

(2012) 12 IPAB CK 0005
In the Intellectual Property Appellate Board
Case No : OA/7/2008/PT/DEL

M/s. Becton Dickinson And Company	Vs	APPELLANT
The Controller Of Patents & Design		RESPONDENT

Date of Decision : 28-12-2012

Acts Referred:

Patents Act, 1970 — Section 2(1)(J), 10(4)

Citation : (2013) 2 MIPR 70

Hon'ble Judges : S. Usha, J;D.P.S. Parmar, Technical Member

Bench : Division Bench

Final Decision : Dismissed

Judgement

D.P.S. Parmar, J

1 . The appellant is aggrieved by the rejection of the patent application No. 1511/DELNP/2005 dated 15/04/2005 for the invention ""High bias gel tube and process for making tube"". The matter came up before us on 30/08/2012 and learned counsel Shri Nitin Masilamani appeared for the appellants.

Submissions by the appellant

Preliminary objection

Failure to Provide a Reasoned Order

2 . At the onset of the argument The counsel for the appellant submitted his preliminary objection that respondent has failed to provide the reasoned order as the unreasonableness of the impugned order is apparent not only from the arbitrary test of obviousness set out in paragraph 7, and the incorrect finding regarding insufficiency of disclosure in paragraph 8, but equally importantly from the text of paragraph 9, wherein the entire body of patent jurisprudence cited by the Appellant has been cursorily dismissed as

irrelevant to the present case, on the ground that such precedent was decided on different technical facts. He relied on Union of India Vs. Jai Prakash Singh, AIR 2007 SC 1363, where it was held that the right to reason is an indispensable part in any adjudication and spelling out the reasons in any order is a basic requirement. The above principles have been cited with approval by this Hon'ble Board in Rolic AG Vs. The Controller General of Patents, TA/6/2007/PT/MUM (M.P. No. 5/2006), wherein it was held that one of the salutary requirements of principles of natural justice is spelling out reasons for the order made i.e. it shall be a speaking and reasoned order.

3 . The counsel for the appellant submitted that in view of the above body of precedent it is apparent that any finding of obviousness is required to be based on justifiable and explicitly stated grounds, and not the ambiguous and speculative statements of the kind provided in paragraphs 7 to 9 of the impugned order. According to the counsel paragraph 7 of the impugned order fails to apply the correct tests for obviousness. In addition, instead of stating the basis on which the learned Controller believes the Appellant's invention would be obvious in view of prior art, paragraph 7 merely provides a speculative and conclusory statement that such invention must necessarily have been visited by inventors of the invention disclosed in. US 3,997,442. Such reasoning is not only bad in law for being conclusory but also comprises a denial of the basic principles of natural justice for failure to provide a speaking order.

4 . If we peruse the order of the respondent we find the respondent has clearly analyzed the claimed invention vis-a-vis the cited prior art and concluded in para 5 that:-

5. It is agreed that the cited documents do not mention the fact that the first region (40) comprises an imaginary upper boundary (44) at which the first region (40) exhibits 360° circumferential contacts with the inner wall (18) and wherein the first region (40) comprises at least 80 vol. % of the gel.

The respondent in para 6 stated that

6. But the pertinent question lies in the fact that whether the mere mention of at least 80 vol. % of the gel in the first region shall constitute an inventive step u/s. 2(1)(J) of the Patent Act 1970 or not.

Further in para 7 the respondent stated his opinion-

7. In my opinion it can not be understood that the inventors of invention disclosed in document US 3997442 during the course of his/her trials have never come across a situation wherein the first region (40) comprises at least 80 vol.% of the gel.

5 . This clearly indicate that while comparing the prior art with claimed invention respondent arrived at forming of an opinion relating to possibility of

situation during the course of trials on US 3997442 to have come across a situation where in the first region (40) comprises at least 80 vol.% of the gel

and stating that ""it shall be also obvious to a person skilled in the art to merely mention that the first region (40) comprises at least 80 vol. % of the gel.

