

Cole Owen

Interview conducted by

Mark Jones, PhD

July 18, 1997

SAN DIEGO TECHNOLOGY ARCHIVE



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Cole Owen



Mr. Owen studied Industrial Engineering at the Georgia Institute of Technology and also obtained a degree in Business. He is a former U.S. Naval Officer and a veteran of two tours of duty in Vietnam. Prior to entering the health care industry, Mr. Owen worked as an industrial engineer for Celanese Fibers Corporation and for American Telephone and Telegraph (AT&T). He was an early member of management at Hybritech, Inc., and was a founder of The Immune Response Corporation and Cortex Pharmaceuticals, Inc. Mr. Owen has been an advisor to founding management for several successful life sciences companies, including Gen-Probe and Biosite, among others. He was a member of the Board of Directors of Applied Molecular Systems. Mr. Owen has held various senior marketing and business positions and has served as the principal of Owen & Associates, a Life Sciences consulting firm. He has substantial experience in technology assessments, product development and the marketing of medical products. Mr. Owen initially became affiliated with the University of California San Diego (UCSD) through its "CONNECT" offices. He has also lectured and taught courses on entrepreneurship for UCSD in the Rady School of Management and for the Graduate School of International Relations & Pacific Studies. He has also taught entrepreneurial courses for the University of Oulu, Oulu, Finland.

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1 **JONES:** Where were you before Hybritech?

2 **OWEN:** I was at Johnson & Johnson. I began at Johnson & Johnson in 1971, after
3 leaving active duty in the Navy, and I left in 1980, when I joined Hybritech. I joined
4 Hybritech because I had worked extensively in my last three or four years while I was
5 with J&J, toward identifying and bringing new technologies into the company. One of
6 the emerging technologies that really caught my interest was in the emerging field of
7 biotechnology. I thought there were some things that would really be of value to us at
8 J&J, and which J&J eventually did get to, but it took a while to get J&J's focus to
9 seriously include biotechnology.

10 **JONES:** And what years were those? Was this the late '70s when you were looking at
11 this?

12 **OWEN:** '77, '78, '79. About '78 or '79, I really got interested in what I thought could
13 be the utility, of monoclonal antibodies for us in both diagnostic and therapeutic
14 applications, us being J&J. And, we did begin to get very involved in monoclonal
15 antibodies, it was limited to some very finite applications. The technology wasn't
16 being investigated in a broad way that I thought could have the greatest utility for us,
17 but later it was. At any rate, as I watched the biotechnology field begin to open up
18 and as I got more and more interested in it, I decided that it was something that I
19 wanted to be involved with. Along the way as one meets industry contacts at trade
20 shows, etc., I met a guy named Bob Byrnes who, at the time was with McGaw Labs,
21 and soon thereafter became the senior business development guy at Genentech. I had
22 also met Robert Swanson, the founder of Genentech and I had had three, or four
23 interviews with them about potentially joining the company.

24 **JONES:** To go there?

25 **OWEN:** I was to the point of literally visiting Genentech to look at houses, because I
26 had made the decision, that if they offered me a job I was going to take it. By that
27 point in our discussions, they had invited my wife and I out to look at houses. I was
28 talking with Bob Swanson during that housing visit, I mean, at that visit. There
29 weren't a lot of people in the company at the time so Swanson was involved in all the
30 interviews. And, during that visit Bob commented to the effect that my background
31 and what I had been doing, suggested that I might be an even better fit with a new
32 company that the same funding guys who started Genentech were starting down in
33 San Diego. The funding source he was referring to was Kleiner-Perkins, the VC firm.
34 'You ought to talk to them,' he suggested. And as soon as I talked to them, my job
35 opportunity suddenly switched from being at Genentech to being at Hybritech. And,
36 I ended up down here rather than up in the Bay Area. So although I joined Hybritech,
37 I actually started talking with Genentech. The transition was logical for me, as
38 suggested by the VC's, because the focus for Hybritech was more specifically relevant
39 to what I had been doing at J&J, since my focus had included monoclonal antibodies
40 for both in vitro diagnostic and for potential therapeutic applications as well.
41 Hybritech was focused exclusively on those two areas, intending to use monoclonal
42 antibody technology as its technology platform. That's how the transition occurred
43 from Genentech to Hybritech. I talked with Ted Greene and with a good friend who
44 had recently joined Hybritech and I accepted a job with the company.

45 **JONES:** Did you get connected with Genentech because they were doing business
46 with J&J?

