



AMP v. U.S.P.T.O. Gene Patenting Case: Oral Argument at the Federal Circuit

By

Ryan B. Chirnomas

On April 4, 2011, the Appellant, Appellee and the U.S. Government presented oral argument before the Court of Appeals for the Federal Circuit in *AMP v. USPTO*, which deals with gene patenting. The parties in this case are the Association for Molecular Pathology, along with many other medical organizations, doctors and patients on one side, and the U.S.P.T.O., Myriad Genetics, Inc., and the University of Utah Research Foundation on the other side. Many amicus briefs have been filed as well. The argument was heard by a panel consisting of Judges Bryson, Lourie and Moore, and was attended by approximately 200 people. Due to the complexity of the subject matter and the presence of Government, the Court granted each side approximately 30 minutes of argument, instead of the usual 15 minutes.

Interestingly, although the parties seemed eager to discuss the merits, approximately half of the time for the Appellant and Appellee was spent discussing the issue of jurisdiction and standing. In particular, Judge Moore seemed very interested in this issue. The Appellants, led by Myriad, argued that there was no immediate controversy between the parties, since Myriad had not contacted any of the parties in over ten years. However, Judge Moore questioned whether those parties previously threatened by Myriad were still refraining from making and using the claimed subject matter due to a continuing fear of litigation over the past decade. Myriad also pointed out that even if the claims at issue were invalidated, it is possible that Myriad could assert the presently uncontested claims against the various plaintiffs, and thus that the Court would be unable to provide the various plaintiffs a remedy to their alleged injury. Judge Moore also seemed very hesitant to agree that the various doctors and patients who were not directly threatened by Myriad had standing, since this might create a precedent where any consumer or potential competitor could file a declaratory judgment action. In other words, Judge Moore seemed hesitant to grant standing to parties who were not under threat of litigation, but merely desired to practice the patented invention or viewed themselves as negatively affected by the patent due to the resulting cost of the patented invention.

Next, Myriad moved on to the merits, mostly discussing the composition claims. In discussion of these claims, much of the discussion was centered on hypothetical scenarios. The

most discussed hypothetical was the question of whether a mineral found in the earth could be considered patent-eligible. The answer to this seemed to depend on the exact process involved in separating the material from the environment which surrounds it. Judge Lourie seemed to think that the isolated DNA was different from that found in nature, but also seemed to draw a distinction between “purification” and “isolation.” Judge Bryson presented a hypothetical where breaking of covalent bonds would create a distinction between patent-eligible and non-patent eligible subject matter. In response to these points, Myriad argued that the isolated product was structurally and functionally different, and presented a hypothetical where the patented subject matter is like a baseball bat: It is made of the same material as in a naturally-occurring tree, but it took human ingenuity to separate the bat from the surrounding wood.

Then, Myriad discussed the method claims. After lengthy discussions of the standing issue and the composition claims, there was very little time remaining to discuss the method claims. Myriad argued that the District Court made a claim construction error in that the District Court considered a DNA “sequence” to be data, rather than a physical molecule. Lourie questioned whether the steps recited in the claims (“analyzing” and “comparing”) were merely a thought process. Myriad quickly argued that these claims were similar to *Prometheus v. Mayo* in that the process necessarily includes a transformation. Time expired before this interesting question could be discussed in significant detail.

Next, the Appellees’ attorney argued on behalf of the various parties. As above, a significant portion of the discussion was devoted to standing. Again, Judge Moore seemed very critical of the Appellees’ standing. In particular, Judge Moore pointed out that the parties who had been specifically threatened by Myriad years ago tentatively stated in their declarations that they might make and use the claimed subject matter if the claims were invalidated. Meanwhile, the parties who were never contacted by Myriad stated in their declarations that they were definitely willing to make and use the claimed subject matter if the claims were invalidated. Thus, there did not seem to be any party who was directly threatened and was definitely prepared to initiate practice of the invention upon potential invalidation of the claims.

