From, January to June the IPO has disposed off 19 oppositions. Out of the 19 decisions, 16 decisions are in respect of pre-grant oppositions. Out of the 16, in nine cases either the applicant abandoned the case or the opposition was withdrawn. For summary of the remaining 7 pre-grant, see below:

Pre-grant opposition in respect of application no. 1185/KOLNP/2007

Claims are directed to glove for detecting the presence of a vaginal infection, said glove being provided with first means for detecting pH and second means for collecting a vaginal sample, the glove being characterized in that said first means are provided with a reporter substance for measuring pH, said second means for collecting vaginal sample are placed on one finger of the glove, and said first and second means are placed in a separate positions on the glove.

Novelty and Inventive step:

The controller has held that it appears that the claims and subject matter of instant application 1185/KOLNP/2007 is falling within the scope of the specification of Dl.

The controller held that it is evident that the prior art document D1 not only relates to the diagnosis and treatment of vaginal infections, but also expressly teaches a glove containing a collection means with one of its embodiments referring to the presence of the detection/reporter substance on the same glove. The controller also stated that, in the said prior art document, there is no restriction /limitation with respect to the position of the reporter substance on the same glove. Further in the prior art document, there is no limitation which requires the reporter substance to be present on the same position as the collection means. Consequently, the controller held that embodiment of the reporter substance being present at a separate position on the same glove is legitimately

included within the scope of the said prior art document Hence Dl was held to teach the instant invention (novelty destroying) and also renders it obvious.

The controller while examining inventive step did not consider the grant in counterpart patents by the patent offices in Europe, Japan, Australia, China and Korea, as he held the same to be not binding on this office, and also considering that D1 disclosed all features of present application based on which the corresponding application was refused in US.

Not Patentable under 3(f):

Dl was also held to teach the instant invention and all its features and therefore rendering it obvious and not patentable under section 3(f) of the Act.

Section 8:

The ground of section 8 was also raised, and the opponent held that the details of lapsed application was not filed, for instance details of US application were not provided. However, the controller held that this is not true as a copy of the record of oral hearing before the board of appeals and interferences ex parte for the corresponding US application no. 11/576,130 was submitted under section 8 requirements by the applicant in CD format.

The application was however refused for lack of novelty, Inventive step and being considered not patentable under section 3(f).

Pre-grant Opposition in respect of Patent Application No. 1865/DEL/2005

The application is titled as "NEW POLYMORPHOUS FORMS OF RIFAXIMIN, PROCESSES FOR THEIR PRODUCTION AND USE THEREOF IN THE MEDICINAL PREPARATIONS".

Rifaximin δ and ε forms are claimed.

Prior claiming:

According to the Controller, a prior claiming ground implies that each averment as claimed in a claim must have been disclosed and claimed in an earlier filed application in India. The controller further held that, since the cited document do not disclose the process for obtaining δ and ε forms of rifaximin, hence does not disclose each part of the claimed invention. Accordingly, in opinion of the controller the claims of the present invention do not attract the provisions of prior claiming and hence the said objection is not sustainable.

Novelty:

According to the Controller, in patent law, anticipation refers to the prior invention or disclosure of the claimed invention by another, or the inventor's own disclosure of the claimed invention by publication, sale, or offer to sell prior to the inventor's application for a patent. Since the end product as obtained and disclosed in the claims of the present application has not been disclosed in any of the cited document, the present invention was held not being anticipated by any of the cited document.

Inventive step:

Obtaining the claimed form of rifaximin was held to be an indeed unexpected result and the controller held that a person skilled in the art at the priority date would have only known of the conversion of rifaximin α to β and vice versa and would have had no knowledge of even the existence of the δ and ε forms. It was concluded by the controller that the present invention is therefore inventive over cited art.

Section 3(d):

The polymorphs claimed (δ and ε) in the present application exhibit values of adsorption which are intermediate compared to the values of the polymorph preparations claimed in prior art (the α- and β-forms). According to the Controller, it is remarkable to note that the α- and β-forms, which in comparison with the δ-form have a lower and higher water content, respectively, exhibit an in-vivo adsorption much lower than the δ-form.

The controller noted that it is not a problem of increasing of bioavailability, Cmax does not have to maximum, but to have active ingredient able to provide different bioavailability and by the value of Cmax obtained, delta form is useful to provide a topical effect with an increased systemic effect, lower than the gamma form, which is associable to an amorphous form. Further, the epsilon form is a form which provides exclusively a topical effect.

The ground of Section 3(d) was therefore interestingly considered to be overcome by the claimed forms.

The controller considering the application as novel, inventive and not falling under section 3(d) granted the same.

Pre grant opposition in respect of 3131 /KOLNP/2011

The subject application is a solid dosage form comprising (A) a solid dispersion of **amorphous bardoxolone methyl** in a glassy matrix formed by a methacrylic acid copolymer admixed with (B) hydroxypropyl methyl cellulose in the form of particle.

