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Cases Studies on Intellectual Property Issues for Bionics

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ABSTRACT: Litigation plague does become a major worry for investors, assignees, inventors and related personnels, even holding a quality patent may not secure enough to be free from patent litigation. As long as the patented technology involoved in considerable profits, competitors will try every possible measure to take over the market, sales order or technology, sometimes aiming to merge or probing core technology, moreover for marketing awareness or brand promotion. Accusing patent infringement through complicated technical data or wordings, patent invalid through anticipation by 35 U.S.C. § 102 or obviouness by 35 U.S.C. § 103, or based on details such as priority dates, publicizing dates, references, filing dates,…etc. Inequidable conducts are new fashions with various tactics like attcking missing lables on embosiments,[2] unsupported spcification[3], obvious to try,[4] experiments details,[5] chemical structure's similarity upon biological efficacy,[6] similarity between dehydrated from and un-dehydrated from,[7] formulation or excipient differences,[8] even a bit late filing information disclosure statement (IDS)[9] for new references, crime fraud exception to the attorney-client privilege,[10] are common tactis in intellectual property disputs. The counteractions will be described in details with cases.

Keyword: infringement; doctrine of equivalence; patent invalid; patent anticipation; patent obviousness

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[2] Aventis Pharma v. Amphastar pharmaceutical & Teva Pharmaceutical, 2007-1280, www.uscourts.cafc.gov, decided on 14 May, 2008

[3] Genentech, Inc. v. Novo Nordisk, 108 F.3d 136142 U.S.P.Q.2d 1001 , 1997

[4] Merck & Co., Inc v Biocraft Laboratories Inc., 874 F.2d, 804-811 (Fed. Cir. 1989)

[5] Apotex Corp. v. Merck & Co., Inc, 2006-1405, www.uscourts.cafc.gov, decided on 16 Nov., 2007

[6] Takeda Chemical Industry v Alphapharm PTY & Genpharm, 2006-1329, www.uscourts.cafc.gov, decided on 28 Jun., 2007

[7] Tap Pharmaceutical & Takeda Chemical Industry & Wako Pure Chemical Industries & Abbott Laboratories v OWL Pharmaceuticals & Oakwood Laboratories, 2003-1634-1635, www.uscourts.cafc.gov, decided on 18 May, 2005.

[8] In re Omeprazole, AstraZeneca v Andrx pharmaceutical & Genpharm, 04-1562-1563-1589, www.uscourts.cafc.gov, decided on 18 May, 2005

[9] See Supra note 6

[10] See supra note 4

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1. BACK GROUND

1.1 Rationale

In order to take over the market, sales order or technology, filing lawsuits is only to attack the competitors but sometimes aiming to merge or probing competitor core technology, moreover, marketing awareness or brand promotion can be the purpose for enterprise to against competitors by accusing patent infringement, anticipation, using references to invalid patents, obviousness, obvious to try…etc, are using common tactics during intellectual property disputs. However, science & technology does play an important role in patent litigation, and those patents were either approved based on advanced, improved or innovative findings, therefore, understanding of the foundation for those science and technology are basic preparation before going to the courts. In addition, for those basic attacking tatics, the definitions and legal rationals are worth to spend more efforts and study carefully together with those patent related Sciences & Technologies. The following are common argued intellectule property issues.

1.2 Infringement

Infringement either literally or under the doctrine of equivalents is the most common cases in patent litigation, however, it is a genuine issue required material fact, the court will request a particularized testimony and linking argument to the 『insubstantiality of the differences』 between the claimed invention and the accused device or process, or with respect to the function, way, result test to support a finding of infringement under the doctrine of equivalents. The evidence must be presented on a limited-by limited basis, however generalized testimony for the overall similarity between the claims and the accused infringer's product or process will not suffice."

Infringement under the doctrine of equivalents does not raise a genuine issue of material fact,[11] "provide particularized testimony and linking argument as to the 『insubstantiality of the differences』 between the claimed invention and the accused device or process is requested, in addition, the outcome of the function, way, result test presented to support a finding of infringement under the doctrine of equivalents is acceptable. Such evidence must be presented on a limited-by limited basis. Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice." [12]

1.3 References

References are the simplest tools to be applied for attacking competitor's patent inval. According to 35 U.S.C. §102[13], a reference[14] is defined as the following:

35 U.S.C. §102 (a) defines the reference as "prior use or knowledge to be considered including the invention must be known or used, by others in the United States before the date of the invention", "prior patent or printed publication to be considered including patented or disclosed in a printed publication by others anywhere in the World before the date of the invention.

