Genentech
A Member of the Roche Group

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Via E-Mail Only: PriorArtAccess@uspto.gov
Mail Stop Comments-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Deputy Director Michael Neas

RE: Comments by Genentech in Response to the USPTO's Request for Comments on Leveraging Electronic Resources To Retrieve Information From Applicant's Other Applications and Streamline Patent Issuance

Dear Deputy Director Neas:

Genentech, Inc. thanks the U.S. Patent and Trademark Office for the opportunity to provide comments in response to the USPTO's "Request for Comments and Notice of Roundtable Event on Leveraging Electronic Resources to Retrieve Information from Applicant's Other Applications and Streamline Patent Issuance," published in 81 Fed. Reg. 59197 (Aug. 29, 2016).

Genentech, a member of the Roche Group, is a leading biotechnology company that discovers, develops, manufactures, and markets human pharmaceuticals for significant unmet medical needs, especially in the areas of oncology, immunology, neuroscience, metabolism, and infectious disease. Genentech has an extensive track record of success in all phases of bringing new disease treatments to patients. Genentech's products include some of the most important treatments for cancer, heart attack and stroke, macular degeneration, and other serious or life-threatening medical conditions.

Today, Genentech has a product pipeline that is among the strongest and most innovative in the biopharmaceutical industry. This is, in large part, the result of significant and ongoing investments in research and development giving rise to multifaceted inventions that underpin Genentech's innovative products. Continued robust patent protection for such inventions is critical to enable Genentech to continue to invest and innovate. Thus, Genentech supports USPTO's continuing efforts to improve the overall patent process.

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The comments below reflect a desire for a robust record to enable high quality examination, fulfillment of Rule 56 requirements, and considerations regarding potential future allegations of inequitable conduct in patent litigation in view of applicable case law.

It is a common practice to cite all references identified by ex-U.S. and WIPO search authorities to the USPTO. Accordingly, Genentech supports a transparent system in which all imported information is placed onto the record. To ensure that the record is complete under this new system, we anticipate that we may be checking the information that is imported automatically by the USPTO. Accordingly, Genentech supports a system that clearly indicates when information enters the record and from what source.

If the USPTO were to adopt a system that automatically provides references or other information to the Examiner, the system should:

- provide to the Examiner references based on clearly-defined selection criteria;
- clearly display when a reference enters the file and when the Examiner considers the reference;
- automatically notify an applicant when a reference enters the file; and
- not penalize applicants under the IDS and PTA rules, for example, for duplicate IDS submissions.

Question 1: In balancing the goals of examination quality and efficiency, should the USPTO monitor other applications, besides domestic parent and counterpart foreign applications, for relevant information located therein for consideration in the instant U.S. application? If so, which other applications should be monitored (e.g., siblings, applications involving the same or related technology, etc.)?

We favor having default and automatic monitoring of only domestic applications with a priority claim to a common patent application, and counterpart foreign applications. We think that this is a bright-line, easily administrable rule that will provide useful information to Examiners in support of robust examination. On balance, a default process which automatically monitors and imports information from other applications (*e.g.*, applications involving the same or related technology) may overburden the Examiner without adding to examination quality. In the biopharmaceutical area, patent applications are often filed in many countries and may cite a large number of references to the USPTO due to the nature of the technical field. Against this backdrop, we believe further adding by default other sources to monitor may result in overburdening the Examiner with information that may be ancillary to the invention under examination while not adding to the robustness of examination.

Question 2: What is the most convenient way to bring an application to the USPTO's attention that should be monitored for information during the examination of a U.S. application (e.g., automated system, applicant notifies the USPTO, etc.)?

We favor having default and automatic monitoring of only domestic applications with a priority claim to a common patent application, and counterpart foreign applications. We think that this is a bright-line, easily administrable rule that will provide useful information to Examiners in support of robust examination.

We do not support a USPTO mandatory requirement for applicants to identify "related" applications (or as stated in Question 1, "applications involving the same or related technology"). In the biopharmaceutical area, products may have multiple patent families covering distinct inventions related to each product. For example, there may be patent applications to the specific chemical or biological product, manufacturing methods useful for making the product, platform technology applications that may relate to the product, or method of use patents that relate to different methods of use of the product. These applications are typically filed at various time points corresponding to the timing of invention over a product's research and development period. To the extent that any mandatory USPTO requirement might be broadly interpreted, there is a potential that an applicant might overburden the Examiner with information that may not actually increase the robustness of examination. Also, to the extent that such a mandatory requirement is not a bright-line rule, problems may arise due to inconsistent enforcement or compliance.

