UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

bioeq IP AG
Petitioner

v.

Genentech, Inc.
Patent Owner

U.S. Patent No. 6,716,602

Inter Partes Review Case No. Unassigned

DECLARATION OF MORRIS Z. ROSENBERG, DSC.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

I. Introduction 1
II. My Background and Qualifications 2
III. Summary of Opinions 4
IV. List of Documents I Considered in Formulating My Opinions 7
V. Person of Ordinary Skill in the Art 12
VI. The '602 patent 13
VII. Claim Construction 15
A. "Increased yield of properly folded polypeptide" (claim 1). 15
B. "Culturing the recombinant host cells under conditions of high metabolic and growth rate" (claims 1, 25); "culturing host cells under conditions of high metabolic and growth rate" (claim 16). 16
C. "Reducing the metabolic rate" (claims 1, 16, and 25) 17
D. "Assembled" polypeptide (claims 11 and 35). 19
VIII. State of the Art Before November 3, 2000 20
A. E. coli was "the most important" host for bacterial production of recombinant proteins as of 2000 21
B. Excess glucose during bacterial fermentation was known to cause acetate accumulation—the main obstacle to obtaining high host cell densities and high protein production 23
C. Glucose-limited fed-batch fermentation minimized acetate accumulation and allowed to maximize bacterial cell mass and recombinant protein production 25
D. Inducible promoters, such as phosphate-dependent promoters, were widely utilized for recombinant protein production 30
E. Recombinant antibody molecules and fragments were routinely produced in bacterial expression systems in 2000 33
IX. Summary Chart of Analysis Over the Art 46
X. The Basis of my Analysis with Respect to Anticipation 46
A. Ground 1: Seeger Discloses Every Limitation of Claims 1, 3, 4, 6, 9, 15, 16, 20, 22, 24, 25, 27, 28, 30, 33, and 39 47
1. Claim 1. 47

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

2. Claim 3. 55
3. Claim 4. 56
4. Claim 6. 57
5. Claim 9. 59
6. Claim 15. 60
7. Claim 16. 62
8. Claim 20. 64
9. Claim 22. 65
10. Claim 24. 67
11. Claim 25. 68
12. Claim 27. 70
13. Claim 28. 72
14. Claim 30. 73
15. Claim 33. 74
16. Claim 39. 75

XI. The Basis of my Analysis with Respect to Obviousness 76

A. Ground 2: Seeger, in view of general knowledge in the art, would have provided a reason to arrive at the method of claims 7, 8, 31, and 32 with a reasonable expectation of success 78
1. Claim 7. 78
2. Claim 8. 80
3. Claim 31. 81
4. Claim 32. 82

B. Ground 3: Seeger and Makrides Would Have Provided a Reason to Arrive at the Method of Claims 10, 12, 23, 34, and 36 with a Reasonable Expectation of Success 83
1. Claim 10. 83
2. Claim 12. 86
3. Claim 23. 89
4. Claim 34. 90
5. Claim 36. 91

C. Ground 4: Seeger and Cabilly would have Provided a Reason to Arrive at the Method of Claims 11, 13, 14, 18, 35, 37, and 38 with a Reasonable Expectation of Success 92
1. Claim 11. 92
2. Claim 13. 95
3. Claim 14. 96
4. Claim 18. 97

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

5. Claim 35. 99
6. Claim 37. 100
7. Claim 38. 101
D. Secondary Considerations of Non-obviousness 103
1. No Unexpectedly Superior Results 103
2. No Long-Felt, Unmet Need 107
3. No Failure of Others 109
4. No Industry Praise 110
XII. Conclusion 111

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

I, Morris Z. Rosenberg, DSc., hereby declare as follows.

I. Introduction

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of bioeq IP AG. ("bioeq") for the above-captioned *inter partes* review (IPR). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is $475 per hour.

3. I understand that the petition for *inter partes* review involves U.S. Patent No. 6,671,602 ("the '602 patent"), BEQ1001, which resulted from U.S. Patent Application No. 10/000,655 ("the '655 application"), filed November 1, 2001. I also understand that the '602 patent's earliest claimed priority date is November 3, 2000, the filing date of U.S. Provisional Patent Application No. 60/245,962. The '602 patent names Dana Andersen, John Joly, and Bradley R. Snedecor as the inventors. The '602 patent issued on April 6, 2004, from the '655 application. I understand that, according to the United States Patent and Trademark Office ("USPTO") records, the '602 patent is currently assigned to GENENTECH, INC. ("GENENTECH").

4. The '602 patent is directed generally to the field of recombinant polypeptide (protein) production, and more specifically to methods of increasing

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.