The aim of present invention as per the Applicant was to provide a formulation with Form B bardoxolone methyl, that while maintaining the high oral bioavailability of Form B also led to similar Cmax, Tmax, and AUC promes compared to the formulations prepared with Form A, i.e., have lower Cmax and lower Tmax values than prior art Form B formulations.

With this aim in mind, as per the Applicant, the inventors of the present invention has prepared the claimed solid dosage form. The solid dosage form of the present invention comprises of two components - (A) a solid dispersion of amorphous bardoxolone methyl in a glassy matrix formed by a methacrylic acid copolymer; and (B) hydroxypropyl methyl cellulose in the form of particles. Thus, Form B in a glassy matrix form with methacrylic acid was admixed with HPMC, wherein HPMC is not an excipient for forming the glassy matrix.

Inventive step:

The controller held that application 3131/KOLNP/2011 is claiming all known components related to delayed release composition e.g. amorphous bardoxolone methyl, hydroxypropyl methyl cellulose and acrylic polymer, except the way of formulating all those components in a different manner. HPMC is not an excipient for forming the glassy matrix but is admixed with Form B in a glassy matrix form with methacrylic acid.

Further at the time of invention, it was held that the skilled person was also well aware of the properties of amorphous compound e.g. (amorphous compound enhances solubility and bioavailability of drug). The controller held the selection of amorphous form as an obvious selection for a person skilled in the art through judicious selection and routine optimization. Moreover, the improved technical effect over the prior art is absent in the subject application.

So essentially the applicant's invention is merely to a process for obtaining the same formulation, using known components rather than a new formulation. Therefore amended claims of application were held to not involve any inventive merit.

Section 3(d):

As per the controller, the applicant of the instant application 3131/KOLNP/2011 has compared only bioavailability data between the crystalline and non-crystalline form of bardoxolone methyl. However nowhere applicant of the instant application 3131/KOLNP/2011 have compared the bioavailability data between the composition of instant application over known composition comprising amorphous form of bardoxolone methyl (CDDO-me) along with hydroxypropyl methyl cellulose which is known from prior art.

Failure to prove efficacy of the composition of instant application 3131/KOLNP/2011 of amorphous form of bardoxolone methyl (CDDO-me) and hydroxypropyl methyl cellulose which has to be considered as a combination of known substance is not patentable u/s 3(d) of the act.

Therefore, the present invention constitute non-patentable subject matter according to the applicant.

Pre grant opposition in respect of 1196/KOLNP/2005

The invention is entitled "METAXALONE Polymorphs"

Inventive step:

The controller held the submission of the opponent regarding inventive step of the present invention is not sufficient and also not clear, so opponents failed to establish this ground properly. Particularly, in the submission of the Opponent submitted after hearing.

The Opponent argued that Process for preparation is obvious with respect to the cited documents because dissolving known drug (Metaxalone) in an organic solvent (which are also known),cooling the solution over a period of time and collecting the crystals of meta<alone is very obvious to person skilled in the art. With reagsrd to the solvent used for crystallization, the Opponent submitted that "Use of solvent like ethyl acetate, ethanol, toluene, chlorobenzerae are known in the prior art references and ethyl acetate is the most commonly used solvent for crystallization this product which is mentioned in prior art specifications, such as US3062827, U53446814, US656298O, hence there is an express need to narrow the scope of solvents to specific category." The argumentation of Opponent regarding the inventive step was held to be not clear and also not sufficient to establish their view regarding lack of inventiveness of claims.

Section 3(d):

There is no support in the specification regarding therapeutic efficacy, except data for Bioavailability studies and pharmacokinetic parameters of crystalline Forms (A and B) have been given.

That bioavailability per se which is physical property of the claimed crystal Form B should not be the criteria for establishing the present section and capable to overcome section 3(d) for the impugned application over the prior art. Hence, the crystalline Form-B (polymorph) as claimed was considered unable to pass the test of Section 3(d).

Pre grant Opposition in respect of 1784/DEL/2006

The applicant 'Samsung India Electronics Pvt. Ltd.' filed this instant application 1784/DEL/2006 titled "Cold storage element"

Novelty:

The controller held that the opponent relied on more than one document (mosaic of documents) to prove the Novelty requirement of applicant's claims for the requirement of section 25(1)(b). No single document is containing all the features of claims 1-6.

The controller held that the Document D1 refers to features such as chest freezers, cold storage element comprising of a casing of plastics material containing sodium or ammonium salts (brine solution), constructed as to be removably mounted in a chest freezer, etc. However the applicant invention is directed to a refrigerator and a freezer section in it and also uses **cross linked hydrated salt solution** comprising of cross-linked Sodium Polyacrylate. The said feature of cross-linked Sodium Polyacrylate is disclosed in the claim 8 of document D3.

