Appeal Decision

Appeal No. 2019-3546

Appellant Corning Incorporated

Patent Attorney YANAGIDA, Masashi

The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2014-560017, entitled "GLASS PACKAGING ENSURING CONTAINER INTEGRITY" (International Publication No. WO 2013/130721 published on September 6, 2013, National Publication of International Patent Application No. 2015-512853 published on April 30, 2015) has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The present application is Japanese Patent Application No. 2014-560017 filed on February 28, 2013 as an international filing date (the claim of priority under the Paris Convention was received by the foreign receiving office on February 29, 2012 in the US), and the history of the procedures is as follows: a notice of reasons for refusal was issued on March 6, 2017; a written opinion and a written amendment were submitted on August 14, 2017; a notice of reasons for refusal was issued on January 30, 2018; a written opinion and a written amendment were submitted on July 6, 2018; the examiner's decision of refusal was issued on November 2, 2018; an appeal against the examiner's decision of refusal was requested on March 14, 2019, and at the same time, a written amendment was submitted; a notice of reasons for refusal was issued by the body on August 18, 2020; and a written opinion and a written amendment were submitted on February 17, 2021.

No. 2 Description of the scope of claims (the Invention)

The inventions according to Claims 1 to 10 of the present application are specified by the matters recited in Claims 1 to 10 in the scope of claims amended by the written amendment submitted on February 17, 2021 (hereinafter referred to as "the Amendment"). The invention according to Claim 1 of the present application (hereinafter referred to as

"the Invention") is as follows:

"[Claim 1]

A container comprising a glass, the container having a thickness and a first surface and a second surface, which is adopted for holding any of a pharmaceutical product, a vaccine, a biologic, a foodstuff, and a solution,

wherein the glass is an aluminosilicate glass having the thickness in a range from 0.5 mm to 1.5 mm and has a first region under a compressive stress, the first region extending from at least one of the first surface and the second surface to a depth of layer in the glass, and a second region under a central tension, the second region extending from the depth of layer,

wherein the central tension is greater than or equal to 15 MPa,

wherein the glass has a Young's modulus E and a Poisson's ratio ν, wherein $(CT^2 / E) \cdot (t - 2DOL) \cdot (1 - \nu) \geq 3.0$ MPa·μm, where CT is the central tension, t is the thickness, and DOL is the depth of layer, and

wherein the central tension is sufficient to allow self-propagation of a crack front through the thickness from the first surface to the second surface and to allow self-propagation of the crack front laterally across at least the first surface."

No. 3 Reasons for refusal notified by the body

The reasons for refusal notified by the body include a reason for refusal based on incompliance with support requirement, and the reasons for refusal are, in summary, as follows.

· Reason for refusal (Support requirement):

It cannot be said that the invention according to Claim 1 before the Amendment is the invention described in the detailed description of the invention. In addition, it cannot be said that the invention according to Claim 1 before the Amendment is within a range such that a person skilled in the art can recognize that the problem of the invention can be solved by the description of the detailed description of the invention, or is within a range such that a person skilled in the art can recognize that the problem of the invention can be solved in view of the common technical knowledge at the time of filing the present application even if there is not a description or suggestion in the detailed description of the invention. Therefore, the description of the scope of claims of the present application does not comply with Article 36(6)(i) of the Patent Act, and the present application does not meet the requirement stipulated in Article 36(6) of the Patent Act.

No. 4 Judgment by the body

The body judges that the reason for refusal shown in No. 3 above has not been resolved and is still reasonable even if the written opinion (including the reply to the inquiry from the body) and the written amendment submitted by the Appellant on February 17, 2021 are taken into consideration. The reasons are as follows.

1 Procedure for determination on the support requirement

It is understood that whether or not a description of the scope of claims complies with the requirement stipulated in Article 36(6)(i) of the Patent Act (what is called "support requirement of the specification") should be determined by comparing the description of the scope of claims with the description of the detailed description of the invention and by examining whether or not the invention described in the scope of claims is the invention described in the detailed description of the invention and is within a range such that a person skilled in the art can recognize that the problem of the invention can be solved by the description of the detailed description of the invention, and whether or not the invention described in the scope of claims is within a range such that a person skilled in the art can recognize that the problem of the invention can be solved in view of the common technical knowledge at the time of filing the present application even if there is not a description or suggestion in the detailed description of the invention (hereinafter, both ranges are collectively referred to as "the range within which a person skilled in the art can recognize that the problem of the Invention can be solved from the description of the detailed description of the invention").

