Ltd*, [1976] 1 SCR 555 at 563 [*Burton Parsons*].

[46] In this case, the parties agree that the skilled person would be a person holding a degree in biomedical or mechanical engineering. They disagree, however, as to that person's practical experience. Seedlings argues that three years' experience would be sufficient, while Pfizer says that five to ten years would be more appropriate. Moreover, Mr. Sheehan, Pfizer's expert, says that this experience must pertain to medical devices, while Mr. DiGasbarro, one of Seedlings's experts, would consider any kind of mechanical design experience.

[47] I am unsure about the usefulness of setting out a precise number of years of experience in the job description of the fictional skilled person. The real concern is that the skilled person must not be inventive. In this regard, Seedlings points to the fact that several of the expert witnesses in this case filed their first patent applications within a few years of graduating. The best answer to that concern is to keep front of mind the fact that the skilled person must not show inventiveness. In any event, if a precise number of years is needed, I would hold that five years is appropriate, as this is the point where the ranges proposed by both parties' experts meet. I would also hold that this experience must pertain to medical devices, given the highly specialized nature of this field.

B. *Defining Common General Knowledge*

[48] The next preliminary issue is the definition of common general knowledge, which is defined as "knowledge generally known by persons skilled in the relevant art at the relevant

time:" *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at paragraph 37, [2008] 3 SCR 265 [*Sanofi*]; see also *Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée*, 2013 FCA 219 at paragraph 65 [*Eurocopter*]; *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at paragraph 25, [2017] 2 FCR 280. It is what the skilled person would know without doing research. It must be distinguished from publicly accessible knowledge: not all public knowledge is commonly known. In this case, the relevant time is the date Seedlings's patent was laid open for public inspection, which is December 4, 2003.

[49] Seedlings does not dispute the identification of common general knowledge proposed by Mr. Sheehan, Pfizer's expert. Mr. Sheehan said that this would comprise knowledge of existing auto-injectors and their internal mechanisms, knowledge of the various manners in which an auto-injector may be activated, as well as common components of those devices, such as housing, syringes, needles, springs, latches and so forth.

C. *Prior Art*

[50] Auto-injectors are not new and many patents have been granted for such devices. In his report, Mr. Sheehan, Pfizer's expert, traces the history of auto-injectors and describes several patented devices.

[51] Two such patents are the focus of arguments regarding anticipation and obviousness. In both cases, Mr. Wilmot is among the named inventors.

[52] The first one, US patent no. 5,295,965 [the ‘965 patent], was issued in 1994 and describes an auto-injector with a needle shield that deploys automatically after injection. Several embodiments of the device are shown in the drawings. Most of them are push-button-actuated. However, one figure shows how the device can be modified to make it front-actuated.

[53] The second one, US patent no. 6,210,369 [the ‘369 patent], was issued in 2001 and describes an auto-injector that is push-button-actuated and that has a needle shield that deploys automatically after injection.

D. *Claims Construction*

[54] It is now well accepted that patent claims should be interpreted according to the modern method of legal interpretation. According to that method, one should give meaning to legal language based on all relevant clues or guides – what Lord Hoffmann once famously called the “factual matrix” in which words are employed: *Investors Compensation Scheme v West Bromwich Building Society*, [1997] UKHL 28, [1998] 1 All ER 98; see also *Sattva Capital Corp v Creston Moly Corp*, 2014 SCC 53 at paragraphs 46–48, [2014] 2 SCR 633.

[55] The Supreme Court of Canada confirmed the application of that method to patent claims in two judgments issued twenty years ago: *Whirlpool*; *Free World Trust v Électro Santé Inc*, 2000 SCC 66, [2000] 2 SCR 1024 [*Free World Trust*], although it labelled it as the “purposive method.” Thus, a claim may be interpreted based on other information found in the patent, whether in the disclosure or in other claims: *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 at 520 [*Consolboard*]. Expert evidence may assist the interpretive exercise,

although the court is never bound by the experts' opinions: *Whirlpool*, at paragraphs 61–62; *Eurocopter*, at paragraph 74. In this process, the court should strive to understand and give effect to the inventor's intention, rather than subvert it through an overly technical analysis of language.

[56] These broad principles are not different from those applicable to the interpretation of legal documents generally. Patents, however, have special characteristics that need to be taken into account in their interpretation. A patent defines a monopoly granted to an inventor in consideration of the disclosure of the invention to the public. It is often described as a bargain, or *quid pro quo*, between the inventor and the public: *Free World Trust*, at paragraph 13; *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at paragraph 37, [2002] 4 SCR 153 [*Wellcome Foundation*]; *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 at paragraph 39, [2017] 1 SCR 943 [*AstraZeneca*]. Thus, the language of the claims perform a notice function: they warn potential infringers of what they must not do. For that reason, courts have typically been loath to resort to extrinsic evidence in the interpretation of patent claims. A third party could not be presumed to know of such evidence and should be entitled to rely on the language of the claims: *Free World Trust*, at paragraphs 33–43. Moreover, it has often been said that patents must be interpreted in a balanced manner, that gives equal consideration to the interests of the inventors and those of the public or, in other words, that is "fair to both patentee and public:" *Consolboard*, at 520.

[57] The interpretation of patent claims must also take into account the structure that the *Patent Act* imposes on patent applications. Section 27 states that an application must contain a

specification, which includes a full description of the invention, its method of constructing and, in the case of a machine, its principle and its "best mode" in which the principle is applied. 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." Section 37 also requires the inventor to provide drawings, whenever the invention can be represented in this manner.

[58] Thus, even though the invention must be described in the specification and drawings, the scope of the monopoly is defined by the claims. The claims are not limited to the "best mode," often called the "preferred embodiment," described in the specification or illustrated in the drawings: *Bombardier Recreational Products Inc v Arctic Cat, Inc*, 2018 FCA 172 at paragraph 54. Conversely, an interpretation of the claims that would exclude the embodiment shown in the drawings or described in the specification is suspect, as it is unlikely to reflect the inventor's intention: *Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2016 FC 580 at paragraph 335.

[59] When the modern method leaves the court undecided as between two potential interpretations, presumptions of interpretation are often used to settle the issue. Seedlings argues that one such presumption is that patents should be interpreted in a way that ensures their validity. That presumption was colourfully described as a "judicial anxiety to support a really useful invention" in a 19th-century English case quoted in *Consolboard*, at 520. In my view, there cannot be such a presumption. It would go against the principle that patents should not be construed "with an eye on the allegedly infringing device in respect of infringement or with an

eye to the prior art in respect of validity to avoid its effect:" *Whirlpool*, at paragraph 49(a). The Federal Court of Appeal has rejected such a presumption in *ABB Technology AG v Hyundai Heavy Industries Co, Ltd*, 2015 FCA 181 at paragraph 45. Upon closer inspection, the reference to "judicial anxiety" appears to relate to the idea that a patent should not be invalidated on a technicality (see, in this regard, *Burton Parsons*, at 563), not a more general presumption of interpretation in favour of the inventor.

(1) Words and Phrases Needing Construction

[60] The parties have identified six phrases or expressions found in the claims of Seedlings's patent that they do not construe in the same manner. I will review each of them and provide my interpretation.

(a) *"flat housing"*

[61] Claim 40, through its dependence on claim 2, describes a device with a "flat housing." The claims, however, do not define "flat." Defining flatness was the subject of lengthy discussion at trial. Broadly speaking, two options are available. First, one may stipulate a bright-line test based on a mathematical comparison between the dimensions of the device along the three axes. That approach, however, bears an arbitrary dimension, as do all exercises of line-drawing. A second option is to adopt a purposive interpretation. Under that approach, one inquires into what the inventors were trying to accomplish by requiring a flat housing. This, of course, results in a less precise definition, which requires the exercise of judgment when deciding whether the patent has been infringed. Yet, this approach is preferable, as it is better

aligned with *Free World Trust* and the rejection of literalism in claims construction and legal interpretation more generally.

[62] The purpose of the flatness requirement is revealed by certain passages of the specification. Paragraph 3 describes the EpiPen Legacy as "relatively bulky." Paragraphs 5 and 8 describe the patented device as "more compact, low-profile." Paragraph 6 explains that this is intended to "facilitate the ease and convenience of carrying, handling and using the device." In this regard, both allergists who testified at trial, Dr. Greenwald and Dr. Upton, agreed that patients are more likely to carry a compact, flat device at all times on their person (see, in particular, Dr. Greenwald's report, paragraphs 89, 97 and 105; Dr. Upton's report, paragraphs 47–48).

[63] Paragraph 42 of the specification then provides the most relevant indication of what the inventors had in mind when they used the word "flat:"

> 42. The device preferably is dimensioned to be held in one's palm and may have peripheral dimensions approximating those of a conventional credit card. […] The thickness of the device is substantially less than either of the length or width and, in the preferred illustrative example, may be in the order of 0.25 inch thick. The device, so dimensioned, has a generally flat appearance. It is carried easily in ones [*sic*] pocket or purse without feeling bulky or uncomfortable thereby increasing the likelihood of it being carried on one's person and being available, if needed. […]

[64] Similar language is found in paragraph 43:

> The term "flat" when used in this specification to describe the housing of the device is intended to mean a configuration that can be confined in a virtual three dimensional envelope having a length, a width, and a thickness, and in which the thickness is substantially less than each of the length and width, with each of

> the length, width and thickness being measured along orthogonal directions.

[65] Thus, I consider that when the inventors used the adjective "flat," they meant that the object so described has a thickness that is substantially less than its length or width. In addition, when the adjective "flat" in used in conjunction with the noun "housing," the inventors meant that the device itself would be of such dimensions that it can easily be carried in one's pocket.

[66] Of course, the dimensions of the preferred embodiment should not be considered as an outer limit of what is acceptable or "flat." Nevertheless, the specification makes it clear that "flat" means an object that can be easily carried in one's pocket. Moreover, the inventors intended "flat" to refer to an object that would be significantly different in shape from the EpiPen Legacy. Indeed, Mr. DiGasbarro agreed that, from a common-sense perspective, the intent was to make the device smaller than the EpiPen Legacy (October 24, 2019, p. 115).

[67] If the above approach is found to be inadequate and a bright-line test is necessary, I would adopt the test proposed by Mr. Sheehan: the thickness of the device must be substantially less than both its length and width, and substantially less means less than 50%. This, I believe, accords with conceptions of flatness in everyday language. A book is flat, but a brick is not. A requirement that the thickness be less than 50% of the other two dimensions is also compatible with the specifications and drawings. No object described as being flat in the patent has a thickness that is more than half of its other dimensions. Moreover, such a requirement provides a substantial margin of manoeuvre for creating embodiments of the invention. In any event, as we will see later in these reasons, nothing turns on the choice between these two approaches.

(b) *"within the housing"*

[68] Claim 2 states: "both of the syringe body and the needle being disposed and maintained within the housing." Claim 40 incorporates that language from claim 2. Claims 44 and 47 and, through their dependence on claim 48, claims 58, 59, 60 and 62 include similar language.

[69] Pfizer's expert, Mr. Sheehan, asserts that "within the housing" means "entirely within the housing." To Mr. Sheehan, that means that where the device includes a needle shield that partially extends outside of the housing before activation, the needle must not extend outside of the housing, even if it is entirely contained within the needle shield.

[70] I reject that submission. It is obvious from the specification and drawings that, in the embodiments of the invention that include a needle shield, "within the housing" really means "within the housing or needle shield." A purposive interpretation focuses on what the inventors intended to accomplish. In this case, they wanted to ensure that the needle would be invisible before the device is activated. Moreover, as Mr. Sheehan recognized in cross-examination (October 28, 2019, pp 105–113), all the drawings show a needle that extends somewhat outside of the housing, but remains within the needle shield. If his proposed construction were to prevail, this would mean that the embodiments disclosed in the patent are not covered by the patent's claims. This would be absurd. Pfizer's position is simply a literal meaning argument that disregards both purpose and context.

[71] Pfizer nevertheless submits that, as claim 2 does not include a needle shield, "within the housing" must mean "entirely within the housing," at least with respect to claim 40, which

depends on claim 2. I disagree. When a claim is dependent on another claim, the dependent claim must be assessed separately from the independent claim: *Zero Spill Systems (Int'l) Inc v Heide*, 2015 FCA 115 at paragraphs 83–94. Thus, when construing claim 40, the elements of claim 2 that are incorporated must be read together with the elements added by claim 19 (on which claim 40 depends) and claim 40 itself. This includes a needle shield.

(c) *"retracted storage position" / "disposed and maintained rearwardly"*

[72] All the relevant independent claims, namely, claims 2, 44, 47 and 48, describe the syringe container or the needle as having a "retracted, storage position." Mr. Sheehan asserts that this means that, in the storage position, the syringe must be closer to the rear end of the device than to its forward end.

[73] I reject that submission. The more logical interpretation of "retracted" is that it refers to the position of the syringe or needle before the device is activated, in contradistinction to its position after activation. This is borne out by the context in which the phrase is found in the various claims. Claim 2, for example, includes the following language:

> … both of the syringe body and the needle being disposed and maintained within the housing in a retracted, storage position, the syringe being movable longitudinally as a unit within the housing from the retracted storage position to an injection position in which the needle extends longitudinally beyond the forward end of the housing to penetrate tissue;

[74] Here, the "retracted storage position" is contrasted to the injection position. For this device to function, it is obvious that the syringe and needle must move from one position to the

other. Nothing in the above-quoted language suggests, however, that the syringe and needle must be placed in the rear part of the device. This would be an unusual reading of the claim.

[75] Mr. Sheehan also argues that the use of the word "storage" in conjunction with the word "retracted" suggests that "retracted" cannot refer simply to the storage position and must have some additional meaning. I disagree. While it is true that different words are presumed to have different meanings, this is a weak presumption that can be rebutted by other interpretive clues: *Wenzel Downhole Tools Ltd v National-Oilwell Canada Ltd*, 2012 FCA 333 at paragraphs 14–17, 52–54, [2014] 2 FCR 459; *Nova Chemicals Corp v Dow Chemical Co*, 2016 FCA 216 at paragraphs 82–83. In this case, as I have shown above, the immediate context demonstrates that the phrase "retracted, storage position" is simply the opposite of the injection position.

[76] Moreover, in claims 19 and 44, the actuator or needle shield is described as having a "retracted storage position." Yet, it is obvious that this component is located at the front end of the device. Thus, "retracted storage position" cannot mean that the component must be located towards the rear end of the device.

[77] Pursuant to section 53.1 of the *Patent Act*, Pfizer asked me to look at the communications between Seedlings and the Patent Office with respect to the prosecution of the '935 patent. It appears that the examiner initially rejected the application on the basis that it was anticipated by the Farrugia 2001 patent, which describes an auto-injector with a flat shape. Seedlings then amended its claims so that references to the "retracted position" became references to a "retracted storage position." It is difficult, however, to draw any firm conclusions from this

exchange, because of a peculiarity of the Farrugia device. Contrary to most auto-injectors mentioned in this case, that device must be "manually loaded." The spring is compressed by the user, by pressing the device onto the injection site. Thus, although the syringe has a retracted position, it is not the storage position. In this context, the addition of the word "storage" to the phrase "retracted position" was certainly meant to differentiate the Seedlings device from the Farrugia device, but not by insisting on the position of the syringe relative to the housing in the storage position.

