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No.CG/F/PG-VI/2010/ 84

Date : 11-05-2010

To
Shri V. Bhaskar
Joint Secretary, Govt. of India
Ministry of Commerce & Industry
Dept. of Industrial Policy & Promotion
Udyog Bhavan, New Delhi-11

Sub: Irregularities in the grant of Indian Patent Nos. 210062 dated September, 17, 2007 and 221306 dated June 20, 2008.- Petition by Shri Prabhakar Mani Pratap, Delhi

Ref: Ministry's letter No. 10/34/2010/IPR-III dated 26.3.2010

Sir,

Kindly refer to your letter No.10/34/2010/IPR-III dated 26.3.2010 enclosing a copy of representation received from Shri Prabhakar Mani Prap, New Delhi on the above subject.

The matter has been thoroughly inquired into with the available files in Patent office, Chennai and by taking opinion from other senior officers of the same field (mechanical) from the Patent Office, Mumbai. The following detailed report is hereby submitted after the enquiry.

(A) Patent No 210062

1. In case of Patent No. 210062 it is submitted that the matter is sub-judice at various level i.e. at Patent Office for Post grant opposition u/s 25(2), at IPAB

for revocation u/s 64, under infringement suit by the Patentee in the High Court and for counter-claim for revocation u/s 64 at Delhi High Court. Hence it is not desirable to conclusively comment on whether the patent is illegitimate or not.

2. Facts of the case in Patent No. 210062

- i) M/s. B. Braun Melsungen AG of Germany has filed an application for patent at P. O. Chennai on 18.8.1998 claiming priority of German application dated 20.8.1997 and the application number allotted was 1857/MAS/1998. The Complete specification included 54 claims.
- ii) Request for examination (RQ) was filed on 25.3.2004. The application was examined by Patent Office, Chennai and First Examination Report was sent on 30.6.2004. All objections were met by the Applicant and, as a result, the application was found in order for grant on 26.5.2005 with all the 54 claims as applied for. This application was examined by Shri A.B.Rajsekaran, Examiner (since resigned) and was granted with all the 54 claims by Shri K.M. Viswanathan , then Asstt. Controller of patents now retired as Deputy Controller on 31-01-2010.
- iii) As the patent application was not published as on 26-5-2005, the patent could not be granted. The application was subsequently published on 9.6.2006 in the Patent Office Journal No.23/2006 u/s 11(A) of the Patents Act. On expiry of six months of publication, and as there was no pre-grant opposition, the application was sent for grant of letters patent and publication u/s 43 (2) by the dealing Asstt. on 6-9-2007 to Mrs. S. Punithavathi Asstt. Controller through Dr. S. P. Subramanian, then Examiner. Mrs. S. Punithavathi generated patent number 210062 on 17-09-2007 for this application along with many other patents.
- iv) Meanwhile Chennai Patent Office received request in Form 13 dated 13.9.2007 for change of the patent agent from M/s Depenning & Depenning to M/s. Anand and Anand which was approved by Shri K.M.Viswanathan, the then Asstt.. Controller on 20-9-2007. The new

action of allowing the pre grant amendment has caused the revenue loss of Rs. 2000/- to the Government.

Both the above allegations are found to be true in view of the facts mentioned in Para (ii) to (v) above. The officers responsible for the above irregularities are : 1) Shri K.M.Viswanathan, Dy . Controller of Patents and Designs (retired on 31-1-2010 from Patent Office as Technical Head) , 2) Shri C.N.Shasidhara, Asstt. Controller of Patents and Designs, Patent Office, Chennai (then Examiner of P & D).

Another allegation by the petitioner is that 28 claims brought in through amendment by the applicant by reducing from 54 claims as filed are not within the scope of the complete specification as filed. The entire specification along with the original and amended claims was referred to Shri Sanjay Kesharwani, Asstt. Controller of P & D (Mechanical) of Mumbai Patent Office. His written opinion is enclosed as Annexure I . He has opined that the amended claims are well within the scope of the complete specification as filed.