47 **OWEN:** No. I had been contacted by a headhunter who was working for McGaw
48 Labs, another California company that was, at the time, part of American Hospital
49 Corporation. [Some years later McGaw became a part of Baxter Healthcare.] I was
50 responsible for certain new products development activities as my responsibility, so I
51 was involved in a lot of different potential new product activities for J&J. This
52 headhunter was looking for someone with new products experience and he just
53 wouldn't turn loose. He kept bugging me about an opportunity he had in Southern
54 California that actually was with McGaw Labs, located in Orange County. That was
55 what started the process for me, although I ended up getting serious about
56 Genentech, then actually joining Hybritech.

57 **JONES:** Was this Hyland?

58 **OWEN:** No, it was on the therapeutic side, with McGaw's infusion products. This
59 headhunter, ("executive recruiter") just wouldn't turn loose. I was traveling to the
60 West Coast regularly anyway, in my work for J&J, because we had done an acquisition
61 of a company in Orange County and I had been involved in helping get those
62 products to market under J&J's banner. Due to the acquisition activities and I was
63 regularly almost next door to McGaw, which I think is how I had become visible to
64 the headhunter. Anyway, this recruiter set up interviews for me at McGaw, which I
65 think was at the time in an old American Hospital Supply facility. The job for which I
66 was to interview was one for which I would have reported to a fellow named Bob
67 Byrnes, whom I had met previously, and who ran the place. Well, between the time
68 that I agreed to an interview and I was next on the West Coast, Bob Byrnes had
69 resigned from McGaw and wasn't there when I showed up for the interview. When I
70 arrived I didn't know he had resigned. I had previously talked with Byrnes a time or
71 two by phone about the job and I was really impressed with him as an individual.
72 After that interview visit to McGaw, when I met other people because Byrnes had
73 resigned, I think I was back in New Jersey at J&J, and the bell rang one day for me. A
74 light came on, and I thought, 'Wait a minute. Why would I go to work for a company
75 where the guy that impressed me, that I thought I'd like to work with, has made a
76 decision to go somewhere else?' Somebody had mentioned to me where Byrnes had
77 gone, so I knew he went to Genentech. I also knew that Genentech existed, so I called
78 Bob and I told him what the situation was. I didn't think I would accept the McGaw
79 job offer and my call to him was really just to close the loop as well as to get his
80 perspective on my intent to not accept the McGaw job. He suggested that my next
81 West Coast trip, 'Why don't you come up and talk with us before you make a
82 decision, because we're getting to the point where we're going to need to expand our
83 business group.'" At the time he was only person with business experience except for
84 the founder, Bob Swanson, I believe. So, a long comment but that was the way that I
85 ended up at Hybritech [from an interview at McGaw with Byrnes to an interview with
86 him at Genentech and then Bob Swanson's suggestion I should talk with his founding
87 VC's about another company they were starting – which was Hybritech, located in
88 San Diego].

89 **JONES:** And when you did come down, who did you interview with? Ted Greene?
90 Others?

91 **OWEN:** Everybody – at that time most candidates were interviewed by several
92 people. Tom Adams who ran R&D, Ted, another fellow named Paul Rosinack, who

93 was a person that I had known previously who had also worked at J&J, Howard
94 Birndorf, Gary David, Walt Desmond, I mean, there weren't that many management
95 level people at the company so you talked with most of them.

96 **JONES:** Was this '83, '84?

97 **OWEN:** No, probably August or September of 1980.

98 **JONES:** Oh, '80. You were there that early? I didn't realize that.

99 **OWEN:** Yes. I predated David Hale and Tim Wollaeger, among others. There were
100 about forty people working at Hybritech at the time I joined, almost all in research.
101 We were located in temporary trailers for admin space, located in one of the parking
102 lots of La Jolla Cancer Research Foundation (now called "The Sanford Burnham
103 Prebys Medical Discovery Institute"). Hybritech rented lab space from La Jolla Cancer
104 and the Hybritech's admin offices were in the temporary trailers, with the research
105 labs within the Research facility buildings. When I started working at Hybritech,
106 several of us lived in a condominium that the company had rented. Tom Adams and
107 I, Russ Saunders, and then later, a fellow named Phil Levenson, lived together, before
108 we each moved our respective families to San Diego.

109 **JONES:** So when you arrived, what was your title then? Was it business
110 development?

111 **OWEN:** No, Howard Birndorf was responsible for business development at that time.
112 Later, Howard had moved on from Hybritech to found Gen-Probe. At that time I
113 became VP of Business Development, but when I arrived my focus was marketing. I
114 was Director of Marketing. I wasn't directing a hell of a lot, as there was no one else
115 in marketing, but marketing was my initial responsibility.