[78] Pfizer also relies on a November 11, 2011 letter to the Patent Office, in which Seedlings wrote the following:

> Moreover in the storage configuration for the Farrugia et al. device the syringe is not in a retracted position as claimed but is, instead disposed in a forward position relative to the housing. To the extent that the rejection may have been based on the retracted position of the syringe relative to the housing in Fig. 7 of Farrugia et al., that is not the storage configuration as claimed and is not a configuration in which the device is "maintained" as claimed. Fig. 7 merely shows the device, in the middle of its operation, at the end of the manual compression or "loading" stroke.

[79] In my view, what Seedlings was trying to convey was that the Patent Office may have misunderstood the drawings of the Farrugia patent and confounded the "retracted position" and the "storage position." The reference to a position "relative to the housing" was meant to clarify the distinction between the storage position and the retracted position in the Farrugia device, not to suggest that Seedlings intended to claim a particular position of the syringe relative to the housing. This, indeed, is consistent with the amendments Seedlings made to the relevant claims.

[80] Contrary to the other independent claims, however, claim 48 refers to "the syringe body and needle *being disposed and maintained rearwardly within the housing* in a retracted, storage position" (emphasis mine). In contrast, claim 47 simply states that "the syringe body and needle are disposed and maintained within the housing." The word "rearwardly" is omitted. This suggests that, in claim 48, the inventors intended to claim an additional distinctive element of their invention.

[81] Mr. Sheehan's argument to the effect that the rearward position of the syringe is what makes the device more compact buttresses this interpretation. Mr. Sheehan made this argument with respect to the interpretation of "retracted, storage position." In this respect, an unusual interpretation should not be given to that phrase simply because the manner in which the components are arranged in the drawings is a clever way of making a compact auto-injector. However, Mr. Sheehan's argument is much more convincing with respect to the "rearwardly within the housing" position of the syringe and needle in claim 48.

[82] In this regard, Seedlings argues that if a box is drawn around the needle and syringe of the '935 patent (for example, on figure 17), it is apparent that they are located somewhat closer to the front end of the device than to the rear end. In my view, this must be assessed based on the common general knowledge. At the time of the invention, the most well-known auto-injectors, including the EpiPen Legacy and the '965 and '369 patents, had a syringe the body of which was located in the front half of the device. If a box were drawn around the syringe and needle of those devices, it would be clearly located in the front part. This is in clear contrast to the '935 patent, in which that box covers almost the whole device, even though there is a small gap

between that box and the rear end, which is necessary to house the spring. In my view, the inventors used "rearwardly" to distinguish their invention from existing devices. Under this interpretation, the embodiments of the Seedlings patent show a syringe and needle "disposed and maintained rearwardly within the housing" and would be within the claims.

[83] Thus, I agree with Pfizer that the syringe and needle must be generally closer to the rear of the housing when in the storage position, but only with respect to claim 48 and its dependent claims. With respect to claims 40 and 44–47, I agree with Seedlings that there is no such limitation.

(d) *"movably mounted"*

[84] Claim 40, through its dependency on claims 2 and 19, and claims 44, 47 and 48 use the word "mounted" or synonyms in two contexts. First, the syringe and needle are said to be "movably mounted with respect to the housing" (claim 44) or "disposed and maintained within the housing" (claims 2 and 47 and, with some variation, claim 48). Second, the actuator or needle shield is "movably mounted in the housing" (claim 19), "to and within the housing" (claim 44), "to the housing" (claim 47) or "movably disposed within the housing" (claim 48).

[85] While the adjective "mounted" may, in the abstract, refer to two elements that are assembled in a fixed position or through a rigid connection, the modifier "movably" shows that this is not how the inventors used the term. "Movably mounted" must mean that components are attached together in a manner such that they cannot be easily detached, but that the attachment

allows for movement within certain bounds. In this regard, I see no difference between "mounted" and "disposed and maintained."

[86] The experts nevertheless disagree on one issue. Mr. Sheehan suggests that the word "mounted," or at least the phrase "mounted to," can only refer to elements that are in direct contact. Messrs. Leinsing and DiGasbarro, on their part, see no meaningful difference between expressions such as "mounted to" and "mounted in." On this issue, I agree with Mr. Sheehan. Auto-injectors are complex devices and the precise arrangement of the components is a material aspect of the invention. Thus, the use of an expression such as "mounted to" conveys the inventors' intention that two components be directly in contact with each other, rather than expressing a more indefinite relationship between them.

[87] In this regard, "mounted to," in claims 44 and 47, may be distinguished from a more general expression such as "disposed and maintained within" in claim 2. The latter expression conveys the idea that a component is located within another component and allowed to move within certain bounds. The former, in contrast, denotes a direct attachment.

[88] It is also telling that the more general expression is used to describe the location of the syringe in relation to the housing. In this regard, the specification and drawings clearly show that the syringe is not in direct contact with the housing. Rather, it is attached to the syringe carrier, which is movably attached to the actuator assembly (or needle shield), which is itself movably attached to the housing. The more specific expression, "mounted to," is only used to describe the relationship between the latter two components.

(e) *"actuation assembly"*

[89] Claims 59, 60 and 62 employ the phrase "actuation assembly." The experts appear to be at least in partial agreement as to its meaning. Mr. Sheehan says that "assembly" refers to a set of components that are assembled together so as to act as a single component. As I understand it, under this interpretation, all the parts of the assembly have to move together; they do not move relative to one another. In Mr. Sheehan's view, the concept of an assembly may also refer to a single, complex component, such as the needle shield/actuator depicted in Figure 9 of the patent (see paragraph 119 of his report). Mr. DiGasbarro, in contrast, testified that an assembly is simply an "assembly of component or components involved in the actuation" (October 23, 2019, p. 144). In his report, he says that the actuator assembly depicted in the patent is a single part (Second Preliminary Statement, paragraph 85).

[90] Mr. Leinsing says (Third Preliminary Statement, p. 20):

> The skilled person would understand an "actuation assembly" to mean a mechanism containing two or more parts, which includes the needle shield, and allows control of or interaction with the power source. Such two or more parts work together to release the power source when the needle shield is pressed against an injection site. Parts of an assembly may be either fixedly attached, or non-fixedly attached.

[91] Nevertheless, Seedlings focuses on the first sentence of the above quote, suggesting that the actuation assembly need not be composed of parts that are attached together. I disagree. It is difficult to think of an assembly when the parts are not attached together. Mr. Leinsing says as much in the passage quoted above. Moreover, 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.

[92] Mr. Leinsing also suggested (Report, August 6, 2019, paragraph 50) that the disclosure of the Seedlings patent shows an actuation assembly that comprises the complex component depicted in Figure 9 as well as the detents and parts of the housing that interact with the fingers located at the end of the complex component. That interpretation, however, is belied by claims 20 and 21, which are not asserted. These claims describe the actuation assembly in a way that clearly excludes the parts of the housing that interact with the fingers of the complex component. It is obvious that the inventors did not use the phrase "actuation assembly" to refer to parts of the housing that may be in contact with the actuator.

[93] Thus, in my view, an actuation assembly consists of one complex part or several parts attached together, either fixedly or movably. Conversely, separate parts do not constitute an assembly if they are merely touching without being attached.

(f) *"coupled to the power source"*

[94] Claim 59 describes "an actuation assembly that includes the needle shield and by which the needle shield is coupled to the power source." Claims 60 and 62 depend on claim 59. The parties disagree as to the meaning of the expression "coupled to."

[95] Mr. Sheehan argues that the expression "coupled to" must mean something different from "operatively associated," which is found in claim 58. Thus, in his view, "coupled to" refers to

components that touch each other, while "operatively associated" would include components that are only in indirect contact.

[96] Mr. DiGasbarro, on the other hand, says that "coupled to" may refer to direct or indirect interaction. He underscores the fact that in the embodiments depicted in the '935 patent, there is only an indirect interaction between the actuator assembly (which includes the needle shield) and the power source, as the syringe carrier is between them.

[97] I think the interpretations offered by the two experts can be reconciled in the following manner. Several components can be "coupled" if they are indirectly connected in a manner that will transmit a force or a movement along the chain. Thus, if A is coupled to B and B is coupled to C, then A is coupled to C.

[98] However, components that are "coupled" to one another need to touch. If they do not, they could still be "operatively associated," within the meaning of claim 58, but not "coupled." For example, if I press a button with my finger, my finger may be "operatively associated" with the button, but not "coupled" to the button. That interpretation ascribes different meanings to different expressions, while also ensuring that the invention described does not fall outside of the claims.

(2) Essential Elements

[99] The next step in the analysis is to distinguish essential and non-essential elements: *Free World Trust*, at paragraph 31. In this case, however, both parties agree that all the elements of the claims are essential. As nothing turns on this, I will say nothing further about this issue.

III. Validity

[100] Having laid this groundwork, I can now embark on a review of Pfizer's allegations regarding the validity of the asserted claims of Seedlings's patent.

[101] Section 43(2) of the *Patent Act* creates a presumption of validity of patents. However, courts have frequently stated that this is a weak presumption: *Abbott Laboratories v Canada (Health)*, 2007 FCA 153 at paragraphs 9–10. Thus, where there is any evidence of invalidity, the outcome is determined on a balance of probabilities, not by the presumption in section 43(2): *Diversified Products Corp v Tye-Sil Corp* (1991), 35 CPR (3d) 350 at 357–359. The party alleging invalidity has the burden of proof.

A. *Anticipation*

[102] Anticipation is the first ground of invalidity alleged by Pfizer. According to Mr. Sheehan, Pfizer's expert, claims 40 and 44–47 are anticipated by the '965 patent and claims 48–54, 56 and 57 are anticipated by both the '369 and the '965 patents. Pfizer does not argue that claims 58–60 and 62 are anticipated.

[103] Seedlings's expert, Mr. Leinsing, agrees that claims 48–54 and 56 are anticipated by the '369 patent only. As a result, Seedlings concedes that those claims are anticipated and is no longer asserting those claims. Nevertheless, Pfizer still seeks a declaration that those claims are invalid.

[104] Thus, the only remaining issues with respect to anticipation relate to claims 40, 44–47 and 57.

(1) Legal Principles

[105] In order to be patentable, an invention must be new or novel: a statutory monopoly cannot be justified if an invention is already available to the public: *Wellcome Foundation*, at paragraph 37. If an invention is not new or novel, it is anticipated. The statutory basis for the novelty requirement is set out by section 28.2(1) of the *Patent Act*.

[106] The two-step test for determining whether a patent was anticipated was developed by the Supreme Court in *Sanofi*, at paragraph 67.

[107] First, the Court must determine whether the skilled person would find that an earlier patent or publication discloses the "special advantages" of the patent in dispute: *Sanofi*, at paragraph 32.

[108] If the patent was previously disclosed, the analysis turns to whether the prior art would enable the recreation of the invention. The second step requires the Court to determine whether

the earlier patent or publication would permit the skilled person to perform or make the invention of the patent in dispute without "undue burden": *Sanofi*, at paragraph 33.

[109] Whether "undue burden" exists is considered in light of the nature of the invention and whether trial and experimentation is common in the relevant art. The skilled person may use his or her common general knowledge as of the relevant time to supplement information contained in the prior patent: *Sanofi*, at paragraph 37. However, the Court may not consider a "mosaic" or combination of publications and patents from disparate sources when determining whether a patent was anticipated: *Beloit Canada Ltd v Valmet OY* (1986), 8 CPR (3d) 289 (FCA) at paragraph 29; *Baker Petrolite Corp v Canwell Enviro-Industries Ltd*, 2002 FCA 158 at paragraph 98, [2003] 1 FC 49.

(2) Application

[110] There is no dispute that the '965 and '369 patents were available to the public and can sustain an anticipation argument.

[111] According to Mr. Leinsing, the '369 patent disclosed all the desirable features of Seedlings's patent, except that it is button-actuated. Thus, as claims 48–54 and 56 do not specify the method of actuation of the device, all their elements are already disclosed in the '369 patent. He explains, at page 21 of his report:

> However, claims 48-54 and 56 are, in my opinion, anticipated by the US 369 Patent, as these claims do not include (among other things) the unique feature of the other claims at issue of the 935 Patent, including a pre and post-injection needle shield that is also the actuator. The 369 Patent is push-button operated, and therefore does not disclose this claimed feature.

[112] In contrast, Mr. Leinsing argues that certain elements of claims 40, 44-47 and 57 are distinctive and are not anticipated. Mr. Sheehan, on his part, says that the distinctive element of claims 40 and 44–47 is the fact that they combine front actuation and a needle shield. He argues that this particular feature is anticipated by the ‘965 patent, which shows, in figure 25, a front-actuated device with a needle shield and teaches, in column 10 of the specification, that any push-button injector can be made front-actuated through the addition, over the push-button, of an outer sleeve that the user grabs, pushing the device onto the injection site. In his report, he illustrated this through the addition of a conceptual blue outer sleeve over several of the figures of the ‘965 patent. With respect to claim 57, he argues that its distinctive element is well within what the skilled person could do.

[113] In my view, claims 44–47 and 57 are anticipated, but not claim 40.

[114] Before explaining why, I must address Seedlings’s argument based on Meridian’s patents regarding the NGA EpiPen. When applying for those patents, Meridian was asserting that the NGA EpiPen is inventive over prior art that includes the ‘369 and ‘965 patents. In other words, they are not anticipated by those two patents. Thus, in Seedlings’s view, Pfizer cannot argue that the Seedlings patent is anticipated by the ‘369 and the ‘965 patents, while putting forward a contrary position with respect to the NGA EpiPen. While superficially attractive, this argument is based on faulty logic. It assumes total correspondence between the claims of the NGA EpiPen patents and those of Seedlings’s patent. Yet, Seedlings’s patent contains many claims, only a few of which are asserted in the present proceedings. It may well be that some of the non-asserted

claims are truly new and are not anticipated. But this does not rule out the possibility that certain claims of Seedlings's patent are anticipated. Each claim must be assessed on its own merits.

(a) *Claim 40*

[115] Claim 40, through its dependence on claim 2, refers to a device that has a "flat housing." Given the construction I gave to "flat" above, none of the devices described in the '965 patent can be said to be flat. They are tubular. Thus, claim 40 is not anticipated.

(b) *Claims 44 and 47*

[116] Claims 44 and 47 describe, in different manners, a front-actuated device. More specifically, these claims describe the actuator (or the needle shield) as having three positions. This is particularly evident in the last paragraph of claim 44, which reads:

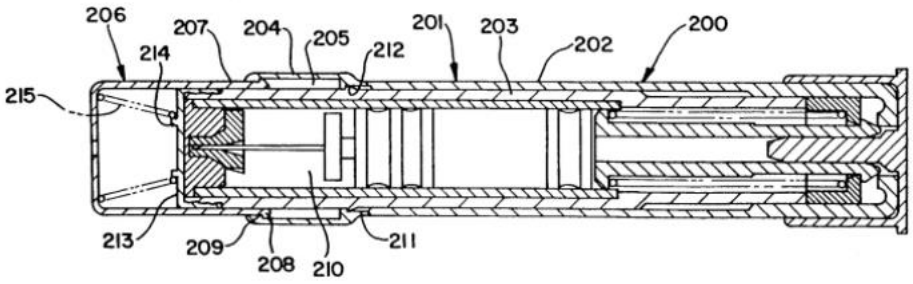
> the needle shield being movable from its retracted storage position to a triggering position located rearwardly of its retracted storage position and to an extended position disposed forwardly of the retracted storage position in which the needle shield covers the sharp forward end of the needle when the needle is in its injection position.

[117] The last three paragraphs of claim 47 use more convoluted language, but in the end, they also describe the three positions of the actuator.

[118] Mr. Leinsing argues that the devices shown in the '965 patent do not have a needle shield or actuator that has those three positions. In my view, this argument is based on an overly formalistic reading of the claims of the Seedlings patent and the specification of the '965 patent.

[119] The devices depicted in the ‘965 patent have a similar combination of positions. For example, figure 25, reproduced below, shows a device that can be actuated by holding it by the housing and pushing it onto the injection site.

FIG. 25



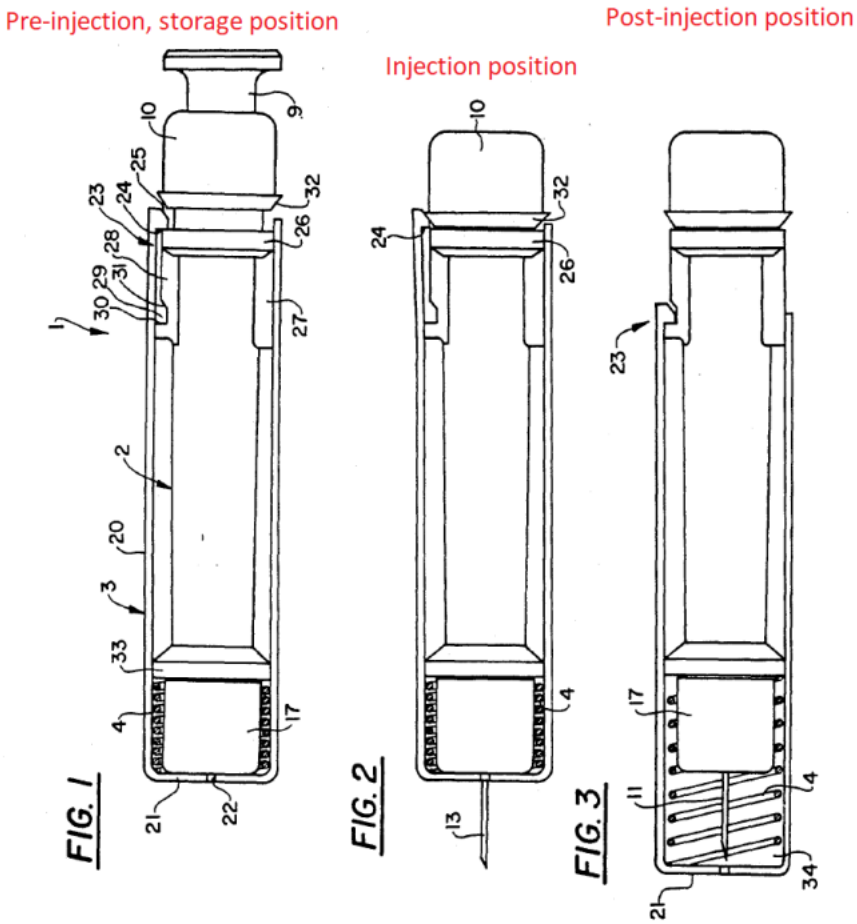
[120] This forward pressure will compress the needle shield spring and move it backwards, relative to the outer housing or to the inner tube that acts as the syringe body. In other words, actuation will move the needle shield from a “retracted storage position” to a “triggering position.” Once injection is complete, the “arrows” of the collet will be fully inserted in what appears to be the power pack. Thus, the outer housing will have room to move towards the power pack and other internal components. As a result, the needle shield will extend further than its pre-injection position, and the needle shield spring will be further decompressed, compared to the situation prior to the injection. Therefore, this device has three positions.

[121] This can also be illustrated with the help of the conceptual blue outer sleeve that Mr. Sheehan added to the other devices depicted in the ‘965 patent. I understand this sleeve to be an illustration of the teachings of column 10 of the ‘965 patent, which, in its relevant part, says:

> Furthermore, the injector of FIG. 24, and indeed any of the automatic injectors, can be made front actuated fool-proof injectors by using the principle of an outer sleeve extending substantially the full length of the injector as exemplified in FIG. 25.

[122] Seedlings argues that this quote simply refers to a specific problem that could arise in the operation of the device illustrated in figure 24 and that was discussed in the preceding lines, hence the reference to making it "fool-proof." I am unable to give such a narrow reading to the above quote. It refers to "any of the automatic injectors" and describes a general principle without limitation. I also note that Mr. Leinsing, in his Fourth Preliminary Statement, at paragraph 16, ascribed a wide scope to the teachings of column 10 and did not attempt to restrict it as he did during his testimony.

[123] A device modified in that manner would also have three positions, as mentioned in claims 44 and 47. A side-by-side comparison of figures 1, 2 and 3, found at page 8 of Mr. Leinsing's Fourth Preliminary Statement, illustrates those three positions. These figures are reproduced below. (One can also refer to pages 18–20 of Schedule 30 to Mr. Sheehan's report.) Figure 1 shows the retracted storage position. Figure 2 shows the triggering position. One can observe that the button, when depressed, is closer to the needle shield, and vice versa. Then, figure 3 shows the extended position, which is obviously different from the storage position.



[124] Had an outer sleeve been attached to the push-button, as suggested by column 10, the three positions would have been even more obviously observable.

[125] Seedlings's experts argue that it would be difficult, in practice, to add an outer sleeve to the devices depicted in the '965 patent and that the device would have to be significantly modified. The '965 patent, however, is presumed to be valid. In any event, I am satisfied that the required modifications would be minor and could be done by a skilled person without undue burden, as they do not involve changes to the internal mechanism.

[126] Mr. Leinsing also asserts that other elements of claims 44 and 47 are not present in the ‘965 patent.

[127] One alleged difference is the fact that the ‘965 patent does not have a conventional syringe that is moved towards the injection position. Rather, the inner body has a liner that allows it to serve as the medication container. Nevertheless, column 13 of the ‘965 patent explicitly states that this could be replaced by a conventional syringe. I agree that the skilled person could do this without undue burden.

[128] Another alleged difference is that some of the devices depicted in the ‘965 patent do not have an actuator or needle shield that is “mounted to and within” (claim 44) or “mounted to” (claim 47) the housing. Nevertheless, at least one of those devices has this characteristic. Mr. Leinsing notes, at paragraph 5c of his Fourth Preliminary Statement, that “[w]ith respect to Figure 25, the needle shield moves within a collar 204. The collar 204 appears to be an extension of the housing 202.” Indeed, this is confirmed by the suggestion in column 10 to the effect that the outer sleeve (e.g., the housing) should extend substantially the full length of the injector. Thus, the “collar” would be an integral part of the housing. For that reason, the needle shield or actuator would be “mounted to and within” the housing, as I have construed this phrase above.

(c) *Claims 45 and 46*

[129] Claims 45 and 46 add elements to claim 44. It is thus necessary to assess whether those additional elements are also anticipated by the ‘965 patent.

[130] With respect to claim 45, the additional element is "means responsive to movement of the needle shield from its retracted position to its triggering position for moving the needle from its retracted position to an injection position." As I found that the devices disclosed in the '965 patent have a triggering position as contemplated in claim 44, it flows logically that they also include "means" for moving the needle to its injection position when the device is triggered.

[131] Claim 46's additional element is "means responsive to movement of the injection needle to its injection position for causing medication to flow to and through the needle." I understand this to refer to a small diaphragm that, in the storage position, insulates the medication from the needle. When the device is triggered, the forward movement of the syringe body causes the needle to puncture the diaphragm, which allows the medication to flow through the needle. This feature is not explicitly disclosed in the '965 patent. Mr. Sheehan nevertheless says that such a mechanism was common in auto-injectors at the relevant time (October 29, 2019, p. 202). It would have formed part of the common general knowledge. Mr. Leinsing does not assert that claim 46 includes any new element. Thus, I find that the skilled person could have added that feature to the '965 patent without undue burden or inventiveness.

(d) *Claim 57*

[132] Claim 57 is dependent on a string of claims beginning with claim 48. As I mentioned above, Mr. Leinsing admits that this string of claims is anticipated by the '369 patent, because they do not specify the method of actuation and could be push-button actuated, like the device in the '369 patent. Nevertheless, Mr. Leinsing argues that claim 57 is not anticipated, because its distinctive element is that "the needle shield extends beyond the forward end of the housing

when the device is in its retracted storage configuration" and the needle shield of the '369 patent is flush with the housing. I agree with Mr. Sheehan, however, that it would be within the common general knowledge of the skilled person to extend the needle beyond the housing without undue burden. Thus, I find that claim 57 is also anticipated.

B. *Obviousness*

[133] Pfizer also argues that all the claims at issue in this case are invalid because they are obvious.

(1) Legal Principles

[134] Obviousness and anticipation are different grounds of invalidity of a patent. When a patent is anticipated, its inventive character is not in question; the issue is that someone else made the same invention before. In contrast, obviousness is a defect that goes to the inventive character. When a patent is obvious, it is simply not an invention. Section 28.3 of the *Patent Act* codifies the requirement that a patent must not be obvious.

[135] While they are conceptually distinct, anticipation and obviousness both invite a comparison between the subject matter of the patent and prior art. Anticipation can only be based on a comparison with a single piece of prior art. A finding of obviousness, in contrast, can be based on several pieces of prior art, provided that the skilled person would have been able, based on common general knowledge, to draw a link between those pieces: *Camso Inc v Soucy International Inc*, 2019 FC 255 at paragraph 125 [*Camso*].

[136] The method for analyzing an allegation of obviousness was set out by the Supreme Court in *Sanofi*, at paragraph 67:

> (1) (a) Identify the notional "person skilled in the art";
>
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[137] The analysis must be performed for each claim taken as a whole. For the purposes of the obviousness inquiry, claims must not be broken into their essential elements: *Procter & Gamble Pharmaceuticals Canada Inc v Canada (Minister of Health)*, 2004 FC 204 at paragraph 95, aff'd 2004 FCA 393, [2005] 2 FCR 269; *Camso*, at paragraph 124.

(2) Application

[138] To the extent that they are not anticipated, I am of the view that claims 40, 59, 60 and 62 are not obvious. Claim 58, however, is obvious.

(a) *Claim 40*

[139] Claim 40, when read together with claims 2 and 19, describes an auto-injector with a flat housing, that is front-actuated and that has an actuator that also serves as a needle shield. That is the "inventive concept" of this claim.

[140] Taken globally, these features were not found in the prior art. The ‘965 patent, as I mentioned above, disclosed a device that was front-actuated and had a needle shield. However, it did not have a flat housing. The flat housing is the difference between Seedlings’s patent and the prior art.

[141] Transforming the front-actuated embodiment of the ‘965 patent into a flat device would have been far from obvious to the skilled person. Making a flat device requires components that are designed and arranged differently than in the more typical cylindrical auto-injectors. This could not be done without deploying significant inventiveness.

(b) *Claim 58*

[142] Claim 58 is dependent on a string of claims, beginning with claim 48, that are anticipated. These claims describe an auto-injector with a needle shield that deploys automatically after injection. The additional element of claim 58 is that the needle shield is also the actuator. Because the other elements are anticipated, I will focus only on the latter element as being the inventive concept.

[143] That inventive concept was found in one embodiment of the ‘965 patent. As described in claim 58, I can see no difference between the inventive concept and what was found in the prior art. Thus, claim 58 is obvious.

(c) *Claims 59, 60 and 62*

[144] Claims 59, 60 and 62 refer to the actuation assembly. I have decided above that this phrase means one complex component or several components that are attached together. In his report, at paragraphs 442, 449 and 459, Mr. Sheehan agrees that if this is the meaning of "actuation assembly," then it is not found in the prior art and those claims are not obvious.

C. *Utility*

[145] It is a basic principle of patent law that an invention cannot be patented unless it is shown to be useful. Pfizer argues that Seedlings's invention is not useful, because it was affected by several design problems and it was not sufficiently reliable when tested. I reject those submissions. To be useful, an invention need not be fool-proof or ready for commercialization. At the date of filing, Seedlings had tested its invention successfully and this, in my view, is enough to show utility.

(1) Legal Principles

[146] In *AstraZeneca*, at paragraph 56, the Supreme Court of Canada explained why a patent is invalid if its utility is not demonstrated:

> The utility requirement serves a clear purpose. To avoid granting patents prematurely, and thereby limiting potentially useful research and development by others, the case law has imposed a requirement that an invention's usefulness be demonstrated or soundly predicted at the time of application, rather than at some later point. This ensures patents are not granted where the use of the invention is speculative. What matters is that an invention "be useful, in the sense that it carries out some useful known objective" and is not merely a "laboratory curiosity whose only possible claim to utility is as a starting material for further

> research" (*Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 (Patent Appeal Board and Commissioner of Patents), at p. 91).

[147] The threshold for utility is low. According to the Supreme Court, "a scintilla of utility will do:" *AstraZeneca*, at paragraph 55. That utility, however, must relate to the patent's subject matter and cannot be for an entirely unrelated purpose: *AstraZeneca*, at paragraph 53. Moreover, in that same case, the Supreme Court rejected the "promise doctrine," whereby a patent would be invalid if it fails to deliver the results that are "promised" in the specification.

[148] Utility can be proved either by demonstration or by "sound prediction," in both cases as of the date of the application. Demonstration is where the device was actually made or built and shown to work. Sound prediction is where, in the absence of actual demonstration, utility is shown by a "sound line of reasoning" based on what was known about the invention as of the date of filing: *Wellcome Foundation*, at paragraph 70.

[149] When utility is based on demonstration, one must keep in mind that the threshold is low. For example, it is not necessary to show that the invention will be a commercial success: *Wellcome Foundation*, at paragraph 54. In the case of medical devices, it is not necessary to show that the device has received or would receive regulatory approval. The fact that a device has not been perfected or may have needed improvements at the relevant date is not a bar to demonstrating utility: *Regents of the University of California v I-MED Pharma Inc*, 2018 FC 164 at paragraph 200 [*I-MED*].

(2) Application

[150] As for all issues of validity, utility should, in principle, be assessed on a claim-by-claim basis. However, I note that both parties have not proceeded in this fashion and have made arguments directed at the utility of Seedlings's patent considered in its totality. I take this to mean that the parties do not see any meaningful distinction between the utility of each claim. For that reason, I am prepared to proceed on the same global basis.

[151] Contrary to Pfizer's position, which places the bar much higher, I am of the view that Seedlings has shown, at the date of its patent application, that its invention had at least a "scintilla of utility." I base my conclusion on two facts: the computerized simulations of the interaction of the components of the device and the successful firing of a prototype. This constitutes actual demonstration. Thus, I need not rely on the doctrine of sound prediction.

[152] Seedlings (through Eclipse) used computer-assisted design [CAD] software to design its auto-injector and to simulate its functioning. According to Mr. DiGasbarro (Second report, paragraphs 83–87), CAD drawings and simulations have become a major tool in the practice of mechanical design. In appropriate circumstances, the use of CAD tools may provide a sufficient basis for the sound prediction of the utility of a mechanical device.