Moving on to the merits, again the discussion focused mostly on the composition claims rather than the method claims. Similar to Myriad’s time, the discussion was focused on several hypothetical analogies, including whether a kidney removed from a human would be patent-eligible. The Appellees stressed that a compound must have different properties in its isolated form in order to be patent-eligible. In response to this, Judge Bryson commented that the isolated DNA may be regarded as having a different function, in that it can be used in genetic testing, while non-isolated DNA cannot. Further, Judge Lourie commented that even if the isolated DNA has the same function as the genomic DNA, it may be considered a different material as compared to the naturally occurring DNA. In closing, Judge Bryson began to pose

another hypothetical question involving a racemic mixture of substances, but abandoned this after the Appellees' attorney stated that he did not know what "racemic" means.

Finally, the Appellees' attorney briefly discussed the method claims. It was argued that this case is unlike *Prometheus*, in that the claims only recite the mental step of comparing. He went on to argue that isolation is not transformative, and furthermore, that DNA does not have to be isolated in order to be compared. Time expired before the Judges could ask detailed questions on this matter.

Next, the Acting Solicitor General, Neal Katyal, argued on behalf the U.S. Government. The Government had asked to present oral arguments about two months ago, and both parties agreed. Previously, the Department of Justice filed an amicus brief arguing that compositions isolated from nature, such as DNA, were not patent-eligible, but that related compositions such as cDNA, probes, primers, recombinant DNA, etc were patentable. The Government backed away from the position that DNA is merely information, and focused on the question of whether the claimed composition was different from that found in nature. Much of the discussion was focused on the question of whether lithium, which is normally not found in its elemental form, would be patent-eligible under the Government's viewpoint. The Government stated that even if it is necessary to break bonds with other minerals in order to isolate lithium, elemental lithium should not be patentable. Finally, Judge Moore asked why the Court should consider addressing a judicially-created exception to patent-eligibility, when Congress could address this matter directly. The Government dodged this question, stating that Congressional silence should not be viewed as an endorsement of patenting of isolated DNA.

Finally, Myriad summarized their position in their rebuttal time. They argued that after isolation of the DNA, it becomes new and useful. In response to Judge Bryson's question about lithium isolated from its naturally occurring environment by breaking covalent bonds, Myriad's attorney stated that this was analogous to the present issue, and that such isolated lithium should be patentable.

Overall, discussion lasted approximately one hour and fifteen minutes, and could easily have been twice that. I have tried to summarize the most important points from notes taken during the hearing; however, the most accurate sense of the Judges' and parties' position can be gained by listening to the recording of the arguments, which will be available online. Although the standing issue and the patent-eligibility of the composition claims were discussed in relative detail, there was simply insufficient time for discussion of the method claims. In view of the time spent discussing standing, my feeling is that there is a significant chance that the Court will avoid discussion on the merits by deciding the case on jurisdictional issues. Judge Moore especially seemed very concerned about this point. As to the composition claims, it seems that Judges Lourie and Bryson may agree with Myriad, but Judge Moore's position was more

difficult to discern. As to the method claims, it is very difficult to predict, since the discussion was so limited. However, Judge Lourie seems to agree with the Appellees on this point. Of course, it is always difficult to determine when a Judge is merely “playing devil’s advocate” and when they are actually leaning towards a particular position. My personal opinion is that the composition claims will survive, but that at least some of the method claims will be invalidated (assuming the case is decided on the merits). A written decision should be issued within 2-3 months; however, it is very unlikely that this is the last you will hear of this case. An *en banc* hearing and/or appeal to the Supreme Court is likely.

Recording of the oral hearing will be available for download here:

<http://www.cafc.uscourts.gov/oral-argument-recordings/2011-04-04/all>

Ryan B. Chirnomas is a Partner in the Biotechnology group at Westerman, Hattori, Daniels and Adrian LLP. Any questions or comments may be directed to rchirnomas@whda.com. This article is for informational purposes only. The comments herein are the views of the author only and do not necessarily represent the views of Westerman, Hattori, Daniels and Adrian LLP or its clients.