HON. WILLIAM C. CONNER INN OF COURT

Three in One: Global Patent Trials

April 18, 2019

Japan Litigation

Judge
Takatoshi Monya

Chief Judge
Makiko Takabe

Judge
Kay Konishi

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Outline of Japan Mock Trial

Part I Introduction
Part II Infringement
1. Preface
2. Literal Infringement
3. Infringement by DOE
Part III Validity
1. Preface
2. Lack of Inventive Steps
Part IV Court's Preliminary Thoughts
Part V Examination of Damages (in case of infringement)
Part VI Judgment

Part I
Introduction

Object of Claim
by Plaintiff

[Injunction]

- The defendant shall not import, assign or offer to assign the product stated in the attached Product List.
- The defendant shall dispose of the product stated in the attached Product List.

[Damages]

- The defendant shall pay Plaintiff eight hundred eighty million (880,000,000) yen and delayed interests at an annual rate of 5% from the day after the complaint is served until the payment completion date.

[Other requests]

- The defendant shall bear the court costs.

Product List

Medication Infusion Device

Model # XYZ

Defendant's Answer

- All the Plaintiff's claims shall be dismissed.
- Litigation costs shall be borne by Plaintiff.

Part II
Infringement

1. Preface

Patent owned by the plaintiff

- The plaintiff owns the following patent:
  - Reg.#: **********
  - Name of the Invention: Medication Infusion Device
  - Application Date: April **, 2006
  - App.#: 2008-507***
  - Int. App.#: PCT/US2006/015***
  - Priority Date: April **, 2005
  - Reg. Date: August **, 2012

Decomposition of the Elements of the Invention

A medication infusion device comprising:

A) a housing adapted to be mounted to the body of a patient, said housing including a reservoir adapted for containing medication;

B) a pump within the housing adapted for directing medication from the reservoir to the blood stream of the patient;

C) an electronic receiver within the housing for receiving a signal from a remote control when the patient has ingested a meal;

D) a blood analysis module adapted for collecting a sample of blood from the blood stream of the patient and measuring the 1,5 AG level of the blood periodically no more often than once per day; and

Cont'd

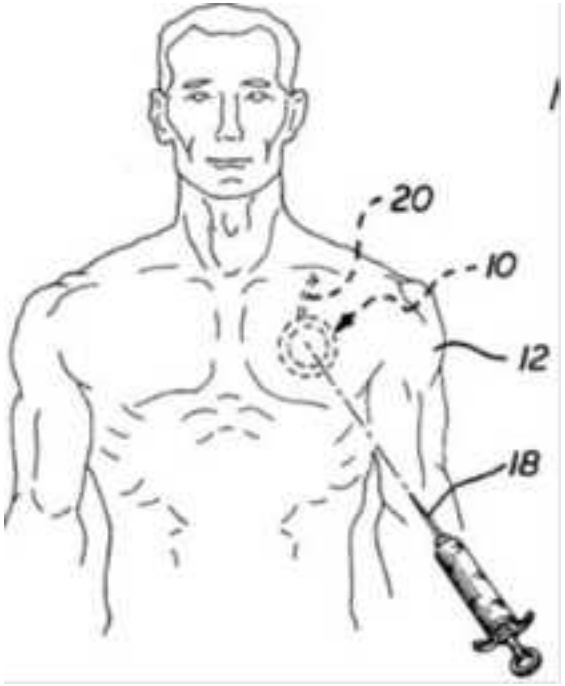
Decomposition of the Elements of the Invention

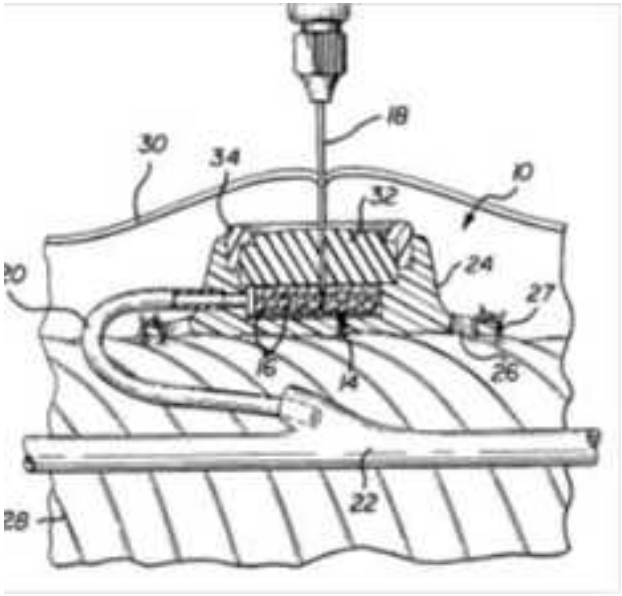
E) a computer processor that

(1) calculates an estimated mean post-meal maximum blood glucose level by means of a correlation function, such as Y= A + B/X, where A and B are constant numbers, X is the measured 1,5 AG value and Y is the estimated mean post-meal maximum blood glucose level and

(2) controls the operation of the pump, whereby the pump operation is adapted to direct medication to the blood stream of the patient after the processor determines the ingestion of a meal, the directed medication being sufficient to control the mean post-meal maximum blood glucose level to an acceptable level.