[153] However, when Eclipse designed the invention, the CAD software it used did not allow for the simulation of forces and pressures. As the auto-injector involved relatively high forces and fragile materials, CAD simulations alone constitute only a partial demonstration of utility. They show that the manner in which the components are arranged and interact together is

appropriate. More is needed, however, to show that those components will withstand the forces and pressures to which they will be subjected during real operation. The testing of the prototype provided this additional evidence.

[154] Eclipse successfully tested a prototype of the invention in April 2003, before the filing date. Pfizer replies that the date of the testing has not been validly proved, that the prototype is different from the device shown in the patent, that the device was not sufficiently reliable to prove utility and, more particularly, that its utility to inject epinephrine was not shown. I will address those issues in turn.

[155] The date of the first successful firing of the prototype is critical, because it happened close to the filing of the patent application. The testing happened at Eclipse's premises in New Hampshire. Neither Mr. Sellers nor Mr. Taylor could remember the precise date. At trial, Mr. Sellers testified that even though he could not remember the precise date, he was sure that it was before May 9, 2003. In cross-examination, however, he recognized that, during his examination on discovery, he had said that he was not sure whether the first firing happened before May 9, 2003, and he conceded that he could not be surer now.

[156] Thus, the only evidence of the date of the first firing is a note in Dr. Rubin's daily notebook, which says that Mr. Sellers called to say that the prototype fired. That note is dated April 1, 2003. A further note made a few days later, but before April 9, 2003, refers to a further phone call announcing three other firing attempts. The first two were successful, but the glass of the syringe broke on the third attempt.

[157] Dr. Rubin testified that he made those notes contemporaneously with the events. Thus, even though Dr. Rubin's testimony constitutes hearsay with respect to the truth of what Mr. Sellers told him, his notes prove that Mr. Sellers called him on a particular date. Mr. Sellers testified in person about the subject matter of those phone calls – the successful firing of the device. I rely on Dr. Rubin's notes for the only purpose of dating that subject matter. Thus, I conclude that the successful firing occurred before the filing of the patent application.

[158] It is obvious that the inner mechanism of the prototype was different from the one shown in the drawings of the '935 patent. For example, it has two springs instead of one and the latch mechanism is different. The question, however, is not whether the prototype is identical to the embodiment depicted in the drawings. Rather, it is whether the prototype falls within the claims: *AstraZeneca*, at paragraphs 53–54.

[159] On that issue, Mr. DiGasbarro asserted that the prototype was within the claims (November 6, 2019, p. 88; Second report, paragraphs 115–119). In this regard, Mr. Sheehan's main criticism was not so much that the prototype was not within the claims, but that the prototype "lowered the bar," in the sense that it was designed in such a way that would reduce the risk of failure, in comparison to the device as depicted in the patent. For example, the syringe vial of the prototype has rounded edges and a plastic plug at the back, which makes it more resistant to the high pressures that it needs to withstand upon activation. In doing so, however, Mr. Sheehan is simply comparing two embodiments of the invention claimed in the patent. He does not set out to show that the prototype was outside the scope of the patent. Thus, on a

balance of probabilities, I conclude that the prototype was within the claims and that its successful testing, if proven, demonstrates the utility of the patent.

[160] This brings me to the assessment of the testing done before the filing of the patent application. The scope of that testing was limited. It consisted of four firings of the prototype. In the first one, which took place on April 1, no needle was installed and no liquid was present in the syringe vial. This firing showed that the internal components interacted with one another in the manner that was expected. A few days later, three additional tests were conducted. This time, a needle was installed and the syringe vial was filled with water. The device was fired into a Styrofoam surface. On the first two tests, the device successfully injected water in the Styrofoam. On the third attempt, the glass vial of the syringe broke. In my view, these tests demonstrated that the device claimed in Seedlings's patent can be used to inject medication. It satisfies the relatively low bar of a "scintilla of utility."

[161] Mr. Sheehan heavily insisted on testing performed after the filing date, which he considers a failure. Eclipse tested the prototype with springs of different strengths and a syringe vial with thicker walls. It also taped that vial to improve its resistance to shocks. In all tests conducted with 8-pound springs, the glass vial broke. A phenomenon called "racking" often occurred, but the witnesses disagreed as to its significance. The parties take different views of the success rate of those tests: Pfizer says that the device worked one third of the time and Seedlings asserts that the success rate was 92%.

[162] As this Court mentioned in *I-MED*, a "scintilla of utility" is demonstrated by a prototype that works imperfectly and that needs improvement. No one would require a 100% rate of success during a first testing campaign. In my view, the occurrence of glass breakage in those tests, especially when an 8-pound spring was used, does not negate the device's utility.

[163] Pfizer also argues that the prototype could not be used to inject epinephrine in an emergency situation, because a very high degree of reliability is required and a stronger spring is needed. This argument, however, is based on the "promise doctrine" abolished by the Supreme Court in *AstraZeneca*. The asserted claims are not limited to the injection of epinephrine. They may relate to other kinds of medication, for which a weaker spring may be appropriate. Although the specification describes the problems related to epinephrine auto-injectors, this does not create a promise that the inventors are required to fulfil. The invention may well have a lower economic value if it is not able to inject epinephrine, but this has no bearing on the legal requirement of utility. The use of the invention to inject medication other than epinephrine is not tantamount to using it "as a paperweight," as the Supreme Court metaphorically said in *AstraZeneca*, at paragraph 53.

D. *Overbreadth*

[164] Pfizer also argues that the asserted claims are invalid for being overly broad. In other words, Pfizer contends that Seedlings is trying to assert a monopoly that is wider that what it actually invented or disclosed. Thus, in Pfizer's view, the claims asserted by Seedlings fail to capture essential features of the invention.

[165] To assess this argument, it is necessary to study the doctrine of overbreadth in some detail. The idea that inventors may not claim more than what they actually invented or disclosed has a respectable pedigree. Yet, the status of overbreadth as an autonomous ground for invalidating a patent has recently been questioned. I will attempt to show that overbreadth still plays a useful role in certain specific categories of cases. Then, having laid this groundwork, I will explain why I find that all the impugned claims are overly broad.

(1) A Theory of Overbreadth

[166] Twelve years ago, the Federal Court of Appeal stated that "[i]t is now settled law that a patent which claims more than what was invented or disclosed can be found invalid for being overly broad:" *Pfizer Canada Inc v Canada (Health)*, 2007 FCA 209 at paragraph 115. This Court has recently applied this doctrine and struck claims that were overly broad: *Aux Sable Liquid Products LP v JL Energy Transportation Inc*, 2019 FC 581 at paragraphs 56–74 [*Aux Sable*]; *Les Laboratoires Servier v Apotex Inc*, 2019 FC 616 at paragraphs 205–242.

[167] Indeed, the doctrine of overbreadth is a necessary consequence of the bargain theory of patent law, adopted in cases such as *Free World Trust*, at paragraph 13; *Wellcome Foundation*, at paragraph 37; *AstraZeneca*, at paragraph 39. According to that theory, a patent is a monopoly granted for a limited time over an invention, in return for a public description of that invention. It stands to reason that the scope of the monopoly must be commensurate with the invention. If it were otherwise, inventors would obtain something of more value than what they deserve.

[168] Despite its longstanding recognition, the doctrine of overbreadth has recently come under attack. Professor Norman Siebrasse has suggested that it has no statutory basis, that it duplicates recognized grounds of invalidity and that it risks becoming a new version of the promise doctrine rejected by the Supreme Court in *AstraZeneca*: "Overbreadth in Canadian Patent Law," online: https://ssrn.com/abstract=3393044 (updated July 19, 2019).

[169] It is not accurate to say that the doctrine of overbreadth lacks statutory footing. It stems, by implication, from the scheme of the *Patent Act*, and in particular section 27(4), which requires "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." If the subject-matter of the invention must be defined, it must be defined accurately and not in an overly broad manner. Thus, the doctrine of overbreadth flows by necessary implication from the provisions of the *Patent Act*, very much like anticipation and obviousness before they were codified in sections 28.2 and 28.3 of the *Patent Act* in 1993. Recognizing overbreadth as a ground of invalidity is not tantamount to adding a new substantive condition of validity of patents. Overbreadth is an issue that arises in the process by which the invention is made public and the monopoly is asserted.

[170] It is true that overbreadth often overlaps with other grounds of invalidity. For example, if certain claims of a patent are anticipated, one can also say that they are broader than the legitimate invention described in other claims. This is what apparently happened in *BVD Co v Canadian Celanese Ltd,* [1937] SCR 221, varied [1939] 2 DLR 289 (PC) [*BVD*]. This may explain why overbreadth is seldom a decisive issue.

[171] Nevertheless, overbreadth sometimes has an independent role to play. Inventors who have a new, non-obvious and useful invention cannot, through the creative use of language, claim something that they have not invented. Justice Ian Binnie of the Supreme Court of Canada colourfully illustrated this principle in *Free World Trust*, at paragraph 32: "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." Although Justice Binnie made this remark in the context of a discussion of the principles of claims construction, the principle also justifies the doctrine of overbreadth. In his paper quoted above, Professor Siebrasse refers to this situation as the "roads to Brighton" problem, that a 19th-century English judge described as follows: "it would [not] be reasonable to say that if one man has a road to go to Brighton by Croydon another man shall not have a road to go to Brighton by Dorking" (*Curtis v Platt*, (1863) 3 ChD 135). In a nutshell, a patent must describe a particular method of achieving a goal; it cannot claim the goal itself. (See also *Wellcome Foundation*, at paragraphs 82–83.)

[172] *Free World Trust* also provides insights regarding the relationship between overbreadth and claims construction. Before assessing whether a claim is overly broad, the court must construe it. In other areas of the law, the tendency would be to give a narrow construction to a legal document, in order to avoid invalidity that would result from a wider construction. This process is known as "reading down:" see, for example, *R v Appulonappa*, 2015 SCC 59, [2015] 3 SCR 754. However, in patent law, reading down seems to be precluded by the directive to the effect that the court should not construe a patent with an eye on invalidity issues: *Whirlpool*, at paragraph 49(a). Moreover, inventors frequently make a long string of alternative claims, typically starting with the broadest and ending with more specific ones, in the expectation that

the narrower ones have a greater chance of surviving challenges to their validity. Given that longstanding tradition, it is not appropriate for the courts to rescue overly broad claims by reading them down.

[173] The case law does not delineate a specific method for the assessment of overbreadth. Usually, a finding of overbreadth flows from the fact that an essential element of the invention is missing from the claims: *BVD*, at 235; *Radio Corp of America v Raytheon Manufacturing Co* (1957), [1956-60] ExCR 98 at 117; *Amfac Foods Inc v Irving Pulp & Paper Ltd* (1986), 12 CPR (3d) 193 at 204–205 (FCA); *Aux Sable*, at paragraph 58. Determining that an essential element is missing from the claims is a delicate endeavour. Essential elements are usually identified on the basis of the presumed intent of the inventors: *Free World Trust*, at paragraphs 58–60. Nevertheless, there is also an objective component to the analysis, in particular whether an element can be substituted without changing the manner in which the invention works: *Free World Trust*, at paragraphs 55–57. The overbreadth analysis will necessarily focus on those objective elements. The Court must do so, however, in a manner that seeks to avoid resuscitating the promise doctrine. In other words, the search for the missing essential element must not morph into an inquiry into the achievement of the invention's objectives.

(2) Application

[174] I agree with Pfizer's submission that there are at least three essential elements of the invention that are not mentioned in the claims asserted by Seedlings: a syringe carrier, a flat reverse syringe or collapsible bellows and a shared latch locking mechanism. This renders all the asserted claims overbroad, and thus invalid.

[175] There are three main reasons for which, in my view, these elements are essential.

[176] First, they are shown in all the embodiments disclosed in the patent. The patent does not teach how to make the invention without these elements. Moreover, Mr. Taylor testified that all but the most preliminary designs incorporated these three elements (October 22, 2019, pp. 171–181, 208–210).

[177] Second, these elements interact with one another and are at the core of the mechanism of the device. In particular, the syringe carrier allows for a smoother distribution of forces on the syringe body, while also unlocking the needle shield after injection. The shared latch locking mechanism allows for the safe positioning of the needle shield both before and after injection. Thus, the device would work differently if they were replaced by other components: *Free World Trust*, at paragraphs 55–57. Replacing those components is not something that the skilled person could do without having recourse to inventiveness.

[178] Third, these components and their arrangement are entirely original. Nothing like this is disclosed in the prior art. Flat syringes are extremely rare. The syringe carrier is an original component that replaces the collet that is typically found in previous auto-injectors. The shared latch locking mechanism is not found in any of the devices that were the focus of discussion at trial or in the expert reports.

[179] To answer the allegation of overbreadth, Mr. DiGasbarro asserted that the drawings, the prototype and the specification are within the claims (Second Statement, paragraphs 160–190).

But, with great respect, this is entirely beside the point. The issue is whether the claims are broader than the invention. The fact that the invention is within the claims does not determine the issue. In reality, one cannot answer an allegation of overbreadth by simply stating that the scope of the invention is defined by the claims. That would be circular.

[180] Likewise, Seedlings's argument that the claims are not limited to the preferred embodiments disclosed in the specification can only carry us so far. The claims may not be limited to the embodiments, but there must be some outer limits. Those outer limits flow from the fact that the skilled person must not deploy inventiveness. Given that a patent is addressed to a skilled person, that person is expected to make minor changes and adjustments to the design disclosed in the specification. The skilled person, however, cannot show inventiveness in doing so. In my view, based on the understanding of the design of auto-injectors that I gained through the trial, making a device that would omit one of the three elements that I identified above would require a substantial redesign. It would constitute a new invention. Thus, Seedlings cannot claim, based on the idea that the embodiments do not exhaust the invention, auto-injectors that do not have the three essential features that I have identified.

[181] Seedlings also suggests that an element cannot be deemed essential for the purposes of overbreadth where it was not found to be so at the claims construction stage. That argument, however, is illogical. Overbreadth arises precisely because a claim fails to include an essential element. By definition, if it is lacking, it could not be construed. Indeed, as I mentioned above, the role of claims construction is not to salvage an overly broad claim by implying limitations or additional essential elements. Thus, one should not be surprised that Mr. Sheehan did not find, at

the claims construction stage, that a syringe carrier, a reverse syringe or a shared latch locking mechanism were essential elements. They were simply not mentioned in the asserted claims.

[182] Seedlings also argued that Pfizer's arguments amount to an attempt to revive the promise doctrine. It criticizes Mr. Sheehan's evidence for insisting on the features that make the device compact, thus focusing on the objective of the invention instead of the invention itself. I do not find it necessary, however, to rely on those parts of Mr. Sheehan's opinion. In my view, it is enough to show that the three elements that I have described above are essential, in the sense that they are an integral part of the invention and that the invention would work differently without them.

[183] Moreover, while this is not dispositive, I note that these three elements are mentioned in other claims that are not asserted in this action. Claims 11 and 13–17 describe a flat reverse syringe. Claim 22 mentions the syringe carrier. Claims 23 and 25 describe the shared latch locking mechanism.

[184] Hence, I find that all the asserted claims are void for overbreadth, because they all fail to include a syringe carrier, a flat reverse syringe or collapsible bellows and a shared latch locking mechanism, which are essential elements of the invention. In doing so, I have not found it necessary to assess whether the flat shape of the device is one of its essential features. It may be that the flatness of the device is better described as a desirable quality, so that its use to find overbreadth would come closer to invoking the promise doctrine. I need not delve further into this issue, as I am able to base my decision on narrower grounds.

