The Example of Myriad Genetics and the Patented BRCA1 Gene

Gene Tests – the El Dorado of Genetic Engineering ?

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I'm a white, European woman, a native of this beautiful city of Basel. I have a pretty high risk of getting breast cancer. It is five times higher than it is for an Asian woman from rural parts of Asia. But when this woman migrates to Europe, to Basel, her risk factor tips up to my risk factor within one or two generations. So it must be something in the environment or in the way we're living here that enhances breast cancer incidence.

A Swedish study by the Karolinska Institute looked at the records of 90,000 twins, identical and non-identical ones, and their differences in getting breast cancer. They found that environmental effects are much more important in triggering breast cancer than genes. They conclude that cancer is not hardwired in the genes. They ask why researchers are not spending more funds on identifying avoidable risk factors of cancer instead of putting all their energies into genetics (Lichtenstein et al.)

In the meantime more extensive meta-studies underline this fact: around 5 % of all breast cancer diseases have a family history of the disease, 95 % do not.

As for the genetic side: researchers at the US firm Myriad Genetics decoded two so-called human breast cancer genes, BRCA1 and BRCA2. (To talk of 'breast cancer genes' is wrong. It's at most a gene mutation, which may enhance the risk of women getting breast cancer.) Researchers at Myriad developed gene tests with these gene sequences.

Now: what happens when a woman gets a positive test result for the BRCA1 gene? She has a 50 to 70% chance of getting breast cancer up until the age of 70. But how can she interpret this probability? Up to now, there are no preventive actions apart from those a woman here in Switzerland is told to take: to examine her breasts after each period and to go to the gynaecologist once a year. The risk-lowering effect of a mastectomy as a prevention is not scientifically proven. The same goes for Tamoxifen and chemotherapy as preventive measures. So what does this positive result mean for her own life, for her quality of life, for her lost hopes and for her fears? A healthy person who is not yet sick but knows that she has a higher likelihood of being so in the future – this is a difficult situation to deal with.

The other interesting factor is that 30 to 50% of all women with a positive test do NOT get breast cancer. Why not? Apparently there are other genes, other factors, other pathways playing a role; it's not a totally determined story, even with a mutation of the genes BRCA1 or -2.

Let's go back to the fact that 95% of all breast cancers do not have hereditary causes. Looking at this figure, I would naïvely think that 95% of all research funds, of all brain-power would focus on finding correlations between environment, nutrition or life-style which cause or are involved with 95% of all breast cancers. This research would focus, for example, on pseudo-oestrogens in the environment, or on nutrition. And I would assume that only 5% of all research funds would go into genetics. But we all know that it's the other way around: although I do not know the exact figures, it's obvious that research is focusing on genetics, on so-called breast cancer genes, on further genetic causes, on further gene tests.

Patents on the BRCA1 gene

This hype over genes may have many causes. One main reason, and this is the hypothesis I want to talk about, is economic interests and patents. I'll do this by taking one example: the so-called breast cancer genes and the US firm Myriad Genetics.

Myriad Genetics applied pretty swiftly for patents on these genes. In the US they have patents on both BRCA1 and BRCA2 genes. In Europe they have three patents on the BRCA1 gene and one patent for the BRCA2-gene, from the European Patent Office in Munich (EPO).

The last European patent on the BRCA1-gene, with the number EP 0705902, was extremely broad. I know it well, because I draw up an opposition to this patent on behalf of the Social Democrats of Switzerland.

This patent includes among other things:

- different variations of the gene sequence BRCA1
- the BRCA1 gene of the wild-type. This means the normal, non-mutated gene which most of us women have.
- all diagnostic and therapeutic applications of these genes
- all vaccines derived 'with the help of this gene'
- all animals which incorporate one of the gene sequences described
- all future applications of these gene sequences, be it for tests, therapies or vaccines, which are not yet known. There was a note lately that BRCA mutations are also connected to pancreatic cancer – so Myriad also has a monopoly control over this research area and market, even though nobody knew about these correlations at the time of the patent application
- all proteins derived from these genes, and all their applications, known or not yet known.