Drawings of the Patent Specification

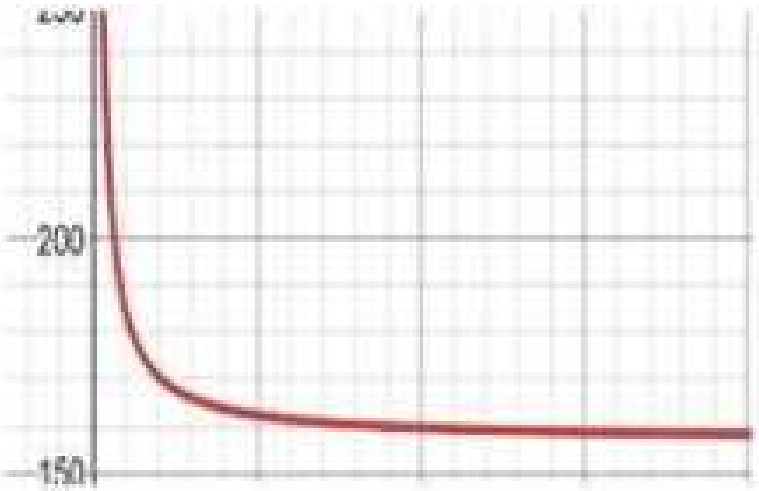




Correlation Function of the Claim 1

$$Y = A + B/X$$

$$A=156.91 \quad B=273.69$$

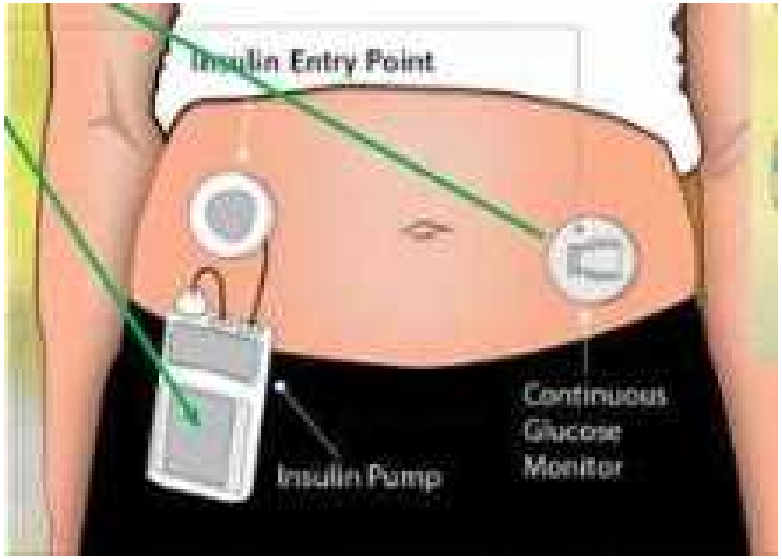


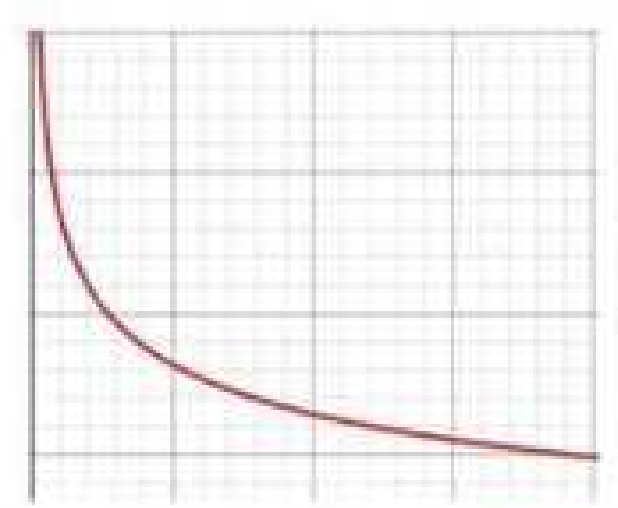
$$Y = 156.91 + \frac{273.69}{X}$$

The Accused Device

$$Y = A * X^{B}$$

A=297.15 B=-0.208





$$y = 297.15x^{-0.208}$$

Issues on Infringement

- Accused Device fulfills Elements A, B, D and E(2)
  - No disputes between the parties
- Issues:

  Whether the Accused Device fulfills
  - "an electronic receiver"("remote control") in Element C; and
  - "such as Y= A + B/X" in Element E(1).

Part II
Infringement

2. Literal infringement
2.1 Element C

Element C

- Claim
  - an electronic receiver within the housing for receiving a signal from a remote control when the patient has ingested a meal
- Accused Device
  - an electronic receiver within the housing for receiving a signal from a separate blood monitor which detects a surge in blood sugar that is interpreted as the consumption of a meal

Fulfillment of Element C

Argument by Plaintiff

- Interpretation of Element C
  - Claim language:
    - "An electronic receiver" receives a signal from "a remote control".
    - The remote control transmits a signal when the patient has ingested a meal.
    - No limitation in the claim that the remote control is operated by the patient.
  - Patent specification:
    - No description in the patent specification supporting such limitation.

Fulfillment of Element C

Argument by Plaintiff

- Feature of the Accused Device
  - The Accused Device has an electronic receiver in the housing receiving a signal from a separate blood monitor.
  - The separate blood monitor transmits a signal when it detects a surge in blood sugar.
  - A surge in blood sugar is interpreted as the consumption of a meal.
- Separate monitor = remote control
  - The separate blood monitor transmits a signal when the patient has ingested a meal.
  - Such separate blood monitor corresponds to a remote control of the patented invention.
- Conclusion
  - The Accused Device fulfills Element C.

1. Non-fulfillment of "an electronic receiver ... a remote control" (Element C)

(Defendant's Arguments)

- Claim construction:
  - "an electronic receiver" in Element C must "receive a signal from **a remote control** when the patient has ingested a meal"
    - If there is no electronic receiver that receives a signal from a remote control, no infringement.

1. Non-fulfillment of "an electronic receiver ... a remote control" (Element C), cont'd (Defendant's Arguments)

- Claim Construction, cont'd
  - "remote control" means a remote control device, which is activated by the patient and which sends a signal when the patient has ingested a meal.
    - An article "a" is put to "remote control" in the claim, and this suggests that "remote control" is a tangible device.
    - In dictionary, "remote control" has (i) a system for controlling something and (ii) a piece of equipment that you hold in your hand and use to control a television, DVD, etc.

1. Non-fulfillment of "an electronic receiver ... a remote control" (Element C), cont'd (Defendant's Arguments)

- Claim Construction, cont'd
  - In the claim language, a signal is sent when the patient has ingested a meal, using a remote control (i.e., a piece of equipment - see (ii) above) and from this limitation "a remote control" is supposed to be activated by the patient.
  - Plaintiff's assertion does not fit the term "a remote control," which is a piece of equipment activated by a user.

1. Non-fulfillment of "an electronic receiver ... a remote control" (Element C), cont'd (Defendant's Arguments)

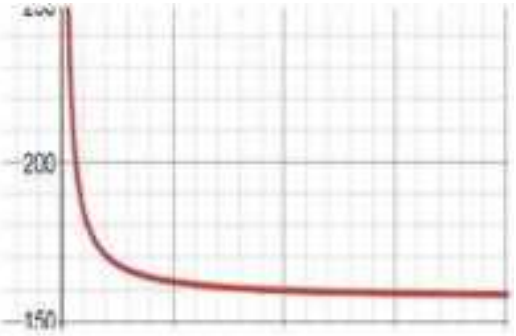
- Under Defendant's claim construction, a remote control equipment is necessary for fulfilling Element C.
- In the Accused Device, there is no remote control equipment.
  - "There is a separate blood monitor which detects a surge in blood sugar that is interpreted as the consumption of a meal. "
- Thus, the Accused Device does not fulfill Element C.

Part II
Infringement

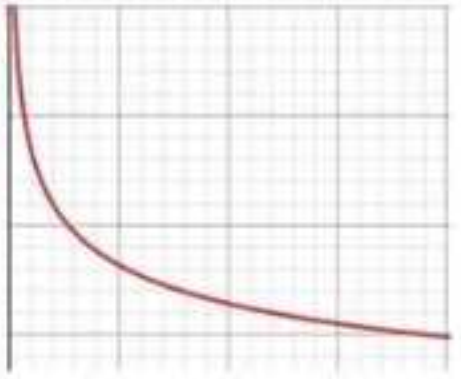
2. Literal infringement
2.2 Element E(1)

Element E(1)

- Claim
  - A computer processor calculates an estimated mean post-meal maximum blood glucose level by means of a correlation function, such as Y=A+B/X
- Accused Device
  - A computer processor calculates an estimated mean post-meal maximum blood glucose level by $Y=A*X^B$ [A=297.15, B=-0.208]



$$Y = 156.91 + \frac{273.69}{X}$$



$$y = 297.15x^{-0.208}$$

Fulfillment of Element E(1)

Argument by Plaintiff

- Interpretation of element E(1)
  - Claim language:
    - "such as"
    - Y=A+B/X is merely an example of function.
    - It is sufficient that a computer processor calculates an estimated mean post-meal maximum blood glucose level.
  - Patent specification:
    - The patent specification describes several functions to calculate an estimated mean post-meal maximum blood glucose level.
    - "such as" includes those functions

Fulfillment of Element E(1)

Argument by Plaintiff

- Feature of the Accused Device
  - The function used by the Accused Device:

    $Y=A*X^B$ [A=297.15, B-0.208]
  - Using the function, the computer processor in the Accused Device calculates an estimated mean post-meal maximum blood glucose level
  - The function is one of those illustrated in the specification
- Conclusion
  - The Accused Device fulfills element E(1).

2. Non-fulfillment of "such as Y=A+B/X" in Element E-1 (Defendant's Arguments)

- Claim construction:
  - "such as Y=A+B/X " in Element E-1 is limited to "Y=A+B/X" or functions having a correlation of R=0.68 or equivalent (at least R＞0.6)
    - Otherwise, the claim is too broad and lacks inventive step.
    - **In light of the prosecution history of the German counterpart patent, whereby the claim scope is limited to functions having correlation of R＞0.6, "such as" should be interpreted in this way.**

2. Non-fulfillment of "such as Y=A+B/X" in Element E-1, cont'd (Defendant's Arguments)

- In claim construction, the level of art among the persons skilled in the art, which is represented by the then current prior art and the common general knowledge, should be considered.

2. Non-fulfillment of "such as Y=A+B/X" in Element E-1, cont'd (Defendant's Arguments)

- It is **common general knowledge** that:
  - there is a certain correlation (i.e., significant negative correlation) between 1,5 AG value and estimated blood glucose level.
- It is **a matter of design variation** that:
  - the use of a computer processor in determining a proper amount of insulin to inject (i.e., bolus);
  - such determination is done with estimated blood glucose level, among others, mean post-meal maximum blood glucose level (rather than actually measured blood glucose level).

2. Non-fulfillment of "such as Y=A+B/X" in Element E-1, cont'd (Defendant's Arguments)

- Unless there is a high level of correlation between X (measured 1,5 AG value) and Y (estimated mean post-meal maximum blood glucose level), the function has no importance.
  - Otherwise, all practical uses of a law of nature, i.e., the correlation between 1,5AG and mean post-meal maximum blood glucose level would be monopolized by Plaintiff, a patentee.
- 0.68 correlation is critical.
  - Correlation shall be 0.6 or more.
  - **The prosecution history of the German counterpart patent also supports this interpretation.**

2. Non-fulfillment of "such as Y=A+B/X" in Element E-1, cont'd (Defendant's Arguments)

- In Accused Device, the computer calculates the estimated mean post-meal maximum blood glucose level by means of the function $Y= A * X^B$,
  - where A and B are constant numbers,
  - X is the measured 1,5 AG value and
  - Y is the estimated mean post-meal maximum blood glucose level.
  - The correlation of the actual value to the estimate with this function is R=0.56.
- Therefore, Accused Device does not fulfill "such as Y=A+B/X."