Prior public use:

The Opponent relied on an Annexure to allege that "A product called Brite Chiller TM Ice" from Coleman to allege this ground. It was argued that the product is available in India at least from 2004 (even before). However as no documentary evidence was submitted by the opponent to establish the allegation of "publically known or publically used before the priority date of that claim". The ground was therefore rejected.

Claims 1 to 6 were therefore allowed. However, claim 7 was found to be not supported by the description and the form 13 filed to add claim 7 and dependent claims was not allowed.

Pre grant Opposition in respect of 6756/CHENP/2009

The Applicant' has filed a patent application for his invention titled as "NOVEL APPLICATION OF APHANAMIXIS POLYSTACHYA EXTRACTS OR FRACTIONS AGAINST 5-LIPOXYGENASE MEDIATED DISEASES"

The claims are directed to bio-enriched extract of acetone insoluble fraction, derived from hydroalcoholic extract of *A. polystachya* plant material.

Novelty:

The controller held that the cited TKDL references are completely silent and have failed to disclose a composition comprising bio-enriched extract of acetone insoluble fraction, derived from hydroalcoholic extract of *A. polystachya* plant material. Therefore all the 8 claims pass the Novelty criteria and hence are considered as Novel

At the time of preparing search reports the European examiner has considered 15 TKDL documents under non-patent literature and 26 patent documents under patent literature. The application was withdrawn in the EP and the Opponent relied on this during the hearing. The controller held that reasons that led the applicant to withdraw the application is not clear. Hence it cannot be concluded that this was due to the 15 TKDL documents that let to withdrawal by the applicant.

In the absence of effective arguments by the opponent; the reference made by the opponent about the said EP application is not considered for the disposal of the instant application.

Inventive step:

The instant invention claims a composition that is 5-lipoxygenase inhibitory composition comprising acetone insoluble fraction derived from hydroalcoholic extract of Aphanamixis polystachya plant material.

As shown in the specification it is agreed that the acetone insoluble fraction of hydroalcoholic extracts (entry 3) of Aphanamixis polystachya and the acetone insoluble fraction when subjected to MCI gel chromatography (entry 5) exhibits 5-lipoxygenase inhibitory activity at a minimum concentration of 1.08mg/ml, which indicates that acetone insoluble fraction of hydroalcoholic extract of Aphanamixis polystachya provides effective therapeutic efficacy before and after subjecting to bio-enrichment using MCI column and thus resulting in cost effectiveness of the product as well as process.

The controller held that except on attacking on the usefulness of the water extract which is used for similar purpose of use in the instant invention, the opponent neither argued with respect to the composition as claimed in the instant application nor on the improved efficacy of the claimed composition. Hence proper comparison of the instant invention with respect to cited documents could not be made. In view of the above arguments the inventive step of the instant invention is acknowledged.

Not patentability under Section 3(p):

Section 3(p) does not allow to get a patent right if the invention is as such is related to traditional knowledge or if the claimed subject matter is a mere combination of different traditional knowledge is also not allowable. Since the present invention is related to such composition which is the result of a novel process of extraction is different from the known composition as cited by the opponent. Hence it was concluded that the instant invention does not fall within the purview of the provisions of the Section 3(p) of the Patents Act.

Pre grant in respect of 4938/KOLNP/2007

Invention is entitled "PYRROLO [2,3-B] PYRIDINE DERIVATIVES AS PROTEIN KINASE INHIBITORS"

Inventive step:

The opponent states that D1 and claimed compound of the instant application both have the same basic structure, the azaindole ring substitute with chloro phenyl, 2 fluoro phenyl and NHSO2. The only difference between claim 1 of the impugned patent application and D1 is presence of –COO- group instead of a ketone group as in the present invention.

The opponent further states that there is indication in D2, wherein ketone and –COO- groups are electron donating species and regarded as carbonyls, both have used in the same bracket indicating that they can be used alternatively.

By comparing the present invention with the cited documents, the controller observed that the alleged claimed compound consisting of two moieties which are linked by a linker –CO- group. The claimed compound is not identical with D1 as alleged by the Opponent.

By analyzing the cited documents D2-D4 the controller observed that the claimed compound is not identical to the compounds as disclosed in D2-D4 and are not suggested by these. D2 relates to compounds and methods for modulating the activity of ACE-2. The cited documents D3 discloses a compound (1,5,6,7-tetrahydropyrrolo[3,2-c]pyridine derivatives) which have been found to suppress appetite and induce weight loss and treating obesity and obesity related disorders. The cited documents D4 discloses certain compounds which are β adrenergic receptor agonists and have utility, hypoglycemic and antiobesity agents.

Section 3(d):

By comparing the cited documents with claimed compound, the controller observed that there is difference in linker in between the two moieties. Claimed compound is not a

derivative of the cited compounds. Therefore the alleged invention does not attract section 3(d) of the Patents Act.

Section 3(e):

Claim-2 refers to composition comprising novel and inventive compound of claim-1. So amended claim-2 does not attract the provision of section 3(e).