35 U.S.C. §102 (b) defines the reference as one year period of public knowledge or use or commercial exploitation before patent application filed

35 U.S.C. §102 (e) defines the reference as described in a US patent & published application, or patent & publication filed by PCT entering US stage invention by another filed before the date of the applicant's invention PCT published application

References must be either in the field of the inventor's endeavor or reasonably pertinent to the specific problem with which the inventor was involved, available at the time of the invention.

[11] Tex. Instrument Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed. Cir. 1996)
[12] PC connector Solutions LLC v. Smartdisk Corp., 406 F.3d 1359, 1364 (Fed.Cir. 2005)
[13] 37 C.F.R. § 1.107
[14] 1952 Patent Act for 35 U.S.C. Section 102

Reference can also be applied to test for obviousness. Whether the features of one reference may be bodily incorporated into another reference will not decisive, but "whether combined teachings render the claimed subject matter obvious".

A prior art reference[15] is analogous if the reference is in the field of applicant's endeavor or, if not, the reference is reasonably pertinent to the particular problem with which the inventor was concerned.[16]

A reference may be said to" **teach away** when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that the applicant took". The degree of teaching away depends on the particular factors, a reference teaches away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant, the nature of the teaching is highly relevant, and must be weighed in substance.[17]

A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness.

1.4 Anticipation

Anticipation is often obscure and hard for people to consider whether the arts are analogous but it is a question of fact. However, there are two criteria relevant in determining whether prior art is analogous:

(1) Whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) If the art is not within the same field of endeavor, whether it is still reasonably pertinent to the particular problem to be solved.

The test for analogous arts is based on the similarity of elements, problems, and purposes. All disclosures of prior art are relevant to the extent if "the references are in analogous fields of endeavor and thus have been considered by a person of ordinary skill in the field of invention."[18] In order to claim on non-analogous references, based on previous description, we are sure that references must not be within the field of the inventor's endeavor, may rely on patentability determinations.

"Analogous art," by common sense means a person of ordinary skill would reasonably have consulted those references and applied their teachings in seeking a solution to the problem that the inventor was attempting to solve.[19] References, of course, is within the scope of prior art, the "content of the Prior Art" and relevant in determining obviousness which is reasonably pertinent to the particular problem with which the inventor was involved.[20] Analogous prior art has to be the art related to one seeking a solution for particular problem, or attempting to achieve a particular result, would look for the purpose of finding the answer to that problem, or suggestions as to the attainment of that result.

The test for analogous art has practiced on the "similarity of elements, problems and purposes."[21] During this type of dispute, the 1952 Patent Act[22] does state upon U.S.C. § 103[23] : "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made."[24]

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[15] MPEP Section 2141.01(a) for case law pertaining to analogous art
[16] In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992)
[17] In re Gurley 31 USPQ2d 1130 (Fed. Cir. 1994)
[18] In re Young, 927 F.2d 588, 591, 18 U.S.P.Q.2d 1089, 1091 (C.A.F.C. 1991)
[19] Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., 21 F.3d 1068, 1071, 30 U.S.P.Q.2d 1377, 1379 (C.A.F.C. 1994)
[20] In re Deminski, 796 F.2d 436, 442, 230 U.S.P.Q. 313, 315 (C.A.F.C. 1986)
[21] Plastic Container Corp. v. Continental Plastics of Okla., 515 F. Supp. 834, 214 U.S.P.Q. 530, 541 (W.D. Okla. 1980)
[22] 1952 Patent Act for 35 U.S.C. Section 103
[23] American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999))
[24] Intellectual Property and High Technology Technical Amendments Act of 2002 (H.R. 2215) (Pub. L. 107 (2002))

1.5 Obviousness

In determining obviousness, the invention must be considered "as a whole", in its entirety rather than piecemeal. The process of determining obviousness has been characterized as not one of merely comparing the claims and the accused embodiment detail for details to see if they match, but rather one of examining the claimed subject matter as a whole to see if, in light of the prior art, it would have been obvious to one skilled in the art. The "difference" between the prior art and the claimed issue constitutes under 35 U.S.C. § 103.