6 . These findings clearly justify that the order of the Controller is reasoned one. Whether reasons of the respondent are correct or not it is altogether

a different matter which can be ascertained when we go through the merit of the case? Therefore, we find the contention of the appellant that

respondents order is not reasoned as baseless.

7 . We shall now examine the merits of the case. The counsel for the appellant submitted that respondent found that the invention claimed by the

Appellant would be obvious to a person of skill in the art based on the prior art disclosed in U.S. 3,997,442, U.S. 6,238,578, U.S. 4,426,290 and also

that the specification fails on the ground of insufficiency of disclosure for the reason that the Appellant has not disclosed in the specification based on

experimental results that how much has been the effect of the claimed particular kind of disposition of gel in the tube in the quality of separation of

different density fluids.

Lack of Inventive Step

8 . The counsel for the appellant submitted that only ground cited by the learned Controller, in refusing the Application is lack of inventive step.

Review of paragraphs 6, 7 and the concluding paragraph of the impugned order indicates that despite generally referring to US 4,426,290 and US

6,238,578 (without establishing their relevance), the learned Controller's finding of obviousness is ultimately premised entirely on US 3,997,442.

9. The counsel for the appellant submitted that the primary reference relied on by the Controller in the impugned order is U.S. 3,997,442 which does

not even make a disclosure of the feature of a first and second region of gel, wherein the first region of gel comprises at least about 80 vol. % of the gel. In fact, the disposition of gel within the prior art collection assembly has been envisaged with a view to facilitate rapid movement of gel towards the center of the tube. This arrangement has a significant drawback, inasmuch that it causes the gel to move too early in the centrifugation process and a barrier to be formed, prematurely before complete blood separation. A serious disadvantage arising from the method of the prior art invention is that rapid flow of the thixotropic gel leads to premature barrier formation and incomplete fluid phase separation. The counsel for the appellant submitted that the Appellant's invention addresses this drawback in the state of the art, by significantly reducing the rapidity of flow of thixotropic gel by ensuring placement of at least 80% volume of the gel in the first (lower) region of the gel and thereby avoiding premature barrier formation. It will be understood that the Appellant's solution—which seeks to reduce rapidity of flow of the thixotropic gel, is diametrically opposed to the teachings of the cited prior art reference, which instead seeks to increase the rapidity of flow of the thixotropic gel.

10. The counsel for the appellant submitted Reference to US 3,997,442 at column 5, lines 41 to 59 clearly establishes that the objective of the prior art reference is to position thixotropic material (gel) so as to assure the rapid initiation of flow of the thixotropic material at normal or customary centrifugation speeds. The cited paragraph specifically states:

Another problem associated with the positioning of the thixotropic partitioning material symmetrically at the bottom of the container relates to the quality of the seal produced by the thixotropic material between the separated phases. The movement of some thixotropic materials from such a position has been found to be sometimes so sluggish that, unless the duration or speed of centrifugation is increased, the thixotropic material may not form an adequate seal between the separated phases. By an adequate seal, it is meant that the seal must be able to remain intact while the lighter, upper-most phase is being poured or decanted from the container. It will be appreciated that an increase in the speed of centrifugation or the duration of centrifugation over that customarily used in the separation of blood is not desirable because such increases are likely to cause excessive hemolysis

or rupturing of the cellular constituents of blood.

11. The counsel for the appellant submitted that based on the above, it is clear that a primary objective of US 3,997,442 is to ensure rapid initiation of

flow of the thixotropic material from its initial position at the bottom of the tube, to a position US 6.238.578

The counsel for the appellant submitted that U.S. 6,238,578 (which has been discussed in the impugned order, but has not been relied on by the

Controller) is yet more irrelevant to the claimed invention as it discloses a collection assembly where gel (22) is disposed and adheres to the inner

surface (29) forming a concentric band (30) around the central portion of the tube (21) between the predetermined upper and lower limits (28, 27)

respectively. The gel (22), after flow thereof has ceased, forms a concentric band (30) with the discontinuous pattern (32) at the top of band (30) and

an opening (33) through which the blood sample (35) may initially pass before centrifugation and formation of the gel barrier. After the gel (22) has set

or flow has ceased, the collection device (20) is ready for the blood sample (35) to be added for centrifugation and separation as described above. It is

submitted that the disclosure in US 6,238,578 is entirely different from the collection assembly claimed in the Appellant's invention and teaches away

from the feature of having a thixotropic gel in a first and second region, wherein said first region exhibits a 360° circumferential contact with the

inner wall of the collection assembly. Said reference specifically requires that the gel be disposed in non-continuous bands along the walls of the

container assembly. Said reference also fails to disclose the limitation that 80 vol. % of the gel is located in the first region adjacent to the bottom wall

of the container assembly.

