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November 10, 2014

Mr. Oliver Neuer
Legal Administration Officer
Legal Division
European Patent Office
27 Erhardtstr.
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GERMANY

Via fax (7 pages) and via mail

Our ref.: F006808/SW/bc

Re.: European patent application no. 12189198.0
in the name of ABBVIE INC.
Legal File No. R14-323/2014

Dear Mr. Neuer,

We refer to your communication dated September 26, 2014 concerning the stay of proceedings under Rule 14 EPC now requested by Gilead Pharmasset LLC (in the following: "Gilead") in connection with the above-identified European patent application, and hereby forward applicant's requests and observations.
As will be discussed, Gilead's request under Rule 14 EPC is nothing more than a crude attempt to delay the grant of the above-captioned patent application after failure to succeed with its prior third party observations filed on January 15, 2014, November 21, 2013 and September 30, 2013, respectively. Incidentally, the instant request under Rule 14 EPC ultimately hinges on the same arguments as already put forward by Gilead in the said third party observations under the heading of lack of patentability and amounts to a clear procedural violation since it has been filed under deliberate circumvention of the relevant provisions of the EPC. Namely, the vindication action filed by Gilead is a circumvention of the requirements defined in J 7/00 and willfully designed *ab initio* to delay (rather than to promote) progress of civil proceedings before the German courts.
Gilead's request constitutes therefore an abusive attempt to expressly displace the normal operation of Rule 14 EPC with the only aim to obstruct Examination proceedings - without having put forward any case of vindication, and without having even met the formal requirements.

1. Requests

The Applicant hereby requests that:
the European Patent Office sets a date under Rule 14 (3) of **two months** after which the proceedings for grant will be resumed.

2. Discretion of the Legal Division

The Legal Division is referred to Rule 14(3) EPC which states:
"*Upon staying the proceedings for grant, or thereafter, the European Patent Office may set a date on which it intends to resume the proceedings for grant, regardless of the stage reached in the national proceedings instituted under paragraph 1. (...)*"

The Legal Division therefore has complete discretion to allow the examination proceedings in respect of the patent application *in re* to continue at any stage.

3. Obvious delaying tactics and contradictory behavior by the third party

Obviously it is Gilead's tactic to delay the application by simply "burying" the proceedings in lengthy litigation to get more time for their planned launch of an infringing product on the European market within short, later this autumn.
To make sure that the goal of "burying" grant proceedings is actually met, Gilead has delayed the German action until now, and moreover Gilead has designed the German action such as to proceed as slowly as possible. Namely, the Administrative Court of Munich is *prima facie* not the appropriate court, as further discussed below.
Filing the case more than one year after the request for Examination in August 2013, moreover with the wrong court can only mean that Gilead is not at all interested in securing as quickly as possible its supposed rights - rather Gilead seeks - now that its third party observations have failed- to delay grant of the patent to AbbVie at any cost.

3.1 The vindication action is a renewed novelty objection in disguise

The vindication action is a renewed novelty objection in disguise. The arguments put forward by Gilead in the vindication action hinge on documents already discussed in examination proceedings and/or unsuccessfully produced in the third party observations. As arguments to support a vindication claim, they are in direct contradiction to Gilead's earlier objections based on alleged lack of novelty.
One of these documents is WO 2013/040492 A2 (Enclosure K9 to the vindication action) which had been cited during prosecution as reference D21 against the novelty of the claims. At sections 21 and 49 of the vindication action, Gilead relies on WO 2013/040492 to show that it has allegedly applied for patent protection prior to the applicant.
Moreover, at chapter II (5), in particular in sections 57-62 of the vindication action, Gilead relies on the notes from an earnings call which took place on February 2, 2012 (Enclosure K26 to the vindication action) which had also been filed by Gilead itself along with its third party observations of November 21, 2013 (reference D17 during prosecution). Note that in the said third party observation dated November 21, 2013 filed with the EPO, Gilead has specifically underscored that the said earnings call constituted a public disclosure and allegedly destroyed the patentability of the claims pending in the application. If the earnings call was public, however, anything disclosed in it became part of the public domain and cannot support a vindication action.

