Case No COMP/M.950.- HOFFMANN - LA ROCHE/ BOEHRINGER MANNHEIM

Only the EN text is authentic.

REGULATION (EC) No 139/2004 MERGER PROCEDURE

Article 8 (2)
Date: 3/5/2011

EUROPEAN COMMISSION

Brussels, 3.5.2011

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PUBLIC VERSION

COMMISSION DECISION
of 3.5.2011

waiving certain commitments in Decision 98/526/EC in Case No IV/M.950 - HOFFMANN - LA ROCHE / BOEHRINGER MANNHEIM with respect to the DNA probes market

(Case No IV/M.950 - HOFFMANN - LA ROCHE / BOEHRINGER MANNHEIM)

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waiving certain commitments in Decision 98/526/EC in Case No IV/M.950 - HOFFMANN - LA ROCHE / BOEHRINGER MANNHEIM with respect to the DNA probes market
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(Only the English text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Agreement on the European Economic Area,

Having regard to Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings[1]and in particular Article 8 (2) thereof,

Having regard to Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings[2] and in particular Article 8 (2) thereof,

WHEREAS:

(1) By Decision 98/526/EC of 4 February 1998 in Case No IV/M.950 - *Hoffmann La Roche/Boehringer Mannheim* ("the Decision"), which was adopted pursuant to Article 8(2) of Regulation (EC) No 4064/89, the Commission declared the operation by which the undertaking Hoffmann – La Roche Ltd ("Roche", Switzerland) acquired control of the undertaking Boehringer Mannheim ("BM", Germany) compatible with the common market and the functioning of the EEA Agreement, subject to full compliance with certain conditions and obligations

(2) The Decision stated that Roche had a dominant position in the EEA-wide market for DNA probes mainly resulting from Roche's high market shares (see recitals 117 to 119 of the Decision), Roche's possession of the patent portfolio for the main technology used for DNA probes - the Polymerase Chain Reaction ("PCR") technology (see recital 120 of the Decision), and the weak position of alternative technologies (recitals 129 to 134 of the Decision). The Commission considered that Roche's dominant position could be strengthened as a result of the acquisition of control over BM given that BM

1 OJ L 395, 30.12.1989, p. 1; corrected version in OJ L257, 21.9.1990, p.13.

2 OJ L 24, 29.1.2004, p. 1.

was a potential entrant having invested substantial efforts in positioning itself on the DNA Probes market (see recitals 124 to 128 of the Decision).

(3) Roche submitted commitments which were made binding in the Decision. Part of those commitments consisted in Roche granting access to its PCR technology to all interested market participants on a non-discriminatory basis under the terms of "Broad" and "Targeted" licenses. To ensure the timely implementation of the commitments Roche undertook to conclude binding license agreements with at least one licensee for a "Broad" license within 12 months from the date the Decision was adopted and to conclude a binding agreement for a "Targeted" license within a period of 3 months from the same date (the "Commitments") (recitals 148 to 151 and 157 to 162 of the Decision).

(4) The scope and price of those licenses was set out in detail in the Commitments according to which the Broad licenses are worldwide licenses for all *in vitro* applications of the PCR technology. Broad licenses have been made available to all interested market players in three options:

- Option A, covering the fundamental PCR patents;
- Option B1, covering the fundamental PCR patents and, in addition, the full Roche PCR patent portfolio as it stood at the time of the Decision;
- Option B2, covering the fundamental PCR patents and additional patents to be selected by the licensee from the full PCR patent portfolio of Roche as it stood at the time of the Decision.

(5) The Targeted licenses are worldwide licenses granted for single parameters to those competitors that only have an interest in a specific disease with as yet unmet medical needs (niche market).

(6) In order to ensure the non-discriminatory treatment of the licensees Roche committed to include in all the contracts a most-favoured-customer clause which aimed at applying comparable conditions to payment terms and reductions of royalty rates over time. In order to keep the licensees apace of all Roche's developments Roche agreed to grant every licensee a license on the future PCR patents. Roche also agreed to appoint a monitoring trustee to secure compliance with the Commitments. The Commitments did not include any time framework, deadline or review clause.

(7) Roche has complied with the obligation assumed in the Commitments to appoint a monitoring trustee and to grant one Broad license within a 12 month period and one Targeted license within a 3 month period. Roche has also complied with the obligation to give access to its PCR technology to all interested market participants. It has granted 35 PCR licenses under the scope of the Commitments, including Broad licenses granted to the following competitors on the DNA probes market: […]*.[3]

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3 Roche's submission of 13 February 2009.

* Parts of this text have been edited to ensure that confidential information is not disclosed; those parts are enclosed in square brackets and marked with an asterisk.

I. FACTS AND PROCEDURE

The request for the waiver of the Commitments

(8) On 24 September 2008 Roche addressed a request to the Commission for the waiver of the Commitments ("request for the waiver of the Commitments").

(9) Roche's request was based on the following grounds: Roche's PCR patent portfolio was no longer a barrier to entry to the DNA probes market as the foundational PCR patents had expired/would expire in the coming years;[4] the Commitments had achieved their purpose, that is to say, Roche's position on the DNA probes market had not been strengthened; and, the system of patents established in the Commitments had an anti-competitive effect as the scope and cost of the licenses did not reflect the market needs for different geographic and target scope of patents.

The market investigation

(10) Following the request for the waiver of the Commitments, a market investigation was conducted in the first quarter of 2009 amongst Roche's competitors, licensees, potential licensees and customers in the DNA probes field.

(11) Although the market investigation confirmed that Roche still had a strong position in the DNA probes market resulting from its ownership of the PCR technology, which is the main technology for the development of DNA probes and the "gold standard",[5] the respondents also mentioned that the price of the licenses offered under the Commitments was too high and the available patent portfolio was no longer adapted to their needs.[6]

(12) Some respondents expressed a concern that Roche would stop granting PCR licenses to the market if the Commitments were to be waived.[7]

(13) In the annual summary of Roche's activity in the field of PCR technology, submitted to the Commission on 1 April 2009, the Trustee expressed its support for Roche's request for the waiver of the commitments.[8]

(14) Following the market investigation and discussion with Roche, the Commission informed Roche by letter of 3 April 2009 (“the Interpretation Letter”) that the Commitments allow Roche to grant licenses outside the scope of the Commitments and

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4 Roche submitted in the request for the waiver of the Commitments that the underlying patents for the main two patent protected improvements to the basic PCR technology, namely reverse transcription PCR (RT-PCR) and the 5' Nuclease PCR (TaqMan) process, will expire in 2011.

5 Replies of competitors to question 19 of the questionnaire to competitors, replies of customers to question 8 of the questionnaire to customers.

6 Replies to question 11, 13 and 23 of the questionnaire to licensees/potential licensees.

7 Replies of competitors to question 22 of the questionnaire to licensees/potential licensees and reply to question 31 of the questionnaire to competitors.

8 Trustee's (Treureva, Switzerland) report of 30 March 2009 submitted to the Commission on 1 April 2009.

thereby allow for flexibility in the granting of licences as long as the licenses are granted on a non-discriminatory basis and Roche continues to grant the licenses as foreseen under the Commitments.

Roche's new PCR licensing programmes

(15) Following the Interpretation Letter, Roche introduced 3 new PCR programs in addition to the Broad and Targeted licensing programmes foreseen in the Commitments. Roche presented those new programmes in its submission of 11 November 2009 to the Commission and in the correspondence of 17 and 24 June 2010.

(16) The new programmes consist of: (i) "Menu à la carte" programme,[9] (ii) "TaqMan probe" license[10] and (iii) chemically modified enzymes (target restricted) programme.[11] According to Roche, those programmes are applied on a non-discriminatory basis and include new down-payments and royalty rates for each type of license. The up-front down-payments are lower than those in the Commitments for the Broad Licenses, reflecting the more targeted scope of the new licences.

(17) Since the Interpretation Letter of 3 April 2009 Roche has granted 15 new PCR-licenses, 9 of which outside the scope of the Commitments.[12]

(18) Out of those 9 PCR-licenses granted outside the scope of the Commitments, 6 are "Menu à la carte" licenses of different geographical scope for specific human pathogens, 2 licenses are worldwide licenses for the manufacturing and selling of the TaqMan probes for the research field and 1 is a license for chemically modified enzymes for a specific target.

(19) The 6 remaining licenses are targeted licenses for different applications granted on a non-discriminatory basis in line with the system established in the Commitments.

Follow-up of the market investigation

(20) In the beginning of 2010 the Commission carried out a follow up exercise to the market investigation by means of conference calls with 5 out of the 7 potential licensees which had participated in the market investigation. That exercise showed that most of those potential licensees of Roche had been offered the possibility to take PCR- licenses

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9 "Menu à la carte" programme consists of PCR patents for different target/ diagnostic parameters (for example, HIV, HCV, HBV, HPV etc.). Depending on the needs of the licensees, they can chose to limit the scope of the licenses to certain regions such as United States, Europe and Rest of the World) the downpayment and royalty rate being paid for each of the regions separately.

10 "TaqMan" that is to say, 5'Nuclease PCR, is a PCR–based technology (improvement) which is still patent protected until 2010/2011. It enables amplification and detection of DNA in real time;, that is to say during the process. The 'TaqMan' programme makes it possible to manufacture and sell TaqMan for internal research in the Diagnostic Research Field.

11 Roche's Chemically Modified license is designed for licensees who only wish to use Roche's patented PCR hot start enzymes in diagnostic kits and sell them world-wide. Besides the possible target restrictions the other requirement for this license program is that the IVD products do not use any additional Roche patents.

12 Roche's e-mail correspondence of 13 September 2010.

under the pre-existing programmes established in the Commitments or the new programmes outside the scope of the Commitments. Some participants stressed that they had not pursued the opportunity to purchase licenses from Roche due to the high prices of Roche's licensing programmes (although in particular the up-front down payments in the licensing programmes outside the Commitments are lower than those for the Broad licences under the Commitments), the scope of the licenses made available and the expected expiry of the PCR patents.

(21) None of the potential licensees contacted raised further concerns as to the future granting of licenses by Roche.

(22) The potential licensees also explained that the high prices of Roche's PCR patents are due to the fact that Roche's PCR-technology is still to be considered to be the "gold standard". Although alternative technologies exist and have been developed during the last decade, according to the respondents those alternative technologies are still less credible and sensitive than the PCR technology. A number of respondents claimed that they intended to use the PCR technology (without a license) after the imminent expiry of the relevant patents.

II. THE COMMISSION'S ASSESSMENT

(23) The Commission can revise its decisions in order to amend or waive Commitments even in the absence of a review clause. According to the Commission notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 ("the Remedies Notice")[13], a waiver or modification of Commitments may in particular be relevant for non-divestiture commitments, such as access commitments, which may be on-going for a number of years. Exceptional circumstances justifying a waiver or modification may be accepted if the parties show that the market circumstances have changed significantly and on a permanent basis. For showing this, a sufficient long time–span, usually several years, between the Commission's decision and a request by the parties is required. For any waiver or modification of commitments the Commission will also take into account the view of third parties and the impact a modification may have on the position of third parties and thereby on the overall effectiveness of the remedy. In this regard, the Commission will also consider whether modifications affect the rights already acquired by third parties after implementation of the remedy.[14]

(24) The requirements for the waiver of commitments referred to in the Remedies Notice are met in this case. More specifically, the circumstances in the DNA Probes market have changed significantly on a permanent basis and there has been a sufficiently long time-span between the adoption of the Decision and the request for the waiver of the Commitments; third parties have been consulted and do not oppose the waiver of the Commitments; the waiver of the Commitments will not affect their effectiveness as they have fulfilled their role and they are no longer effective; and, the waiver of the Commitments will not affect third parties' rights.

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13 OJ C 267, 22.10.2008, p. 1.

14 Paragraph 74, the Remedies Notice.

(i) Significant change in the market circumstances on a permanent basis

Increase in the number of players active on the market and evolution of Roche's market position

(25) The circumstances in the DNA Probes market have changed significantly since the adoption of the Decision in 1998.

(26) Firstly, nowadays there are more players with significant market shares on the DNA probes market than at the time of the Decision. The increase in the number of market players results from the fact that 35 PCR licences have been granted to competitors of Roche in the DNA probes field under the Commitments, 9 of which are Broad licenses, that is to say, world-wide licences for all fundamental PCR patents and, in addition, access to the whole or part of Roche's patent portfolio existing in 1998. In addition, 9 licences with a different scope from the licenses foreseen in the Commitments have been granted recently.

(27) In the Decision the Commission named the following main competitors of Roche on the DNA Probes market in the countries which were part of the EEA in 1998: Abbott (< 5%), Chiron (14%),[15] Organon (< 5%) and Genprobe (< 5%).

(28) Table 1 shows that although Roche is still the main player, its overall market share has decreased from [60-70]*% to [40-50]*% and several new competitors have entered the market: Novartis, Qiagen/Diagen, Becton Dickinson, Cepheid and Bio-Rad Laboratories.

[15] Chiron has been considered to have a particular strength in HIV in vitro diagnostics – [20-30]*% and HCV in vitro diagnostics – [20-30]*% in the EEA.

