EXHIBIT 1010

Japanese Patent office
Trial Board
Written Appeal Decision

5. Patented Invention 1 [Claim 1]

(5-1) Comparison between Patented Invention 1 of this case and the invention of the Exhibit 1 by Party A

(a)[Surgery [(b) [excitation light, [(c) an excitation light source mounted on a halogen lamp with a bandpass filter, [(d) [excorporeal, [(e) [near-infrared fluorescence excitation light from the pigment that is generated by excitation light, [(f) [a CCD camera having a TV lens mounted thereon with a sharp-cut filter for selecting only the fluorescence from the pigment, [(g) [imaging, [(h) [near-infrared fluorescence image, [and (i) [near-infrared fluorescence excitation light] in the invention of Exhibit 1 by Party A

Correspond to

(a) [surgery (b) [a first radiation that excites a fluorescent pigment, [(c) [an irradiation means, [(d) [externally to the patient body, [(e) [a second radiation emitted by the fluorescent pigment, [(f) [camera, (g) [visualizing, [(h) [contrast image, [and (i) [a radiation outside the visible spectrum] respectively, in Patented Invention 1 of this case.

Also, [the flow of an in vivo liquid medium (such as blood or spinal fluid) [in the invention of Exhibit 1 by Party A and [blood flow [in Patented Invention 1 of this case are shared in that they both are [a flow of an in vivo liquid medium]

Also, [a near-infrared fluorescence tracer comprising a complex (ICG-HDL) of indocyanine green (ICG) of a near-infrared area fluorescence pigment and human high density lipoprotein (HDL)] in the invention of Exhibit 1 by Party A and [ICG [in Patented Invention 1 of this case are shared in that they both are [an infrared fluorescence tracer being carried in the flow of an in vivo liquid medium]

Further, in the invention of Exhibit 1 by Party A. the detection is carried out after exposure for a predetermined time by a CCD camera and the signal from the CCD camera is subjected to data-processing with an image-processing device to achieve imaging; and in Patented Invention 1 of the case, the contrast image of the coronary artery bypass is obtained at a rate of at least 15 images per second. They both are shared in that the contrast images of the target to be observed are obtained at a predetermined rate.

Still further, by [wave front[in Patented Invention 1 of this case, Patented Invention 1 of the case defines it as [visualizing the movement of a fluorescent pigment being carried in the blood flow in a coronary artery bypass graft]. In addition, at [0071] of the Patent Specification of this case, there is described [The saline was used to flush in the line and to ensure passage of a complete a bolus through the femoral vasculature, producing a sharp wave front]. Judging from the fact that the wave front is formed as a result of the passage of a bolus, the [wave front]in Patented

area being between the blood containing ICG and the blood containing no ICG]. On the other hand, in the invention of Exhibit 1 by Party A, the time-dependent observation is targeted at the location of and a change in concentration of the near-infrared fluorescent tracer that is moving in the living body by virtue of the flow of the in vivo liquid medium (such as blood or spinal fluid). While infrared fluorescence is emitted from the area of the in vivo liquid medium containing the infrared fluorescence tracer, the infrared fluorescence is not emitted from the area of the in vivo liquid medium not containing the infrared fluorescence tracer. It is thus understood that these situations of radiations will be visualized. And at the time, in order for the location and concentration change of the near-infrared fluorescence tracer to be observed in a time-dependent manner, it is evident that the observation is made on a boundary area moving with time, said boundary area being between the in vivo liquid medium that contains ICG and the in vivo liquid medium that does not contain ICG. Therefore, commonality exists between [observing the location of and a change in concentration of the near-infrared fluorescent tracer that is moving in the living body by virtue of the flow of the in vivo liquid medium (such as blood or spinal fluid) in a time-dependent manner [in the invention of Exhibit 1 by Party A and [the wave front formed by the blood containing ICG is visualized [in Patented Invention of this case, in regard to [visualizing the wave front formed by the flow of an in vivo liquid medium containing a near-infrared fluorescence tracer]

Thus, it is acknowledged that both correspond to each other with respect to:
[A device for visualizing the flow of a near-infrared fluorescence tracer being carried in the flow of an in vivo liquid medium during surgery, the device comprising:
an irradiation means for emitting a first radiation that excites the tracer; and
a camera for detecting a second radiation emitted by the tracer, to obtain a contrast image;
wherein the irradiation means and the camera are located externally to the patient body; the wavelengths of the first and second radiations are within the band regions of excitation and emission spectra for use with the tracer; and the camera is capable of visualizing as a viewable image the radiation outside the visible spectrum and obtains the contrast image of the target of observation at a predetermined imaging rate, whereby a wave front formed by the flow of the in vivo liquid medium containing the tracer is visualized];

but that they differ from each other with respect to the points below.

(Difference point 1)
While the tracer in the flow of the in vivo liquid medium in Patented Invention 1 of this case is ICG, it is an ICG-HDL complex in the invention of Exhibit 1 by Party A.

(Difference point 2)
In Patented Invention 1 of this case, the flow of the in vivo liquid medium in which the tracer moves by being carried is a blood flow in a coronary artery bypass graft. On the other hand, the blood flow in the coronary artery bypass graft is not described in Exhibit 1 by Party A although blood is illustrated as the in vivo liquid medium.