Nevertheless, Gilead directly contradicts itself by claiming, in sections 36-37 of the vindication action, that Gilead itself (which was an entirely different company from Pharmassett at the time of 2009-2010 and, in fact, was a competitor of Pharmasset) invented and owned the combination product covered by the claims pending in the EP application requested to be stayed, before Gilead's acquisition of Pharmasset in 2011-2012. But Gilead has made no case, nor can it, that applicant had access to any confidential or non-public information from Gilead from which it can make a claim for entitlement to the invention, cf. sections 53-55 of the vindication action. Gilead merely alleged

that applicant had access to certain information from Pharmasset. However, even according to Gilead, Pharmasset did not invent or own the combination product at issue.
It is thus apparent that the arguments put forward by Gilead in the vindication action do not relate to "entitlement" under Art. 60 and 61 EPC, but are simply arguments of lack of novelty and/or inventive step under Articles 52-56 EPC.
Such arguments, however, are not appropriately dealt with in a case of entitlement before a national court instead of the appropriate forum for such arguments, which is the Opposition Division of the EPO. The request filed by Gilead amounts thus to an abuse of procedure, aimed at delaying grant of the instant application and ultimately also at delaying the institution of an opposition against such grant. In relying on arguments under Articles 52-56 EPC, Gilead has filed a vindication action although Gilead is well aware that no case for entitlement actually exists, since anything which is publically disclosed falls into the public domain and hence cannot be misappropriated by any means. Moreover Gilead has requested suspension of the instant grant proceedings, although no damage to Gilead's patent position could have been expected, had Gilead raised its purported arguments more appropriately within a European opposition proceedings.
Clearly, the procedure enabling the Legal Division to stay grant of an application is not aimed at a situation as the present in which Gilead attempts to overcome the Examining Division's negative ruling (in the examination report dated June 3, 2014) according to which neither D17 nor D21 constitute any obstacle against patentability, by trying now to employ said documents D17 and D21 as a basis to distort proceedings under Rule 14 EPC before the Legal Division.
Furthermore this proves not only that Gilead was aware of the patent application and all relevant facts at least since September 2013, but did not file an action in a national court in Europe until September 2014. It is also completely contradictory if Gilead first alleges that the claimed-subject matter was publicly known at filing/priority date and now asserts that the claimed-subject matter was its proprietary know-how and misappropriated by the applicant. These contradictory statements show very clearly that the action in the national court was only filed in order to trigger a stay of the examination under Rule 14 in order to delay the grant of the patents after the attempt to prevent the grant via third party observations failed. Therefore, grant proceedings should be immediately resumed.

3.2 No action filed in the appropriate court

Gilead is not interested in settling the issue at hand as soon as possible. This is clearly indicted by the fact that Gilead has filed the entitlement action for the European patent application with the Administrative Court of Munich. Even though German Courts have in principle jurisdiction in the present case, the Administrative Court of Munich is clearly not the appropriate national Court ("zuständiges nationales Gericht"). Namely, questions pertaining to the entitlement of a patent application come under the jurisdiction of the Civil Court, see § 143 PatG. For EPO-related patent matters, the appropriate Civil Court is the Regional Court of Munich, since the EPO has its residence in Munich, Art.II § 10 IntPatÜG. Therefore the Administrative Court of Munich will refer the case to the Regional Court of Munich. Generally, this will take several weeks or even months. This is absolutely superfluous considering that Gilead could have filed the vindication action directly with the competent court.

3.3 No service of the action on the applicant

The vindication action has not yet even been served to the applicant. By choosing the Administrative Court of Munich Gilead takes advantage of very specific national rules for actions pending in Administrative Courts, which deal with actions against the public administration and have no jurisdiction in the present matter. Gilead has only chosen the Administrative Court of Munich in order to quickly establish commencement of proceedings. At first glance, this may look like an effort to quickly start both, the vindication action and, consequently, the stay before the

EPO. In fact, as above mentioned, Gilead simply tries to circumvent all procedural requirements that Gilead would have had to observe, if Gilead would have had filed the vindication action with the appropriate national court, i.e. the Regional Court of Munich. All in all, Gilead's decision to file the action with the Administrative Court of Munich has to be seen as an attempt to create a "pending" national case without having to fulfill the requirements for a pending German civil case as listed in J7/00. It is a purely tactical choice with the aim of delaying the actual outcome of the vindication action as much as possible.