TABLE 1

DNA Probes market - market shares – countries which were part of the EEA in 1998		
	Market shares in the Decision (1998)	**Market shares in 2007**
Roche	[60-70]*%	[40-50]*%
Abbott	[0-5]*%	[10-20]*%
Novartis	n/a	[5-10]*%
Siemens(ex-Chiron)[16]	[10-20]*%	[5-10]*%
Qiagen/Digene	n/a	[5-10]*%
Becton Dickinson	n/a	[5-10]*%
bioMerieux (Organon)	[0-5]*%	[0-5]*%
Gen-Probe	[0-5]*%	[0-5]*%
Cepheid	n/a	[0-5]*%
Bio-Rad Laboratories	n/a	[0-5]*%

Source: Roche's submission of 23 September and 30 October 2008.

(29) The structure of the market has also changed with respect to the applications available in the area of DNA probes for in vitro diagnostic and their significance. In the Decision the following applications were considered as main applications: HIV[17], HCV,[18] MTB[19] and STD[20]. There are currently more applications available and the main application is blood screening which accounts for [20-30]* % of the turnover of all

16 […]*

17 Human immunodeficiency virus

18 Hepatitis C Virus

19 Mycobacterium tuberculosis

20 Sexually Transmitted Diseases

applications in the DNA *in vitro* diagnostic field. Although Roche has a very strong position in blood screening, Novartis is also a strong player within this field.

(30) Table 2 sets out the market shares of Roche and its competitors for the main applications in 2007:

TABLE 2

	Blood Screening	***HIV***	***HCV***	***CT/NG[21]***	***HBV[22]***	***HPV[23]***	***MTB***
Roche	[50-70]*%	[30-50]*%	[50-70]*%	[10-30]*%	[50-70]*%	[10-30]*%	[50-70]*%
Abbott	[0-10]*%	[10-30]*%	[10-30]*%	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%
Becton Dickinson	[0-10]*%	[0-10]*%	[0-10]*%	[30-50]*%	[0-10]*%	[0-10]*%	[10-30]*%
bioMerieux	[0-10]*%	[10-30]*%	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%
Novartis	[30-50]*%	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%
Gen-Probe	[0-10]*%	[0-10]*%	[0-10]*%	[10-30]*%	[0-10]*%	[0-10]*%	[30-50]*%
Qiagen	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%	[70-90]*%	[0-10]*%
Siemens	[0-10]*%	[10-30]*%	[10-30]*%	[0-10]*%	[10-30]*%	[0-10]*%	[0-10]*%

Source: Roche's submission of 30 October 2008

(31) Although Roche's market shares for the applications in Table 2 remain significant, Roche faces competition from other players for each of those applications. The main competitors have also acquired a Broad licence to Roche's technology under the Commitments[24] and they are therefore no longer limited by a lack of access to Roche's technology. The results of the market investigation also anticipate possible further changes in market circumstances in terms of an increase in the number of applications and the entry of new players into the market.[25]

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21 Chlamydia trachomatis and neisseria gonorrohoeae

22 Hepatitis B Virus

23 Human papilloma virus

24 […]* have been granted Broad licenses under the Commitments.

25 See: responses to the questionnaire to customers – question 12.

Situation of the patents in relation to the PCR technology

(32) Another factor relevant to the assessment of whether or not a significant change has taken place in the market circumstances on a permanent basis is the expiry of most of the 119 PCR-related patents to which Roche undertook to grant access on the basis of the Commitments, including the foundational patents. More specifically only 23 of the 119 PCR-related patents listed in the Commitments are still in force. Those patents will expire in the Union between 2013 and 2018.[26]

(33) Therefore the PCR technology is no longer widely patent protected and the basic elements of PCR technology remain in (or will soon belong to) the public domain. Hence, companies which have not obtained the PCR license from Roche on the basis of the Commitments are (or will soon be) able to access those technologies.

Change of the market structure on a permanent basis

(34) The change in the structure of the DNA probes market resulting from the increase in the number of market players, the changes with respect to the applications available in this field and the expiry of a large majority of Roche's PCR-related patents can be considered permanent. In particular, the licensees will keep the licenses even if the Commitments are waived and will continue to have access to up-dates of Roche's PCR patents according to the terms of the licenses.[27] In addition, there has been a long period, of 10 years, between the Commission's decision and Roche's request for the waiver of the Commitments, as required in the Remedies Notice.