2 Description of the scope of claims

It can be said that the description of Claim 1 in the scope of claims of the present application is as described in No. 2 above and is an invention of "a container" including the matter specifying that "the central tension is greater than or equal to 15 MPa, wherein the glass has a Young's modulus E and a Poisson's ratio ν, wherein $(CT^2 / E) \cdot (t - 2DOL) \cdot (1 - \nu) \geq 3.0$ MPa·μm, where CT is the central tension, t is the thickness, and DOL is the depth of layer."

3 Description of the detailed description of the invention

The detailed description of the invention, whose excerpted description is omitted herein, includes descriptions regarding [Technical Field] ([0002]), [Background Art] ([0003]), [Summary of Invention] ([0004] to [0009]), [Description of Embodiments] ([0011] to [0050]), and " representative embodiments" ([0051] to [0057]) of the Invention.

4 Compliance with the support requirement (Comparison and examination between the description of the scope of claims for patent and the description of the detailed description of the invention)

(1) Object of the Invention

In the detailed description of the invention in the specification of the present application, there is no itemized description regarding the problem to be solved by the invention, but in [0004] of [Summary of Invention] column, there is the following description:

"The present disclosure provides a strengthened glass container or vessel such as, but not limited to, vials for holding pharmaceutical products or vaccines, and foodstuff containers (e.g., bottles, baby food jars, etc.) in a hermetic and/or sterile state. The strengthened glass container undergoes a strengthening process that produces compression at the surface and tension within the container wall. The strengthening process is designed such that the tension within the wall is great enough to ensure catastrophic failure of the container, thus rendering the product unusable, should sterility be compromised by a through-wall crack. This tension is greater than a threshold central tension, above which catastrophic failure of the container is enhanced, thus significantly reducing or eliminating any potential for violation of container integrity."

According to the above description, it is understood that one aspect of the object of the Invention is to "provide a strengthened glass container or vessel such as vials for holding in a hermetic and/or sterile state" by being "designed such that the tension within the wall is great enough to ensure catastrophic failure of the container, thus rendering the product unusable, should sterility be compromised by a through-wall crack."

In addition, in [0003] of [Background Art] column, there is a description that "Cracks that extend through the wall thickness may form, compromising content sterility but not leading to catastrophic failure of the package. Such cracks may result in recalls when detected by a health care professional or end consumer at the point of use, and can be costly to the pharmaceutical or foodstuff manufacturer", and in [0024] of [Summary of Invention] column, there is a description that "In the typical non-stressed case (A), if the single crack is hidden, for example, by a label, a patient or administering professional may be unaware of the loss of sterility." Further, in [0015], there is a description that "Such crack splitting ensures that a breach of the integrity of the container does not go unnoticed." From the above descriptions, it is understood that another aspect of the problem of the Invention is to ensure that a breach of integrity of a container (container failure) due to crack splitting can be noticed.

That is, it can be said that the problem of the Invention is, in short, to "provide a

strengthened glass container or vessel such as vials for holding in a hermetic and/or sterile state" by "ensuring catastrophic failure of the container due to the tension within the wall, should sterility be compromised by a through-wall crack" and, in addition, to ensure that container failure due to crack splitting can be noticed.

(2) Specific examples (Examples) described in the detailed description of the invention

First, focusing on specific examples (Examples), the [Examples] column does not exist in the detailed description of the invention. Instead, " representative embodiments" are shown in [0051] to [0057], in which specific examples corresponding to Examples can be recognized.

In fact, as the above-mentioned specific examples, it is described that "alkaline earth aluminosilicate glass vials described in the specification of U.S. Patent Application No. 13/660,450" ([0052]) were employed which was subjected to treatments such as ion exchange and to the predetermined drop test.

