14 Euro|Biotech|News Nº 1-2 | Volume 13 | 2014

INSIGHT EUROPE

IP FLASH

Inter Partes Review –

One Year Later

By Paul A. Calvo, Ph.D. Miklos Gaszner, Ph.D. Attorneys at Sterne, Kessler, Goldstein & Fox, Washington, D.C.

• On September 16, 2012, *Inter Partes* Review (IPR), a new trial-like procedure at the United States Patent and Trademark Office (USPTO), became available to challenge the validity of patents. IPR was created to reduce court litigation volume by providing a streamlined process to challenge patent validity on the basis of prior

art. Its rapid adoption suggests the new procedure may achieve this goal.

827 petitions for IPR had been filed as of January 16, 2014, including ~50 in the bio/ pharma sector. Only two final decisions have issued thus far. In both cases, all reviewed claims were found to be obvious. IPRs allow a validity challenge only on the basis of anticipation (novelty), or obviousness (inventive step) over patents and printed publications. There is no time limit for petitioning an IPR, except that an accused infringer cannot use IPR to challenge a patent more than one year after a complaint alleging infringement has been filed in the courts. IPRs consist of two stages: a petition to institute trial in front of the newly created Patent Trial and Appeal Board (PTAB), and the trial itself. The petition must show that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged. So far 80-90% of the petitions have met this standard.

The two major benefits of IPR over courtbased litigation are a shorter time to decision and reduced cost. A decision on instituting trial is promised within six months from filing an IPR petition; a final decision on validity is promised within 12 months from initiating the trial. This time-frame is generally less than half that needed for an initial decision in court-based litigation. The PTAB has established procedural rules to meet this accelerated timeframe – for example, by limiting the scope of discovery

and claim amendments. Due to the limited discovery and speedy conclu-

sion of trial, IPR cost is significantly lower than court-based litigation.

IPR also offers procedural advantages over court-based litigation for challenging patent validity. Such as (1) the challenged patent is not presumed valid; (2) invalidity is adjudicated using a lower evidentiary standard (preponderance of evidence) than in court-based litigation (clear and convincing evidence); (3) claims are construed more broadly (broadest reasonable interpretation) than in court-based litigation (ordinary and customary meaning); (4) the PTAB is composed of specialists in patent law with a strong technological background who are receptive to complex technical arguments, and (5) the PTAB decision controls, even if it is contrary to the decision of a concurrent court-based litigation. IPR also provides a venue to attack a patent before the patent owner asserts it. In its brief existence, IPR has already become a favored tool for invalidating patents. And because of the distinct advantages it provides over court-based litigation, the use of IPR is only expected to grow.

AGRI-BIOTECH

Veteran takes on Greenpeace

▶ Brussels – Canadian Greenpeace veteran Patrick Moore has started an EU campaign aimed at supporting market approval of Vitamin A-enriched Golden Rice in the Philippines. In mid-January in Berlin, Moore said that all of the required field tests had been carried out to get the genetically modified rice approved. Due to political pressure, however, the government of the Phillippines announced last November that it will not allow the GM rice to be planted before at least 2016. Moore, whose campaign is supported by well-known GM technology proponents, now says that "Greenpeace must make an exemption. Since the Golden Rice has been developed, 8 million children have died from Vitamin A deficiency."

But it still remains unclear whether Moore's campaign – which led him to Berlin, Hamburg, London, Amsterdam and Brussels – is just another sideshow in the opinion war between GM proponents and opponents. Since Moore left Greenpeace in the 1980s, he has been the Managing Director of Greenspirit Strategies, a company that offers paid PR services. In Berlin, he pointed out that he dislikes damning any technologies for non-scientific or nonethical reasons.

Revived GM debate in the EU

The matter of GM acreage is still up in the air in the EU. In September, the Court of Justice of the European Union in Luxembourg finally slammed the Commission's failure to reach a timely decision on what would be the EU's second approved GM crop for cultivation: Pioneer Hi-Bred's GM maize 1507. In mid-January, the European Parliament voted not to approve the Bt maize, which has been in limbo for 12 long years. The Council of EU Ministers now has to take a stand in mid-February. GM opponents have already started campaigning against the GM crop in EU Member States, calling GM technologies "high-risk biotech".