JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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Date July 25th, 2011

Ms. Fiona Warner
Intellectual Property Office
Concept House, Cardiff Road,
Newport, South Wales, NP10 8QQ
United Kingdom

Dear Ms. Fiona Warner,

Re: YOUR CONSULTATION ON THE RESEARCH AND BOLAR EXEPTIONS

The Japan Intellectual Property Association (JIPA) is a non-governmental organization that was established in 1938, which represents users of intellectual property systems. As an association having about 900 Japanese leading companies, JIPA submits recommendations and proposals to the relevant authorities and organizations with regard to the establishment of intellectual property systems overseas and improvements in the implementation thereof.

As for recruiting comments *"THE RESEARCH AND BOLAR EXEPTIONS - An informal consultation on patent infringement in pharmaceutical clinical and field trials"* on your website, we reviewed the issues carefully and would like to submit our opinions for the issues today.

Your deeply consideration on these matters will be appreciated.

Yours faithfully,

Emiko Yano

(Emiko Yano)
Chairperson of Pharmaceutical and Biotechnology Committee
Japan Intellectual Property Association
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OUR OPINIONS TO YOUR CONSULTATION ON THE RESEARCH AND BOLAR EXEPTIONS

Japan Intellectual Property Association
Pharmaceutical and Biotechnology Committee

In the section below, Pharmaceutical and biotechnology committee of Japan Intellectual Property Association indicates its opinions on the following specific issues.

2. *Are there any particular circumstances in which you are, or have been, at risk of infringing a patent when carrying out clinical or field trials? Do any particular types of clinical and field trials give rise to an increased risk of patent infringement e.g. using comparators, trials for combination drugs, biosimilars.*

Patents which claim production method or intermediate of the drug might have a risk of infringing a patent when carrying out clinical trials or field trials. Recently, companion diagnostic patent gets relevant since recent practice of clinical trial have required an establishment of companion diagnosis during the clinical trial. Our member companies have had experiences to face risks for infringement of third party patents which claim a research tool, combination drug or use of a compound not limited by its structure.

3. *How often does the risk of infringement influence your decision to use the UK as a base for clinical and field trials? Does this risk increase the likelihood of you conducting trials elsewhere in the EU and beyond? It would be useful if you could quantify your response e.g. as a proportion of all such trials you run.*

Quantification is difficult to be determined since a decision where clinical trials would be held depends on circumstances including various factors including the number of patients, regulatory affairs to elucidate the clinical trials we want and so on. But, it is no doubt that the risk of infringement would give an influence to a decision where clinical trials would be held.

4. *If the risk of patent infringement when carrying out clinical or field trials in the UK was removed would this influence your company strategy on placing such trials in the UK? If so, would this translate into a positive impact on the activities, the people, or the amount of work done in the UK, including work done*

by Clinical Research Organisations (CROs)?

Although new drug company takes into account various factors which have an impact for a decision in which the placing such trails could be held, the risk of patent infringement is one of relevant factors to a decision. If a risk of patent infringement when carrying out clinical trials in the UK would be removed, it might give a weight for such a decision which leads to an increase of values to the patients, doctors and businesses including the amount of work by CRO in UK.

5. If sufficient evidence is forthcoming to establish that there is a problem, there may be several options available to address the problem. Please rank the following options in order of preference and give reasons for your preference:
a) Change EU legislation to match the current US situation as determined by case law.
b) Change EU legislation, not necessarily to give an equivalent to the US situation, but to harmonise law throughout the EU in this area.
c) Change UK patent law unilaterally to exempt from infringement all activities relating to regulatory approval of a drug product.
d) Change UK patent law to exempt from infringement all activities relating to public health issues [e.g. including studies required by National Institute for Health and Clinical Excellence (NICE)];
e) Agreements within industry which govern practice on the issue of patent infringement in clinical and field trials, either in particular cases or more generally.
f) Other. Please provide details.

As long as the scope for exemption would be expanded to clinical trials of new drugs and field trials, we would like to respectfully request to fill the gap between EU States. From that context, there is no preferences between a) and b).

Conclusive Words :

Pharmaceutical and biotechnology committee of Japan Intellectual Property Association (JIPA) is formed by representatives of member companies from various sectors including pharmaceutical, food, diagnosis, biotech, electronics industries. Pharmaceutical and Biotechnology committee, one of the committees organized in JIPA has been

studying various issues regarding with application, prosecution and enforcement of pharmaceutical and/or biotechnology patents and sending our messages through various means including submission of articles to a journal relating to intellectual properties and an exchange of opinions with various parties including bar association, patent attorneys association, academia and patent offices in and out of Japan. We highly appreciate that the UK patent office has been improving the quality of public administration for intellectual properties in consideration of a proper balance between parties involved.

Considerable costs and time are required for FTO analysis since the sponsors pay their efforts on watching the status of the examination of the relevant patents and evaluating a possible infringement. If the sponsors would examine the possibility to carry out clinical trials for new drugs, a risk for patent infringement might let the sponsors hesitate to carry out clinical trials in UK. This is because it might require prior investment to market approvals including FTO analysis and license which could not be required if the sponsors would carry out the trials in e.g. Germany, France, Italy and the like, in spite that a likelihood of success for development of new drugs is very scarce. Current imbalance of the scope of the research exemption between EU States might give a bias for selecting the States where clinical trials for new drugs should be carried out. The obstacles for carrying out clinical trials in specific States of EU should be removed since the promotion of clinical trials in all the States of EU might give a benefit in economics and public welfares to EU Commission and all the residents in EU through a contribution to increase of clinical trials and market approvals for new drugs in EU.

The attempts to expand a scope of patent exemption to a clinical use of drugs other than generic drug or field study by the UK patent office are highly appreciated because we believe that the expansion could drive the advanced therapy through promoting the revolution of new drugs into the market. We also believe that the expansion also could maximize its economic value and contribute to the medical industries in UK through the increase of an opportunity for therapeutic study expected to be held in UK.

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