E. *Insufficient Disclosure*

[185] Section 27(3) of the *Patent Act* states that the specification must contain a description of the invention to a degree of detail that enables the skilled person to make it. Pfizer argues that Seedlings's patent does not meet this requirement. Pfizer's arguments in support of that ground of invalidity, however, constitute a restatement of its arguments related to utility or overbreadth. Thus, Pfizer says that the specification only enables the skilled person to make the embodiment described in the specification and not other embodiments covered by the claims, which is essentially an overbreadth argument. It then says that the embodiment described in the specification does not work, which is tantamount to claiming lack of utility.

[186] In cross-examination, however, Mr. Sheehan admitted that a skilled person could make the preferred embodiments based on the disclosure (October 30, 2019, pp. 30–31). This is sufficient to meet the requirement of section 27(3). Hence, Seedlings's patent is not invalid because of insufficient disclosure.

IV. Infringement

[187] As I have concluded that all the asserted claims are invalid, it is not strictly necessary to determine whether they are infringed by the NGA EpiPen. Nevertheless, as the issue was fully argued, I think it is useful to give my opinion on infringement.

A. *Legal Principles*

[188] In *Free World Trust*, the Supreme Court of Canada explained the method for determining if a patent has been infringed. The essential elements of the claims of the patent must first be

identified. Then, the allegedly infringing device must be compared with the claims of the patent, not with the device made by the inventors: *Free World Trust*, at paragraph 70. If all the essential elements of the claim are found in the accused device, there is infringement. In contrast, if an essential element is missing, there is no infringement.

B. *Analysis*

[189] Seedlings argues that the NGA EpiPen infringes claims 40, 44–47, 58 and 60–62 of its patent. Given Mr. Leinsing's opinion regarding anticipation, Seedlings no longer argues that the NGA EpiPen infringes claims 48–54 and 56. It also no longer asserts claim 57.

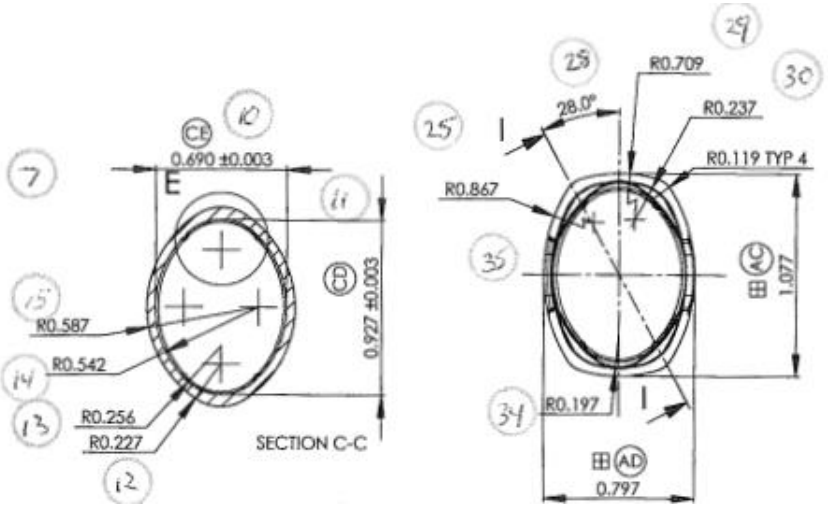
[190] The parties agree that the only essential elements that are relevant to the inquiry are those that were discussed at the claims construction stage. Thus, I need not consider whether other elements are missing.

(1) Claim 40

[191] Claim 40 is not infringed for the very simple reason that the NGA EpiPen is not flat.

[192] Seedlings took great pains to argue that the NGA EpiPen is flat. It noted that it has an oval shape that is flatter than a pure cylinder like the EpiPen Legacy. It also underscored the advantages of that oval shape – instructions are easier to read, the device does not start to roll by itself when placed on a slightly inclined surface and users find it easier to grip.

[193] Nevertheless, I have construed "flat" as meaning an object the thickness of which is substantially less than either of its length or width. The following cross-sections of the outer tube of the NGA EpiPen illustrate its shape. The figure on the left depicts the middle of the tube and the figure on the right shows a cross-section of the rear end.



[194] The NGA EpiPen is about 2 cm in thickness, 2.6 cm in width and 14 cm in length. Thus, its thickness is about 75% of its width. This is not substantially less. Even though small differences may be substantial with respect to small devices, this would not be true when the difference is expressed as a percentage.

[195] If it were necessary to resort to a bright-line test, I stated that a flat device's thickness would need to be less than 50% of its length or width. Here, the ratio of 75% is far from meeting that test.

[196] Moreover, I note that Mr. Leinsing himself, while he was "blinded" and did not know that the NGA EpiPen was the allegedly infringing device, stated that "a housing that was

round/tubular, or close to round/tubular, would not be understood to be "flat"" (Third Preliminary Statement, p. 3). In my view, the housing of the NGA EpiPen is "close to tubular."

(2) Claims 44–46

[197] One of the essential elements of claim 44 is that the needle shield is mounted to and within the housing. As I mentioned earlier, "mounted" means that components are attached together in a manner such that they cannot be easily detached, but that the attachment allows for movement within certain bounds. In addition, "mounted to," in contrast to broader expressions such as "mounted in" or "mounted within," means that the two components so mounted must be directly touching.

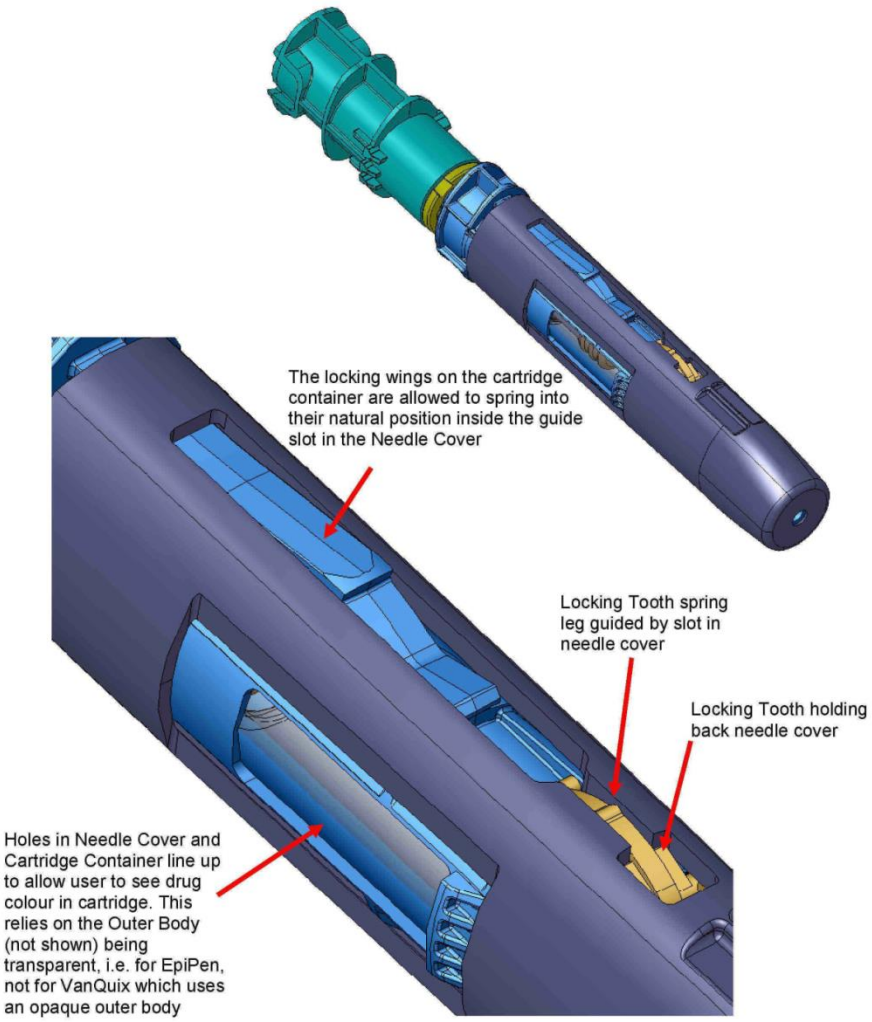
[198] The experts on infringement, Mr. DiGasbarro for Seedlings and Mr. Sheehan for Pfizer, devote little attention to the issue of whether the NGA EpiPen's needle shield is "mounted to" the housing. At paragraph 41 of his Third Preliminary Statement, Mr. DiGasbarro simply refers to his analysis with respect to claim 40, which does not require the needle shield (described as the actuator) to be "mounted to" the housing, but only "mounted in" the housing. This analysis simply describes the movement of the needle shield inside the NGA EpiPen. Mr. DiGasbarro repeated this analysis at trial (October 23, 2019, pp. 160–162).

[199] At paragraph 54 of his infringement report, which deals with claim 44, Mr. Sheehan asserts that the NGA EpiPen's needle cover is not "mounted to" the housing or outer body, because it is not "directly fixed" to it. The demonstration that follows, however, is focused on the

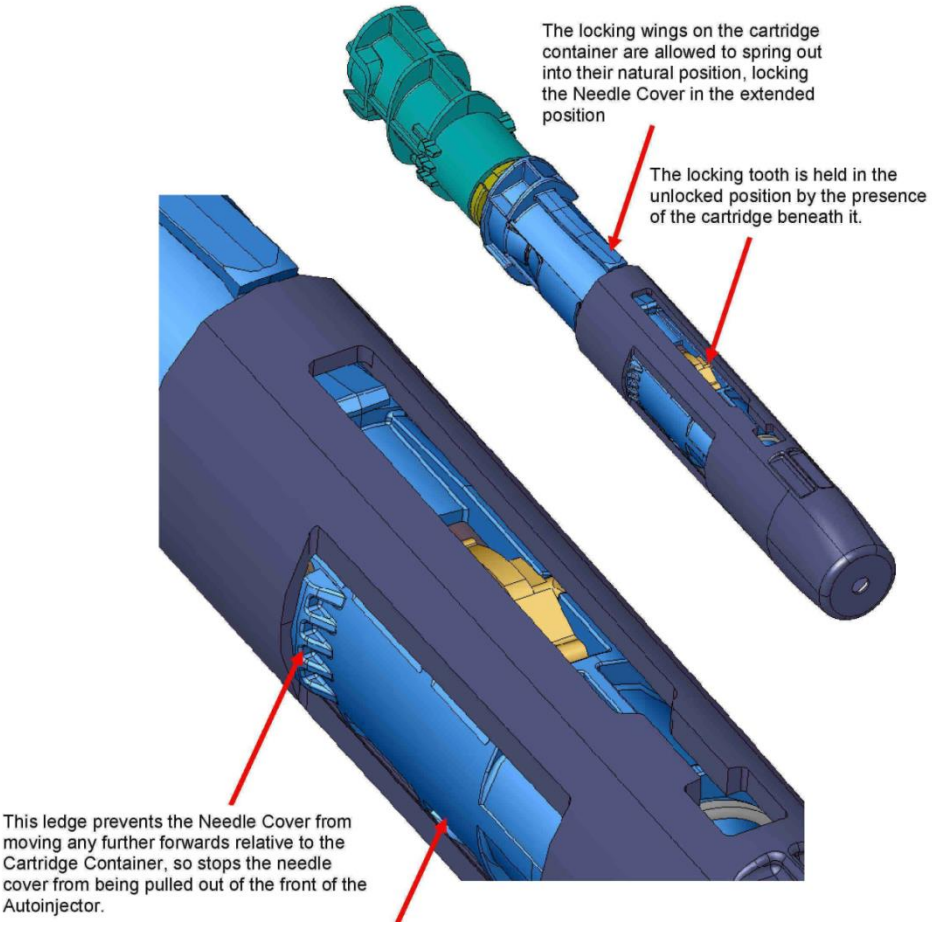
gaps between the needle cover, the cartridge container and the “power pak inner,” which is an unrelated issue.

[200] A review of the three-dimensional illustrations of the inner parts of the NGA EpiPen, however, clearly shows that the needle shield, or needle cover, is mounted to the cartridge container and not to the outer body or housing. Those illustrations form part of a document produced by Meridian for patenting purposes. They are the basis of Mr. DiGasbarro’s infringement opinion.

[201] The first illustration shows the needle cover in a retracted, pre-injection position. The needle cover is shown in darker blue and the cartridge container, in lighter blue. One can easily see that the needle cover slides over the cartridge container. The protruding parts of the cartridge container constrain the longitudinal movement of the needle cover. Thus, the needle cover cannot be easily removed from the cartridge container – it is attached, or “mounted” to it.



[202] Another illustration shows the needle cover in an extended, post-injection position. Again, one can see that the protruding parts of the cartridge container, in particular the "ledge" that is emphasized in this illustration, constrain the movement of the needle cover and keep it firmly attached to the cartridge container.



[203] Thus, the NGA EpiPen's needle cover is "mounted to" the cartridge container, not the housing. As such, it does not infringe claim 44 of Seedlings's patent.

[204] The same analysis applies to claims 45 and 46, which are dependent on claim 44. The additional elements found in those two claims are not in dispute.

(3) Claim 47

[205] One of the essential elements of claim 47 is an "actuator mounted to the housing." The parties do not agree as to whether the NGA EpiPen's needle cover can be considered as the device's actuator. During his testimony, Mr. Wilmot demonstrated that an NGA EpiPen could

operate without the needle cover, which would show that the needle cover is not the actuator. Seedlings objected to this demonstration, arguing that it did not comply with this Court's notice to the profession regarding experimental testing. I need not resolve the issue, either in its procedural or substantive dimension. Even if the NGA EpiPen's needle cover is considered to be the actuator, claim 47 is not infringed, because, as I have shown with respect to claim 44, the needle cover is not "mounted to" the housing.

(4) Claim 58

[206] Claim 58 depends on claim 48, which requires "the syringe body and needle being disposed and maintained rearwardly within the housing in a retracted, storage position." I have interpreted that phrase as requiring the syringe and needle to be generally closer to the rear of the housing when in the storage position.

[207] In the NGA EpiPen, the syringe and needle are not generally closer to the rear end of the device. They are located in the forward half, as clearly shown in the drawings reproduced in Schedule A.

[208] Thus, claim 58 is not infringed. The same holds true with respect to claims 59, 60 and 62, which depend on claim 58.

(5) Claims 59, 60 and 62

[209] There is an additional reason for which claims 59, 60 and 62 are not infringed. An essential element of those claims is that there be an "actuation assembly that includes the needle

shield and by which the needle shield is coupled to the power source." This element is not present in the NGA EpiPen.

[210] First, I have construed the term "actuation assembly" as consisting of one complex component or several components that are attached together, fixedly or movably. In this sense, the NGA EpiPen does not have an actuation assembly. Mr. DiGasbarro argues that the NGA EpiPen has an actuation assembly consisting of the needle shield, the cartridge container and the "power pak inner" (Third Preliminary Statement, paragraph 101). These components, however, are not attached to one another. In particular, the drawings reproduced in Schedule A clearly show that the cartridge container is not attached in any way to the "power pak inner," and therefore those parts cannot constitute an "actuation assembly." In fact, the NGA EpiPen is actuated through the interaction of several components that do not constitute an "assembly" within the meaning that I have ascribed to this term.