Part II
Infringement

3. Infringement by DOE
3.1 Element C

Doctrine of Equivalents

- Five requirements of DOE set by the Supreme Court
  1. Not essential
  2. Replaceable
  3. Easy to replace
  4. Not obvious
  5. Not estopped
- Burden of proof

  1, 2 and 3: Plaintiff (patentee)

  4 and 5: Defendant

Infringement by DOE / Element C

Argument by Plaintiff

- 1st Requirement of DOE – Not Essential
  - Essential part of the invention
    - Measuring 1,5AG value (element D)
    - Calculating an estimated mean post-meal maximum blood glucose level using the 1,5AG value (element E(1))
      - Note: the correlation function is not the essential part
    - Directing medication to the blood stream of the patient sufficient to control the mean post-meal maximum blood glucose level to an acceptable level (element E(2))
  - Not Essential
    - An electronic receiver for receiving a signal from a remote control when the patient has ingested a meal

Infringement by DOE / Element C

Argument by Plaintiff

- 2nd Requirement of DOE – Replaceable
  - Purpose of the invention
    - To detect post meal hyperglycemia and treat it
  - Function and effect of the invention
    - Measuring 1,5AG value
    - Calculating an estimated mean post-meal maximum blood glucose level using the 1,5AG value
    - Directing sufficient amount of medication to the blood stream of the patient
    - Thereby, controlling the mean post-meal maximum blood glucose level to an acceptable level

Infringement by DOE / Element C

Argument by Plaintiff

- 2nd Requirement of DOE – Replaceable
  - Accused Device
    - Accused Device does not have a remote control manually activated by the patient
    - Instead, Accused Device has a separate blood monitor which detects a surge in blood sugar.
    - A surge in blood sugar is interpreted as the consumption of a meal.
    - Even if the electronic receiver receives a signal transmitted by a blood monitor instead of a signal transmitted by a remote control manually activated by the patient, the processor may determine if the patient has ingested a meal from the signal.
    - Accordingly the purpose of the invention can be achieved by replacing the remote control with a separate blood monitor and an identical function and effect can be obtained.

Infringement by DOE / Element C

Argument by Plaintiff

- 3rd Requirement of DOE – Easy to Replace
  - It is well-known that blood sugar surges after meal.
  - A device that detects a surge in blood is widely used.
  - Accordingly, person having ordinary skill in the art could easily replace the remote control with a blood monitor which detects a surge in blood sugar.

Defendant's arguments regarding non-infringement by DOE (Element C)

- Non-fulfillment of the 1st Requirement [i.e., "a remote control" is tangible and is activated by a patient; these features are essential.]
  - In light of the purpose of the invention, as alleged by Plaintiff, "[t]o detect ***post meal*** hyperglycemia and treat it," to precisely detect a post meal status is important.
  - "a remote control" in the patented invention serves to back up the processor's calculation to improve the preciseness.
    - "This may ***require*** the patient to use the remote control to signal consumption of a meal if the processor cannot determine this occurrence." (FACTS, the 4th para.)
  - A separate blood monitor in the Accused Device is supposed to detect a surge in blood sugar; however, this cannot sufficiently back up.

Defendant's arguments regarding non-infringement by DOE (Element C), cont'd

- Non-fulfillment of the 2nd Requirement
  - The purpose of the invention is:
    - to provide patients with hyperglycemia a *proper* medication
      - by keeping the A1c under a certain level, e.g., 8%; and
      - by stabilizing their blood glucose lever after meal.

Defendant's arguments regarding non-infringement by DOE (Element C), cont'd

- In light of this purpose, a remote control must be activated or inactivated by a patient.
  - In other words, without a remote control activated by a patient, the post meal status cannot be detected precisely.
- The purpose of the invention *cannot* be achieved by replacing the remote control with a separate blood monitor, and an identical function and effect *cannot* be obtained.
  - "This may ***require*** the patient to use the remote control to cause the pump to infuse the medication if the processor cannot determine when a meal has been consumed" (FACTS, the 4th para.)

Defendant's arguments regarding non-infringement by DOE (Element C), cont'd

- Non-fulfillment of the 3rd Requirement
  - Defendant does not dispute the fulfillment of this requirement.
    - Plaintiff's argument on this requirement(*) contains admission of the patent invalidity - the lack of inventive step.
      - *(*) It is well-known that blood sugar surges after meal.*
      - *(*) A device that detects a surge in blood is widely used.*

Part II
Infringement

3. Infringement by DOE
3.2 Element E(1)

Infringement by DOE / Element E(1)

Argument by Plaintiff

- 1st Requirement of DOE – Not Essential
  - Essential part of the invention
    - Measuring 1,5AG value (element D)
    - Calculating an estimated mean post-meal maximum blood glucose level using the 1,5AG value (element E(1))
    - Directing medication to the blood stream of the patient sufficient to control the mean post-meal maximum blood glucose level to an acceptable level
  - Not Essential
    - The function Y=A+B/X is NOT essential.
    - It is merely an example.

Infringement by DOE / Element E(1)

Argument by Plaintiff

- 2nd Requirement of DOE – Replaceable
  - Purpose of the invention
    - To detect post meal hyperglycemia and treat it
  - Function and effect of the invention
    - Measuring 1,5AG value
    - Calculating an estimated mean post-meal maximum blood glucose level using the 1,5AG value
    - Directing sufficient amount of medication to the blood stream of the patient
    - Thereby, controlling the mean post-meal maximum blood glucose level to an acceptable level

Infringement by DOE / Element E(1)

Argument by Plaintiff

- 2nd Requirement of DOE – Replaceable
  - Accused Device
    - The function used by Accused Device is $Y=A*X^B$ [A=297.15, B=-0.208]
    - The correlation of the actual value to the estimate with the functions;
      - Invention: R=0.68
      - Accused Device: R=0.56
    - The functions are both sufficiently high to clinically use to detect post meal hyperglycemia and treat it.

Infringement by DOE / Element E(1)

Argument by Plaintiff

- 3rd Requirement of DOE – Easy to Replace
  - The claim recites an example of function, namely Y=A+B/X.
  - It is common general knowledge that there is a certain correlation between 1,5 AG value and estimated blood glucose level.
  - The higher blood glucose level is, the lower 1,5AG level is.
  - Accordingly, person having ordinary skill in the art could easily replace the function Y=A+B/X with $Y=A*X^B$.