The other point to pay attentions is the trend of technology, which provides suggestion or motivation for minor changes. A trend might very well constitute a suggestion or teaching to one of ordinary skill in the art to make "minor" change from the prior art in accordance with that trend to produce the claimed invention.[25] The existence of a trend depends on the content of the prior art. What the prior art would have taught one of ordinary skill in the art at the time of this invention? Evidence cutting against a trend includes various different methods used in the prior art to solve the problem faced by the inventor.

Under 35 U.S.C. §103, teachings of references can be combined only if there is some suggestion or incentive to do so while the prior art of record fails to provide any such suggestion or incentive. Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. Unless the prior art suggested the desirability of the modification, the mere fact that the prior art may be modified suggested by the examiner does not make the modification obvious.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.[26] It is not allowed to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. When consider the obviousness, "one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention".[27]

Failure to provide the necessary suggestion or motivation will create a presumption that the combination of references selected by the examiner to support the obviousness rejection was based on hindsight. [28] Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.

1.6 Obviousness to try

What Constitutes "Prior Art" Under 35 USC 103?

(1) It must be deemed pertinent or relevant to the claimed subject matter

(2) It must be deemed prior in time to the date the claimed invention was made

"Obvious to try" is not the standard under Section 103 has been directed mainly at two kinds of error. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. "Obvious to try" meant to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it."[29]

[25] Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 45 USPQ2d 1981. In re CHU, 36 USPQ2d 1089 (Fed. Cir. 1995)
[26] In re Geiger 2 USPQ 2d 1276 (Fed. Cir. 1987)
[27] In re Fritch 23 USPQ2d 1780 (Fed. Cir. 1992)
[28] In re Rouffet 47 USPQ2d 1453 (Fed. Cir. 1998)
[29] In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)

"The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, rather than the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." [30]

The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of non-obviousness.[31] Furthermore, known disadvantages in old devices which would naturally discourage search for new inventions may be taken into account in determining obviousness.[32]

1.7 Patentability

A prima facie case of un-patentability is established when the information compels a conclusion that a claim is un-patentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.[33]

Granting a patent on the discovery of an unknown but inherent function "would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art.[34]

"The mere age of the references is not persuasive of the un-obviousness of the combination of their teachings, absent evidence that, notwithstanding knowledge of the references, the art tried and failed to solve the problem."[35] The claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose.[36] One cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references.[37] Reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention.[38]

The fact that a combination would not be made by businessmen for economic reasons does not mean that a person of ordinary skill in the art would not make the combination because of some technological incompatibility.[39]

References teach away from the invention or render prior art unsatisfactory for intended purpose. However, "the nature of the teaching is highly relevant and must be weighed in substance.

A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.[40] It is improper to combine references where the references teach away from their combination.[41]

2. CASES DISCUSSION

2.1 Aventis Pharma v. Amphastar pharmaceutical & Teva Pharmaceutical[42]

This is a very tricky case, as many years later, the inventor was called back to the court to explain the complicated science and missing label on comparative experiments. Finally, due to the missing label and titration based comparison for low molecular weight heparins ("LMWHs") to find out the best mode. Aventis' expert witness and inventor were considered "intent to deceive".

30 In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981)
31 In re Hedges, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986)
32 United States v. Adams, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966).
33 37 CFR. 1.56(b)(2)(ii) effective as of March 1992
34 596 F.2d at 1022, 201 USPQ at 661
35 In re Wright, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA 1977)
36 MPEP Section 2143.01
37 In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981)
38 In re Gorman, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991)
39 In re Farrenkopf, 713 F.2d 714, 219 USPQ 1 (Fed. Cir. 1983)
40 In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994)
41 In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)
42 See supra note 1

Missing label in embodiments could happen very often in patents, very minor but extremely important details. But whether it is fair to ignore the profound science in the whole patent but focused on one or two missing labels, will it be fair?