[211] Second, for similar reasons, the needle shield of the NGA EpiPen is not "coupled to" the power source. As I mentioned above, components that are "coupled" need to be in contact at all times, in contrast to components that are simply "operatively associated."

[212] Of course, all the components of the NGA EpiPen form part of the same device and can all be said to be at least in indirect contact with one another. But "coupled" must mean something more precise, otherwise all components of all devices would be "coupled."

[213] What is relevant is that, in the storage position, the cartridge container does not touch the "power pak inner." Moreover, while the needle shield permanently touches the cartridge container, those permanent contact points do not transmit any force or movement. Rather, actuation is effected when surfaces that are not otherwise in contact are pressed together. That may be an "operative association," but not a "coupling."

V. Remedies

[214] I have found that the claims asserted by Seedlings are invalid and that, in any event, they are not infringed by the NGA EpiPen sold by Pfizer. As a result, Seedlings's action will be dismissed and Pfizer's counterclaim, which seeks a declaration that the asserted claims are invalid, will be allowed.

[215] Because Seedlings's action is dismissed, it is not strictly necessary to decide whether it would have been entitled to the monetary remedies it was seeking. Nevertheless, in case my judgment is reversed on appeal, I believe it is useful to provide my opinion on the main issues between the parties with respect to remedies.

[216] Given that there is currently no alternative to the NGA EpiPen in the Canadian market, Seedlings quite properly refrains from seeking an injunction, but asks the Court to reserve its right to do so at a later date should an alternative product become available. I do not find it useful to comment on this request at this stage.

A. *Reasonable Royalty*

[217] Section 55(2) of the *Patent Act* entitles the patentee to claim "reasonable compensation" with respect to infringement that took place after the patent application was filed, but prior to the grant of the patent. It is generally recognized that a reasonable royalty constitutes such a "reasonable compensation:" *Jay-Lor International Inc v Penta Farm Systems Ltd*, 2007 FC 358 at paragraph 122 [*Jay-Lor*]; *Eli Lilly and Co v Apotex Inc*, 2014 FC 1254 at paragraphs 19–20, [2015] 4 FCR 601; *Dow Chemical Co v Nova Chemicals Corp*, 2017 FC 350 at paragraph 64, [2018] 2 FCR 154 [*Dow Chemical*]. It may also provide a remedy for the period after the patent was granted, if no other remedy (for example, an accounting of profits) is warranted.

[218] To estimate that reasonable royalty, we assume that instead of infringing, Pfizer would have sought a licence from Seedlings. We then estimate the value of that licence. Of course, such a licence was never in fact granted. Thus, to assess the value of that licence, we need to engage in an exercise of hypothetical negotiation. We ask ourselves what terms would Seedlings and Pfizer have agreed to if they had decided to negotiate a licence. That methodology is well anchored in economics literature. It has often been employed by this Court: see for instance, *Merck & Co, Inc v Apotex Inc*, 2013 FC 751 at paragraphs 149–152, [2015] 1 FCR 405 [*Merck*], aff'd 2015 FCA 171, [2016] 2 FCR 202; *Dow Chemical*; *Jay-Lor*. Both parties' experts, Dr. Heeb for Seedlings and Dr. Meyer for Pfizer, have employed this method and agree on its general outline.

[219] Basically, the hypothetical negotiation exercise involves the determination of the licensor's minimum willingness to accept [MWA] and the licensee's maximum willingness to

pay [MWP]. These represent the points at which the parties would no longer be willing to agree and would walk away from the negotiation. To identify the MWA and MWP, one needs to understand each party's next best alternative [NBA]. This can be illustrated by a hypothetical negotiation between a farmer and a food distributor for the sale of a certain product. The farmer's NBA would be the possibility of selling to another food distributor. Thus, if the farmer knows that another food distributor would pay $500 a tonne for the product, that would be the farmer's MWA. Likewise, the food distributor's NBA would be the possibility of buying the same product from another farmer. Thus, if another farmer is willing to sell the product for $1000 a tonne, that would be the food distributor's MWP. In that example, the parties would negotiate a price between $500 and $1000 a tonne. Thus, the alternative transactions that the parties may enter into to achieve their objectives constitute their NBAs and frame the negotiation.

[220] The hypothetical negotiation takes place at the time of first infringement. This is because the defendant would have needed a licence at that time to avoid infringing the plaintiff's patent. Therefore, the exercise must be informed by the then existing situation. Changes that took place later are not relevant, as the parties would not have been aware of them at the time of the hypothetical negotiation. Subsequent events may only be relevant insofar as it can be said that they would have been expected or anticipated by the parties at the time of negotiation.

[221] In this case, the experts disagree about the time at which the hypothetical negotiation would have taken place and the parties who would have been involved in that negotiation. Dr. Heeb argues that the negotiation must involve the defendant, Pfizer Canada, which first infringed

in May 2011. Dr. Meyer states that the exercise must be performed at the time of first infringement, in early 2010, with the party that then infringed, namely King Canada. This would be consistent with *Merck*, at paragraphs 156–162. Given that Pfizer Canada continued the business of King Canada, I tend to agree with Dr. Meyer. In any event, Dr. Meyer recognized that nothing of substance turns on the choice of the date or party.

[222] With that in mind, I will turn to the two main areas of contention between Dr. Heeb and Dr. Meyer, namely, Pfizer's MWP and Seedlings's MWA. While I will speak of Pfizer's MWP, it is of course King Canada who would have been involved in that negotiation, but no evidence was presented to the effect that this would have made any difference in the negotiating behaviour.

(1) Pfizer's Maximum Willingness to Pay

[223] Both experts assess Pfizer's MWP on the basis that its NBA is to continue making and selling the EpiPen Legacy instead of the NGA EpiPen, or reverting to the Legacy EpiPen after the NGA EpiPen was found to infringe Seedlings's patent. It cannot be seriously disputed that, in 2010, or even in 2011, this would have been technically feasible.

[224] The experts disagree, however, as to the consequences of such a change. Pfizer's factual witnesses have forcefully argued that reverting to the EpiPen Legacy would not have had any impact whatsoever on its sales. On that basis, Dr. Meyer asserts that Pfizer would not have been willing to pay anything to Seedlings to buy a licence that would have allowed it to make and sell the NGA EpiPen. Dr. Heeb, in contrast, assumes that Pfizer's sales would have been affected. He

then estimates what that effect would have been and how much Pfizer would have been prepared to pay to avoid that situation.

[225] In my view, the factual premise of Dr. Meyer's opinion is untenable. I also reject Pfizer's criticism of Dr. Heeb's assumptions. Thus, I accept his calculation of Pfizer's MWP.

(a) *The Effects of Reverting to the EpiPen Legacy*

[226] What must be assessed at this stage is King Canada's perception, in 2010, of the effects of not migrating to the NGA EpiPen and keeping, or reverting to, the EpiPen Legacy. In that exercise, what took place afterwards is irrelevant. Thus, I must assess King Canada's perception of competitive threats at that time, not whether those threats subsequently materialized or disappeared.

[227] King Canada began selling the EpiPen in 2006. From that date until 2010, it had been able, through sustained marketing efforts, to stabilize and increase its market share and to grow the market itself. Nevertheless, it was conscious that it was then facing increased competitive threats, as new products were expected to come to the market in the near future.

[228] In this context, it is clear that the NGA EpiPen's needle cover was a competitive advantage. Mr. Handel, who was King's vice-president at the time, candidly admitted this (October 31, 2019, pp. 128, 133). Moreover, King Canada's marketing plans for the transition from the EpiPen Legacy to the NGA EpiPen emphasized the fact that the latter would be the only auto-injector with needle protection (Exhibit P49, Tab 6).

[229] Ms. Armstrong, who was King Canada's director of marketing, recognized in cross-examination that, at that time, King Canada considered the Intellijject auto-injector to be a significant competitive threat (October 31, 2019, pp. 221–222, 226–227). That device offered sharps protection, in addition to being smaller. King Canada also expected other competitors to enter the market within a short time-frame (*ibid*, 228–231).

[230] This is summarized in the following exchange (p. 233):

> MR. VAN BARR: Thank you.
>
> It's fair to say, Ms. Armstrong, that the business plans we have been looking at certainly note a concern with competition; is that fair?
>
> MS. ARMSTRONG: It is.
>
> MR. VAN BARR: And your business plans specifically note certain advantages with the NGA.
>
> MS. ARMSTRONG: Yes.
>
> MR. VAN BARR: One of those advantages being the only auto-injector with automatic sharps protection, right?
>
> MS. ARMSTRONG: Right.

[231] Mr. Handel also testified that Meridian invested $38 million in the design of the NGA EpiPen (October 31, 2019, p. 135). It is entirely implausible that Meridian would invest such a large amount of money without expecting any return. While the transition from the EpiPen Legacy to the NGA EpiPen was expected to be revenue-neutral, that simply meant that the manufacturing cost and the sale price would remain the same. Thus, even though King did not expect to make a larger profit per unit sold, it must have believed that the transition to the NGA EpiPen was necessary to maintain a competitive advantage and, ultimately, its market share.

[232] Both parties put forward the evidence of allergists – Dr. Greenwald called by Pfizer and Dr. Upton called by Seedlings – to show how prescribing habits would have been affected if King Canada or Pfizer had to revert to the EpiPen Legacy. While they do not fully agree on the relative merits of each auto-injector, their evidence shows that prescribing allergists pay attention to the various features of each device. Thus, some allergists may not give much importance to sharps protection, but others will. It follows that it is not possible to say that all allergists will consider the EpiPen Legacy and the NGA EpiPen as being fully equivalent. This evidence is consistent with the proposition that reverting to the EpiPen Legacy would have had some detrimental effect on sales.

[233] In an attempt to show that the introduction of the NGA EpiPen did not have an effect on sales, Dr. Meyer conducted a study comparing the sales of the EpiPen Legacy in the year prior to the change with the sales of the NGA EpiPen in the year following the change. She found that the growth of the sales was in fact higher during the last year of the EpiPen Legacy than during the first year of the NGA EpiPen. These results, however, prove little. They could simply show that the transition to the NGA EpiPen was necessary for Pfizer to maintain its competitive advantage and to keep increasing its sales. Indeed, the graph found at Schedule D of Dr. Meyer's report also shows that EpiPen sales are sensitive to the presence of competitors in the market. In any event, Dr. Meyer's study was made after the fact and cannot have influenced Pfizer's (or King Canada's) expectations in a hypothetical negotiation taking place in 2010.

[234] Thus, if King Canada had not been able to sell a device with needle protection in 2010, it is reasonable to assume that it would have felt more vulnerable to competition. It would have

been prepared to pay an amount that is more than *de minimis* to avoid being placed in that situation.

[235] It should be emphasized that, in order to come to that conclusion, I need not rely on subsequent Pfizer Canada business plans, even though I admitted them into evidence as business records.

(b) *Calculating Pfizer's MWP*

[236] Hence, Pfizer's MWP is the difference between the profits it expected to make by selling the NGA EpiPen and those it would have expected had it been required to sell the EpiPen Legacy instead. In 2011, Pfizer made forecasts of its profits for the NGA EpiPen for the following years. However, it never made any forecasts of the profits it would make with the EpiPen Legacy.

[237] For this reason, Dr. Heeb had to make a hypothetical calculation of Pfizer's expected profits with the EpiPen Legacy. Of course, this is a hypothetical exercise and there is no way of knowing what Pfizer's executives would have really thought at the time. Dr. Heeb's hypothesis is that, contrary to Pfizer's assumption of a 3% growth of its NGA EpiPen sales every year, Pfizer's sales of the EpiPen Legacy would have remained flat, that is, they would not have shown a year-over-year growth.

[238] Pfizer criticized Dr. Heeb's assumption for being arbitrary. Moreover, it questioned Dr. Heeb's choice of a particular forecast, as the document from which it comes contained other

scenarios, some more positive and others more negative. Yet, there is an inescapable arbitrary component in making hypothetical calculations of this nature. All the qualitative evidence suggests that the NGA EpiPen has a competitive advantage over the EpiPen Legacy, but there appears to be no precise manner of quantifying what Pfizer would have lost had it been forced to sell the latter. In those circumstances, Dr. Heeb's hypothesis of flat sales instead of a steady growth appears reasonable. No one has suggested a more reasonable alternative, apart from reiterating Pfizer's argument that reverting to the EpiPen Legacy would have had no impact whatsoever on its sales.

[239] Moreover, I am far from certain that choosing another forecast scenario would have made a significant difference. Even if one were to forecast a steady decline in the sales of the NGA EpiPen, there would be an even more pronounced decline with the EpiPen Legacy. Thus, there would still be a difference in the profits Pfizer would have expected to make with each device, quite possibly of the same magnitude as in the scenario Dr. Heeb selected.

[240] Pfizer did not suggest that the other aspects of Dr. Heeb's calculation of its MWP were wrong. Hence, having found no fault with his methodology, I accept his result.

(2) Seedlings's Minimum Willingness to Accept

[241] The experts also disagree with respect to Seedlings's MWA. Dr. Heeb concludes that Seedlings's MWA is the value of the [redacted] licence. In other words, he assumes that Seedlings would have walked away from the negotiations if it had been offered less attractive terms than those it obtained from [redacted]. Dr. Meyer, in contrast, argues that Seedlings's

MWA is *de minimis*. The basic reason for her conclusion, stated at paragraph 53 of her report, is that Seedlings would not have foregone anything by entering in a licencing agreement with Pfizer.

[242] The proper approach, in my view, is to identify clearly Seedlings's NBA. In other words, we should try to understand at what point Seedlings would have rationally walked away from the negotiations. Dr. Heeb puts it as follows at paragraph 39 of his report:

> Similarly, negotiators for Seedlings must take into account their expectations regarding the profits that Seedlings would make if it were to license the technology to Pfizer, compared with its profits if it did not.

[243] Contrary to Dr. Heeb, I do not find that the terms of the [redacted] licence constitute a threshold below which Seedlings would not have accepted to contract. Under the hypothetical bargaining scenario, Seedlings does not have to choose between licensing to Pfizer and licensing to another firm on terms similar to those of the [redacted] licence. (In any event, it is far from clear that, in 2010, Seedlings had any realistic expectation of selling a licence to anyone.) Moreover, it is unclear that Seedlings's hypothetical license to Pfizer would have had to be exclusive. Thus, by negotiating with Pfizer, Seedlings was not foregoing the opportunity of selling a licence to someone else on terms similar to those of the [redacted] licence; that is not its NBA.

[244] Rather, Seedlings's NBA, if it has any, is the incremental profits it would have made by not selling a licence to Pfizer. Intuitively, one could say that there are no profits to be made by not licensing a patent. Nevertheless, Dr. Heeb points out, correctly in my view, that there is a

potential chain of events that would result in some value accruing to Seedlings of not licensing its patent to Pfizer. In broad strokes, this chain can be described as follows:

- Seedlings walks away from the negotiation, forcing Pfizer to revert to the EpiPen Legacy.
- By reverting to the EpiPen Legacy, Pfizer becomes more vulnerable to competition.
- [redacted] enters the market and captures a greater share of the market than it would have been able to capture had Seedlings enabled Pfizer, through a licence, to market the NGA EpiPen.
- [redacted] then pays a greater royalty to [redacted].
- The value of [redacted] shares increases.
- The value of Seedlings's [redacted] increases.