The Priority claim of this patent application is the US Application No. 09/097170, dated 12-6-1998. USPTO granted this patent with patent no. 6117108 with 25 claims. Subsequently, USPTO has granted many other patents based upon this priority in which number of claims as high as 100. So, prima facie I do not find any thing unnatural in reducing the claims from 54 to 28. What really matters is whether the amended claims fall within the scope of the originally filed complete specification..

(B) Patent No.221306

(1) Facts of the case:

- i) Patent Application No.581/MAS/2001 was filed on 13-7-2001 by B.Braun Melsungen AG, Germany for their invention "Intravenous Catheter device" claiming the priority of i) US application No.09/648,641 dated 14/8/2000 and ii) German application no. 201 04 539.7 dated 16/3/2001 through their agent M/s De

Penning & De Penning. The specification contained 6 claims including an omnibus claim instead of 5 claims as mentioned in the petition.

ii) The application was examined by Shri N.V. Rammurthy, the then Examiner of P & D (since resigned and left the office) and report submitted to the then Asstt. Controller Shri K.M.Viswanathan on 14-3-2005. Asstt. Controller ordered on 18-3-2005 for issue of FER after 18-month publication u/s 11 (A). However, it is seen that the First Examination Report (FER) was issued on 24/2/2006 without 11(A) publication by Shri C.R. Rakesh, Examiner of P &D. Shri Rakesh resigned and left the Patent office. FER contained many objections including the citation of US application no. 611,7108 as the prior art. The response to FER was received on 20-2-2007 from M/s De Penning & DE Penning, Applicant's Agent with amendment of claims making them commensurable with EPO granted claims in EP 1180381 (3 in numbers) . Amended claims. Were examined by the then examiner Shri C.N.Shashidhara on 27-2-2007 and recommended for the grant of patent with the claims as amended subject to disposal of pre grant opposition if any received after 11 (A) publication. On the same day, the Asstt. Controller Shri K.M.Viswanathan ordered for grant of patent in file. The applicant was intimated about the grant on 12-3-2007. The application was published u/s 11(A) on 14-9-2007 in the Patent office journal No. 37 of 2007.

iii) Meanwhile, a new patent agent Ms Archana Shankar of M/s Anand & Anand was taken on record on 18.9.2007 on the basis of form 13 filed by the Applicant on 13.9.2007. The Applicant further another Form-13 on 21/9/2007 requesting for amendment of claims (addition of claim no. 4). The proposed amendment (addition of 4th claim), as requested by the applicant, was examined in the light of the description and earlier claims by Shri C. N. Shashidhara, the then Examiner of P &D on 26-11-2007 and recommended that "the proposed amendment appears to be within the scope of claims of the specification before the amendment and, hence, may be allowed." He has also referred to the visit of the patent agent to the Patent Office, Chennai to discuss the case on 21-11-2007.

Mr. Shashidhara orally confirmed to me that Shri Shantikumar, then a patent agent with M/s Ananad and Anand was the person who visited and discussed the matter with Mr. Viswanathan in his presence. Shri Shantikumar has retired as the CGPDTM in 1984. The controller allowed the amendment on 4/12/2007 and granted the patent accordingly.

iv) As the publication u/s 11(A) was done only on 14-9-2007, the letters patent was not issued. The file was put up on 10-6-2008 to Shri S.P Subramanian the then Asst. Controller for generation of patent number and issue of letters patent. The patent number 221306 was generated on 20-6-2008.

2) Main allegation regarding this patent is :

“ In patent number 221306 , an additional independent claim was on Sept. 2007 (request received on Sept. 21, 2007) added post examination and pre grant publication but before grant. This additional claim was an additional enhancement in the scope of the patent and as per section 57 of the Patent Act, any substantial amendment made to the application before grant must be published. Once again the publication was not done and the public was denied the right to oppose”.

Section 57 allows pre grant amendment of claims, but such amendment must be within the scope of the complete specification as originally filed. Such amendments need not be published as per the Act and Rules but the public have the right to inspect the file and oppose the patent under section 25(1). This opportunity was available in this case also.