4. Offer of undertaking not to withdraw or transfer the patent application

To prove that the applicant has no intention to avoid a decision by the national court, the applicant offers herewith the undertaking not to withdraw or transfer the patent application in re until the issue of ownership is resolved in the national courts. This will protect Gilead from any disadvantage in case that they should – against any expectation – succeed in the German vindication action.
It is furthermore established that Gilead can also raise its alleged entitlement to the invention also as a defense in any infringement proceedings brought by the applicant on the basis of any patents issued on the pending applications (see BGH GRUR 2005, 567 – Schweißbrennerreinigung). So there is no need to stay the examination proceedings with a view to potential infringement proceedings on the national level either.

5. Efforts by the applicant to speed up the entitlement proceedings

As we have highlighted above, it is of utmost importance for the applicant to get a judgment on the merits of the vindication action as soon as possible. For this reason, the applicant asked the Administrative Court of Munich to serve the vindication action directly to its legal representatives in Germany. Furthermore, the applicant filed a motion to the Administrative Court of Munich to refer the lawsuit to the appropriate national court, i.e. the Regional Court of Munich. This shows clearly applicants interest to quickly start with the entitlement proceedings and to avoid the time-consuming translation and service of the vindication action – as required under the Hague Convention – to the applicant in the USA.

We hereby declare that the applicant will make any effort to accelerate the entitlement proceedings before the Regional Court of Munich. Since the vindication action is without any merits (see above point 3.1) and its only purpose is to delay the proceedings for grant we are quite confident that the Regional Court of Munich will agree to speed up the proceedings.

6. Balance of Interests

6.1 Rule 14 EPC and the Protocol of Recognition as an instrument to balance interests

Considering all of the foregoing, it is submitted that the EPO is granted the power to perform a preliminary examination of the jurisdiction as identified in Section I of the Protocol of Recognition when it has to issue a decision on the suspension of the grant proceedings of a patent application under Rule 14 EPC.

Such examination in fact comes under its remit and its scope if we read the rule in the legal context as identified above and if we interpret it in light of the principles expressed by the EPO Boards of Appeal (for example in the decision J06/03, point 20).
In fact, the suspension of the proceedings for the grant of a patent application as per Rule 14 EPC must be considered as an instrument to balance the interests of the third party requester and of the owner of the application, as well as, more generally, the public interest in a fair and rational operation of the system.

Indeed, while on the one hand there is the interest of the third party requesting the suspension in preventing the owner of the patent application from being able, in the time necessary to obtain a ruling that establishes the actual ownership of the patent, to withdraw the patent application or a designation thereof, or transfer it to third parties or amend it, on the other hand there is the interest of the owner in obtaining as soon as possible the grant of his or her patent right which, in fact, becomes effective only after grant - for example, in many Contracting States it is possible to obtain a ruling against infringing parties only after the patent is granted by the EPO. A delay in the grant of a patent (or, in this case, of the application *in re*, which was subject to accelerated examination proceedings) evidently causes serious detriment to the owner of the patent application.

If we consider that the vindication action filed by Gilead is without any merits. If we also consider that Gilead has made deliberate effort to circumvent the rationale of J007/00 (see points 3.1-3.3 thereof) by filing the vindication action with a non-appropriate Court, even though Gilead could have filed its action instead with the competent Court, i.e. the Regional Court of Munich. If we finally consider that Gilead could have asked for *interim* relief before the Regional Court of Munich. It gets very clear that Gilead's conduct evidently aims at delaying clarification as much as possible. The request for stay is therefore abusive. This justifies a quick resumption of the proceedings for grant – as highlighted e.g. in the Guidelines for Examination at Part A IV. 2.3., second paragraph. Therefore, AbbVie requests that proceedings for grant be resumed within the next two months.

6.2 Impact on Gilead

If, in the present case the examination proceedings are resumed, the possible impact on Gilead is either that the application is granted or that the application is refused.
Since Gilead alleges, at sections 44-46 of the vindication action, that the claims in the suspended application would cover subject matter explicitly or implicitly derivable from their own priority application U.S. 61/535885 (Enclosure K23 to the vindication action) of 16.09.2011 which can be found in the file of WO 2013/040492 A2 (Enclosure K9 to the vindication action, pending before the EPO as EP2709613), then a refusal of the suspended patents cannot damage the patent position of Gilead, since Gilead appears to believe to have coverage of the subject-matter in its own application. The same would be true for Gilead's prior granted patent EP 2203462 B1 and for prior pending application EP 2430014 A1 stressed at section 47 of the vindication action.