[245] Thus, Seedlings would rationally walk away from the negotiation if Pfizer offered a royalty that is less than the increase in the value of Seedlings's share in [redacted] resulting from Pfizer being forced to revert to the EpiPen Legacy. Dr. Heeb, however, does not attempt to quantify that increase in value. Indeed, there is considerable uncertainty with respect to several links of this chain of events. The hypothetical negotiation takes place in 2010 and it was not certain, at that time, that [redacted] would successfully enter the market. The terms of the [redacted] are not in evidence before me, other than a reference to [redacted]. I do not know the scope of the royalty payable by

[redacted]. With respect to the increase in the value of [redacted] that would result from increased royalty revenue, this would be an expectation anchored in common sense, although anyone would also expect the value of a relatively small firm to be subject to important variations. Lastly, it is unclear that Seedlings would have been able to realize the increased value of its [redacted]. [redacted]. [redacted] [redacted].

[246] Thus, while I agree that, in theory, Seedlings could reap some benefit by not selling a licence to Pfizer, in my view, this benefit was too distant and hypothetical to induce Seedlings to walk away from the negotiation. There was no rational reason for leaving any money on the table, irrespective of Seedling's opinion of what a licence was worth. In the end, as Seedlings had no real NBA, I agree with Dr. Meyer that Seedlings's MWA is *de minimis*.

(3) Division of the Gains of Trade

[247] Where the licensee's MWP exceeds the licensor's MWA, there is an overlap between what the parties are prepared to accept. In other words, this is a situation where both parties will gain by entering into an agreement. The issue then becomes the divisions of those gains of trade. Dr. Heeb puts forward three methods for allocating those gains between the parties. He then averages the results of these three methods. He concludes that Pfizer would obtain 83.6% of those gains and Seedlings, 16.4%. There is no serious dispute between the experts in this regard.

[248] Thus, the reasonable royalty that Seedlings would have obtained in the hypothetical negotiation is 16.4% of Pfizer's MWP, which amounts to 2.05%. Had I found infringement, I

would have held that Seedlings was entitled to a compensation equal to 2.05% of the net sales revenue of the NGA EpiPen.

B. *Accounting of Profits*

[249] Seedlings also asserts that it is entitled to an accounting of the profits made by Pfizer for the period after the patent was granted in 2014. For the reasons set out below, I would not have allowed Seedlings to elect an accounting of profits.

[250] Section 57(1) of the *Patent Act* allows the Court to make an order "for and respecting inspection or account," which is usually understood as an order for the accounting of profits. In *Laboratoires Servier v Apotex Inc*, 2008 FC 825 at paragraphs 502–503, aff'd 2009 FCA 222, Justice Snider explained the conceptual difference between damages and an accounting of profits :

> While both damages and accounting of profits are intended to provide compensation to a wronged plaintiff, the fundamental principles underlying the two remedies and the practical considerations are substantially different.
>
> The object of an award of damages is to make good any loss suffered by the plaintiff as a result of the defendant's infringement of the patent. Quantification of the award is based on the losses suffered by the plaintiff; any gains realized by the defendant because of its wrongdoing are not relevant. On the other hand, an accounting of profits is based on the premise that the defendant, by reason of its wrongful conduct, has improperly received profits which belong to the plaintiff. The objective of the award is to restore those actual profits to their rightful owner, the plaintiff, thereby eliminating whatever unjust enrichment has been procured by the defendant. Calculation is based on the profits wrongfully gained by the defendant; any other losses suffered by the plaintiff are irrelevant.

[251] It is generally agreed that accounting of profits is a discretionary remedy: *Merck & Co, Inc v Apotex Inc*, 2006 FCA 323 at paragraph 127, [2007] 3 FCR 588. The case law provides some guidance as to the factors that may be taken into account in the exercise of that discretion, although not in the form of a structured test. For example, in *Beloit Canada Ltd v Valmet-Dominion Inc*, [1997] 3 FC 497 (CA) at paragraphs 109–121, the Federal Court of Appeal stated that there was no presumption in favour of accounting of profits and that this remedy may be refused because of delay, misconduct or knowledge of the infringement.

[252] The fact that the patentee does not practice the invention may also be taken into account in deciding whether to award an accounting of profits. In other words, where the patentee does not itself manufacture, distribute or sell the invention, it cannot be entitled to the profits made by the infringer with respect to those activities. Indeed, if the patentee made its profits by selling licences, it should not be entitled to compensation beyond a reasonable royalty. See, in this regard, *Colonial Fastener Co v Lightning Fastener Co*, [1937] SCR 36 at 45; *Lubrizol Corp v Imperial Oil Ltd* (1992), 45 CPR (3d) 449 at 474 (FCA); *Unilever PLC v Proctor & Gamble Inc* (1993), 47 CPR (3d) 479 at 525 (FCTD), aff'd (1995), 61 CPR (3d) 499 (FCA); *Alliedsignal Inc v du Pont Canada Inc*, 1998 CanLII 7464 at paragraphs 21–22 (FCTD), aff'd 1999 CanLII 7409 (FCA); *Jay-Lor*, at paragraph 119; *Frac Shack Inc v AFD Petroleum Ltd*, 2017 FC 104 at paragraph 283, reversed on other grounds, 2018 FCA 140; *Human Care Canada Inc v Evolution Technologies Inc*, 2018 FC 130 at paragraph 437, reversed on other grounds, 2019 FCA 209.

[253] Seedlings never had any intention of manufacturing, distributing or selling an auto-injector. Dr. Rubin always understood that Seedlings would need to "partner" with larger

organizations or, in other words, to sell a licence to a manufacturing firm (October 21, 2019, p. 142). In that context, it is difficult to say that Seedlings was entitled to profits that it would never have made in any scenario. In fact, an accounting of profits along the lines suggested by Seedlings's expert would result in an award that would be up to twenty times the reasonable compensation I would have been prepared to grant. This would be a tremendous windfall for Seedlings. Had it sold a licence to King Canada in 2010 or Pfizer in 2011, it would never have received anything close to the amount it now claims.

[254] Moreover, Seedlings waited until 2017 to file its statement of claim, even though it became aware of the NGA EpiPen in late 2009 or early 2010 and the first alleged infringement in Canada took place in the first quarter of 2010. The explanations given by Seedlings for that delay were not convincing. Even if Seedlings had to wait until the issuance of the Canadian patent – perhaps because all the claims of its US patent refer to a "flat" device – it is difficult to understand why three more years were necessary to begin this action. The result of that delay is that the amount of profits that Pfizer would have to account for is vastly superior to what it would have been if the action had been initiated in a timely fashion.

[255] Seedlings argues that Pfizer knew or ought to have known that it was infringing its patent and that this is a consideration in favour of an accounting of profits. There is, however, no evidence of wilful infringement. Although certain documents show that Meridian was aware of Seedlings's LifeCard project as early as 2004 (Exhibit S47; testimony of Tom Handel, October 31, 2019, pp. 130-131), Mr. Wilmot's evidence to the effect that he was not aware of Seedlings's patent and did not in any way use Seedlings's technology in the design of the NGA EpiPen

remains uncontradicted (October 29, 2019, pp. 34–35). Thus, had I found infringement in this case, it would have been, at best, a situation where two inventors made the same invention independently, but Seedlings filed its patent application first.

[256] Seedlings also argued that it notified Pfizer US of its infringement in 2012 and offered to negotiate a licence. There is no evidence, however, that Seedlings's letter to that effect was ever transmitted to, or received by Pfizer US. That Seedlings could not produce proof of receipt is surprising. That Pfizer Canada would take the position that it has no knowledge of what its parent company may have received is also surprising. Be that as it may, there was no evidence of any follow-up or any subsequent initiatives taken by Seedlings to make Pfizer aware of its infringement. Sending a one-page letter and doing nothing for the next five years does not convey to Pfizer the impression that there was a serious infringement issue. At the very least, one would have expected Seedlings to put Pfizer Canada on notice as soon as the Canadian patent was issued in 2014.

[257] For those reasons, I conclude that an accounting of profits would not have been a proper remedy, had I found infringement.

[258] In reaching that conclusion, I am mindful that this Court has, on a number of occasions, stated that accounting of profits has a deterrent purpose. But for the availability of that remedy, potential infringers would be induced to take a chance and, if caught, would simply have to pay the royalty that they owed in the first place. This is known in the law and economics literature as the "efficient breach" conundrum: Ejan Mackaay and Stéphane Rousseau, *Analyse économique*

du droit, 2nd ed (Paris and Montreal: Dalloz and Thémis, 2008) at 437–440. No case was cited to me, however, where the need to deter potential infringers overcame the fact that the plaintiff did not practice the invention. In any event, courts may award punitive damages, which bear a deterrent purpose, where the defendant wilfully infringed the plaintiff's patent: *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2012 FC 113 at paragraphs 417–456, aff'd by *Eurocopter* (FCA). Seedlings, however, does not claim punitive damages and, for the reasons stated above, I cannot make any finding of wilful infringement.

[259] Given my conclusion, I do not find it useful to comment on the other issues raised by Seedlings's claim for an accounting of profits.

C. *Pre-judgment Interest*

[260] Had I found Pfizer liable, I would have ordered it to pay pre-judgment interest, not compounded, at the annual average bank rate published by the Bank of Canada plus 1%, since the filing of the statement of claim.

[261] There was a debate at trial about the rate of interest that would be applicable to an accounting of profits. In those cases, the plaintiff may be entitled to interest at a higher rate, typically the defendant's borrowing rate: *Dow Chemical*, at paragraphs 166–174.

[262] When reasonable compensation is awarded under section 55(2) of the *Patent Act*, however, the practice of this Court is to award interest at a lower rate, typically the rate set by the Bank of Canada, to which an additional 1% may sometimes be added. See, for example, *Uponor*

AB v Heatlink Group Inc, 2016 FC 320 at paragraph 307; *Airbus Helicopters, SAS v Bell Helicopter Textron Canada Limitée*, 2017 FC 170 at paragraph 443; *Human Care Canada Inc v Evolution Technologies Inc*, 2018 FC 1304 at paragraph 9 of the order.

VI. Disposition

[263] For the foregoing reasons, I will dismiss Seedlings's action. Pfizer did not infringe the asserted claims of Seedlings's patent. Moreover, the asserted claims are invalid.

[264] I will also allow Pfizer's counterclaim and declare claims 40, 44–54, 56–60 and 62 of Seedlings's patent invalid, as they are overly broad, some of them are anticipated and one of them is obvious.

[265] The parties agreed to reserve the issue of costs. Accordingly, Pfizer will have 30 days from the date of this judgment to make submissions in writing as to costs. Seedlings will have 15 days from the receipt of Pfizer's submissions to respond. In both cases, those submissions should not exceed 15 pages.

JUDGMENT in T-608-17

THIS COURT'S JUDGMENT is that:

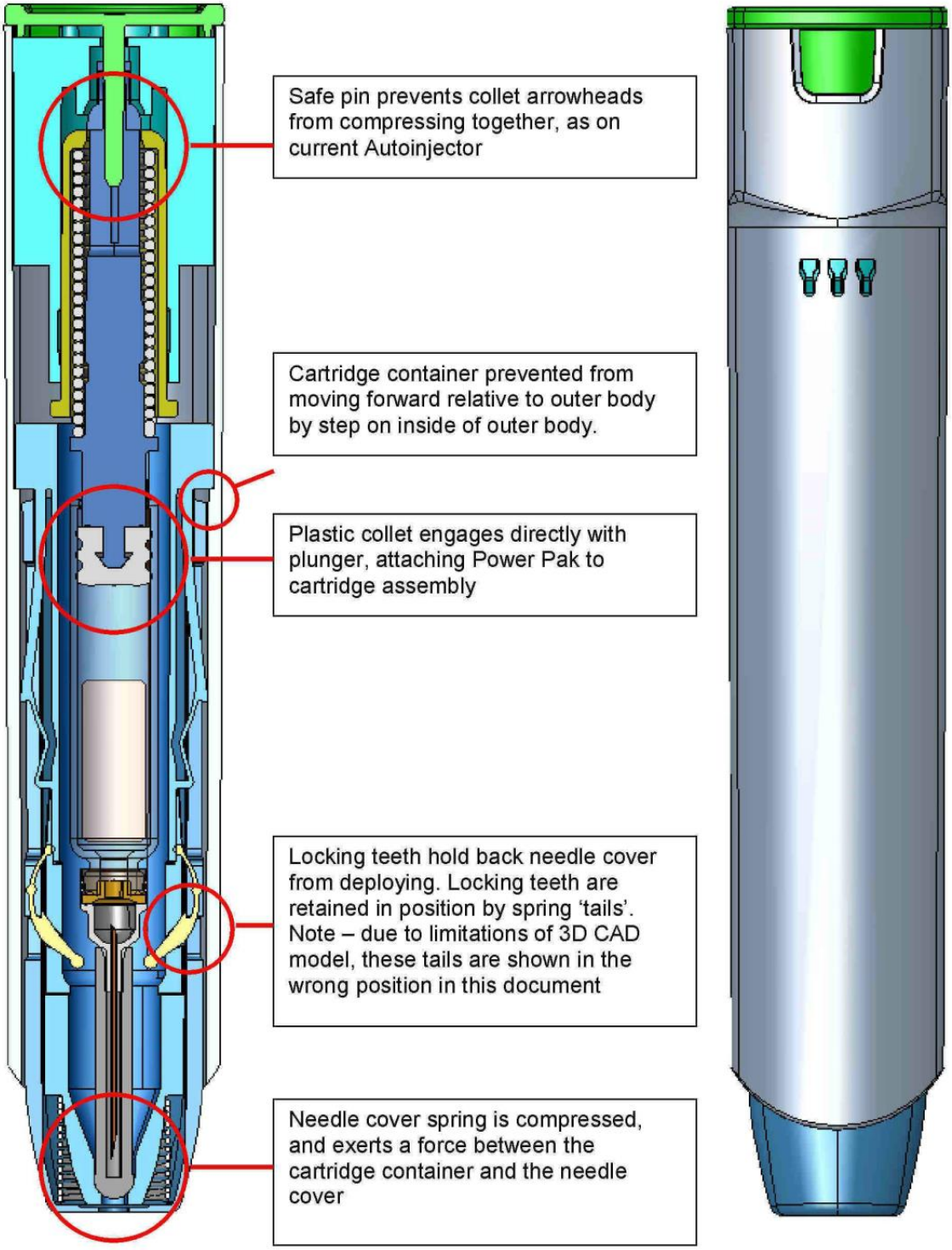
1. Plaintiff's action is dismissed.
2. Defendant's counter-claim is allowed.
3. Claims 44–54 and 56–57 of Canadian patent no. 2,486,935 are invalid for being anticipated.
4. Claim 58 of Canadian patent no. 2,486,935 is invalid for being obvious.
5. Claims 40, 44–54, 56–60 and 62 of Canadian patent no. 2,486,935 are invalid for being overly broad.
6. Defendant did not infringe claims 40, 44–47, 58–60 and 62 of Canadian patent no. 2,486,935.
7. The issue of costs is reserved.