A requirement to make an affirmative statement on the record as to which applications are related applications could be onerous and present a real risk of overburdening an Examiner without adding to examination quality.

Question 3: How should the USPTO determine which information from the monitored applications to provide examiners while ensuring they are not overburdened with immaterial and marginally relevant information?

The Examiner should be provided all references identified during the search and examination of domestic applications with a priority claim to a common patent application, and counterpart foreign applications, including A, X, and Y references.

All information provided to an Examiner from the monitored applications should be imported into the image file wrapper and the Examiner should provide a clear indication in the record that the Examiner has considered the information. Otherwise, it is likely that an applicant will separately submit information to the USPTO in an IDS in order to have the information (e.g., a reference) considered by the Examiner. Depending on the timing of this IDS submission and the IDS rules implemented by the USPTO in support of the proposed new system, there is a risk that an RCE or other continuing prosecution filing may be required in order to get this IDS considered by the Examiner. This is contrary to the USPTO's stated goal of streamlining prosecution.

The USPTO asked at the Roundtable held September 28, 2016 whether office actions from counterpart foreign applications should be automatically imported. In the

biopharmaceutical area, we often file patent applications in many countries, and as such, there may be a large number of foreign office actions in some patent families. In view of this potentially large number of foreign office actions, we would welcome confirmation of whether the USPTO will provide Examiners with translations of automatically imported non-English information, such as office actions and references. Further, if foreign office actions will be automatically imported, we respectfully request that the USPTO consider whether the Examiners should be trained in differences between foreign and U.S. legal standards for patentability and procedure, as there are substantive differences between foreign and U.S. legal standards for patentability and procedure. Finally, we note that the pending claims may differ between the U.S. application under examination and a counterpart foreign application. In this circumstance, the foreign office action may be ancillary to the invention under examination.

Question 4: If the USPTO were to import information from applicant's other applications, how should the USPTO document the information imported into the image file wrapper of the instant U.S. application? For example, should the record reflect which domestic parent or counterpart foreign application the information was imported from, the date that the information was imported, and whether the examiner considered the imported information?

The record should reflect the following information:

(1) Which domestic application or counterpart foreign application the information was imported from;

(2) Type of information (*e.g.*, reference), and title and full citation for the information;

(3) The date that the information was imported by the USPTO into the image file wrapper of the application under examination;

(4) An indication that the Examiner considered the information. This would be analogous to the current practice of the Examiner initialing a Form 1449 to indicate that references have been considered. Any information automatically imported into the image file wrapper from domestic applications or foreign counterpart applications should be indicated as considered by the Examiner;

(5) The source of the paper (*e.g.,* examination report in particular foreign counterpart application, date of the action if available) in which the reference is cited. This will assist applicants in locating the relevant action for review or other reasons; and

(6) Categorization information (e.g., X, Y, A, etc.) if available.

In addition to the documentation above, the USPTO system should have the functionality to send an alert to applicant when information is added to any given patent application record. This alert would assist in minimizing duplicative disclosure by making applicant aware that information has been imported onto the image file wrapper. This would also assist applicants

who are citing information from the U.S. record in foreign countries (such as Israel) where references cited in the U.S. record must be provided in the foreign counterpart application(s).

For applicants who have their own internal IDS database management systems, it would be useful if the USPTO system is designed to permit easy export of cited information data, such as title, date and full citation information and copies of references, in a text-editable format that could be directly ported to an IDS database.

Question 5: Taking into consideration the information that is publicly available in PAIR, what information should be part of a patent? For example, should prior art references and classification information still be listed on the front page of a patent?

Generally, practitioners find the compiled cited reference information on the face of the patent to be useful. If the same information is displayed at another location, for example in PAIR, that would be acceptable provided it is displayed in a condensed format and would not require practitioners to have to search for and review IDS forms, form 892s, and, if the current proposed system is implemented, records of automatically imported information (*e.g.*, references). It would also be useful to be able to download the citations and references in batch format in order to submit them in other foreign jurisdictions.

Thank you for your consideration.

Respectfully,

Irene T. Pleasure, Ph.D., J.D.
Senior Associate General Counsel
Head of Patents, Senior Director