Intellectual Property Appellate Board
Guna Complex Annexe-I, 2nd Floor, 443 Anna Salai, Teynampet, Chennai-600 018.
Tele: 24328902/03 Fax: 24328905 email id: ipab.tn@nic.in Website: http://www.ipab..gov.in

OA/32/2014/PT/CHN

TUESDAY, THIS THE 29TH DAY OF DECEMBER, 2020

HON'BLE SHRI JUSTICE MANMOHAN SINGH — **CHAIRMAN**
HON'BLE DR. B.P. SINGH — **TECHNICAL MEMBER (PATENTS)**

EVONIK ROHM GMBH
OF KIRSCHENALLEE,
64293 DARMSTADT,
GERMANY, A GERMAN COMPANY……..... APPELLANT

(Represented by: Ms. MeeraVenugopal Gobind)

Versus

ASSISTANT CONTROLLER OF PATENTS AND DESIGNS
GOVERNMENT OF INDIA, PATENT OFFICE
INTELLECTUAL PROPERTY RIGHTS BUILDING
GST ROAD, GUINDY
CHENNAI- 600 032 ... RESPONDENT

(Represented by - None)

ORDER

Hon'ble Shri Justice Manmohan Singh, Chairman

Hon'ble Dr. B.P. Singh, Technical Member (Patents)

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 17/02/2014, passed by the Respondent, being the Assistant Controller of Patents & Designs, under Section 15 of the Indian Patents Act, refusing to grant the Appellant's Indian patent application no. 5321/CHENP/2007.
2. The present Invention as submitted by the appellant:

   2.1 The present invention according to the main claim 1 relates to pharmaceutical form comprising an active ingredient-

containing core which is coated with a mixed polymeric coating of one or more polymers (I) with one or more polymers (II). The formulation according to the present invention is suitable to modify the time release profile of coating for pharmaceutical dosage forms without affecting the dissolution pH-value. Accordingly, an active ingredient release profile is attained, in which the active ingredient is released by comparison with a pharmaceutical form coated with polymer (I) alone starting at the same pH but more slowly.

3. Further, the appellant submits as under to justify their case:

3.1 It is very clear from the objections that D1 i.e. (WO 2004/041255 A1) discloses at para [0043], a combination of 40% PVP (poly vinyl pyrrolidine) and an 85/15 mixture of Eudragit 15NE/Eudragit FS

3.2 The applicant in response to the hearing notice, further defined claim 1 by combining the features of previous claim 2, but by excluding PVP. Applicant's pharmaceutical form as claimed in claim 1 does not contain PVP, whereas the combination disclosed by D1 contains PVP.

3.3 The cited document D1 (WO 2004/041255 A1) describes a dosage form for release in liquid form. The dosage form shows an osmotic effect. This is achieved by a two layer coating. An "ascending release membrane" thereby produces together with a semi permeable membrane above an osmotic pressure which is used to control the release of the active ingredient. As stated above, the relevant portion of D1 as cited in the hearing notice as anticipating the present invention is under paragraph [0043] of D1 which discloses that the exemplary hard cap dosage forms were coated with an "ascending release membrane" which comprises a mixture from three

polymers: 40% PVP-XL-10 + 60% (85/15 EUDRAGIT® NE/FS-Blend). EUDRAGIT® FS is a polymer (I) in the sense of the present application. EUDRAGIT® NE is a polymer (II) in the sense of the present application. The exclusion of PVP polymers from the polymer mixture of the present claim 1 made claim 1 outside the scope of the disclosure of D1 and thus claim 1 is novel over D1.

3.4 Further, claim 1 was also proved to be possessing inventive step over the disclosure of the cited documents D1 and also over D2 (WO01/15683), D3 (WO 2004/062577) and D4 (US2004/0091538- US equivalent of D1) which were cited in the first examination report.

3.5 **Problem and solution:** The problem to modify the time release profile of coating for pharmaceutical dosage forms without affecting the dissolution pH-value is solved by the present invention as claimed. Accordingly, an active ingredient release profile is attained, in which the active ingredient is released by comparison with a pharmaceutical form coated with polymer (I) alone starting at the same pH but more slowly. Neither D1 nor D2 to D4 are providing any hint to this problem. D1 is concerned with osmotic active pharmaceutical compositions and leads away by including fast disintegrating excipients. From D2 neither suitable polymer mixtures nor suitable proportions can be derived. D3 discloses mixtures with polymers different from those of the present invention. Therefore, the present claims should be novel and inventive.