Judge Rader filed dissenting to express his few comments on the decision for "intent to deceive" that (1) patent was written by patent agent not the inventor. (2) Highly respected scholar will not risk his reputation for hiding one or two label just for the patent.

Was these 2 missing labels were absent minded mistakes or purposely behaviors? Writing mistake or laboratory mal-management? Intent to deceive is a state of mind, and it is indeed hard to find the truth. Unexpected result not proportion to the chemical structure concentration, it happens, especially for protein products, biological effect sometimes can not be rationalized.

2.2 Merck & Co., Inc v Biocraft Laboratories Inc[43]

In this case, the main arguments were the Amliloride hydrochloride (K+ conserving) combined with hydrochlorothiazide (Na + excreting), both are well known to be diuretic and can be used to treat hypertension. In old days, the concept is Amliloride hydrochloride and hydrochlorothiazide both are already known diuretics, therefore, there is no doubt that combination must be more powerful diuretics and more effective to treat hypertension. It seemed "obvious to try", *prima facie* obvious.

Judge Bissell even filed dissenting, a composition must be assessed for obviousness only after consideration of its chemical structure as well as its pharmaceutical and biological properties. Hindsight is not the standard for determining obviousness. "Obvious to try" which is not barred by 35 U.S.C. § 103. An invention is "obvious to try" where the prior art gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful.[44]

2.3 Apotex Corp. v. Merck& Co[45]

Apotex asserted state law claims against Merck for common law fraud and tortious interference with prospective economic advantage, and sought to compel discovery pursuant to the crime fraud exception to the attorney-client privilege. During patent litigation, competitor sometimes play games to distract attention, or attack just for the purpose of attack. However, Federal Rule of Civil Procedure 60(b)(3) could also be pursuant for the certain strategy, in order to obtain this exception to the privilege, Apotex must make a prima facie showing of some foundation for the asserted fraud but in vein.

"Fraud upon the court should embrace only that species of fraud which does or attempts to subvert the integrity of the court itself, or is a fraud perpetuated by officers of the court so that the judicial machinery cannot perform in the usual manner its impartial task of adjudging cases that are presented for adjudication", fraud upon the court is typically limited to egregious events such as bribery of a judge or juror or improper influence exerted on the court, affecting the integrity of the court and its ability to function impartially.

Apotex's United States patents No. 5,573,780 (the '780 patent) although specified its own process involves the detail steps, as set forth in claim 1 of the '780 patent:

1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:

(i)(a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or

(b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass;

[43] See supra note 3
[44] See supra note 28
[45] See supra note 4

thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water;

(ii) drying the wet mass, and;

(iii) further processing the dried material into tablets.

However, Merck has market enalapril (the leading ACEI for treating hypertension, heart failure, …etc) for years globally, no matter how good this patent coulc be, the timing of filing a patent, publicizied the information were the key issues in this case.

2.4 Takeda Chemical Industry v Alphapharm & Genpharm[46]

TZD is new type of anti-diabetic medicine which claimed additional benefit on insulin resistance. Competitor used Takeda's own patent to attck Takeda's patents for obviousness. Whether an invention would have been obvious under 35 U.S.C. §103 is a "question of law", review de novo, based upon underlying factual questions which are reviewed for clear error following a bench trial. If we compare three Takeda's US patents nos: 4,687,777(the '777' patent), 4,287,200(the '200' patent), 4,444,779(the '779' patent) in Fig. 1, they are indeed made progress from time to time.

