**United States District Court**
**District of Massachusetts**

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| **Oxford Immunotec Ltd.,** | ) | |
| | ) | |
| **Plaintiff,** | ) | |
| | ) | |
| **v.** | ) | **Civil Action No. 15-13124-NMG** |
| | ) | |
| **Qiagen, Inc. et al.,** | ) | |
| | ) | |
| **Defendants.** | ) | |
| | ) | |

**MEMORANDUM & ORDER**

**GORTON, J.**

Plaintiff Oxford Immunotec Ltd. alleges defendants Qiagen, Inc., Quest Diagnostics, Inc. and Laboratory Corporation of America Holdings infringed six of its patents relating to a method for diagnosing tuberculosis.

Defendants filed a joint motion to dismiss, asserting plaintiff's patents are invalid. On August 31, 2016, Magistrate Judge Donald L. Cabell entered a Report and Recommendation ("R&R"), recommending dismissal of plaintiff's "kit" claims but denial of defendants' motion to dismiss plaintiff's "method" claims. Both parties timely objected to the R&R.

## I. Legal Standard for Patentable Subject Matter

The parties agree that the two-step framework for patentable subject matter described in Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012),

controls. First, the Court must determine whether the patent claims are "directed" to one of the patent-ineligible concepts, including natural laws and phenomena. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting Mayo, 132 S. Ct. at 1296-97). If the claims are not directed to an ineligible concept, the claims are patentable. Id. If the claims are directed to an ineligible concept, then the Court must look for an "inventive concept" by determining whether the elements of the invention, individually and combined, "transform" the claims into an application eligible for a patent. Id.

## II. Report and Recommendation on the Motion to Dismiss

### A. Kit Claims

The Magistrate Judge recommended dismissing plaintiff's "kit" claims because the peptides used in plaintiff's diagnostic kit exist in nature and have not been changed beyond the act of isolation from the larger ESAT-6 protein (step one) and the peptide claims do not include any inventive concept (step two). Although the R&R is well-reasoned, this Court concludes that dismissal of the kit claims at this stage would be premature.

Magistrate Judge Cabell agreed with the defendants argument which relies primarily on Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013). The Supreme Court in Myriad concluded the plaintiff's patent for isolating

the BRCA1 and BRCA2 genes in DNA was not patentable subject matter because

> Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them.

Id. at 2116.

The Magistrate Judge rejected plaintiff's contention that Myriad focuses on the "informational" element of DNA, which is different from plaintiff's "functional" peptides. The Supreme Court in Myriad noted, however, that the patent claims did not "rely in any way on the chemical changes that result from the isolation of a particular section of DNA." Id. at 2118. The Supreme Court concluded that,

> [Myriad's] claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.

Id. (emphasis omitted).

Unlike Myriad's claims, which were concerned with information contained in the BRCA1 and BRCA2 gene sequences, plaintiff's claimed peptides, as described in its patents, are alleged to be chemically different than the naturally occurring amino acids in the ESAT-6 protein and that purportedly results in the peptides behaving differently in plaintiff's in vitro tests than would the amino acids in the ESAT-6 protein. In other words, plaintiff contends that the peptides arise from

"human ingenuity" and have a distinctive character and use. See Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980). If plaintiff's claims in its complaint are true, as presumed for the purpose of the pending motion, the Court cannot conclude that the "only plausible reading of the patent" is that it is drawn to ineligible subject matter. See Ultramerical, Inc. v. Hulu, LLC, 722 F.3d 1335, 1339 (Fed. Cir. 2013) (emphasis omitted).

**B. Method Claims**

Next, Magistrate Judge Cabell recommended allowing plaintiff's method claims to proceed because they improved on existing testing procedures for tuberculosis and thus succeeded under step two of the Mayo analysis. With respect to the method claims, which the Magistrate Judge recommends should survive defendants' motion to dismiss, the defendants object to the findings and move this Court to reject the R&R.

Defendants aver that plaintiff's method claims involve "routine and conventional" steps lacking an inventive concept. The steps in the method claims, when considered in combination, however, improve on the current testing methods for tuberculosis and, accepting plaintiff's factual allegations as true, there was no in vitro diagnostic test for tuberculosis in common use before plaintiff developed its test. As Magistrate Judge Cabell concluded, those alleged facts are sufficient on a motion to

dismiss to survive step two of the analysis because they express an inventive concept.

**ORDER**

For the foregoing reasons,

1) Plaintiff's objections to the Magistrate Judge's Report and Recommendation ("R&R") (Docket No. 81) are, with respect to the kit claims, **SUSTAINED**,

2) Defendants' objections to the Magistrate Judge's R&R (Docket No. 82) are, with respect to the method claims, **OVERRULED**, and

3) The R&R (Docket No. 75) pertaining to defendants' motion to dismiss is, with respect to the method claims, **ACCEPTED and ADOPTED**, but, with respect to the kit claims, **REJECTED**.

**So ordered.**

/s/ Nathaniel M. Gorton_____
Nathaniel M. Gorton
United States District Judge

Dated September 30, 2016