3.6 Usually, the release characteristics of polymer mixtures cannot be foreseen. The certain release profile of the present application was not known to the public. The solution of the

present invention shows an unexpected result which goes beyond a pure admixture.

3.7 D1 (WO 2004/041255 A1): PVP-XL-10 is a cross-linked polyvinyl pyrrolidone polymer which is used as excipient for extremely fast disintegration (explosion tab). It is apparent for a skilled person that a coating according to D1 [0043] page 26, which includes 40 % of this fast disintegrating excipient, will disintegrate immediately after contact which moisture, which means at latest in the stomach. In comparison to a coating with polymer (I) alone the polymer mixture from D1 would never show a slower release profile.

3.8 Present claim 1 is distinguished from D1 with respect to polymer II and also restricted in that "...an active ingredient release profile in which the active ingredient is released by comparison with a pharmaceutical form coated with polymer (I) alone starting at the same pH but more slowly is attained." Thus, polymer mixtures in which the active ingredient is released by comparison with a pharmaceutical form coated with polymer (I) alone starting at the same pH not more slowly or even accelerated are excluded.

3.9 This is of advantage especially for the colon release, where the closed coating starts to release the active ingredient around pH 7.0 in a sustained manner. Usually the release characteristics of polymer mixtures cannot be foreseen. The certain release profile of the present application was not known to the public.

3.10 In the examples middle and right column of table 1 and left and middle column of table 2 the ratios of polymer I (FS30D) and polymer II (NE30D) are varied. The ratio of polymer I increase in a row of 5, 10, 20 and 50 % while polymer II

decreases in a row of 95, 90, 80, and 50 %. In each column the coating thickness is varied from 6, 10 and 15 %. A skilled person can derive the following conclusions:

3.11 The thicker the coating is the more the active ingredient release is delayed.

3.12 The more of EUDRAGIT® NE (polymer II) is added to EUDRAGIT® FS (polymer I) the more the active ingredient release is delayed.

3.13 Where the active ingredient release at 180 min is 5 – 95 %. Preferably 10 – 50 % (s. p. 51) proper coatings are obtained which may fit to certain desired release profiles.

3.14 By further adjusting the coating thickness or the ratios of the EUDRAGIT® FS/EUDRAGIT® NE mixture almost any desired active ingredient release may be obtained by the skilled person.

3.15 Table 3 shows the effect of two other polymers II, Kollicoat SR30D and Aquacoat ECD instead of EUDRAGIT® NE. A skilled person can derive the following conclusions:

3.16 The thicker the coating is the more the active ingredient release is delayed (the same effect as above)

3.17 The delay effect of Kollicoat SR30D is less or comparable to EUDRAGIT® NE at a ratio FS30D/Kollicoat SR30D 10:90.

3.18 The delay of effect of Aquacoat ECD is stronger than that of Kollicoat SR30D and that of EUDRAGIT® NE at a ratio FS30D/ Aquacoat ECD 10:90. By increasing the amount of FS30D and decreasing the amount of Aquacoat ECD suitable values may be reasonably expected.

3.19 Thus, by further adjusting the coating thicknesses or the mixture ratios almost any desired active ingredient release may be obtained by the skilled person also for mixtures of EUDRAGIT® FS with Kollicoat SR30D or Aquacoat ECD

3.20 Thus, the examples in the tables 1 to 3 enable the skilled person to adjust different inventive polymer mixtures to match the active ingredient release which is desired for a certain formulation. It is believable that this principle of simple adjustment will work for any combinations of polymers I and II as claimed.

3.21 One object of the present invention is to provide the skilled person in the field of pharmacy and galenics with new means for the coating of drug forms. The object is solved as claimed. The claims are supported by the description and the examples as stated above. By the certain choice especially of the (meth)acrylate polymer type I with a glass transition temperature of not more than 70°C it becomes possible to work with polymer mixtures without the disadvantage of the "pH-shift" effect which is known from mixtures in the state of art (s. p. 6-9 in the present specification).

