



## **Setting the Record Straight:**

### **Comments on Recent Media Reports Regarding BRCA1/2 Patents**

Dear Physician/Healthcare Provider:

In the past few months there have been numerous reports discussing Myriad's patents on the *BRCA1* and *BRCA2* genes. In these reports, various statements have been made on topics that are important to you and your patients. We wanted to provide some additional background information on these topics so that you will have all of the relevant facts.

#### **RESEARCH HAS NOT BEEN HINDERED**

- It has been, and still is, Myriad's policy and practice to allow scientists to conduct research studies on the *BRCA1* and *BRCA2* genes freely.
- Since the discoveries of *BRCA1* and *BRCA2* more than 18,000 scientists have researched the *BRCA* genes, publishing more than 8,600 research papers.
- Myriad also has a policy to collaborate with researchers on studies relating to the *BRCA1* and *BRCA2* genes. In fact, since the *BRCA1* and *BRCA2* genes were discovered, Myriad has collaborated with over 440 outside researchers and participated in more than 110 research programs/studies by outside researchers.
- Myriad provided research testing services at a fraction of the commercial testing price to researchers conducting research funded by NCI or another Institute under the National Institute of Health. During this program, 178 scientists received the discounted research testing services and 5,932 individuals were tested for *BRCA* mutations.

#### **PATIENT ACCESS TO TESTING IS EXTENSIVE**

- In a recent study published by the Duke Institute for Genome Sciences & Policy (IGSP) they found that "It is, therefore, difficult to attribute reduced access to *BRCA* testing to patents. We cannot exclude the possibility that [Myriad's] investments in education about hereditary breast and ovarian cancer and testing have actually had the opposite effect of INCREASING access to testing."
- To date, Myriad has performed over 500,000 BRCA*Analysis*<sup>®</sup> tests from over 40,000 healthcare providers. More than 90% of the BRCA*Analysis* tests ordered by healthcare providers are covered by insurance. There are more than 2,600 insurance payors, comprised of more than 80,000 insurance plans covering over

130 million lives, which reimburse for the *BRCAAnalysis* test. As a result, the weighted average out-of-pocket cost for patients testing is less than \$100.

- To assist patients in obtaining the insurance benefits to which they are entitled, Myriad has set up a large Billing and Customer Service Department. Almost 150 individuals in this department interact daily with patients, their doctors and their insurance companies to help patients work through the complexities of insurance coverage that could potentially prevent patients from receiving important testing services.
- We also understand that there are patients in our country who do not have insurance and need help. Since 1996 when *BRCAAnalysis* was launched, Myriad has had a financial assistance program directly providing testing at no charge to low-income, uninsured patients. Just in the last four years, more than 3,000 patients have received free *BRCA* testing under this program.

### **PRICING “COMPARABLE TO TESTS DONE BY OTHER LABORATORIES”**

- The HHS Secretary’s Advisory Committee on Genetics, Health, and Society (“SACGHS”) in March 2009 released a Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. This Draft Report clearly stated: “One surprising finding from the case studies was that the **per-unit price of the full-sequence *BRCA* test**, which often is cited as being priced very high, **was actually quite comparable to the price** of other full-sequence tests done by polymerase chain reaction (PCR), **at both nonprofit and for-profit testing laboratories.**”
- In a recent study published by the Duke Institute for Genome Sciences & Policy (IGSP) their findings stated that “Prices for *BRCA*1 and 2 testing do not reflect an obvious price premium attributable to exclusive patent rights compared with colorectal cancer testing, and indeed, Myriad's per unit costs are somewhat lower for *BRCA*1/2 testing than testing for colorectal cancer susceptibility.”

### **SECOND OPINIONS ARE AVAILABLE**

- Since Myriad launched *BRCAAnalysis* in 1996, we have not received a single request (or even the suggestion) by anyone to seek a “second opinion” at another lab. We would gladly honor such a request if one is received.
- There are various laboratories in the US available for confirmatory testing under licenses from Myriad. Many of these labs have been performing testing for specific *BRCA* mutations for the past ten years. For example, testing for specific *BRCA* mutations is available in both the University of Chicago Genetic Services Laboratories and Yale DNA Diagnostic Laboratories. Information on their testing services for *BRCA* mutations is readily accessible on Internet.

## **NO IMPACT TO MYRIAD FROM PATENT RULING IN NEW YORK**

- The ACLU is challenging 15 claims under 7 patents that relate to BRCA testing. Under these 7 patents, there are a remaining 164 claims which are not being challenged. Additionally, Myriad has another 16 issued U.S. patents with various claims that relate to its BRCA testing which are also not being challenged. Myriad believes that the final outcome of this litigation will not have a material impact on Myriad's operations due to the patent protection afforded Myriad under the remaining claims and patents not being challenged.

## **VALIDITY OF PATENTS ON ISOLATED DNA**

- Patents on isolated DNA were granted on the basis that isolated DNA is a chemical composition which is not found in nature or the human body, and which has important diagnostic and therapeutic uses that cannot be accomplished with a human's natural or native DNA as found in the body. It is these new uses which demonstrate the "handiwork of man" for which patent protection, for a limited period of time, is afforded.
- Since 1980, patents have been granted on thousands of isolated DNA that relate to approximately 20% of human genes, many to academic institutions. Hundreds of companies and thousands of jobs have been created during this time period, establishing the United States as the global leader in biotechnology. A reversal of this policy of allowing patents on isolated DNA would severely impact the private investment that has fueled the explosion of advances in biotechnology and jeopardize many of the jobs created during this timeframe.
- Myriad believes that the claims under the *BRCA* patents to isolated DNA and method claims are patent-eligible subject matter under section 101 of the Patent Act. Myriad is confident that, upon appeal, the Court of Appeals for the Federal Circuit, will uphold these claims as patent-eligible.

We hope you find this information useful. If you have any additional questions please feel free to contact your local Myriad representative. If they are unable to answer any concerns, they will gladly identify additional resources that can assist. We appreciate all that you do to provide this life-saving information to your patients and remain firmly committed to providing you the highest quality testing services in the future.

Sincerely,

Mark C. Capone

President

Myriad Genetic Laboratories, Inc.