"Sébastien Grammond"

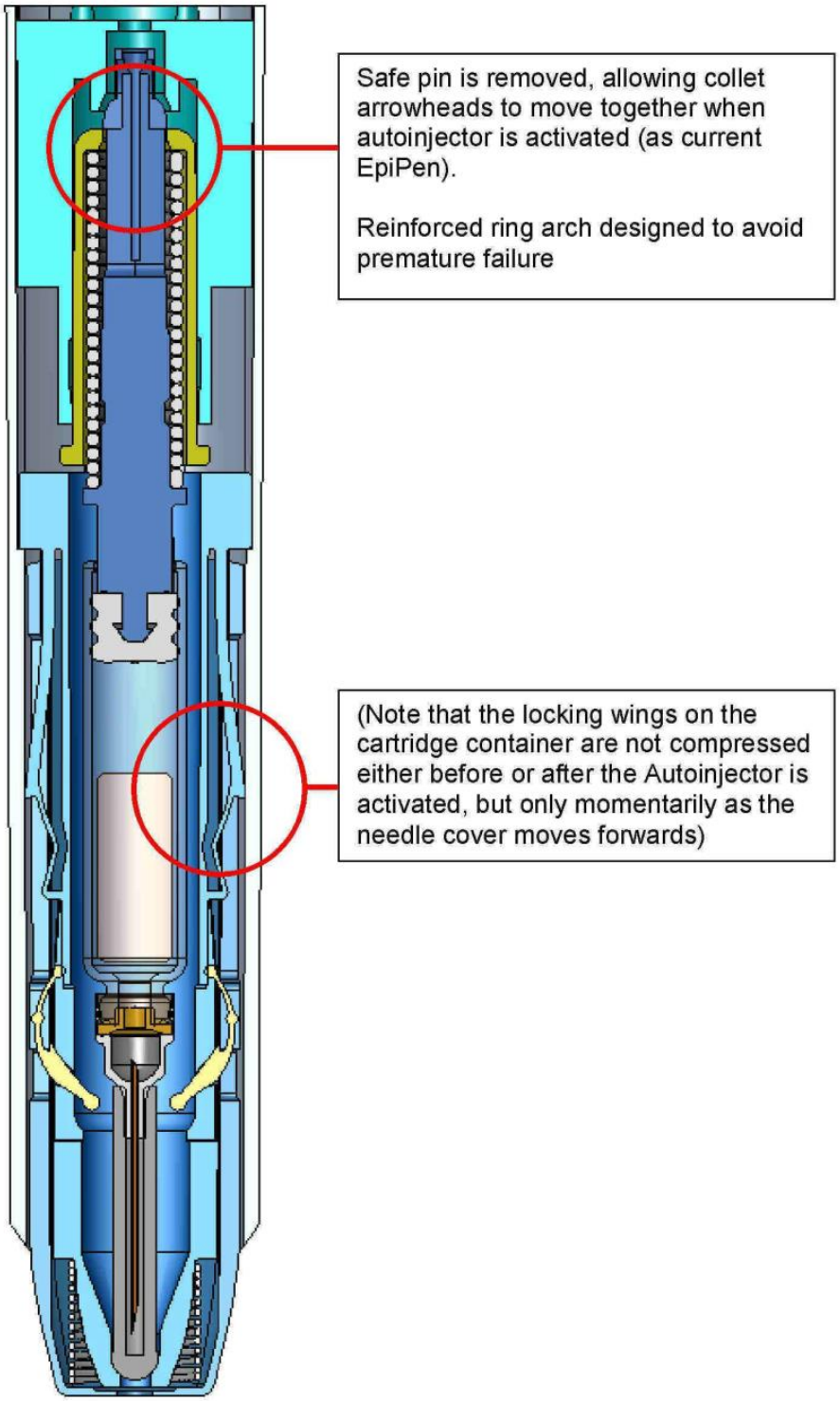
Judge

SCHEDULE A – NGA EPIPEN

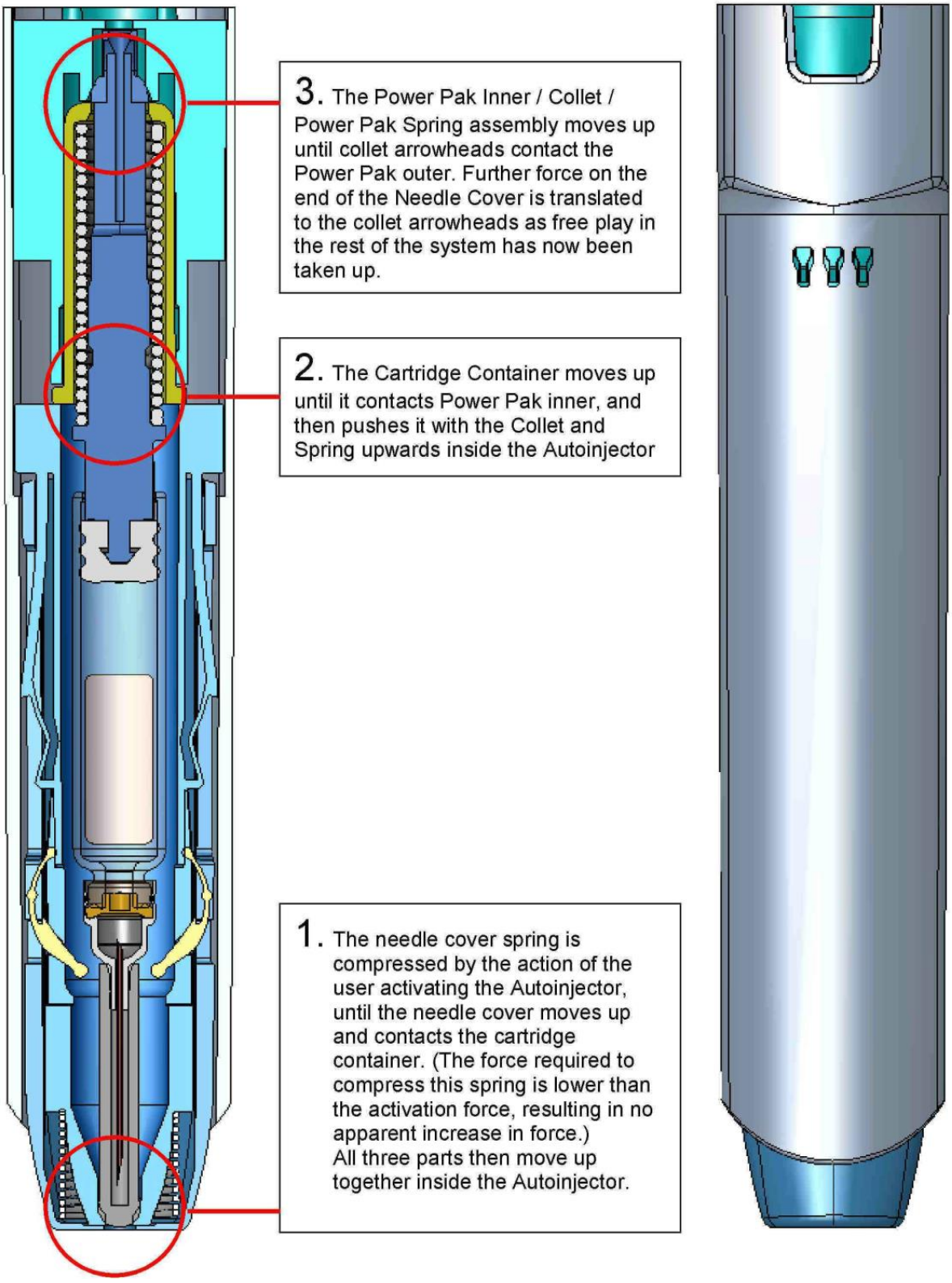
Stage 1: Unactivated Autoinjector



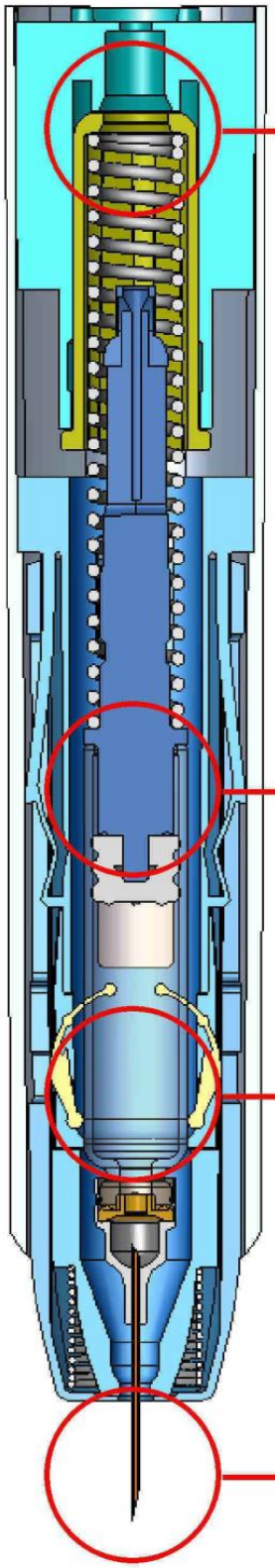
Stage 2: Safe pin removed to prepare Autoinjector for activation



Stage 3: User activates Autoinjector – initial movement in Autoinjector mechanism



Stage 4: User activates Autoinjector – drug delivered

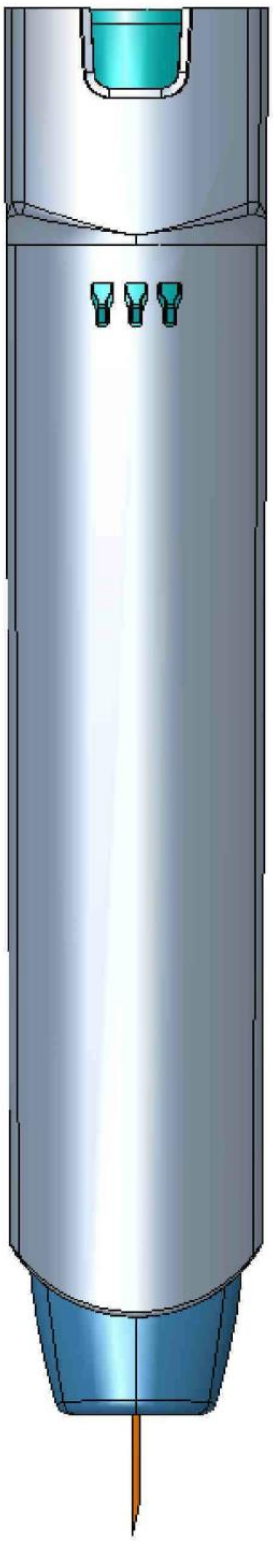


4. The upper end of the Power Pak Spring forces the Power Pak inner into the Power Pak outer,(which cannot move, as it is fixed to the outer body.)

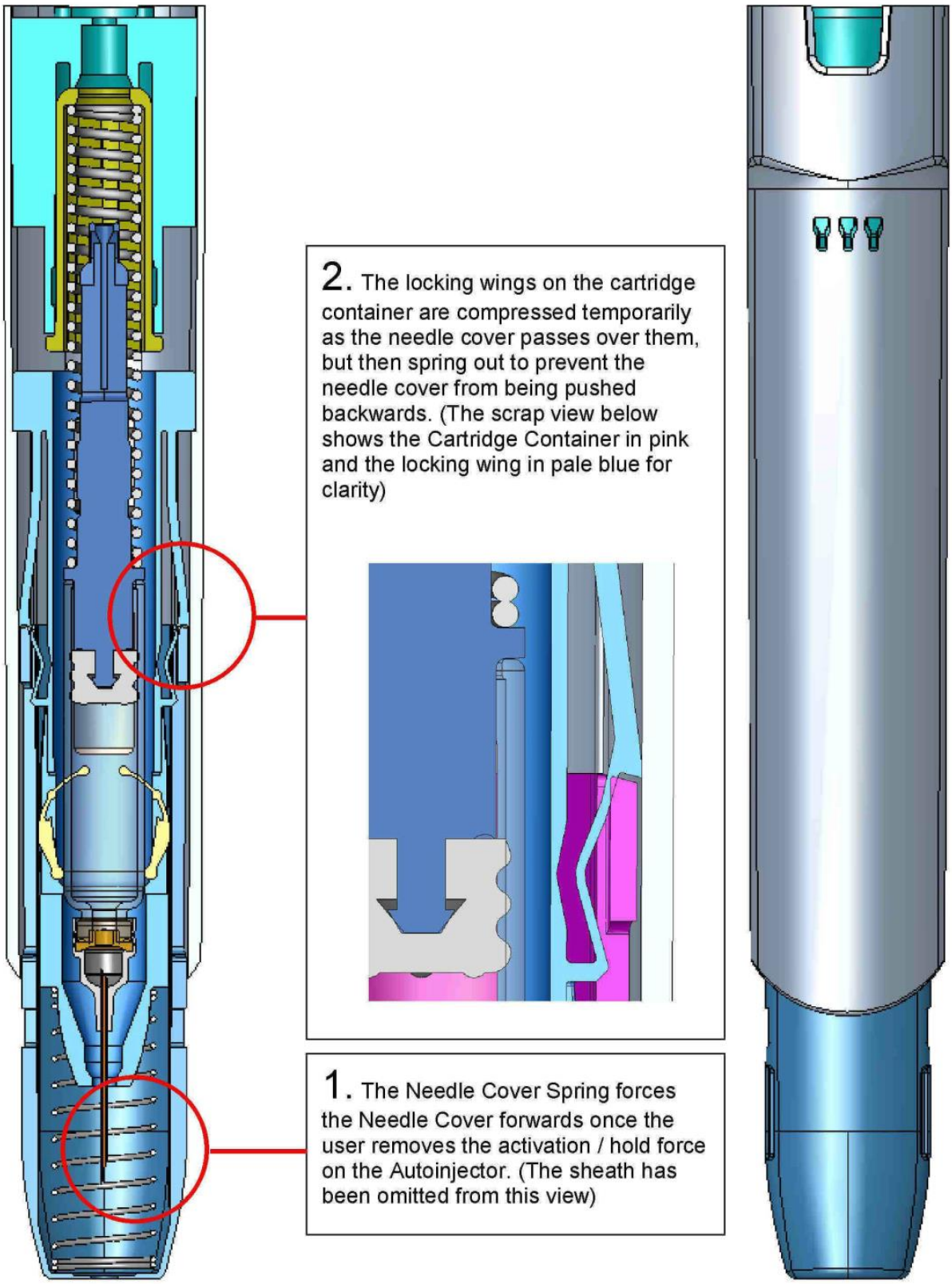
3. Once the needle has extended, the diaphragm bursts and the drug is forced down the needle, allowing the plunger and collet to move further into the cartridge.

2. As this happens, the Cartridge forces the locking teeth out so that the needle cover is unlatched. Note that the needle cover is not being retained by the locking teeth at this point because it has been forced up by the activation pressure (see previous page)

1. The Power Pak spring forces the Cartridge Assembly forwards, pushing the needle out through the sheath. (The sheath has been omitted from this view for clarity and ease of illustration)



Stage 5: Needle Cover moves forward



2. The locking wings on the cartridge container are compressed temporarily as the needle cover passes over them, but then spring out to prevent the needle cover from being pushed backwards. (The scrap view below shows the Cartridge Container in pink and the locking wing in pale blue for clarity)

1. The Needle Cover Spring forces the Needle Cover forwards once the user removes the activation / hold force on the Autoinjector. (The sheath has been omitted from this view)

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

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