Conclusion

(35) On the basis of the above it can be concluded that a significant change of market circumstances has taken place on a permanent basis since the adoption of the Decision in 1998. In addition, as explained in Section I, Roche has recently granted licenses outside the context of the Commitments and has thereby demonstrated that it is prepared to grant licenses in the absence of the obligation to do so.

(ii) Third parties have been consulted and do not oppose the waiver of the Commitments

(36) As indicated in Section I, in the first quarter of 2009 the Commission undertook a market investigation whereby Roche's competitors, licensees, potential licensees and customers in the DNA probes field were consulted about the impact of a possible waiver of the Commitments. In addition, a follow up exercise was conducted by means of conference calls with potential licensees in 2010. That follow-up exercise had, among others, the purpose of verifying the likelihood of the risk that Roche would stop

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26 The Patent protected PCR-related technologies listed in the Commitments which will expire between 2013 and 2018 are: 3 improvements of basic PCR process patents (out of 18 patent protected); 2 detection methods (out of 15); 8 enzyme related patents (out of 22); 2 detection of HIV (out of 5); 1 detection of HCV; 3 patents for miscellaneous pathogens (out of 13); 2 patents in relation to human genetics (out of 13); 2 patents for sample preparation (out of 5).

27 As indicated in recital 6, in order to keep the licensees apace of Roche developments Roche undertook in the Commitments to grant every licensee a license on the future PCR patents. As indicated by the Parties in their submissions of 24 September 2008 and 13 February 2009, that commitment has been fully implemented.

granting licenses if the Commitments were to be suspended, which had been brought to the Commission's attention during the market investigation.

(37) The outcome of the market investigation and the follow-up exercise show that third parties do not oppose the waiver of the Commitments. Furthermore, the participants in the follow up exercise did not mention the risk that Roche would not grant licenses if the commitments were to be suspended.

(iii) The waiver of the Commitments will not affect their effectiveness: the Commitments have fulfilled their role, they no longer respond to the market needs and their waiver would not affect the position of third parties' rights

The Commitments have fulfilled their role

(38) The Commitments were aimed at avoiding the strengthening of Roche's dominant position on the EEA-wide DNA probes market as a result of the elimination of potential competition resulting from the acquisition of control by Roche over BM, which was, at the time the Decision was adopted, a potential entrant on that market.

(39) The granting of at least one Broad License within 12 months following the adoption of the Decision and one Target license within 3 months of the same date ensured timely entry on that market. The subsequent granting of 35 PCR licenses in the context of the Commitments, including 9 Broad licenses, has facilitated further entries with the end result that, the number of significant players currently active on the market is higher than in 1998 and Roche's position has not been reinforced. Hence, the Commitments have fulfilled their role of facilitating entry into the EEA-wide DNA probes market, compensating for the loss of potential competition resulting from the acquisition by Roche of a potential competitor.

The Commitments no longer respond to the market needs

(40) In its request for the waiver of the Commitments Roche claimed that the system of patents established in the Commitments did not reflect the market needs for different geographic areas and target scope of patents.

(41) Roche's claims have been confirmed by the results of the market investigation and the follow up exercise carried out by the Commission.

(iv) The waiver of the Commitments would not affect the rights of third parties

(42) The licenses granted under the Commitments would remain in force even if the Commitments were to be waived. The effectiveness of those licenses cannot be undermined by the waiver of the Commitments as they remain in force and are fully enforceable by the licensees.

III. CONCLUSION

(43) Consequently, in the view of the permanent changes in the structure of the EEA-wide DNA probes market, particularly the increase in the number of significant players active on that market and the fragmentation of Roche's PCR patent portfolio, having consulted interested third parties and taking into consideration that the waiver of the Commitments cannot affect their effectiveness as they have fulfilled their role, that they no longer reflect the market needs and that their waiver would have a neutral effect on the rights of third parties, it is appropriate to allow Roche to waive the Commitments relating to DNA probes set out in Part VI-B of that Decision,

HAS ADOPTED THIS DECISION:

Article 1

The Commitments relating to DNA probes set out in Part VI-B of Decision 98/526/EC are waived with effect from the date of the adoption of this Decision.

Article 2

This Decision is addressed to:

F.Hoffmann – La Roche Ltd
Grenzacherstrasse 124
CH-4070 Basel
Switzerland

Done at Brussels, 3.5.2011

For the Commission
(signed)
Joaquín ALMUNIA
Vice-President of the Commission