3.22 The choice especially of the (meth)acrylate polymer type I narrows claim 1 comparatively strong. At the moment there is only one polymer I commercially available on the market which is EUDRAGIT® FS from applicant's own company. The claim is further limited by the restriction with respect to polymer II and the aspect of the slowed down release in comparison to coatings with polymer I alone. Taking this in mind it becomes apparent that the present claim is not a broad but a rather narrow claim.

3.23 The beneficial effect of the present invention is that it enables the skilled person to create new drug release profiles with the use of the limited number of polymers which are available. Thus for many purposes the skilled person can work with the

polymer mixtures as claimed without the need to develop new polymers with different monomer compositions.

3.24 The Respondent has erred in ignoring the feature of Claim 1: "…an active ingredient release profile in which the active ingredient is released by comparison with a pharmaceutical form coated with polymer (I) alone starting at the same pH but more slowly is attained." It is not lawful to ignore a claimed feature.

3.25 Respondent has erred in ignoring the presence of large amounts of PVP-XL-10 as used in D1 (WO 2004/041255 A1). PVP-XL-10 is a cross-linked polyvinyl pyrrolidone polymer which is used as excipient for extremely fast disintegration (explosion tab); whereas presently claimed invention does not include PVP and thus is distinguished from D1 by said technical feature and in alleging that claim 1 is distinguished from D1 only by the functional feature.

3.26 Appellant humbly submits that it is apparent for a skilled person that a coating according to D1 [0043], which includes 40 % of this fast disintegrating excipient, will disintegrate immediately after contact with moisture, which means at latest in the stomach. In comparison to a coating with polymer (I) alone the polymer mixture from D1 would never show a slower release profile (s. table 2, p. 52 with the release profile of EUDRAGIT® FS alone). Present Claim 1 clearly excludes formulation according to D1 [0043] and thus are novel over D1.

3.27 To prove that the mode of action of PVP-XL10 is fairly evident to a skilled person, Appellant cites hereby Zhang et al. (2010) "Comparison of Superdisintegrants in Orally Disintegrating Tablets, Pharmaceutical Technology, Vol 34, Issue 7, pp. 54 –

65. (ANNEX-A of the Appeal). In the sense of the Article of Zhang et al. PVP-XL10 is a superdisintegrant which disintegrates a compressed tablet at a concentration of only 5% within 20 – 40 seconds.

3.28 It is further evident that the release rate in D1 is not dependent on the pH value since the dosage form shows an osmotic effect. This is achieved by a two layer coating. An ascending release membrane thereby produces together with a semi permeable membrane above an osmotic pressure which is used to control the release of the active ingredient. The osmotic effect is mainly due to the presence of the crosslinked superdisintegrant PVP-XL-10 which strongly soaks the water from the environment. The EUDRAGIT® NE/FS-Blend in this polymer mixture has no time to react pH dependent. The EUDRAGIT® NE/FS-Blend in D1 has the function of an elastic binder nothing more. In contrast the use of the polymer mixture as claimed has the function of slowing the release rate down compared to a polymer (I) alone as characterised by the functional feature of Appellant's claims. Because of the anionic groups present in polymer (I) is it evident that the active ingredient release is pH dependent.

3.29 Further Appellants respectfully submit that the claims are novel and the Respondent has erred in holding that the claimed invention lacks in novelty in view of WO 2004/041255 (D1) by stating in the paragraph 16 of the impugned order. The reasoning as provided above by Respondent, especially the statement that "D1 disclosure meets all the structural limitations of present claims" is incorrect for the following reasons.