On the other hand, if the suspended application proceeds to grant, then no damage is caused to Gilead either, since Gilead can allow the granted patent to lapse at any time, should Gilead eventually deemed to be entitled to the patents.

Accordingly, due to the fact that Gilead has claimed that the subject matter of the suspended application would appear to be identical with subject matter in its own applications and patent(s), Gilead cannot lose patent protection for the subject matter, since protection may then be derivable from its own applications and patent(s), and Gilead's situation is thus the same whether the suspended patent applications are granted or refused.

Moreover, any payment made by Gilead would be returned if Gilead could show to be the actual owner of the allegedly vindicated right. Thus Gilead does not face the risk to suffer any losses if the stay would be lifted.

Furthermore, Gilead will always have the option and the right to file an opposition and thereby have an opportunity of trying to limit the scope of protection in the suspended application.

6.3. Risk of infringement and consequences for the applicant

On the other hand, it is of great importance to the applicant that the prosecution of the application is not delayed. Applicant has good reason to suspect that its competitor, Gilead, is planning to launch an infringing product on the European market within short.

Namely, Gilead received approval from the FDA to market the PSI-7977/GS-5885 Combination in the United States for treating HCV genotype 1 patients without interferon under the trade name HARVONI. HARVONI consists of a fixed-dose combination of PSI-7977 and GS-5885 consisting of 90 mg of GS-5885 400 mg of PSI-7977. The prescribing information directs that HARVONI be administered once daily for 12 weeks. On September 26, 2014, the EMA recommended the authorization of HARVONI. It can be expected that Gilead obtains a marketing approval for HARVONI from the European Medical Agency some time before year end 2014.
It would cause applicant serious and irreparable harm if this would be allowed to happen in a situation where applicant does not have its patent application in question granted. Considering the above stated, it is obvious that applicant's interest of having a patent granted for its application clearly outweighs Gilead's interest of having its claim for entitlement tried by a Court before the grant of said applications.
It is specifically noted that granting a stay would cause the applicant irreparable harm in respect of the permanently lost possibility to claim full damages (instead of only reasonable compensation for use during the application stage) and sanctions such as interlocutory injunctions against infringing sales by Gilead during the stay. Note further that royalties are not available in all Contracting States prior to grant.

The resulting situation is thus clearly unfavorable to AbbVie, in that AbbVie would suffer increasing losses with the length of the stay, whereas Gilead would not even run the risk to suffer any losses at all, even if the patent was granted immediately to AbbVie.

Also, by the time that the stay will be lifted, the market may move to next generation products.
In contrast a granted patent would not prevent Gilead from raising the entitlement as a defense against any enforcement of the granted patents in Court. Thus, the entitlement issue now raised before the European Patent Office could be raised by Gilead in Courts of the Contracting States both, as an invalidity defense, and as a request for a declaratory judgment concerning entitlement (as already attempted before the Administrative Court of Munich). In that context the entitlement issue could and would also be fully considered and the decision to stay would also be subject to appeal.

Note further that the impact of a stay on the applicant exceeds by far the actual object of the entitlement action. Namely, in the European Search report, a number of different inventions, totally unrelated to Gilead's alleged vindication claim has been identified, all of which will be affected by the stay.

6.4 Conclusions

Clearly the picture arising in the present case is not one justifying stay of grant of the application *in re*, since Gilead has tried to grossly circumvent the rationale of J 007/00 in order to maximize delay of proceedings. Moreover, Gilead in its Writ submitted to the Administrative Court in Munich has even not made a case of vindication, but merely has argued lack of novelty and/or inventive step. In such a situation, the only commensurate and proportional procedure/action would be to await the grant of the patent applications and -thereafter- initiate opposition proceedings or invalidity proceedings at the relevant national Courts.

Furthermore, the granted patent enables the right holder of that right to enforce it against infringers.

Thus, the risk that the applicant will not be in the position to have enforceable rights granted for up to some years because of the possibility for Gilead to cause procedural delay from the beginning of entitlement proceedings poses a major problem.

As, for the reasons outlined above, the balance of interest clearly tips in favor of the applicant, the Legal Division is respectfully requested to exercise its discretion under Rule 14(3) EPC for resuming grant proceedings without delay.

Respectfully submitted,

Micaela Nadia Modiano
European Patent Attorney