Defendant's arguments regarding non-infringement by DOE regarding Element E(1)

- The specific function Y=A+B/X, as recited in the claim, is essential.
  - It is common general knowledge that
    - there is a certain correlation between 1,5 AG value and estimated blood glucose level.
  - Unless there is a high level of correlation between X (measured 1,5 AG value) and Y (estimated mean post-meal maximum blood glucose level), the function has no importance.

Defendant's arguments regarding non-infringement by DOE regarding Element E(1), cont'd

- The function Y=A+B/X with correlation of R=-0.68 is essential.
- Therefore, the substitution of this element bars a DOE infringement from being established.

Part III
Invalidity
1. Preface

Invalidity Defense (Defendant's Arguments)

- Lack of Inventive Step

- [Lack of Patent Eligibility]
  - does not seem to stand under Japanese law and practice (see the next slide)

[Patent Eligibility]

- Statutory “invention” shall be “a creation of technical idea utilizing a law of nature” (Japan Patent Act, Art.2(1))
- JPO Examination Guidelines give both lists of eligible and non-eligible subject matters
- Patent eligibility is “as a whole” question
- No prior art reference is considered in eligibility test

[Patent Eligibility]

- List of eligible subject matters, eligible if:
  - (1) claimed invention concretely performs control of a physical equipment; or
  - (2) claimed invention concretely performs information processing based on the technical properties such as a physical, chemical, biological or electric properties of an object
- List on non-eligible subject matters, non-eligible, if:
  - (1) any laws other than a law of nature (e.g., economic laws);
  - (2) human-conceived rule (e.g., gaming rule);
  - (3) mathematical formula; or
  - (4) mental activities

Defendant's invalidity arguments

- Invalidation Defense [No. 1]: Lack of inventive step in view of Johnson in combination with the common general knowledge
  - Claim 1 of the Patent shall be invalidated under Article 29(2)(lack of inventive steps), and Plaintiff's enforcement is not permitted under Article 104-3 of the Japanese Patent Act.
  - Claim 1 of the Patent lacks inventive step in view of Johnson in combination with the common general knowledge (and design variation).

Similarity of the Problems to be Solved

(Defendant's Arguments)

The Patent

- The invention relates to a method to evaluate blood glucose excursions and postprandial hyperglycemia in diabetic patients.
- Improving treatment of diabetes properly controlling bolus of insulin and other possible medication.

Johnson

- The object of this invention relates to a medication infusion device that includes the capability of remotely controlled.
- Improving treatment of diabetes properly controlling bolus of insulin and other possible medication.

Comparison between Claim 1 and Johnson

Claim 1	Johnson
A) a housing adapted to be mounted to the body of a patient, said housing including a reservoir adapted for containing medication;	Disclosed. An external infusion device 10 (housing) includes reservoir 34 adapted for containing medication. - Such external infusion device can be mounted to the body.
B) a pump within the housing adapted for directing medication from the reservoir to the blood stream of the patient;	Disclosed. The external infusion device 10 is an external infusion pump.

Comparison between Claim 1 and Johnson

Claim 1	Johnson
C) an electronic receiver within the housing for receiving a signal from a remote control when the patient has ingested a meal,	Disclosed. the RF programmer 12 (remote control) will also provide the use with the ability to perform the following functions: deliver a bolus, suspend/restart the external infusion device... - "when the patient has ingested a meal" is suggested, since the patient is capable of choosing when to send signals in the above description.

Comparison between Claim 1 and Johnson, cont'd

Claim 1	Johnson
D) a blood analysis module adapted for collecting a sample of blood from the blood stream of the patient and measuring the 1,5 AG level of the periodically no more often than once per day; and	Partially disclosed. A glucose monitor and Bolus Estimator 14 (together "a blood analysis module"), which measure the blood glucose (BG) level and suggest a bolus (the infusion amount), are disclosed. - The remainder (the 1,5 AG level of the blood periodically no more often than once per day) is undisclosed.

Comparison between Claim 1 and Johnson, cont'd

Claim 1	Johnson
E) a computer processor that (1) calculates an estimated mean post-meal maximum blood glucose level by means of a correlation function, such as Y=A+B/X, where A and B are constant numbers, X is the measured 1,5 AG value and Y is the estimated mean post-meal maximum blood glucose level and	Partially disclosed. A processor 18 is disclosed. - The remainder is undisclosed. (*)
(2) controls the operation of the pump, whereby the pump operation is adapted to direct medication to the blood stream of the patient after the processor determines the ingestion of a meal, the directed medication being sufficient to control the mean post-meal maximum blood glucose level to an acceptable level.	Partially disclosed. The processor 18 controls the operation of the pump, whereby the pump operation is adapted to direct medication to the blood stream of the patient . - The remainder is undisclosed. (*)

(*) In the problem, this is described as "the abstract concept of controlling the pump based on calculation of an estimated mean post-meal maximum blood glucose level by means of software."

Finding of the identical elements and differing elements (Defendant's Arguments)

- identical elements
  - A) a housing adapted to be mounted to the body of a patient, said housing including a reservoir adapted for containing medication;
  - B) a pump within the housing adapted for directing medication from the reservoir to the blood stream of the patient;
  - C) an electronic receiver within the housing for receiving a signal from a remote control
  - D) a blood analysis module adapted for collecting a sample of blood from the blood stream of the patient and measuring the blood glucose-related level; and

Finding of the identical elements and differing elements, cont'd

- identical elements, cont'd
  - E) a computer processor that [(2)] controls the operation of the pump, whereby the pump operation is adapted to direct medication to the blood stream of the patient after the processor determines the ingestion of a meal, the directed medication being sufficient to control the blood glucose level to an acceptable level.

Finding of the identical elements and differing element, cont'd

- differing elements
  - Regarding Element C, a signal is sent from a remote control when the patient has ingested a meal.
  - Regarding Element D, the level to be measured is the 1,5 AG level of the blood.

Finding of the identical elements and differing element, cont'd

- differing elements, cont'd
  - Regarding Element E(1), a processor calculates an estimated mean post-meal maximum blood glucose level by means of a correlation function, such as Y=A+B/X, where A and B are constant numbers, X is the measured 1,5 AG value and Y is the estimated mean post-meal maximum blood glucose level and
  - Regarding Element E(2), the glucose level is controlled with the mean post-meal maximum blood glucose level.

Common General Knowledge

- In Japanese practice, a patent can be invalidated due to the lack of inventive steps in view of a main prior art in combination with a common general knowledge, which fills the gap between the present invention and the main prior art. (e.g., IP High Court May 14, 2018(Gyo-ke No. 2017-10087))

A matter of design variation(*Sekkei-jiko*)

- If a differing element is a matter of design variation for a person skilled in the art, such element does not establish inventive step. (See Examination Guideline, Part III, Chapter II, 2, Section 2, 3.1.2(1). e.g., IP High Court February 26, 2009 (Gyo-ke No. 2008-10162))

Common General Knowledge and Design Variation in this case

- It is common general knowledge that
  - there is a certain correlation between 1,5 AG value and estimated blood glucose level.
- It is a matter of design variation that:
  - the use of a computer processor in determining a proper amount of insulin to inject (i.e., bolus); and
  - such determination is done with estimated blood glucose level, among others, mean post-meal maximum blood glucose level (rather than actually measured blood glucose level).

Counter Argument to Invalidity Defense

Argument by Plaintiff

- Comparison with Johnson

	Defendant	Plaintiff
A	Disclosed	Agree
B	Disclosed	Agree
C	Disclosed	Agree
D	Partially disclosed	Disagree/Not disclosed
E(1)	Partially disclosed	Agree
E(2)	Partially disclosed	Agree

- Claim 1 of the Patent does NOT lack inventive step

Comparison between Claim 1 and Johnson

Argument by Plaintiff

Claim 1	Johnson
D) a blood analysis module adapted for collecting a sample of blood from the blood stream of the patient and measuring the 1,5 AG level of the blood periodically no more often than once per day; and	NOT disclosed - There is no blood analysis module that periodically measures the 1,5 AG level of the blood. - The glucose monitor in Johnson provides the current glucose reading.
E) a computer processor that (1) calculates an estimated mean post-meal maximum blood glucose level by means of a correlation function, such as Y=A+B/X, where A and B are constant numbers, X is the measured 1,5 AG value and Y is the estimated mean post-meal maximum blood glucose level and	Partially disclosed. - A processor 18 is disclosed. - But, it does not calculate an estimated mean post-meal maximum blood glucose level.

Inventive Step

Argument by Plaintiff

- No motivation to replace the glucose monitor in Johnson with a 1,5 AG level monitor
  - The glucose monitor in Johnson provides the current glucose readings.
  - It is cumbersome to measure the 1,5 AG and calculate the mean post-meal maximum blood glucose level instead of measuring glucose level directly.
  - Johnson and other prior arts do not disclose the mean post-meal maximum blood glucose level
  - There is no blood analysis module to be mounted to the body of the patient which measures the 1,5 AG level of the blood periodically.

Inventive Step
Argument by Plaintiff

- Conclusion
  - A person skilled in the art could not have replaced the glucose monitor proving the current glucose readings with a 1,5 AG level monitor and a computer processor calculating an estimated mean post-meal maximum blood glucose level using the 1,5 AG level.

Part IV
Court's Preliminary Thoughts

Court's Preliminary Thoughts

- Issue on Infringement
  - Literal Infringement
    - Element C / Element E (1)
  - Infringement by DOE
    - Element C / Element E (1)
- Issue on Invalidity
  - Lack of Inventive Step

Part V
Damages

Damages

- Tort (Civil code 709)
  1. Violation/infringement on someone's rights/interests
  2. Value of Damage
  3. Causation between the infringement and the damage
     - Special provision for 2 and 3 in Patent Act (see the next slide)
  4. Intention or negligence
     - Negligence is presumed under Article 103 of the Patent Act.

- Punitive damages is NOT allowed!

Damages

- Article 102 of the Patent Act - Presumption of the Value of Damage
  - Paragraph 1: Plaintiff's profit

    [Plaintiff's profit per unit] * [number of units defendant sold]
  - Paragraph 2: Defendant's profit basis
  - Paragraph 3: Royalty basis

Damages
Argument by Plaintiff

- Damages requested by the Plaintiff:

880,000,000 JPY

(about 8 M USD)

Damages
Argument by Plaintiff

- Reasons
  - Start of the Defendant's business: April 11, 2013
  - Filing date of the complaint: April 10, 2018
  - Estimated sales volume and turnover are:
    - Annual sales volume: 2,000 Units
    - Total sales volume: 10,000 Units
    - Price per unit: 200,000 JPY (1,800 USD)
    - Total turnover: 2,000,000,000 JPY (18,000,000 USD)

Damages

Argument by Plaintiff

- Defendant's Profit Rate: at least 40%
- Defendant's Profit: 2 billion JPY * 40%

  800 million JPY (7.2 M USD)
- Plaintiff's damage is presumed to 800 M JPY Under Article 102 Paragraph 2.
- Attorney's fee:

  80 million JPY = 10% of the damage above

Damages
Argument by Plaintiff

- Conclusion
  - The Plaintiff suffered 880 M JPY by the infringement of the Defendant.

Damage Calculation by a Court-Appointed Expert

- Upon a request by a party (typically Plaintiff, patentee), the court appoint a neutral expert (e.g., certified accountant) so that she/he reviews Defendant's accounting documents and calculate the amount of damages for patent infringement.
  - In this case, upon Plaintiff's request, Plaintiff appointed a certified accountant as neutral expert.
- A report of the Court-Appointed Expert is scheduled to be submitted within 2 months - on October XX, 2018.

Examination of Damages

2 months later…

- A report of the court-appointed expert was submitted on October XX, 2018, as scheduled.
- The Court reviewed the report and determine the amount of damages.
- The Court set a final hearing date on March XX, 2019.
- The date for the delivery of a judgement is scheduled for April 18, 2019 at 10:15am.

Part VI
Judgment

Judgment - Issues

- Issue on Infringement
  - Literal Infringement

    [Please also see Referential Slide Nos. [84-85] for claim construction]

    - Element C / Element E (1)
  - Infringement by DOE

    [Please also see Referential Slide Nos. [89-90] for "Essential Part " of DOE]

    - Element C / Element E (1)
- Issue on Invalidity
  - Lack of Inventive Step
- Damages
  - Paragraph 2 of Article 102: Defendant's profit base

Referential Slides
For Better Understanding of the Judgment

A) Claim Construction (Art. 70 of the Japanese Patent Act)

B) Supreme Ct. decision in Ball Spline Case (Feb. 24, 1998)
- 5 requirements for Doctrine of Equivalents

C） IP High Ct. (Grand Panel) decision in Maxacalsitol Case (March 25, 2016)
- The burden of proof for DOE
- Finding of the Essential Part in DOE

D) Supreme Ct. decision in Maxacalsitol Case (March 24, 2017)
- Finding of Special Circumstances (among others, intentional exclusion)

A) Claim Construction

- Art. 70(1) of the Patent Act

"the technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application."

- Art. 70(2) of the Patent Act

"the meaning of each term used in the scope of claims shall be interpreted in consideration of the statements in the description and drawings attached to the application."

Claim Construction, cont'd

- The technical level of a person skilled in the art as of the filing or an ordinary meaning defined in the dictionary may also be taken into consideration for claim interpretation.

B) Ball Spline Case (Feb. 24, 1998)

- Five requirements held by the Supreme Ct.

  (1) the different part is not the essential part of the patented invention;

  (2) the purpose of the patented invention can be achieved, and the same function and effect can be produced, even if said part is substituted with a corresponding part of the Subject Product, etc.;

  (3) a person ordinarily skilled in the art could have easily conceived of the aforementioned substitution as of the time when the Subject Product, etc. was manufactured, etc.;

Ball Spline Case (Feb. 24, 1998), cont'd

(4) the Subject Product, etc. is neither identical with publicly known nor could have been easily conceived of by a person ordinarily skilled in the art based on said publicly known art, as of said filing date; and

(5) there are no special circumstances, such as where the Subject Product, etc. was intentionally excluded from the claims during the patent prosecution.

C) IP High Court Decision in Maxacalsitol Case (March 25, 2016)

1. The burden of proof

The patentee has the burden of allegation and proof for the 1st through the 3rd requirements,

while the accused infringer has that for the 4th and 5th requirements.

IP High Court Decision (March 25, 2016), cont'd

2. Finding of the "Essential Part"

– The essential part of a patented invention in the first requirement means
  - a characteristic part
    – which is written in the claims;
    – which constitutes a unique technical idea; and
    – which is not seen in prior art; and

IP High Court Decision (March 25, 2016), cont'd

2. Finding of the "Essential Part", cont'd

– the aforementioned essential part should be found:

- by first grasping
  - – the problem to be solved
  - – means for solving the problem and
  - – its effect

  of the patented invention [called "the solving principle" in Japanese academia]

  based on the claims and the specification,
- and then determining such "essential" part.

D) Supreme Court Decision in Maxacalsitol Case (March 24, 2017)

- The patent applicant's failure to state the substituted structure in a patent claim, even though it is easily conceivable at the time of filing, cannot be considered as "intentional exclusion (special circumstance)" that bars a DOE infringement.

Supreme Court Decision (March 24, 2017), cont'd

- However, if the applicant is objectively and externally deemed as:
  - (i) having recognized a structure that is outside the scope of claims as a replacement of an element of the patent claim, and
  - (ii) **indicating** that she/he **dare [consciously] not** refer to such structure in the patent claim,

  --> the structure should be found intentionally excluded (i.e., there is a "special circumstances" barring DOE).

Thank you!

Hon. William C. Conner Inn of Court

Three in One: Global Patent Trials

- Japan Team
  - Honorable Makiko Takabe, Chief Judge, the Intellectual Property High Court
  - Dr. Shoichi Okuyama, Okuyama & Sasajima
  - Kay Konishi, Konishi & Nagaoka
  - Takatoshi Monya, Nishimura & Asahi
  - Akira Watanabe, Nakamura & Partners
  - Yoshikazu Iwase, Anderson Mori & Tomotsune

Judgment – Main Text

1. The defendant shall not import, assign or offer to assign the product stated in the attached Product List.
2. The defendant shall dispose of the product stated in the attached Product List.
3. The defendant shall pay Plaintiff five hundred thirty million (530,000,000) yen and delayed interests at an annual rate of 5% from April 18, 2018 until the payment completion date.
4. The rest of the plaintiff's claims shall be dismissed.
5. The plaintiff shall bear one-fourth of the court costs while the defendant shall bear the remaining costs.

Ⅰ Issue on Infringement

1 Literal Infringement

- Claim Construction
  - According to the Patent Act of Japan, the technical scope of a patented invention shall be determined based upon the claim terms. In addition, the patent specifications can be considered in order to interpret the meaning of the claim terms.
  - The technical level of a person skilled in the art as of the filing or an ordinary meaning defined in the dictionary may also be taken into consideration for claim interpretation.

Ⅰ Issue on Infringement, cont'd

(1) Element C

– "remote control" means “manually activated to transmit a signal by the patient”

- by consulting the dictionary for the meaning of the term “remote control”, it is recognized that “remote control” ordinarily means (i) a system for controlling something and (ii) a piece of equipment that you hold in your hand and use to control a television, etc.
- taking into account that only the patient actually know whether he/she has completed a meal

Ⅰ Issue on Infringement, cont'd

– Since “a separate blood monitor” in the Defendant product is implanted in the body of the patient and cannot be manually activated by the patient in order to transmit a signal to “an electronic receiver”, it does not correspond to “a remote control” of Element C.