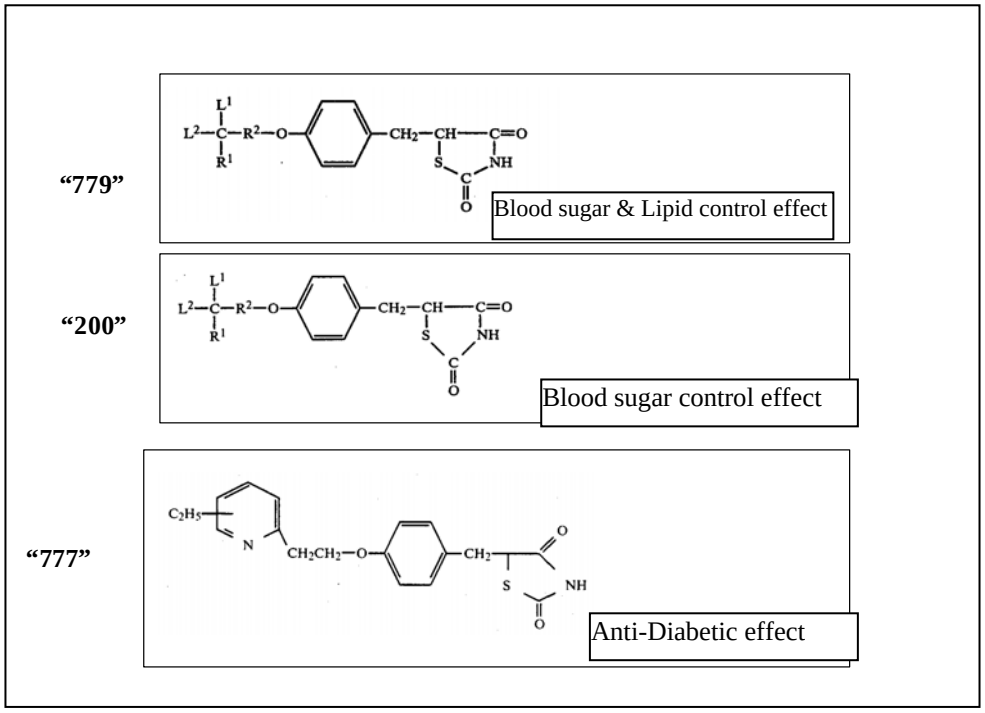

Fig 1:

Theafter, the competitors turned the direction to chemistry on the C_2H_5 substitution. The argument was whether the ethyl subsitution is the skills in the art, luckily, witness suggested that chlorination on Pyridyl ring is common but not methylation. Takeda also proved unexpected result on low toxicity which was the key.

If the differences between the subject matter sought to be patented and the prior art are such that the subject matter sought to be patented and the prior art are such that as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. §103(a), a patent is presumed to be valid, 35 U.S.C. §282, the evidentiary burden to show facts supporting a conclusion of invalidity, which rests on the accused infringer, is one of clear and convincing evidence.

[46] See supra note 5

2.5 Tap Pharmaceutical & Takeda Chemical Industry & Wako Pure Chemical Industries & Abbott Laboratories v OWL Pharmaceuticals & Oakwood Laboratories[47]

Product in suit was a 9 amino acids sequence, more potent than nature version. Takeda sucessfully recevied five indications arrpoved from FDA on Prostate cancer, Endometriosis (suggested 6 months treatment), uterine myoma (suggested 3 months treatment), central precocious puberty (CPP), Pre-menopause breast cancer. Takeda also developed 1 month depot vial, 3 months depot vial, 6 months depot vial, vial plused syringe, formulation without gelatin forms with patents respectively.

However, competitors attacked on the differntiation for reaction adding dehydrated form (glycolide or lactide) and un-dehydrated form (glycolic acid or lactic acid), Takeda was too conservative during the claim construction which led to too narrow explaination. Competitor tried to rule out one selection, then leave themselves the room for business.

For scientist, both dehydrated form (glycolide or lactide) or un-dehydrated from (glycolic acid or lactic acid) can be used for reactions with minor adjustment as it should be conisder as the skills in the art. However, for people in law profession do not see things in this way, it would be totally different stuffs for them as the different structures with different names. Again, it would be more tricky for scientist to answer whether they are the same or they are different. In fact, dehydrated form of glycolide or lactide are not quite the same as the un-dehydrated from of glycolic acid or lactic acid, but they are also not so different. But in the court, during the deposition, if you were the scientist, shall you answer they are the same or they are different? Turly tough.