As patent-owner you can ask for license fees or cross-licenses; this is what most patent-owners have done up to now. But you also have the right to exclude others completely from your patent invention. Myriad Genetics is aggressively trying to make use of the exclusion right granted by the patent. They want to be the only group, world-wide, to make use of this patent and to develop gene tests. The firm even forbids all other labs, institutes or firms to carry out the tests. Probes for a gene test have to be sent from all over the world to Myriad's Institute in Salt Lake City. In the US, Myriad Genetics successfully denied all other labs the right to develop similar tests, because of the patents they hold. The costs of the tests went up immensely. In some countries the costs for a test doubled. As a consequence, the Canadian 'Hereditary Cancer Program' in British Columbia cancelled all in-house testing.

In Europe, the Curie Institute in Paris, which also offers gene tests on BRCA1, was one of the many who filed opposition to one of the BRCA1 gene patents. The Curie Institute argues that Myriad's procedure hinders independent research. It has gene tests cheaper than Myriad's, apparently better suited for BRCA1 gene mutations prevalent in Europe. But the Curie Institute is afraid it will be forced to abandon these tests because of the Myriad patents.

Another point is that Myriad is aggressively campaigning for their gene tests in the States. They started to broadcast TV ads in Atlanta and Denver. The advert showed an attractive woman telling the viewer, 'Breast cancer runs in my family. I wondered if it would be inevitable. I found it didn't have to be.' A small note indicates that a doctor's approval is needed. But persistent patients should get a doctor's permission without problems. Apart from being a lie – there is no preventive breast cancer cure, as the ad is suggesting – this campaign illustrates plainly that careful counselling programs, or national control

programmes are ‘devout wishes’, as we say in German. Together with internet ordering they’re making a nonsense of all these trials to carefully control and accompany gene test programmes.

Not only Myriad Genetics

I often hear from proponents, ‘OK, Myriad is exaggerating, we all know that, and breast cancer is a special case,’ etc. But I do not agree.

First, there seems to be huge economic potential, a multibillion market on gene tests in the area of genetic engineering and genomics, an area where there have been many promises and few achievements up to now, and where shareholder values are therefore in rather bad shape. So gene tests seem to be the El Dorado of genetic engineering and genomics. And gene tests can be patented, because human genes can be patented.

Second, other firms are already following in Myriad’s footsteps and are using their patents to exclude other researchers and institutes from entering their area. This is bad news for research and for public health: if diagnostics and treatment of a common disease are monopolised by one single multinational firm, this firm dictates all the conditions – a dangerous development.

Third, patents on genes grant an exclusive and broad monopoly control. The first one to get there takes it all. You stake out your claims in a vast research area, and it’s blocked for all others. This might also explain the aggressiveness and hasty and fierce competition in this research area: you have to be first or the market will punish you.

Fourth, it seems obvious to me that patents are increasingly directing research: only research projects with the prospect of lucrative patents will be financed. So breast cancer research on genes, with the prospect of acquiring a gene patent, will be financed; breast cancer research on environmental interactions will not, because you can not patent environmental interactions.

This point seems especially problematic. Just a few weeks ago there was a congress in Bonn on genomics, ‘Bonn Genomics 2003’, with many experts in this field. The overall impression was, according to the press, that of a ‘loss of orientation’. The gigantic expenditure of research into genomics is barely rewarded. The results up to now have been disappointing. To view diseases mainly from a genetic perspective seems to be a cul-de-sac. The links claimed between genes and diseases are overstated. It’s obvious that many common diseases, and also many cancers, are too complex for simple gene tests; they are caused by hundreds of genes, together with hundreds or thousands of gene products and other molecules, together with psychological, social and environmental factors. And many cancer experts say today that looking more closely at carcinogenic substances could bring us farther ahead.

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