US 4.426.290

The counsel for the appellant submitted that US 4,426,290 (which has been discussed in the impugned order, but has not been relied on by the

Controller) discloses an apparatus for separating blood according to the present invention wherein at the bottom of a separation tube (1) (a 10-ml.

tube) is contained a thixotropic gel-like material (2) in a depth of about 15 mm. At the center on the upper surface is formed a generally cylindrical

cavity (3) (diameter of the opening 4 mm. and depth 3 mm). A centrifugal separation is carried out for the gel-like sealant with strain (that is, a cavity

(3)) formed in advance so that the gel-like sealant is easily fluidized by a stress smaller than the one required for the prior-art processes. Thus, U.S.

4,426,290 also teaches away from the claimed invention as it does not disclose a high bias gel configuration, and instead, specifically requires that the

thixotropic gel layer at the bottom of the test tube includes a cavity to permit and assist in migration of the gel during centrifugation. In contrast, the

Appellant's invention does not require any cavity and instead utilizes the high bias second region of the gel disposed within the collection assembly to

assist in migration of gel during centrifugation. In fact, at column 1, lines 43 to 57 of US 4,426,290 the prior art reference specifically rejects the

approach adopted by the Appellant's invention, in the following manner.

In order to overcome the above-mentioned problem, a blood-separation tube has been devised in which the sealant as described above has a slant

surface so that the sealant is readily flowable upon centrifugal separation (U.S. Pat No. 3,997,442).

In such prior-art blood-separation tube, however, it is necessary in order to produce satisfactory flowability to have the upper surface of the sealant

being slant at a considerably large angle. The upper surface slanted at a larger angle will suffer from a deficiency of being broken during

transportation or handling of the product. It is also disadvantageous that the manufacturing line for forming such a slant surface is complex and costly

because it requires an operation, for example, centrifugal operation which should be carried out not on a continuous basis but on a batch basis

12. The counsel for the appellant submitted that in addition to teaching away from the Appellant's invention, the cited prior art reference also makes no

disclosure that the first region of gel comprises at least about 80 vol. % of the gel is in a lower region, and as such would suffer similar issues of

premature gel movement and barrier formation during centrifugation as the remaining prior art references.

13. The counsel for the appellant contended that in view of the above, none of the cited prior art references, either individually, or taken in

combination, disclose the novel and inventive feature of the claimed invention i.e. that the gel comprising continuous first and second regions, said first

region located at or adjacent to the lower end and the second region extending upward from a portion of the first region, wherein the first region

comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall and that the first region comprises at least 80 vol.% of the gel.

14 . The counsel for the appellant submitted that the Appellant's invention is significantly removed from each of the prior art references cited by the learned Controller, whether considered individually or in combination with each other. Further, the primary reference relied on by the Controller (US 3,997,442) actually discourages the skilled person from adopting the technical solution provided by the Appellant. The counsel for the appellant submitted that as none of the cited prior art references, either individually, or taken in combination, disclose the novel and inventive feature of the claimed invention i.e. the gel comprising continuous first and second regions, said first region located at or adjacent to the lower end and the second region extending upward from a portion of the first region, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall and that the first region comprises at least 80 vol.% of the gel, therefore, the respondent erred in arriving at the decision on the lack of inventive step.

15. The counsel for the appellant submitted that the respondent should have applied the *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, 1985 and *Bishwanath Prasad Radhey Shyam Vs. Hindustan Metal Industries*, (1979) 2 SC legal tests applicable to establishing inventive step.