The other important issue in this case is proper language in patent writing, never use 【containing 】in the claim which could be attacked as non-professional writing. **In Takeda's US patent no: 5476663 (the "663 patent): Claim 1**

【A prolong release microcapsule for injection, which comprises particles **containing** a water-soluble drug, the particle being dispersed in a spherical microcapsule matrix composed of a copolymer of lactic acid and glycolic acid having a comonomer ratio within the range of about 100/0 to 50/50 and an average molecular weight within the ranged of about 5000 to 200,000, the spherical microcapsule matrix having an average diameter of 2 to 200 um and an excipient selected from the group consisting of mannitol, sorbital, lactose and glucose, which particles are produced by in-water drying. 】

With profound scientific evidences and conservative characters, Takeda managed to succed in the past litigations. However, this time, Takeda was attacked on inequitable conduct, simply because 2 papers added information disclosure statement (IDS), competitors could exaggerate that Takeda purposely delay submitting important information, intent to deceive, in case the negative approval decision by examinor. Although, those two paper was considered to be non-inflential for the decision of patent approval but the time consuming, litigation expanses increase, tension and pressure for the stock price…etc, the cost is huge.

2.6 In re Omeprazole, AstraZeneca v Andrx pharmaceutical & Genpharm[48]

AstraZeneca is one of the leading pharmaceutical company in the world, Omeprazol generated billions revenus to the company for years, with new slow release form, this new version of omeprazole continuely its services to contribute tons of cash into AztraZeneca with more than five indications on Duodenal ulcer, Gastric ulcer: short term treatment, Treatment of gastroesophageal reflux disease (GERD), Maintenance of healing of erosive esophagitis and Phtologcal hypersecretory conditions. Not only performed the legendary litigation role model in intellectual property, AstraZeneca also made a brilliant track records on medical/clinical trials and marketing planning.

[47] See supra note 6
[48] See supra note 7

Till date, there were more than three waves litigation ongoing for generic companies, most of generic companies either tried to change coating polyers or excipients, however, when consider the primary concern for the invention, if the key ingredient remain the same, without major process/ manufacture improvement or new formulation, it is hard to survive when confronting the top tier attorneies hired by AstraZeneca. Let us compared the Astrazeneca's US patent no 4,853,230 (the '230 Patent) and 4,786,505(the '505 Patent) with the patents from generic companies:

Claim 1 of Astrazeneca's '230 patent

An pharmaceutical preparation comprising

(a) a **alkaline reacting core** comprising an **acid-labie pharmaceutical active substance** and an alkaline reacting compound different from said active substance, an alkaline salt of an acid-labile pharmaceutical active substance, an alkaline salt of an acid-pharmaceutically active substance and an alkaline reacting compound different from said active substance;

(b) An **inert subcoating** which **rapidly dissolves or disintegrates in water disposed on** said **core region**, said subcoating comprising one or more layers of materials selected from among tablet excipients and polymeric film-forming compounds and alkaline compounds; and

(c) an enteric coating layer surrounding said subcoating layer, wherein the subcoating layer isolates the alkaline reacting core from the enteric layer **that the stability of the preparation is enhanced**.

(2) Genpharm's formulation:

a sugar core;
an active drug layer (containing micronized omeprazole) sprayed onto the sugar core;
a protective coating layer of HMPC (hydroxypropyl methy;cellulose) sprayed onto the active drug layer; and
an enteric coating sprayed onto the protective coating

(3) Cheminor' s formulation:

a core pellet (containing omeprazole and *meglumine* [N-methylglucamine], an alkaline compound);
a coating made of polyvinylpyrrolidone ('PVP");
an enteric coating (made of eudragit L100-55, triethyl citrate and magnesium stearate).

(4) Andrx' s formulation:

a sugar core;
a **homogenized** suspension of micronized omeprazole, sodium laury sulphate (dispersant), disodium hydrogen phosphate (stablizer), lactose (filler)m providone (binder), and water, sprayed onto the core;
A **homogenized** enteric coating containing hydroxypropyl methylcellulose phthate ("HPMCP"), acetyl alcohol, talc, acetone, and isopropyl alcohol.

(5) KUDCo's formulation:

(a) **a microtablet core** (containing omeprazole, HMPC, and lactose particles);
(b) a subcoat (same as that of the '505 and '230 patents); and
(c) an enteric coat (same as that of the '505 and '230 patent)

(6) Claim 1 of Astrazeneca's '505 patent

An oral pharmaceutical preparation comprising

(a) a **core region** comprising an **effective amount** of a material selected from the group consisting of omeprazole plus an **alkaline reacting compound**, an alkaline omeprazole salt plus an alkaline reacting compound and an alkaline omeprazole salt alone
(b) An **inert subcoating** which is **soluble or rapidly disintegrating in water disposed on** said **core region**, said subcoating comprising one or more layers of material selected from among tablet excipients and polymeric film-forming compounds, and
(c) an outer layer disposed on said subcoating comprising an enteric coating

Only KUDCo was not infringed both '230 and '505 patents, therefore, small change of formulation or excipients although made the wording difference, however, if the nature of the technology (using polymer for coating the capsule) was not improved with differntiable advancement, the patentability will be challenged if the profits are considerably attracktive..