3.30 The present invention is related to a pharmaceutical form comprising an active ingredient-containing core which is

coated with a mixed polymeric coating, of one or more polymers (I) with one or more polymers (II),

wherein polymer (I) is a copolymer of methyl methacrylate, methyl acrylate and methacrylic acid,(Eudragit NE) and polymer (II) is a copolymer of methyl methacrylate and ethyl acrylate,

a copolymer of methyl methacrylate and ethyl acrylate and methacrylic acid (Eudragit FS),

a copolymer of methyl methacrylate, ethyl acrylate and trimethyl-ammoniumethyl methacrylate,

polyvinyl alcohols, polyvinyl alchol-polyethylene glycol graft copolymer, starch and derivatives thereof, polyvinyl acetate (PVAc), vinyl acetate-vinylpyrrolidone copolymer, hydroxyethylcellulose (HEC), hydroxypropylcellulose (HPC), hydroxypropylmethylcellulose (HPMC), hydroxymethylethylcellulose (HEMC), ethyl cellulose (EC), methyl cellulose (MC), cellulose esters, cellulose glycolate or a mixture of said polymers;

whereas the portions of D1 (paragraph 0043) as allegedly anticipating the present invention discloses an ascending release membrane formed of three components viz., Eudragit NE (ethyl acrylate, methyl methacrylate copolymer), Eudragit FS (methyl acrylate, methyl methacrylate, methacrylic acid copolymer) and PVP XL-10 (crosslinked polyvinyl pyrrolidine).

3.31 The mixed polymeric coating of present claim 1 can be a combination of Eudragit NE and Eudragit FS whereas D1 discloses a combination of Eudragit NE, Eudragit FS and PVP XL-10. From the amended claims it is very clear that the third polymer in the present invention cannot be PVP. Thus the

present claim 1 is clearly distinguished D1 by technical features. Thus the Respondent's statements as quoted above are absolutely against facts.

3.32 Under Paragraph 12 of the impugned order Respondent has stated that "Applicant's response to this objection made in the written submission appears to be factually incorrect. Applicant states that claim 1 has been amended to include the essential technical features. However the technical feature that the applicant claims to have now included already existed in the claims before hearing".

3.33 Appellant humbly submit that the above statement is not correct since the applicant has amended claim 1 to restrict polymer II thereby clearly reciting the essential technical feature in claim1and clearly distinguishing it from D1. It may be noted that the portion of claim 1 defining polymer II as below was included in claim 1 in view of the objections of the hearing notice. This clearly differentiated claim 1 from D1 in that it polymer II is not PVP as recited in D1.

3.34 In the Patent Law, it is well established that to anticipate a patent, a prior publication or activity must contain the whole of the invention impugned; i.e., all the features by which the particular claim attacked is limited. In other words, the anticipation must be such as to describe, or be an infringement of the claim attacked.

3.35 As referred in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, it was held: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

3.36 In Farbewerke Hoechst ... vs Unichem Laboratories And Ors. on 11 July, 1968 it is referred in para 15 that "To anticipate

a patent, a prior publication or activity must contain the whole of the invention impugned; i.e., all the features by which the particular claim attacked is limited. In other words, the anticipation must be such as to describe, or be an infringement of the claim attacked."

3.37 In the present case, it is clear that D1 does not disclose the impugned subject matter of claim 1 i.e., all the features of claim 1. If the invention of the cited para 0043 of D1 is worked, it would result in a combination containing PVP which not infringe the impugned claim 1, which does not have PVP.

3.38 Thus the respondent has erred in refusing the claims as lacking novelty.

3.39 Section 10(4) and (5)

Respondent has erred in holding the present invention as not patentable under Section 10(4) and (5). Under paragraph 11 of the impugned order, the Respondent has stated the following:

"Objection 2 of hearing notice has to be addressed first so that essential technical features recited in claim 1 can be identified. The objection was regarding the following feature of claim 1 - " ..... an active ingredient release profile in which the active ingredient is released in comparison with a pharmaceutical form coated with polymer I alone starting at the same pH but more slowly is attached." This is essentially the objective of the present invention. Page 6; lines 26-33 of the current description states the objective of the present invention as - " It was therefore intended to find a solution which makes it possible to modify in a simple manner the time course of the active ingredient release characteristics of anionic or carboxyl group containing polymers without at the

same time influencing the dissolution pH thereof" An invention cannot be distinguished solely by reciting the desired end result. Product claims should ideally define the invention through positive technical and structural 6 features. In those rare instances where due the technical nature of the invention, if it is possible to define the invention only in terms of technical or functional features, then applicant should state reasons for the same. The present invention does not appear to fall into those rare instances. Further applicant has not presented any reasons to the contrary. It is true that the present claims carries technical features in addition to the above functional feature. However, as can be seen in the following novelty analysis, the technical features are already recited in claim 1. The only difference is the above functional feature, which is a reflection of the desired end result of the present invention. Claims have to define the subject matter of invention for which protection is sought so as to distinguish the present invention from prior art. In the instant case the distinction is attempted to be made purely by the objective of the invention, which fails the purpose of section 10(4) (c)".