That is, the above-mentioned specific examples describe that: "The alkali aluminosilicate glass vials" having "3.00 ml nominal volume, 3.70 cm height, 16.75 mm diameter, and 1.1 mm wall thickness" "were ion exchanged in a KNO_3 (technical grade) salt bath at 450°C for 8 hours. All vials were depyrogenated at 320°C for l hour and cooled to a temperature of less than 90°C" ([0052]), and the drop test of such vials "facilitates detection of any failure that would compromise the integrity of the dropped vial" ([0055]); and a failure mode rate ([FIG. 8]) and delayed failure ([0056]) when the central tension varies from 5.7 to 59.0 MPa by changing ion exchange time.

However, none of the above-mentioned specific examples describes the Young's modulus E, the Poisson's ratio ν, and the depth of layer DOL regarding the above-mentioned ion exchanged alkali aluminosilicate glass vials, and in the first place, there are no specific examples showing that the inequality "$(CT^2 / E) \cdot (t - 2DOL) \cdot (1 - \nu) \geq 3.0$ MPa·μm" is satisfied. In addition, it can be said that "alkaline earth aluminosilicate glass vials described in the specification of U.S. Patent Application No. 13/660,450" comprise a glass composition "comprising from about 67 mol% to about 75 mol% of SiO_2; from about 6 mol% to about 10 mol% of Al_2O_3; from about 5 mol% to about 12 mol% of alkali oxide; and from about 9 mol% to about 15 mol% of alkaline earth oxide" ([0034]). However, from the glass composition, values of the Young's modulus E, the Poisson's ratio ν, and the depth of layer DOL are not unambiguously determined, and a person skilled in the art cannot recognize that the above-mentioned inequality is satisfied. Thus, it cannot be said that the above-mentioned ion exchanged alkali aluminosilicate glass vials are specific examples of the Invention. That is, specific examples

corresponding to the Invention cannot be found in the above-mentioned " representative embodiments". Therefore, from the " representative embodiments" of the detailed description of the invention, it cannot be recognized that the Invention is included in "the range within which a person skilled in the art can recognize that the problem of the Invention can be solved from the description of the detailed description of the invention."

(3) Description other than specific examples (Examples) described in the detailed description of the invention as well as common technical knowledge

Further, in light of the description of the detailed description of the invention other than the above-mentioned " representative embodiments", regarding the above matters specifying the Invention, it can be recognized that there are formal descriptions that "In some embodiments, the threshold central tension CT_{limit} is at least about 15 MPa, which is sufficient to cause a single crack to propagate without lateral branching." ([0026]), "For glass containers having a wall thickness in a range from about 0.5 mm to about 1.5 mm, the stored elastic energy SEE, in some embodiments, should be at least about 3.0 MPa·μm (i.e., $(CT^2 / E) \cdot (t - 2DOL) \cdot (1 - \nu) \geq 3.0$ MPa·μm) in order for cracks to self-propagate laterally through the container wall." ([0027]), and "[Table 1]

表１　亀裂進展レベルと、各レベルに関連する中心張力、積分中心張力、保存弾性エネルギー

レベル		CT (MPa)	ICT (MPa·μm)	SEE (MPa·μm)
1	亀裂進展、ある程度の遅れあり	15	15000	3.0
2	亀裂進展、遅れなし、または短時間の遅れ	30	30000	9.5
3	亀裂進展、分岐	45	42000	15.0

表１　亀裂進展レベルと、各レベルに関連する中心張力、積分中心張力、保存弾性エネルギー　Table 1　Levels of crack propagation and central tension, integrated central tension, and stored elastic energy associated with each level

レベル　Level

亀裂進展、ある程度の遅れあり　Crack propagation, some delayed

亀裂進展、遅れなし、または短時間の遅れ　Crack propagation, no delay or short delay
亀裂進展、分岐　Crack propagation, bifurcation

"

([0028]), etc. However, from such descriptions, even a person skilled in the art cannot predict performance and properties relating to the problem of the Invention, and thus cannot recognize that the problem can be solved.