3. CONCLUSION

3.1 How to overcome Obviousness

In order to overcome the obviousness, evidence from some of ordinary skill were skeptical of the advantages of the invention may show "unexpected result". General skepticism of those in the related art not only amounting to teaching away but also "relevant and persuasive evidence" of non-obviousness.[49] An inventor has probed the strengths and weakness of the prior art and discovered an improvement that escaped those who came before is indicative of not obviousness.[50]

It is not sufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements.[51] The evidence that the combination was not viewed as technically feasible must be considered, for conventional wisdom that a combination should not be made is evidence of non-obviousness. The motivation in the prior art to combine the references does not have to be identical to that of the application to establish obviousness.[52]

It is not required to support an obviousness rejection if a prior art reference explicitly contain all the necessary features of the claimed invention. The key is the "inherent teaching of a prior art reference can be used to overcome an obviousness rejections"[53]

3.2 How to overcome anticipation

There are few suggestions for overcome anticipations as listed below:

A factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed invention.

A person of ordinary skills, upon reading the reference, would be discouraged from following the path set out in the reference, unexpected results are often applied tactics.

Applicants may argue that the examiner's conclusion of obviousness is based on improper hindsight reasoning. However, "any judgement on obviousness is a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper."[54]

As discussed in Manual of Patent Examination Procedure(MPEP) Section 2143.01 there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings. The federal circuit has produced a number of decisions overturning obviousness rejections due to lacking of suggestion in the prior art of the desirability in combining references. In addition to the material in MPEP Section 2141.02, prior art must be considered in its entirety, including disclosures that teach away from the claims and MPEP Section 2143.01 proposed modification cannot render the prior art unsatisfactory for its intended purpose or change the principle of operation of a reference.

[49] Gillette Co. v. S.C. Johnson & Son 16 USPQ2d 1923 (Fed. Cir. 1990)
[50] Fromson v. Anitec Printing Plates, inc. (Fed. Cir. 1997)
[51] Arkie Lures, Inc. v. Gene Larew Tackle, Inc. 43 USPQ2d 1294 (Fed. Cir. 1997)
[52] In re Kemps, 40 USPQ2d 1309 (Fed. Cir. 1996)
[53] In re Grasselli, 218 USPQ 769 (Fed. 1983)
[54] In re McLaughlin 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

3.3 What is the most important lessons after all:

Upon the previous cases, in order to defense the infringement, obviousness or anticipation, the following legal countermeasures experiences are recommended:

(1)The literal infringment must be prevented before submission, it is unforgiveable to be found the exactly the same figures or description in the prior art belonged to the applicant.

(2) Applicant's FTP (file transfer protocol) and website will also be considered as proper public communication case by case.

(3)Filing date and publicity date are crucial details required extra attentions even during the paper submission through internet/e-mail.

(4) Laboratory managemnt shall be carefully maintained and monitors for all data and writing.

(5) Carefully communication with patent agent throughout the whole patetn writing process

REFERENCE

American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501

Apotex Corp. v. Merck & Co., Inc, 2006-1405, www.uscourts.cafc.gov, decided on 16 Nov. 2007.

Arkie Lures, Inc. v. Gene Larew Tackle, Inc. 43 USPQ2d 1294 (Fed. Cir. 1997)

Aventis Pharma v. (2008). Amphastar pharmaceutical & Teva Pharmaceutical, 2007-1280, www.uscourts.cafc.gov, decided on 14 May,

Intellectual Property and High Technology Technical Amendments Act of 2002 (H.R. 2215) (Pub. L. 107 (2002))

United States v. (1966). Adams, 383 U.S. 39, 52, 148 USPQ 479, 484.