

SUBJECT MATTER ELIGIBILITY FORUM – MAY 9, 2014

USPTO Madison Auditorium North

Alexandria, VA 22314

1:00 PM – 5:00 PM

Comments of the Biotechnology Industry Organization (BIO)

Good afternoon. My name is Hans Sauer. I am Deputy General Counsel for IP for the Biotechnology Industry Organization, on whose behalf I testify today. I thank the USPTO for the opportunity to participate in this public forum.

Very few of BIO's 1,100 member companies and institutions are in the business of providing diagnostic services. BIO's members research and develop innovative medicines, vaccines, diagnostic products, agricultural technology, and industrial and environmental biotech products. BIO member companies operating in areas that have little or nothing to do with human genetics are beginning to receive 101 rejections of claims to pharmaceutical compositions, industrial enzymes, methods of treatment using medicinal molecules, and other inventions that were neither considered nor discussed in recent Supreme Court decisions.

BIO members believe that the PTO has gone beyond interpretation of recent Supreme Court decisions, and has engaged in unwarranted extrapolation and expansion of law, in ways not prompted by the *Myriad* decision. Notable examples of such expansion in the guidelines include the application of a new 101 rationale to combination products - which were last addressed by the Supreme Court in *Funk Bros.* and *Chakrabarty* and with respect to which *Myriad* was entirely silent. Methods of drug administration or treatment – never questioned by the Supreme Court - are another example. The implicit but clear abandonment of cases like *Parke-Davis*, *In re Merz*, *In re Bergstrom*, *In re Kratz*, and *Merck v Olin Mathieson*, which were briefed to the Supreme Court but neither discussed nor overruled, are another example.

The subject matter eligibility guidelines were understood and publicly represented by the PTO as a significant departure and revision of examination practice. Prior to issuance of the *Myriad* decision the PTO adhered to a set of examination practices and guidelines that incorporated Supreme Court caselaw up to and including the most recent decisions – the question then is whether anything in *Myriad* required a comprehensive re-evaluation of all the cases that preceded it. We don't believe it did. The Supreme Court in *Myriad* clearly indicated that it neither meant to break new ground nor to revise its prior decisions. The Court's multiple cautionary statements about the narrowness of its holding, and of all the questions it was explicitly NOT deciding, similarly signal a narrow, incremental decision that does not warrant broad changes in examination practice.

It is relevant that the PTO, in issuing the new eligibility guidelines, is neither interpreting the statute it is charged with implementing, nor is it promulgating procedures to govern the conduct of proceedings in the Office. The PTO is merely interpreting court decisions interpreting prior court decisions interpreting judicially-created exceptions from the statute. In this role, the PTO is no better positioned to establish an authoritative interpretation of the Supreme Court's 101 jurisprudence than are the lower courts. By setting forth its reinterpretation of Supreme Court caselaw in actionable guidelines, and also in implicitly declining to follow other intermediate and lower court precedent, the PTO has thus assumed a quintessentially judicial function. Yet the PTO is part of the political branches of government, and as such must be mindful of the public right of participation in agency policymaking. Such public participation helps ensure that agencies do not expand the scope of their statutory authority, helps assess an agency's legal interpretations for rationality, and encourages agencies to take care in resolving interpretive issues. The guidelines were understood to be significant and acknowledged by USPTO officials as significantly changing examination practice. In the past, the USPTO has published such significant guidances for public comment and finalized them only after public consultation. Yet in this instance there was no opportunity for public comment or participation by the regulated community. But even though the lack of public participation and the absence of an open deliberative process weakens any claim to authoritativeness, the guidelines are already causing significant business uncertainty and potential unintended harm.

The Supreme Court's *Myriad* decision, by one account, directly invalidated claims in about 8,700 currently maintained U.S. patents. And that is if the decision is understood to apply only to isolated or purified nucleic acid molecules. The majority of these patents don't even have anything to do with human medical applications, relating instead to agricultural technology, food and beverage manufacturing, industrial microbiology and other industrial uses of biotechnology. Expanding *Myriad's* holding to all claims to isolated or purified natural molecules like antibiotics and other medicinal substances, and combinations thereof, and fermentation or distillation products or bacterial enzymes, will not only prospectively block inventors from acquiring commercially meaningful protection for products that were never even mentioned by the Supreme Court. Doing so also casts a shadow over thousands of issued patents that the PTO now says would never be issued if they were examined today and – implicitly - should never have been issued in the first place.

Such policy statements matter. They affect marketplace perceptions of real-life investment-backed commercial products. You can be assured that companies take notice if the PTO effectively says that their product should never have been patented in the first place.

Given that the guidelines may be a lot more consequential than meets the eye, the absence of a policy justification is remarkable. The PTO's interpretation of the Supreme Court cases, as applied to biotech, is not the only permissible one. It will be years before the currently unstable 101 jurisprudence will get settled in the courts. So what policy choice did the PTO make when it picked its current interpretation from all the different reasonable interpretations of these cases? Does the PTO believe the Supreme Court really meant to strike down claims to fungal antibiotics or industrial enzymes that go into laundry detergents? Does the PTO believe it is implementing the intent of Congress when it last passed Section 101? Or that a more draconian interpretation of Supreme Court pronouncements will advance the

progress of the useful arts better than alternative readings? We're left to guess, because that's a discussion we never had.

The PTO is explicitly charged with advising the President on IP policy. It can and has actively driven policy change, even seeking legislative action and other steps in furtherance of its own institutional interests and in response to concerns and problems in segments of the user community. The state of 101 jurisprudence, even just in the biotech space, is ripe for a policy dialogue outside the forum of the courts. And if clarification of the law is needed, the PTO is an appropriate public forum to begin the process of democratically deciding what needs to be done. BIO believes that Supreme Court precedent stands in tension with itself. It has split the lower and intermediate courts and has spawned endless legal commentary and dissensus. There is no unified reading of *Funk*, *Benson*, *Flook*, *Diehr*, *Chakrabarty*, *Pioneer*, *Bilski*, *Mayo*, and *Myriad* that is fully coherent, free of internal tension, and that operates harmonically with the other requirements of patentability. We need the PTO to acknowledge that reality. And we need a dialogue not only over how to best interpret the caselaw we've been given, but also whether that caselaw leads us to the right place. If we can arrive at a solution that's responsive to the problems the Supreme Court sought to address without causing unintended harm in areas it never contemplated, then that's what we should be striving for. The guidelines, however, are too overinclusive to meet that objective.

[closing...]