From:
Sent: Friday, August 13, 2010 5:18 PM
To: Restriction_Comments
Cc:
Subject: docket no. PTO-P-2010-0030, comment on restriction USPTO

Dear Sir,

Attached please find comments on restriction practice in the USPTO, submitted on behalf of the U.S. patent counsel of sanofi-aventis.

Best regards,

Serena Farquharson-Torres, Ph.D., J.D.
Senior Director, Head, Global Immuno-Inflammation Patent Support
sanofi-aventis U.S. Inc.
1041 Route 202-206
Mail Code: BWD-303A
Bridgewater, NJ 08807
USA
Telephone: 908-231-2836 – Fax: 908-231-2626
E-mail: serena.farquharson-torres@sanofi-aventis.com

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Federal Register Notice: Vol. 75, No. 113, Monday, June 13, 2010; pp. 33584 – 33587.

Patent and Trademark Office Docket No.: PTO-P-2010-0030

Action: Request for comments

Title: "Request for Comments on Proposed Changes to Restriction Practice in Patent Applications"

COMMENTS IN RESPONSE TO THE REQUEST FOR COMMENTS PROPOSED CHANGES TO RESTRICTION PARACTICE IN PATENT APPLICATIONS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The U.S. patent department of sanofi-aventis appreciates the opportunity to submit comments in connection with the United States Patent and Trademark Office (U.S.P.T.O.) Notice, "Request for Comments on Proposed Changes to Restriction Practice in Patent Applications," Federal Register Notice: Vol. 75, No. 113, Monday, June 13, 2010; pp. 33584 – 33587. Sanofi-aventis is a global healthcare company engaged in the research, development, manufacture and marketing of healthcare products. Our business is diversified and includes pharmaceuticals comprising Rx (prescription) drugs, consumer healthcare business (over-the-counter / combined OTC and Rx drugs) and generics; vaccines and animal health. Sanofi-aventis calls for the U.S.P.T.O. to seriously consider our comments in its effort to improve the quality and consistency of restriction requirements made by its Office personnel.

Below we provide comments about restriction practice based on feedback from individual in-house patent attorneys engaged in daily prosecution of patent applications covering both chemical and biological inventions.

In surveying the restriction practice experienced by our in-house patent counsel at sanofi-aventis, in both the chemical and biological fields, it was found that current restriction practice often resulted in inconsistent, unpredictable and excessive divisions of the originally filed invention. For example, it was one attorney's experience that in a second divisional application covering a single protein, a 9-way restriction was received. Consequently, by the time prosecution is complete it is likely that there will be at least 11 issued patents. It is important to note, that the original application granted into a patent with a representative set of claims covering the major aspects of the invention; but, in order to obtain full coverage, as was originally intended, it became necessary to file multiple divisional applications. As a result, subsequent divisional applications will end up covering only 1 or 2 claims at a time. This example is useful to illustrate the inconsistency of restriction practice, since this 9-way restriction is of a second divisional application, indicating that the original invention had already been restricted and now is being further restricted. This results in piecemeal prosecution of the application and could lend to confusion of the public as to what is covered by patent protection.

Each attorney had very similar experiences, but this example is useful to illustrate how the current restriction practice forces attorneys to make crucial choices regarding sacrificing full coverage of the invention, in an effort to control exponential expenses such as filing fees, prosecution fees and eventually annuity fees associated with filing of each divisional application.

It is important to note, that since restriction practice necessarily takes place very early in the prosecution process, it takes place well before even a developmental candidate is identified and definitely well before knowing whether the application will cover a commercial product. In fact, a great majority of patents filed in the pharmaceutical industry do not cover developmental candidates or more importantly, commercial products.

The real world consequences of the inconsistent and unpredictable divisions being made of inventions are numerous and have future ramifications. For example, attorneys are forced to decide whether to seek full coverage and file all divisional applications or to take a chance and only cover the majority of the invention and not necessarily file all divisional applications. This decision must be made at a time when it is unknown whether the application covers the next block buster drug or just another one of the many thousands of compounds that never go any further than the lab bench.

Thus, it is crucial that restriction practice be brought under control with simple and clear guidance for both the Examiner and the practitioner.

Another frustration for practitioners is the idea of declaring that compounds and method of treatment using those compounds are patentably distinct and therefore warrant separate applications. The reasoning regularly provided by the Examiner, during prosecution, is that if it can be conceived that the claimed compound can be used in another method of treatment that is not covered in the patent application and likewise, if an unclaimed compound could be used in the claimed method of treatment, the claimed compound and method of treatment are patentably distinct. But it is every attorney's intent to cover not only the compound, but also the method of treatment using that compound if they are both claimed in the same patent application, thus it becomes apparent that the reasoning being used by the Examiner is solely for the purpose of forcing a division of the invention and not to truly identify patentably distinct inventions.

Furthermore, confusion arises when we continue to find obvious type double patenting (OTDP) when compositions and methods using those same compositions are presented in separate applications.[1] If methods and compositions being patentably distinct from each other is basically black letter law at the U.S.P.T.O., then why is this not true when OTDP is considered?

Another concern of sanofi-aventis in-house patent counsel is the need for training of the Examiners using a clearly defined process to improve the consistency from one Examiner to the next. For example, a restriction requirement was issued by one Examiner and subsequently the case was re-assigned to another Examiner. The newly assigned Examiner contacted the practitioner in order to provide notice that a new and very different restriction requirement would be issued. If there was a clearly established parameter to divide subject matter into separate inventions, that everyone understood (e.g., Examiners and practitioners alike) we would not encounter this disheartening result.