The main issue to be answered is whether the claim 4 as granted (brought through pre grant amendment) is within the scope of originally filed complete specification or not.

The matter was referred to Shri Vikas Sharma, Assistant Controller of P&D, (Mechanical) for his opinion. The opinion rendered by him is enclosed as Annexure – II.

As per his opinion the granted claim 4 (brought through pre grant amendment) is not fully within the scope of originally filed complete specification.

Hence the allegation is more or less proved.

It may be noted that there is no litigation pending either as a post grant opposition under section 25(2) or for revocation under section 64 in IPAB.

- 3) The petitioner further demanded that both the patents may be revoked under section 66 of the Patents Act by Central Government. Section 66 of the Patents Act is reproduced below :-

Section 66 - Revocation of patent in public interest - Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.

As mentioned by the petitioner in his petition Patent No. 210062 is already under litigation in the Delhi High Court and the matter is sub-judice. Both the Single Bench and Divisional Bench refused to grant injunction against the alleged infringer. This patent is also under challenge in IPAB under section 64 of the Act. As there is no injunction against manufacture and sale of the patented product in India it may be presumed that the product is freely available in India. In the absence of any supporting

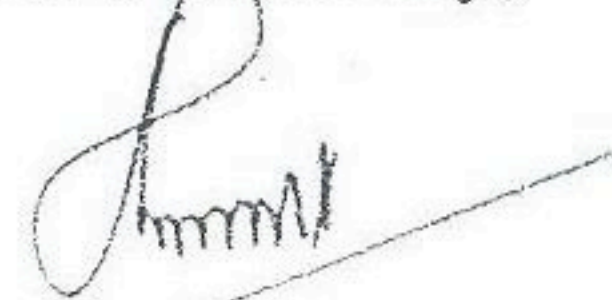
proof it would not be possible for me to conclude that the price of the patented device has escalated.

Judicial remedy is available under the Patents Act for revocation of any wrongly granted patents and as mentioned above the Patent No. 210062 is already under challenge. In view of the above, I am of the opinion that there is no sufficient ground to proceed under section 66 of the Patents Act.

4) Conclusion:

- 1) Amendment of claims in Patent No. 210062 was allowed in the Chennai Patent Office after the patent was granted which is highly irregular and improper. This action is clearly against the provisions of section 57 and 59 of the Patents Act. The officers responsible for this irregularity are (i) Shri K.M. Viswanathan, Deputy Controller of P&D (Retired on 31-1-2010) and (ii) Shri C.N.Shashidhara, Assistant Controller of P&D, Chennai Patent Office. Government may take appropriate action against them.
- 2) Amendment in the form of addition of a 4th independent claim in Patent No. 221306 was also irregular as the same was beyond the scope of originally filed complete specification. Above two officers were responsible for this irregular action.
- 3) After going through all the facts and circumstances of the above two patents I am of the opinion that there is no sufficient grounds to invoke section 66 of the Patents Act in this case.

Yours faithfully,



(P.H.Kurian)

Controller General of Patents, Designs and Trade Marks

SPRING CLIP SAFETY IV CATHETER

Granted to:-
B. Braun Melsungen AG

By:-
Controller of Patents, Chennai.

Construction Features of the Basic Embodiment of the Claimed Invention	Ref. No.	Remarks
Catheter	10	
Needle Hub	12	
Axial Opening	14	
Needle	16	
Sharpened Tip	18	
Sleeve	20	
Flash Chamber	22	
Hollow Tubular Catheter	24	
Catheter Hub	26	
Catheter Hub's Distal Section	28	
Catheter Hub's Proximal Section	30	
Catheter Hub's Luer Fitting	32	
Catheter Hub's Axial Passageway	34	
Flash Chamber	36	
Protective Needle Guard	40	
Spring Clip's Distal Arm	42	
Spring Clip's Curved Lip	44	
Spring Clip's Pointed End	46	
Mating Groove in Catheter's Inside	48	
Spring Guard's Transverse Segment	50	
Spring Guard's U-shaped Upper End	52	
Spring Guard's Vertical Arm	54	
Spring Guard's Openings	56, 58	
Slot in Needle Shaft	60	
Bulge	61	

It has been studied from the Complete Specification as filed and comparing its disclosures with the Patent Claims 1-53 as filed originally and then with the claims 1-28 as GRANTED, that there is no overshooting the scope of the invention in the latter (1-28) claims than those in the original (1-53) claims filed.

The invention pertains to the Clip Guard in its various embodiments for Retaining the Needle in a ready position (for fluid administration in a patient's body) and then for safety to any healthcare worker after administering this fluid by allowing the retraction of the Needle into the catheter hollow body and covering the Needle tip by one resilient portion of the Safety Guard, so that there is no chance of accidental needle stick to him/her, which may transmit dangerous diseases like AIDS, hepatitis etc., if the needle tip is not in a safe position after fluid administration.

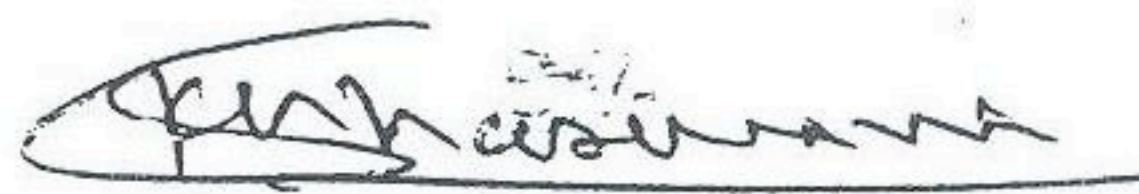
Under section 57 of the Applicant amend his/her application/complete specification subject to section 59, which only provides that the amendments should be by way of "disclaimer, correction or explanation" only. It clearly states that –

"no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment."

In the present case, original claims 1-53 were drawn from the disclosure therein, however they were just too many in number and the number of claims sets were also too many (26 sets). Moreover, due to no indications of reference numerals of the respective constructional features, they were not very clear in their scope.

The granted claims 1-28 are drawn from the same disclosure in the original complete specification. However, now the number of claim sets has been reduced to merely 5. Though, in the granted claims also reference numerals have not been indicated.

Therefore, the granted claims 1-28 fall wholly within the disclosures in the original complete specification and also not beyond the scope of the original claims 1-53.



07-25-2010
(Sanjay Kesharwani)

Assistant Controller of Patents & Designs
Patent Office, Mumbai.

Report : In the matter of Indian patent No. 221306 whether added fourth claim is enhancing the scope of the earlier granted three claims

I examined the status of the granted claims and found

Para 1 . Same application has been granted by USPTO with 53 claims, by EPO, JPO and Germany with 3 claims and by Australian Patent office with 6 claims (including one omnibus claim). In Australia after grant claims were corrected though keeping the number same as 6, Moreover two divisional applications has also been granted in Australia with 9 Claims, and 11 claims respectively.. In Australia description and drawings were amended to give more details about the figures 10A and 10B and Indian Patent Office has granted 3 claims verbatim to EPO claims.

Para 2. Complainant **allegation** that added 4th claim is beyond the scope of the originally filed claims . All the claims are oriented to a projection(136a, 136b,136c,136d), which forms a retaining element for the needle guard(120). This is also claimed in the alleged fourth claim where this projection is shown to be annular protrusion , moreover needle positioning in ready mode and retraced back mode has been explained . But force analysis to explain the functioning in both the positions which is done in alleged claim is not supported by the description.

Para3 Australian amendments in description fully support the force analysis i.e why in Divisional Patent they have sought protection for the matter similar to Alleged claim4.

Opinion: I am of the opinion that alleged fourth claim though is not fully within the scope of the description , but all essential features which are essential for its enablement follow from description except some of the features which we may take as more or less inherent in nature(though as in Australia they have been given in more detail with bringing analysis concentrating on added drawings 10-A,10-B), but they can assumed to follow from functioning of the invention also.

Vikash
11.5.10

Vikash sharma
Assistant Controller Patents & Designs