



OCTOBER 2004

NEWSLETTER
of the BeSHG

Belgian Society of Human Genetics

www.beshg.be**Board**

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Dear colleagues, dear friends,

The 5th BeSHG meeting is approaching:

The 5th BeSHG meeting will be held in Liège on Friday the 28th of January 2005. The theme is **Genetics and Inflammation**. Several international speakers have confirmed their attendance and we look forward to an interesting program (*for details, see next page*). In addition, as last year in Ghent, a session for selected oral communications from young scientists (< 35 years) is planned. **Dead-line for all abstract submission (for oral or poster) is Friday 10/12/2004** (to BeSHG secretary Frank Speleman: franki.speleman@UGent.be). First authors of abstracts will be notified early January. Registrations forms will be distributed soon.

This year, an evening reception is also organized at the end of the scientific meeting, so that we all have a better chance to discuss with each other on this exciting day with a full program. Another novelty will be the best poster award, which will be handed out to the investigator with the best poster at the end of the meeting.

Several companies working in the field of molecular genetics will also be present.

So mark 28/1/2005 in your agenda for BeSHG Liège.

Next General Assembly

will take place in **Liège**, on **Friday 28th of January 2005**.

Call for board membership:

As each year, 4 board members have to be elected. If you are interested, please make your candidacy known to the president of the society (vikkula@bchm.ucl.ac.be) before 31/12/2005.

LIEGE 28.1.2005: GENETICS OF IMMUNITY AND INFLAMMATION

(subject to modifications)

9H00-9H30 Registration, evaluation form
coffee & croissants

9H30-10H30

Dr. Jean-Laurent Casanova (Necker, Paris, France):

The human model: a genetic dissection of immunity to infection in natural conditions

Dr. Jean-Pierre Hugot (Hopital Robert Debré, Paris, France):

The genetic contribution to Crohn Disease

coffee

11H00-12H30

Selected oral presentations by young investigators

12H30-14H30 *Lunch & Posters (free viewing)*

13H30-14H30 **BeSHG General assembly**

14H30-15H30

Dr. Alain Fischer (Hopital Necker, Paris, France):

Lessons from the study of inherited disorders of the immune system

Dr. Stephen Holgate (Southampton General Hospital, Southampton, U.K):

New Asthma Genes and their Putative Functions Identified by Position of Cloning

coffee

16H00-17H00

Dr. Amalio Telenti (University of Lausanne, Lausanne, Switzerland): Human susceptibility to HIV

Dr. Klaus Lindpaintner (Roche Genetics and Roche Center for Medical Genomics, Basel, Switzerland):

Pharmacogenetics - state of the art?

17H00-18H30 Reception

Workgroups

Two new workgroups have been initiated: the Workgroup on Constitutional Cytogenetics (headed by Joris Vermeesch joris.vermeesch@uz.kuleuven.ac.be) and the Workgroup on Acquired Cytogenetics (headed by Anne Hagemeyer: anne.hagemeyer@med.kuleuven.ac.be). The intended goals are (1) to make guidelines for clinical protocols with the aim to prevent confusion among patients and medical professionals that interact with cytogenetic laboratories due to different practices in different centers, (2) to make guidelines on good laboratory practise in Cytogenetics and (3) to present research work and initiate collaborative studies. *Progress in these workgroups will be presented at the BeSHG meeting.*

Our web-site: <http://www.beshg.be>. Suggestions to the board:

Remember, as member of the BeSHG you are cordially invited to make suggestions to the board for improvement of our society's activities. One of the important activities is our web-site (<http://www.beshg.be/>). But is it useful to you? Is it needed? And if yes, what would you like to see on it? Let us know via the Liège meeting questionnaire or directly by e-mail.

Future BeSHG meetings:

The 2006 meeting will be held in Antwerp, and Loverval has offered to host the 2007 meeting. Other applications are welcome and can be submitted to the president of the society until 31/12/2005. **Decision on 2007 host will be made during the general assembly in Liège.**

BRCA1 and BRCA2 patents opposition:

After the oral hearing in May in Munnich, the European Patent Office (EPO) has REVOKED Myriad's first BRCA1 patent (EP 699754:'Method for diagnosing a predisposition for breast and ovarian cancer').

Gert Matthijs reports:

"We spent 2 exciting days at the oral hearings in Munich. The French opponents were represented by Mr. Warcoin and his co-worker Mrs. Faivre-Petit, with Dr. Stoppa-Lyonnet and Prof. Lenoir. The 'pan-European' group of opponents was represented by our attorney Mr Bird and his co-worker Mr. De Baere, joined by Prof. Stratton, Dr. Halley and me. Myriad was represented by 2 attorneys from a London-based patent office, Mrs. Irvine and Mr. Webb. They had brought Dr. Critchfield, President of Myriad Genetics Laboratories, and Dr. Shattuck-Eidens, one of the inventors.

The first day was almost entirely spent on discussing the scope of the invention, and the definition of the first claim. It originally read: "A method for diagnosing a predisposition for breast and ovarian cancer in human subject which comprises determining in a tissue sample of said subject whether there is a germline alteration in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide having the amino acid sequence set forth in SEQ. ID. NO:2 or a sequence with at least 95% identity to that sequence, said alteration being indicative of a predisposition to said cancer."

We have succeeded in keeping the strict reference to SEQ. ID. No 2 in the claim, and in removing the '95% identity'. The reason for that is that we knew that SEQ. ID. No 2 was not correct on the first priority date, but also that we wanted to limit the scope of the invention. On the discussion about 'sufficiency of disclosure', Myriad won, i.e. the EPO accepted that on the basis of the patent as filed, the 'skilled person' has enough information to find mutations in the BRCA1 gene, and relate them to cancer. I personally think that this is bad news for the opponents. It means that whoever identifies a mutation in a gene, could claim all possible mutations in that gene.

The critical point has been the discussion about the priority dates. In the patent application, filed on 12.08.1994, SEQ. ID. No2, which contains the AA sequence of BRCA1, was incorrect. Myriad has filed the correct sequence only on 24.03.1995, after it had been in Genbank for several months. The Opposition Division has accepted our arguments, and has moved the priority date to 24.03.1995.

As a result, the patent was revoked on the basis of 'lack of inventive step', i.e. by 24.03.1995, the BRCA1 sequence and the diagnostic test were in the public domain. This means that the European laboratories may go on testing. However, this is not the final end of the story, because Myriad has the possibility to restart the case before the Appeal Board of the EPO. This is a procedure that will probably last a couple of years. Of course, we hope that the conclusions of the Appeal Board will be the same as those today.

We include this information to show that it has been a very technical discussion, and that the patent was killed on the basis of formal criteria. In other words, the discussion on 'inventive step' – other than the one that relates to the late priority date - has not taken place. Or, the EPO has not questioned the patentability of this gene per se.

The French and Belgian attorneys have really been working as a team, and the success is a result of more than 2 years of intense preparations and close collaboration between the Belgian-Dutch group and the French group.

This is not the end of the BRCA1 and BRCA2 patents story. Myriad still owns the 2 other patents on the BRCA1 gene, and a patent on the BRCA2 against which we have also filed oppositions. The EPO has scheduled the oral hearings: for the third patent (EP705902: '17q-Linked breast and ovarian cancer susceptibility gene') on January 19-21, 2005 and for the second patent (EP705903: 'Mutations in the 17q-linked breast and ovarian cancer susceptibility gene') on January 24-26, 2005. For the BRCA2 patent, the hearings have not been scheduled yet. So we will be back in Munich soon.

We hope that we will be able to further count on you for the next phase - the appeal - and for the huge task which still lays ahead: to try and convince the EPO and the European Parliament, that the public and patients, and the social health care system in Europe, would be better off if

genetic diagnostic methods would not be patentable at all. Also, please note that, if we run out of funds to finance these oppositions, the whole effort will be void. So, we really count on the Belgian Centers for Human Genetics, the Belgian government, the patients associations and private partners - if they will - for effective support.

Please spread the news!"

In the mean time, Gert Matthijs has also become the chairman of the new Patenting and Licensing Committee (PLC) of the European Society of Human Genetics, which was created at the ESHG meeting in Munich. He is counting on us though for continuous support of his activities in this field.

Yours faithfully,

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Don't forget www.beshg.be !