⇒The Accused Device does not fulfill Element C.

Ⅰ Issue on Infringement, cont'd

(2) Element E(1)

– The meaning of "such as Y=A+B/X" in Element E(1)

- considering the meaning of the term “such as”, a person ordinary skilled in the art as of the filing understands that “Y=A+B/X” is merely an example of the correlation function for calculating an estimated mean post-meal maximum blood glucose level (Y) from the measured 1,5AG level of the blood (X).
- It is supported that the patent specification describes the other several correlation functions to be used to calculate for the same purpose.

Ⅰ Issue on Infringement, cont'd

– Since the correlation function “$Y=A*X^B$ [A=297.15,B-0.208]” of the Accused Device can be used for the purpose of calculating an estimated mean post-meal maximum blood glucose level and is one of the embodiments described in the specification, it fulfills "such as Y=A+B/X" in Element E(1).

⇒The Accused Device fulfills Element E(1).

➡The Accused Device does not literally infringe the Plaintiff’s Patent.

Ⅰ Issue on Infringement, cont'd
(Doctrine of Equivalents)

2 Infringement by Doctrine of Equivalents

(1) the 1st requirement (non-essential part)

– the essential part of the Patented Invention is recognized as follows:

- Measuring 1,5AG value (element D)
- Calculating an estimated mean post-meal maximum blood glucose level using the 1,5AG value (element E(1))
- Directing medication to the blood stream of the patient sufficient to control the mean post-meal maximum blood glucose level to an acceptable level (element E(2)).

Ⅰ Issue on Infringement, cont'd (Doctrine of Equivalents)

– The Accused Device is deemed to have the characteristic part which constitutes a unique technical idea that is not seen in prior art in the statements in the scope of claims of the Patented Invention.

  • On the other hand, “a separate blood monitor” which is not “manually activated to transmit a signal by the patient” in the Accused Device is not the essential part of the Patented Invention.

⇒The Accused Device is recognized as fulfilling the 1st Requirement of DOE.

Ⅰ Issue on Infringement, cont'd
(Doctrine of Equivalents)

(2) the 2nd requirement

– The purpose of the Patented Invention is recognized to detect post-meal hyperglycemia and treat it, and the function and effect of the Patented Invention is deemed as follows:

- measuring 1,5AG value;
- calculating an estimated mean post-meal maximum blood glucose level using the 1,5AG value;
- directing sufficient amount of medication to the blood stream of the patient;
- thereby, controlling the mean post-meal maximum blood glucose level to an acceptable level.

Ⅰ Issue on Infringement, cont'd
(Doctrine of Equivalents)

– Since “a separate blood monitor” in the Accused Device detects “a surge” in blood sugar and “the surge” is deemed to be indicating that the patient has ingested a meal.

– Accordingly the purpose of the Patented Invention can be achieved by replacing “a remote control” with “a separate blood monitor” and an identical function and effect can be obtained.

⇒The Accused Device is recognized as fulfilling the 2nd Requirement of DOE.

Ⅰ Issue on Infringement, cont'd
(Doctrine of Equivalents)

(3) There is no dispute on the 3rd requirement of DOE (easiness of replacement).

(4)The Defendant does not assert on the 4th requirement and the 5th requirement of DOE for which a person who denies the application of DOE has the burden of allegation and proof.

➡The Accused Device infringes the Plaintiff's Patent by DOE and falls within the technical scope of the patented invention.

Ⅱ Issue on Invalidity (Inventive Steps)

1 Standard for Inventive Step

– To determine whether invention easily conceivable based on a prior art,

(i) motivation to overcome the difference to arrive at the present invention,

– Burden of proof for (i) --> Defendant

(ii) obstructive factor or advantageous effects over the prior art.

– Burden of proof for (ii) --> Patent holder

Ⅱ Issue on Invalidity (Inventive Steps), cont'd

2 Analysis of the Differences

(1)Regarding Element D

- The blood analysis module in the patented invention measures 1,5 AG level of the blood and the measurement is performed periodically, no more than once per day.
- On the other hand, the glucose monitor in the cited invention measures “blood glucose level” and *Johnson* does not disclose the timing of the measurement.
- Therefore, they are different in the substance to be measured and timing of the measurement.

Ⅱ Issue on Invalidity
(Inventive Steps), cont'd

(2)Regarding Element E

– there is no dispute in that, while both the patented invention and the cited invention include “a computer processor”, the processor of the cited invention does not function or operate as is stated in E(1) and E(2).

Ⅱ Issue on Invalidity (Inventive Steps), cont'd

3 [Discussions]

(1)For the Difference concerning Element D,

- it is recognized that the measurement of 1,5 AG level of the blood had only been performed for research purposes and it is not found in common general knowledge that the measurement of 1,5 AG level of the blood could have been performed automatically with a portable device at the time of the filing (Priority date).

(2)For the Difference concerning Element E

- any of the documents cited does not disclose such medication infusion devise which is capable of calculating the amount of medication to be infused with the obtained 1,5 AG level.

➡Defendant's invalidity defense on the grounds of lack of inventive step is not established.

Ⅲ Issue on Damages

- The court found that
  - the Plaintiff's damage is found to be presumed to be 480 million JPY based on Article 102(2)
    - the marginal profit per unit is 60 thousands JPY
    - the total sales volume of the Defendant product during five years is 8 thousands.

    —The written opinion of the court-appointed expert
  - the attorney's fee is found to be 50 million JPY

➡amount 530 million JPY

Ⅳ Conclusion

– that the Plaintiff's claim seeking an injunction against the import, assignment, etc. of the Accused Devices and disposal thereof is reasonable.

– that the Plaintiff's claim seeking the payment of damage is reasonable as far as seeking the payment of 530 million JPY.