3.40 Appellant submits that the above statements of the Respondent are simply incorrect in that present claim is different from the prior art not only with respect to the functional features but the technical features recited in claim 1 clearly distinguishes claim 1 from the prior art".

3.41 Therefore the claims of the present invention clearly define the scope of the invention, and there is no undue burden on a person skilled in the art to determine the scope.

3.42 Appellant also respectfully submit that it always is allowed in patent law that the claims are broader than the examples.

Otherwise it would be easy to circumvent a patent and the patent would be worthless. Thus it is not justified to restrict the claims to the scope of the examples. Therefore Appellants feel that the patent should be allowed in view of the considerable claim restriction presently done.

3.43 Since the subsidiary claims are dependent from the independent claim 1, the subsidiary claims also derive their novelty accordingly and the conclusion derived by the Respondent is flawed.

3.44 Appellant also respectfully submits that the grant of the patent in other corresponding countries over the same cited documents (Please see the bibliography page of the enclosed patent EP 1890682 B1).

3.45 In this regard Appellant refers to the Hon'ble IPAB decisions as follows which emphasize the importance of considering the allowance in the corresponding applications worldwide.

4. We have analysed the order of the Respondent. It has been revealed that the respondent has taken objection of lack of novelty under section 2(1)(j) of the Patents Act, 1970 and that under sections 10(4)(c) and 10(5) of the Patents Act, 1970.

5. The objections are totally contradicting themselves. If the learned Controller is not very sure about the actual scope of the invention as he holds that the claims are not properly defining the essential technical feature(s) of the invention as is evident by his observation quoted herein below:

> It is true that the present claims carries technical features in addition to the above functional feature. However, as can be seen in the following novelty analysis, the technical features are already recited in the prior art. The only difference is the above functional feature, which is a reflection of the desired end result of the present invention. Claims have to define the subject matter of invention for which protection is sought so as to distinguish the present invention from prior art. In the instant case the distinction is attempted to be made purely by the objective of the invention, which fails the purpose of section 10(4) (c).

claimed compounds itself do not result in a [illegible]
of claim 1.This is a further indication of the undue burden falling on any one trying to ascertain the scope of the invention as presently claimed. Therefore the subject matter of amended claims do not meet the requirement of section 10 (4) (c) and 10 (5) because the claims do not define clearly the scope of the invention for which protection is sought in terms of the essential technical features.

6. In such a situation, how the observation on lack of novelty can be taken for sure. Particularly, so when the appellant has merged the feature(s) of claim 2 to claim1, to make the scope narrower and to define the invention, further.

7. We have also seen the submissions of the appellant and their arguments wherein he refers to the granted EP claims on the identical citations. We have reviewed the complete patent family and found that in many other jurisdictions, "use" claims have been allowed. In EP however both 'use' and 'Pharmaceutical form" claims have been allowed. The claims filed at IPO are not identical.

8. The objection of lack of 'novelty' taken simultaneously with that about non-clarity of scope of protection sought, in absence of properly defined essential feature(s); is contradictory in itself and cannot stand the scrutiny of law. If the Controller is not sure about the scope and the definitiveness of the claims at the first instance, how he can surely tell that all the features are anticipated by document D1.

9. We are, therefore, inclined to give a fresh opportunity to the applicant, who shall submit the amended set of claims to respondent, within 2 weeks from the date of issuance of this order, clarifying all his official requirements, based on the facts described in the complete specification.

10. Hence, we set aside the impugned order dated 17/02/2014 issued by the respondent, and direct the respondent to decide the matter on merit, in accordance with law, within 3 months from the submission of the amended set of claims and after giving a fair

opportunity of the applicant of being heard, if so requested, by the appellant.

11. Keeping in view the above facts and circumstances, the instant appeal is allowed. No cost.

-Sd/-

(Dr. B.P. Singh)
Technical Member (Patents)

-Sd/-

(Justice Manmohan Singh)
Chairman