(Difference point 3)

With respect to the predetermined imaging rate at which the contrast images of the target of observation are obtained, contrast images are obtained at a rate of at least 15 images per second in Patented Invention 1 of this case. On the other hand, acquisition of contrast images at a rate of [at least 15 images per second is not described although exposure times of one second and eight seconds are illustrated in the invention of Exhibit 1 by Party A.

(5-2) **Judgment on Patented Invention 1 of this case by this Board**

The aforementioned difference points will be studied.

(Concerning the difference point 1)

It is a well-known technology that a fluorescence imaging device using ICG as the near-infrared fluorescence tracer is used to carry out angiography (see the technologies of Exhibit 1 by Party A and 6 by Party A). On the other hand, as to the Exhibit 1 by Party A in addition to disclosing that ICG-HDL complex is used as a near infrared ray fluorescent tracer to eliminate the restriction of the optimum site which is limited in angiography using ICG single body, since it cannot be affirmed that the excorporeal fluorescence imaging device described in Exhibit 1 by Party A has a one and inseparable configuration with ICG-HDL which cannot detect anything other than the infrared rays from the ICG-HDL, it is obvious to the person skilled in the art, who has been exposed to the invention of the Exhibit 1 by Party A that either of ICG or ICG-HDL is arbitrarily used as the infrared fluorescence tracer at the site of application which has thus far been unrestricted. Therefore, as to the angiography to which ICG has conventionally been applicable, ICG, which is well known in fluorescence imaging devices, may be employed instead of the ICG-HDL complex as the infrared fluorescence tracer in the invention of Exhibit 1 by Party A : it is merely a design matter that the person skilled in the art can appropriately perform.

(Concerning Difference points 2 and 3)

Judging from the fact that the invention of Exhibit 1 by Party A is an excorporeal fluorescence imaging device for use during surgery, it is evident that the invention places into the visual field the views of the surgery that, as the target for which the excorporeal fluorescence imaging device is used, whose observation is made on the flow of a fluorescent pigment being carried in an in vivo liquid medium.

Further, during coronary artery bypass surgery, that the surgery during which the flow of a fluorescent pigment being carried in a blood flow in a coronary artery bypass graft is observed (i.e., during the coronary artery bypass surgery) is well known (see the technologies of Exhibit 1 by Party A and 7 by Party A and 8 by Party A8). In addition, the Exhibit 1 by Party A illustrates a flow of blood as the flow of an in vivo liquid medium in which the tracer moves, and also describes angiography using the ICG single entity as the prior art at [0007] and [0041). Furthermore, as stated as described above, if it is based on the design matter by the person skilled in the art as to which of the ICG-HDL complex or the well-

easily conceive that the surgery for which the invention of Exhibit 1 by Party A is applied is decided to be the aforementioned well-known surgery during which the flow of the fluorescent pigment being carried in the blood flow in the coronary artery bypass is observed, and that the well-known ICG is used as the tracer so that the flow of the fluorescent pigment being carried in the blood flow in the coronary artery bypass may be observed.

Then, at the time, when fluorescence imaging is conducted on a target that is different from that in the embodiment described in Exhibit 1 by Party A, the device will be used under observation conditions that correspond to the target in question, which is merely a matter that the person skilled in the art appropriately selects. If based on the three points below, the person skilled in the art can appropriately achieve to adjust the working speed to a rate of at least 15 images per second at which the contrast images of the coronary artery bypass are acquired.

(1) It is a well-known technology that in a fluorescence imaging device for visualizing fluorescence from ICG in a blood flow, a boundary area moving with time, said boundary area between the blood containing ICG and the blood containing no ICG is acquired as images at a rate of at least 15 pieces per second (see the technologies of Exhibit 5 by Party A Party A and 6 by Party A)

(2) A CCD camera C2400-75i (manufactured by Hamamatsu Photonics Co. Ltd.) used in the Embodiment of Exhibit 1 by Party A, viewed from Exhibit 9 by Party A technology, is synchronized with the NTSC system capable of obtaining 30 pieces per second, and by using together with an image-processing device ARGUS20 used in the Embodiment of Exhibit 1 by Party A, it is a CCD camera for fluorescence observation capable of improving low contrast images as more viewable ones by contrast enhancement or image intensification. Furthermore, according to technological matters of Exhibit 16 by Party A, 17 by Party A, 26 by Party A and 27 by Party A, its use in combination with the image-processing device ARGUS20 allows for visualization of the flow of ICG being carried in the blood flow in CABG at even an image acquisition rate of at least 15 pieces per second.

Specifically, according to the Exhibit 3 by Party B it is reported that the SPY system, which is claimed to be the device involving the Patented Invention 1 of this case by the Demandee, displays a control brightness of 190 with an exposure time of 66 milliseconds, a device that simulates the device of Exhibit 1 by Party A is reported to display a control brightness of 10 with an exposure time of 66 milliseconds. Here in the exhibit 3 by party B, the device that simulates the device of Exhibit 1 by Party A has its image acquisition rate enhanced to at least 15 images/sec and its integration mode released (Demandee's Written Statement (Second) dated March 12, 2008, page 4, lines 17-22.) and it is not described that adjustment of gain in camera sensitivity has been carried out, in view of these, it is recognized that gain adjustment of camera sensitivity was not performed in the Exhibit 3 by Party B. Moreover,

If based on the test result that the device that simulates the device in the aforementioned Exhibit 1 by Party A displayed a control brightness of 10 with an exposure time of 66 milliseconds

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