

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.  
Before the Honorable Clark S. Cheney  
Administrative Law Judge

In the Matter of  
**CERTAIN STRONTIUM-RUBIDIUM  
RADIOISOTOPE INFUSION SYSTEMS,  
AND COMPONENTS THEREOF  
INCLUDING GENERATORS**

Investigation No. 337-TA-1110

**CORRECTED EXPERT REPORT OF NORBERT J. PELC, Sc.D.**  
October 1, 2018

Oct 1, 2018  
DATE

*Norbert Pelc*

Norbert J. Pelc, Sc.D.

**Table of Contents**

I.	INTRODUCTION .....	1
II.	MY BACKGROUND, QUALIFICATIONS AND COMPENSATION .....	1
A.	Background and Qualifications.....	1
B.	Identification Of Expert Testimony In The Last Four Years.....	3
C.	Compensation .....	4
III.	LEGAL PRINCIPLES .....	4
A.	Perspective of a Person of Ordinary Skill in the Art .....	4
B.	Presumption of Validity.....	6
C.	Anticipation.....	6
D.	Written Description.....	7
E.	Non-Obviousness.....	8
F.	Assignor Estoppel .....	9
G.	Prosecution Laches .....	11
H.	Inventorship .....	12
IV.	PRIORITY DATE AND OVERVIEW OF THE ASSERTED PATENTS.....	13
A.	Priority Date.....	13
B.	Overview Of The Asserted Patents.....	14
V.	THE COMMISSION'S CLAIM CONSTRUCTION .....	17
VI.	RESPONDENTS ARE ESTOPPED FROM CHALLENGING THE VALIDITY AND ENFORCEABILITY OF THE ASSERTED PATENTS.....	18
VII.	THE ASSERTED PATENTS ARE NOT UNENFORCEABLE DUE TO PROSECUTION LACHES .....	22
A.	There Was No Unreasonable And Unexplained Delay .....	22
1.	'467 Application .....	23
2.	'200 Application .....	27
3.	'484 Application .....	27
4.	'320 Application .....	28
B.	There Was No Prejudice .....	29
VIII.	RESPONSE TO DR. STONE'S IMPROPER INVENTORSHIP ARGUMENT .....	31

IX.	ANTICIPATION REBUTTAL .....	33
X.	THE ASSERTED PATENTS ARE NOT INVALID AS OBVIOUS .....	35
XI.	THE KLEIN THESIS, ALONE OR IN COMBINATION WITH OTHER REFERENCES, DOES NOT RENDER THE ASSERTED CLAIMS OF THE ASSERTED PATENTS OBVIOUS .....	38
A.	The Klein Thesis, Alone or in Combination with CardioGen-82, Tate, Medrad Intego, Akiyama, or Duchon, Does Not Render The Asserted Claims of the '826 Patent Obvious.....	39
1.	Independent Claim 1 of the '826 Patent .....	39
2.	Dependent Claim 2 of the '826 Patent.....	65
3.	Dependent Claim 3 of the '826 Patent.....	69
4.	Dependent Claim 5 of the '826 Patent.....	71
5.	Dependent Claim 9 of the '826 Patent.....	73
6.	Dependent Claim 10 of the '826 Patent.....	80
7.	Dependent Claim 11 of the '826 Patent.....	82
8.	Dependent Claim 12 of the '826 Patent.....	87
9.	Dependent Claim 13 of the '826 Patent.....	89
10.	Dependent Claim 14 of the '826 Patent.....	91
11.	Dependent Claim 17 of the '826 Patent.....	93
12.	Dependent Claim 18 of the '826 Patent.....	94
13.	Dependent Claim 19 of the '826 Patent.....	97
14.	Dependent Claim 28 of the '826 Patent.....	103
B.	The Klein Thesis, Alone or in Combination with CardioGen-82, Tate, Medrad Intego, Akiyama, or Duchon, Does Not Render The Asserted Claims of the '869 Patent Obvious.....	104
1.	Independent Claim 1 of the '869 Patent .....	104
2.	Dependent Claim 2 of the '869 Patent.....	126
3.	Dependent Claim 3 of the '869 Patent.....	128
4.	Dependent Claim 4 of the '869 Patent.....	130
5.	Dependent Claim 5 of the '869 Patent.....	132
6.	Dependent Claim 8 of the '869 Patent.....	133
7.	Dependent Claim 14 of the '869 Patent .....	133
8.	Dependent Claim 24 of the '869 Patent .....	135
9.	Dependent Claim 27 of the '869 Patent .....	142
10.	Dependent Claim 28 of the '869 Patent.....	144
11.	Dependent Claim 29 of the '869 Patent .....	147
12.	Dependent Claim 30 of the '869 Patent .....	149
C.	The Klein Thesis, Alone or in Combination with CardioGen-82, Tate, Medrad Intego, Akiyama, or Duchon, Does Not Render Obvious the Asserted Claims of the '870 Patent .....	151