In fact, it seems that it is common among some Examiners, where there is a required election of species, that the elected species is used as the basis of the search, but then to deem

[1] Sun Pharmaceutical Indus., Ltd. v. Eli Lilly and Co., (No. 2010-1105 (Fed. Cir.)July 28, 2010), Federal Circuit recently held that the method claim of using gemcitabine for treating cancer is not patentably distinct from the compound claim of gemcitabine, when the use of treating cancer was already disclosed in the compound patent. The court held that the method of treatment patent was invalid based on obvious type double patenting.

the rest of the scope of the Markush claim as non-elected subject matter even though no prior art is found. This is improper and results in an arbitrary division of the Markush claim based on Applicant's election of species.

Another common practice is where restriction is based on class and subclass. The Examiner automatically separates the invention into many different groups, simply based on the fact that a randomly selected substituent, of their subjective choosing, would be categorized in a different class from a different substituent on the otherwise, same compound. The use of the class system is not aligned with current search practice in the digital age. Historically, searches involved working through a hard copy and separating similarly classed inventions into the same shoe box, which understandably would be burdensome. However, designing an individual search based on what is presented in a Markush type of search or using a digitized classification system in which multiple classes are entered could result in a manageable finite set of results. Specifically, there is a good probability that a search for five-membered heterocycles would involve multiple classes; but, those classes could be similar enough to search together in a Markush type of search and still result in a manageable finite set of results. Likewise, in searching key words, although the terms might be of different types, they could all be entered and still result in a workable finite set of results.

Modernized systems such as STN and Merged Markush System (MMS) both are types of substructure searches, and Derwent Fragmentation Code can and are regularly available to achieve more efficient and tapered searches over what the Classification System allows when examining Markush-type claims. These modernized search engines fully support maintaining a key structural element of a Markush-type claim, while allowing for structural diversity of substituents from the core of a molecule, and further variations on that core.

Along with training Examiners to use the search tools described above, it would also be beneficial to train Examiners to be better able to identify patentably distinct inventions when it comes to Markush-type claims. Currently, the Examiner requires Applicants to identify a specific species on which to base the initial search. This is a useful place to start, in that it greatly simplifies the search and the search is then expanded until an anticipatory reference is identified. It would still need to be determined whether the claims would be obvious in view of that anticipatory reference. But the determination of whether other claims would be obvious in view of that reference should be based on the determination of what a person of ordinary skill in the chemical arts would consider to be an obvious Markush

grouping. The discussion would be based on the group having a community of chemical or physical characteristics, which justify their inclusion in a common group. One could imagine similar results for biological patent applications, if the claims that should be maintained as part of the same invention would be determined by a person of ordinary skill in the biological arts. In any case, restrictions should not be repugnant to principles of scientific classification as is often the case in current restriction practice. Even in current practice, however, once restriction determinations have been made, it should be part of the standard procedure to again, consider rejoinder of the non-elected subjected matter in an effort to establish the broadest allowable subject matter.

In addition to the training necessary for making the restriction itself, there needs to also be a change in the traversal process. Currently, the Examiner that issues the restriction requirement is the same Examiner who considers whether the traversal of the restriction requirement has any merit and whether it would be an undue burden to deal with the invention as a whole. Although Examiners are capable of being persuaded from their initial view point, as they are during the course of patent prosecution, this initial step of grouping inventions has such an exponential impact on the number of applications being filed and thereby the associated costs. Thus, it would be beneficial to have an immediate supervisor review any well reasoned traversals that the Examiner finds unpersuasive, before the first Office Action on the merits has issued. Such a practice could potentially eliminate much of the inconsistent and excessive divisions resulting from flawed reasoning that may not be realized by one person; A second opinion by a supervisor could prevent the Examiner from expending time and resources possibly evaluating an incomplete or mistakenly categorized set of claims.

Finally, it is also a shared idea among practitioners that with all of the problems around restriction practice, the U.S.P.T.O. should evaluate the option of following PCT rule 13 Unity of Invention practices as it is followed in many other countries and as the U.S.P.T.O. have some experience with as well.[2] The Unity of Invention standards; i.e., that individual compounds encompassed by a Markush structure must share a "*single structural similarity*" and a "*common utility*" seem to be more consistent with covering the invention as a

[2] see MPEP §1850

whole. In fact, following the Unity of Invention standard would be consistent with existing U.S. Restriction Laws of 35 U.S.C. §121.[3]

Conclusion

The U.S. patent department of sanofi-aventis appreciates the U.S.P.T.O.'s reaching out to the patent community for comments on restriction practice from a practitioner's perspective and remains committed to provide any further exchange deemed beneficial to improve patent prosecution for all involved.

Dated: August 13, 2010 Respectfully submitted,

/Serena Farquharson-Torres/

Serena Farquharson-Torres, Reg. No. 54,093

sanofi-aventis U.S. LLC
US Patent Operations
Route #202-206 / P.O. Box 6800
MAIL CODE: BWD-303A
Bridgewater, NJ 08807-0800
Telephone: 908-231-2836
Telefax: 908-231-2626

[3] See 35 U.S.C. §121 "If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application that complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention."