

The examination is being carried out on the **following application documents**:

Description, Pages

1-34 as published

Claims, Numbers

1-15 filed with entry into the regional phase before the EPO

Drawings, Sheets

1-8 as published

1 Article 123(2) EPC

The amendments filed with the entry into the regional phase before the EPO dated 12. 5. 2008 do not introduce subject-matter which extends beyond the content of the application as filed and are thus in accordance with Article 123(2) EPC.

2 Article 88 EP (Claiming priority), Article 89 EPC (Effect of priority right)

The present application claims priority from US374285 filed on 13. 10. 2005. Claims 1 and 8-15 have a valid claim to priority from US374285. The relevant date for said claims is therefore 13. 10. 2005 (Art. 89 EPC).

Claims 2-7 do not have a valid claim to priority from US374285, since this document does not disclose the use of base, intermediate and upper cut-off levels and the respective values for these cut-offs listed in the claims. The relevant date for the subject-matter of claims 2-7 is the filing date of the present application, namely 13. 10. 2006.

2 Article 53(c) EPC

Claims 1-15 relate to methods in which a serum or plasma sample is obtained from a mammal. However, obtaining a serum or plasma sample would include a method of surgery, which falls under the exceptions of patentability as outlined under Article 53(c) EPC. The applicant should restrict the claims to *ex vivo* or *in vitro* methods.

3 Cited documents

3.1 Reference is made to the following document; the numbering will be adhered to in the rest of the procedure:

D1: WO 2004/005544 A (NOVARTIS AG [CH]; NOVARTIS PHARMA GMBH [AT]; CHIBOUT SALAH-DINE [FR];) 15 January 2004 (2004-01-15)

D1 discloses methods for monitoring, prognosing, diagnosing and/or treatment of