In fact, Cited Document 1 (International Publication No. WO 2011/145661), which was cited in the examiner's decision of refusal issued on November 2, 2018 and was publicly known before the priority date of the present application, describes that regarding an ion exchanged aluminosilicate glass having a thickness of 1.0 mm ([0055], [0060], [Table 4] to [Table 11], etc.), a Young's modulus E, a Poisson's ratio σ, a surface compressive stress S, and a compressive stress layer depth t of the glass ([0055] to [0057], [0060], [0083], [Table 4] to [Table 11], etc.). When the central tension CT = (CS × DOL) / (t - 2DOL) and the stored elastic energy SEE = $(CT^2 / E) \times (t - 2DOL) \times (1 - \sigma)$ are calculated from these values, there exist Examples (e.g., Examples 1 to 3 in [Table 4]) which meet the requirements that the central tension CT is greater than 15 MPa and the stored elastic energy SEE is equal to or greater than 3.0 MPa·μm. However, although the ion exchanged aluminosilicate glasses in these Examples meet all of the requirement of "aluminosilicate glass having a thickness in a range from 0.5 mm to 1.5 mm", the requirement of a central tension being greater than or equal to 15 MPa, and the requirement of $(CT^2 / E) \cdot (t - 2DOL) \cdot (1 - \nu) \geq 3.0$MPa·μm, such ion exchanged aluminosilicate glass is a "glass for chemical tempering, which is less likely to have cracking resulting from flaws before chemical tempering treatment, latent scratches at the time of processing the glass and chipping, and which has a reduced possibility of spontaneous breakage resulting from the cracking which occurs when the obtainable chemically strengthened glass is used" ([0017]). Thus, it cannot be said that the ion exchanged aluminosilicate glass in the Examples of Cited Document 1 is a glass which can solve the above-mentioned problem of the Invention.

That is, it cannot be said that there existed the common technical knowledge before the priority date of the present application which is sufficient to enable us to recognize that if a central tension is greater than or equal to 15 MPa and $(CT^2 / E) \cdot (t - 2DOL) \cdot (1 - \nu) \geq 3.0$MPa·μm is satisfied, a crack self-propagates laterally through a container wall and the above-mentioned problem of the Invention can be solved.

Therefore, further taking into consideration the description other than the above-

mentioned " representative embodiments" of the detailed description of the invention as well as the common technical knowledge before the priority date of the present application, it cannot be recognized that the Invention is included in "the range within which a person skilled in the art can recognize that the problem of the Invention can be solved from the description of the detailed description of the invention."

(4) As examined in (2) and (3) above, "the range within which a person skilled in the art can recognize that the problem of the Invention can be solved from the description of the detailed description of the invention" does not include the Invention. Thus, it is clear that the "Description of the scope of claims " (The Invention) in No. 2 above does not exist within the range.

Therefore, in light of the procedure for determination in 1 above, it can only be said that the description of the scope of claims for patent of the present application does not comply with the support requirement.

5 Appellant's allegation

The Appellant alleges in the written opinion submitted on February 17, 2021 that the Invention solves the above-mentioned problem by including the requirement of "an aluminosilicate glass having a thickness in a range from 0.5 mm to 1.5 mm", the requirement of a central tension being greater than or equal to 15 MPa, and the requirement of $(CT^2 / E) \cdot (t - 2DOL) \cdot (1 - \nu) \geq 3.0MPa \cdot \mu m$, all of which were added by the Amendment.

However, as examined in 5 (2) and (3) above, even if the detailed description of the invention is examined in detail, it is obvious that no discussion has been made regarding $(CT^2 / E) \cdot (t - 2DOL) \cdot (1 - \nu)$ and that there is no evidence to support that those requirements solve the problem of the Invention. Therefore, the Appellant's allegation above cannot be accepted.

6 Summary as to the support requirement

As described above, the description of Claim 1 in the scope of claims for patent of the present application does not comply with Article 36(6)(i) of the Patent Act. Thus, the present application is not in compliance with the provisions stipulated in Article 36(6) of the Patent Act.

No. 5 Closing

As described above, the present application does not comply with the requirement

stipulated in Article 36(6)(i) of the Patent Act. Thus, without examining other matters, the present application falls under Article 49(4) and therefore should be rejected.

Therefore, the appeal decision shall be made as described in the conclusion.

June 29, 2021

Chief administrative judge: MIYAZAWA, Takayuki
Administrative judge: SUEMATSU, Yoshinori
Administrative judge: GOTO, Masahiro