16. The counsel submitted that in view of above the test of inventive step reference to paragraph 7 of the impugned order makes it apparent that the learned Controller has applied a standard of obviousness to the Application that contradicts the tests set out by the Hon'ble Apex Court and which are well established in patent jurisprudence. As stated earlier, the learned Controller explains his finding of obviousness as follows:

In my opinion it cannot be understood that the inventors of invention disclosed in document US. 3,997,442 during the course of his/her trials have never come across a situation wherein the first region (40) comprises at least 80 vol.% of the gel.

17. The counsel relied on the *Re Woodruff*, 919 F. 2d 1575, *Iron Grip Barbell Co. Inc. vs. USA*. Sports 392 F. 3d 1317 and *Re Geisler*, 116 F. 3d 1465 in support of the test for obviousness where invention claims a specific range

within Prior Art and submitted that the learned Controller was accordingly wrong in rejecting the application for lack of inventive step.

Insufficiency of Disclosure

18. The counsel submitted that Paragraph 8 of the impugned order, read with the concluding paragraph of said order cite insufficiency of disclosure as

another ground for refusal of the Application. The counsel argued that lack of experimental data demonstrating new and unexpected results of the

Appellant's invention over the disclosure in US 3,997,442 does not give grounds for insufficiency of disclosure. He submitted that the learned

Controller appears to be of the view that the experimental data submitted along with the Appellant's written submissions dated December 6, 2007 with

a view to demonstrating new and unexpected results over the invention disclosed in US 3,997,442, should have been included in the specification. It is

submitted that this finding by the learned Controller is not supported by the provisions of the Patents Act. He added that the Appellant's specification

satisfies the requirements for sufficiency of disclosure set out in Section 10(4) of the Patents Act. The counsel submitted that experimental data

demonstrating new and unexpected results over prior art cited by an Examiner or Controller may be submitted even where such data has not been

provided in the specification itself.

19. Now we shall deal with question raised by the respondent ""whether the mere mention of at least 80 vol. % of the gel in the first region shall

constitute an inventive step u/s. 2(1)(J) of the Patent Act 1970 or not?

20. According to the specification the present invention relates to body fluid collection containers, in particular blood collection tubes, capable of

separating phases of different density, using a gel separating medium. The summary of the invention relates to an improved fluid collection container,

containing a gel separation medium. According to the invention, the gel is disposed in the tube in a manner and geometry that is readily

manufacturable, and which overcomes potential gel movement issues.

21. The invention as claimed in finally amended claim 1 is reproduced below:-

1. A collection container with a high bias gel (10) comprising: an upper end (12), a lower end (14), and a sidewall (16) between the upper and lower

ends (12, 14) having inner and outer walls (18, 20), and a gel (22) located in the

container (10) in contact with a portion of the inner wall (18), wherein the gel (22) comprises continuous first and second regions (40,42), the first region (40) located at or adjacent to the lower end (14), and the second region (42) extending upward from a portion of the first region (40), wherein first region (40) comprises an imaginary upper boundary (44) at which the first region (40) exhibits 360° circumferential contact with the inner wall (18) and wherein the first region (40) comprises at least 80 vol. % of the gel.

22. Since counsel for the appellant has not separately argued the merits of dependent claims 2-17, they will stand or fall with independent claim 1.

23. The discussion of the related art in the specification referred to the problem as stated below Gel movement i.e., getting adequate movement of the

gel upon centrifugation, can sometimes be an issue. US patent 3,997,442 suggests one solution, but improvements are always desired.

24. High bias gel collection containers are known in the art but it has been observed that said art suffers from certain drawbacks including that of

premature gel movement. If we examine the prior art we find:

US patent 3,997,442

US patent 3,997,442 disclosed asymmetrical disposition of the thixotropic material (Gel). The method disclosed for separating and partitioning heavy

and light phases of multiphase fluid includes an initial step of positioning a quantity of thixotropic material asymmetrically within the closed end of a

tubular container, such that the thixotropic material has an upper surface which is inclined relative to the side wall of the container, thereby forming a

downwardly extending fluid receiving space between the upper surface of the thixotropic material and an opposing sidewall portion of the closed end

of the container. The specification further disclosed that the initial positioningin manner thus described has been found to, first assure the rapid

initiation of the flow of the thixotropic material..... second "" that is along portion of the sidewall 22"" Such rapid initiation "" the previous

method..... initially positioned symmetrically at the bottom end of the container..... "" This invention also provides the gel in the tube in a manner

that overcomes issues relating to gel movement.

U.S. 4,426,290

US patent 4,426,290 disclosed gel-like sealant with strain (that is, a cavity) formed in advance and it also in example test "example 2" and "figure 7

disclosed that the sealant with cavity was placed in the separation tube in such way that the upper surface was inclined at an angle of about 30°.

This slant clearly indicate the asymmetrical disposition of the thixotropic material (Gel) as disclosed in US patent 3,997,442. Further the cavity formed

upon the surface of the gel like sealant may be at any position and in any shape. [Col 4 line 3-4]. In Fig 6 a position closer to one of the walls of the

tube is shown. [Col 4 line 6-7]. The specification also disclosed that it is essential that stress in centrifugal separation is concentrated at the cavity to

produce stain in the gel like material and the shear force is provided [Col 4 line 13-15]. Further it is disclosed that "According to the present invention,

on the other hand, the centrifugal separation is carried out for the gel-like sealant with strain (that is, a cavity) formed in advance so that the gel-like

sealant is easily fluidized by a stress smaller than the one required for the prior-art processes." [Col 3 line 50-62]

25. If we compare the present invention with the above cited documents we find the claimed distinct feature (claimed improvement) in the invention is

the positioning of the thixotropic gel in two distinct regions within the collection assembly-a first region and a second region-wherein said first region

exhibits a 360° circumferential contact with the inner wall of the test tube and at least 80 vol. % of the gel is disposed within said first region and

located adjacent to the lower wall of the container.

26 . The Closest prior art document is US 4426290 which discloses an apparatus (tube) for separating blood comprising: a tube with a closed bottom

end; a thixotropic gel-like sealant having a specific gravity intermediate between the gravities of serum and clot phases of blood, said sealant being

contained at the bottom end of said tube and having an upper surface spaced from the bottom of said tube; and a cavity formed in said sealant when

said tube is at rest, said cavity being intermediate the edges of said sealant and extending from said upper surface towards the bottom of said tube but

not reaching the bottom of said tube, said cavity being formed by said sealant alone without, any cavity maintaining members in said tube.

The Claimed invention discloses A container (tube) comprising a side wall having inner and outer walls and located between the upper opening end

portion of the lower closed end, and an upper open end portion, further comprising a gel disposed in the container in contact with a portion of the inner wall region and the second region comprises a first continuous, located in the vicinity of the lower closed end at the bottom.

27. Both prior art and the claimed invention have matching features:

- A container comprising a side wall having inner and outer walls and location between the lower closed end, and an upper open end portion,
- Comprises a gel disposed in the container in contact with the inner wall portion of the container.
- The gel disposed within the tube comprising a second region and the first region is contiguously located in the vicinity of the closed end at the bottom

or closed end at the bottom region of said first and second region such that it extends upwardly from a portion of the first region to include an upper

boundary on the first virtual area is indicative of contact of 360° on the circumference and the inner wall of the container.

28. In the above prior art, as a method of placement of the gel, if we see "the figure 1" of US 442 and "figure 7" of US' 290 we find that the virtual

contact region where two regions meet is indicative of the contact 360° on the circumference and the inner wall, which is self-evident. Hence

there is no inventive step involved to specifically claiming the self evident feature of the prior art not explicitly mentioned.

29. Having said so we are now left with the last feature of the invention VIZ and that the first region comprises at least 80 vol.% of the gel. This

feature in fact refers to the capacity of the gel in the first region. Teachings in US' 290 i.e. 'Cavity in the gel close to the wall and slant of 30°'

and in US '442 i.e. disclosure of asymmetric placement of gel are appropriate for the person skilled in the art to achieve the results claimed by the

present invention.

30. In addition, the capacity of the gel of the first region, in the present invention and capacity of the gel of the first region as disclosed in US' 442 and

US' 290 in order to quickly start the flow of substances like thixotropic gel, can be arranged to concentrate if partial stress is applied to the gel at the

time of centrifugation. It is well known among those skilled in the art to make the capacity of the gel about 80% by volume. Therefore, for those

skilled in the art, present invention can be carried out appropriately and it can at

best be said to be a matter of optimisation of the numerical range relating to the volume of the gel. It is therefore obvious to the person skilled in the art to achieve the claimed disposition of the gel of the present invention applying the well-known matters described above. Moreover, the difference of the claimed invention as compared to the prior art is one which can readily be conceived by those skilled in the art and invention as claimed is one which falls in the range of ordinary skill in the art with expectation of success. Hence the alleged technical advance and so called surprising result/effect of the present invention is such that it is obvious from the matters disclosed in the prior art cited by the respondent.

31 . The counsel for appellant has relied on few case laws relating to specific selection of parameter from known range. We find an interesting observation relating to obviousness made in the judgment of the United States Court of Appeals for the Federal Circuit in *Pfizer, Inc. v. Apotex, Inc.* in 2006-1261 (2007):

The Court held that "'a suggestion, teaching or motivation to combine the relevant prior art teachings to achieve the claimed invention does not have to be found explicitly in the prior art references sought to be combined, but rather 'may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself'". However, irrefutable evidence showed that a skilled chemist at the time would simply make known pharmaceutically-acceptable salts of whatever active ingredient with which he or she was working at the time. Pfizer had admitted prior art documents which disclosed the use of benzene sulphonate for improving the bioavailability of other pharmaceuticals. The Court said this is therefore highly relevant in weighing the factors relating to obviousness. "'The District Court had held in that case that the invention was non-obvious because in 1986, it was generally unpredictable as to whether a particular salt would form and what its exact properties would be. The Court of Appeal held that this finding is correct, but the conclusion flowed from the factual finding is not correct. The Court held that "'obviousness cannot be avoided simply by showing of some degree of unpredictability in the art so long as there was a reasonable probability of success. The Court held that indeed, a rule of law equating unpredictability to patentability, applied in this case, would mean that any new salt-including those specifically listed in

the '909 patent itself-would be separately patentable, simply because the formation and properties of each salt must be verified through testing. This cannot be the proper standard ""since the expectation of success need only be reasonable, not absolute. We also note that the 909 patent placed no limitations on the acid addition salt whatsoever, except that it be non-toxic and formed from an acid containing a pharmaceutically-acceptable anion. Thus, although Dr. Wells testified that it was not guaranteed whether amlodipine besylate would form and what its salient characteristics would be this does not overcome (the prior art's) teaching that [amlodipine besylate] will work"" Corkill. 771 F. 2d at 1500. Considering all the evidence, we conclude that the District court clearly erred in finding that Apotex failed to produce clear and convincing evidence that one skilled in the art would have had a reasonable expectation of success with the besylate salt of amlodipine.

32. We find this conclusion on obviousness appears to be more applicable to this case. Here too, the prior arts (US' 290 and US' 442) while not experimenting with capacity of gel in the first region specifically did not exclude it. The person skilled in the art while taking the initial step in advance of positioning a quantity of thixotropic gel asymmetrically in general would have reasonable hope of success in positioning it in specified quantity in first region including 80 volume % of gel. All the claimed paradigms were self evident in the prior arts. The unpredictability of success cannot rule out obviousness. So even if different positions /capacity of gel may lead to different results, the expectation of success was reasonable especially since it was known that asymmetrical disposition of gel before centrifugation improved the activity of separation and partitioning of heavy and light phases of a multiphase liquid. Therefore, selection of an optical numerical range by experiments from the publicly known art is merely as an exercise of ordinary creativity of a person skilled in the art, and hence it does not qualify to be called as having an inventive step. In view of the above findings, we are inclined to agree with the impugned order and accordingly the appeal is dismissed. No order as to costs.