1.	Independent Claim 1 of the '870 Patent .....	151
2.	Dependent Claim 2 of the '870 Patent.....	165
3.	Dependent Claim 8 of the '870 Patent.....	168
4.	Dependent Claim 9 of the '870 Patent.....	175
5.	Dependent Claim 10 of the '870 Patent.....	177
6.	Dependent Claim 11 of the '870 Patent.....	180
7.	Dependent Claim 12 of the '870 Patent.....	182
8.	Dependent Claim 13 of the '870 Patent.....	184
9.	Dependent Claim 16 of the '870 Patent.....	186
10.	Dependent Claim 17 of the '870 Patent.....	186
11.	Dependent Claim 27 of the '870 Patent.....	189
<b>XII.</b>	<b>THE CARDIOGEN-82 INFUSION SYSTEM, ALONE OR IN COMBINATION WITH OTHER REFERENCES, DOES NOT RENDER THE ASSERTED CLAIMS OF THE ASSERTED PATENTS OBVIOUS .....</b>	<b>191</b>
A.	There Is No Motivation To Combine The Rubidium-82 Elution System Disclosed In CardioGen-82 And The Klein Thesis With The FDG Systems Disclosed In Tate And The Intego Operation Manual .....	191
B.	CardioGen-82, Alone or in Combination With The Klein Thesis, Tate, Intego Operations Manual, or Duchon, Does Not Render Obvious the Asserted Claims of the '826 Patent .....	193
1.	Independent Claim 1 of the '826 Patent .....	194
2.	Dependent Claim 2 of the '826 Patent.....	202
3.	Dependent Claim 3 of the '826 Patent.....	204
4.	Dependent Claim 5 of the '826 Patent.....	205
5.	Dependent Claim 9 of the '826 Patent.....	206
6.	Dependent Claim 10 of the '826 Patent .....	209
7.	Dependent Claim 11 of the '826 Patent.....	210
8.	Dependent Claim 12 of the '826 Patent.....	213
9.	Dependent Claim 13 of the '826 Patent.....	214
10.	Dependent Claim 14 of the '826 Patent .....	215
11.	Dependent Claim 17 of the '826 Patent .....	216
12.	Dependent Claim 18 of the '826 Patent .....	217
13.	Dependent Claim 19 of the '826 Patent .....	218
14.	Dependent Claim 28 of the '826 Patent.....	220
C.	CardioGen-82, Alone or in Combination With The Klein Thesis, Tate, Intego Operations Manual, or Duchon, Does Not Render Obvious the Asserted Claims of the '869 Patent .....	220
1.	Independent Claim 1 of the '869 Patent .....	222
2.	Dependent Claim 2 of the '869 Patent.....	234
3.	Dependent Claim 3 of the '869 Patent.....	235
4.	Dependent Claim 4 of the '869 Patent.....	236
5.	Dependent Claim 5 of the '869 Patent.....	238

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

6.	Dependent Claim 8 of the '869 Patent .....	238
7.	Dependent Claim 14 of the '869 Patent .....	239
8.	Dependent Claim 24 of the '869 Patent .....	240
9.	Dependent Claim 27 of the '869 Patent .....	245
10.	Dependent Claim 28 of the '869 Patent .....	247
11.	Dependent Claim 29 of the '869 Patent .....	248
12.	Dependent Claim 30 of the '869 Patent .....	249
D.	CardioGen-82, Alone or in Combination With The Klein Thesis, Tate, Intego Operations Manual, or Duchon, Does Not Render Obvious the Asserted Claims of the '870 Patent .....	251
1.	Independent Claim 1 of the '870 Patent .....	252
2.	Dependent Claim 2 of the '870 Patent .....	259
3.	Dependent Claim 8 of the '870 Patent .....	260
4.	Dependent Claim 9 of the '870 Patent .....	263
5.	Dependent Claim 10 of the '870 Patent .....	264
6.	Dependent Claim 11 of the '870 Patent .....	265
7.	Dependent Claim 12 of the '870 Patent .....	266
8.	Dependent Claim 13 of the '870 Patent .....	268
9.	Dependent Claim 16 of the '870 Patent .....	268
10.	Dependent Claim 17 of the '870 Patent .....	269
11.	Dependent Claim 27 of the '870 Patent .....	271
XIII.	OBJECTIVE INDICIA OF NONOBVIOUSNESS.....	272
A.	There Was A Long Felt But Unmet Need .....	272
B.	Copying.....	276
C.	Failure Of Others .....	281
XIV.	CONCLUSION.....	283

# 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.