116 **JONES:** And what kind of work were you doing initially?

117 **OWEN:** Getting products ready to go on the market. We had three or four research
118 use only products already available or at least very near availability. I think the
119 hepatitis product, a monoclonal antibody to a "Hepatitis B" antigen, was already
120 announced. In the next several months we put out, I don't know, a couple of dozen of
121 research-use products, primarily for use by academic researchers, and then, in June or
122 July-ish of '1981, we put out the first in vitro diagnostic for clinical laboratory use that
123 used monoclonal antibodies instead of polyclonal antibodies as the respective

124 antibody reagents. Our first test was an IgE test for use in assessing a patient's allergic
125 response status. So, since "marketing" at the time included all sorts of new product
126 delivery elements, I did a lot of different things. I mean, I think I probably drafted the
127 first package insert for the IgE product. Tom Adams refined it of course, but I think I
128 started the drafting process. I identified at the FDA the individual who would review
129 our monoclonal-based products. We didn't have a clinical or regulatory group at that
130 point in time, so each of us wore a lot of hats.

131 **JONES:** What was it like going from J&J, this huge company, to, you know, this little
132 start up?

133 **OWEN:** Actually, certainly, there was a big adjustment, but because I had been
134 running new products activities at J&J and I had been involved in new product
135 development activities for literally the last five years that I was at J&J. It wasn't
136 terribly different at Hybritech in terms of the mechanics of the things that needed to
137 be done. What was different was that we didn't have the resources at Hybritech that
138 you were accustomed to at J&J, of course, but you had the same kind of needs.
139 Because of J&J's product management position followed the classic Proctor and
140 Gamble model, or did at that time, that meant that the product manager, whether
141 your title was product manager, product director, or new product director, whatever,
142 you were literally involved everywhere that the product or product line was involved.
143 If there was a shipping problem, it was your problem. If there was a label problem, it
144 was your problem. Packaging breaking during shipping or vials leaking? Your
145 problem. So, unlike many other companies where the title "product manager" means
146 the person many have a very narrow focus and may essentially be the market research
147 analyst for the given product, that wasn't the case at J&J. You really were responsible
148 for all aspects of the product, and you were involved in all aspects of keeping the
149 product on the market and supporting it. You had to be aware of QC lot releases, the
150 cause of any back order, etc., so at Hybritech the needs with respect to new product
151 delivery activities really were not different to what I was accustomed to doing. The
152 major difference, however, was that at Hybritech you had to go find the resources
153 that you needed. That was different, because at J&J, you would have available the
154 resources. If you had a packaging problem, there was a packaging department. If you
155 had a legal problem, you called the legal department. QC problem? You could get a
156 committee together that knew everything about everything related to QC for
157 pharmaceuticals or devices. At Hybritech we basically didn't have anybody you didn't
158 see that day around you in either the offices or the labs. So, you relied much more on

159 your experience and your infrastructure of industry contacts and the network of
160 people that you knew, and of course, with outside service vendors such as legal
161 counsel and outside accountants – because we had none of those resources internally.

162 **JONES:** Did you utilize outside services for, say, dealing with the regulatory stuff, the
163 FDA, or manufacturing?

164 **OWEN:** Yes, eventually we did. We used outside legal counsel with the FDA in
165 Washington, for instance, when we could not get a response from the FDA regarding
166 our pending initial product submission. We needed to interact with the FDA in a
167 structured way and they were just non-responsive. We got the excuse we couldn't get
168 a meeting because there were no available conference rooms – across a period of
169 weeks – if you can believe that. And, they would not accept our offer to rent a
170 conference room in a local hotel. We were simply getting no response. At some point
171 later in time, and not much later in time, Ted and Tom went back to Washington to
172 meet with the FDA. Ted had identified legal counsel for advice on FDA matters, one
173 of the highly visible law firms in Washington that specialized in regulatory issues.
174 With that legal firm representing us, we got our meeting. The FDA immediately knew
175 that we were serious and the result was more communication and easier
176 communication – but the cost had been having to acquire some fairly pricey legal
177 counsel. The FDA then put some new ground rules in place regarding the approval
178 process for our particular emerging technology, so then we knew how we needed to
179 respond to the needs and requirements from the FDA side of the discussion. [Keep in
180 mind that at that time no company had submitted a diagnostic product for FDA
181 clearance that utilized monoclonal antibody technology. The FDA hadn't really
182 codified any rules about what needed to be done by someone making application for
183 such a product and the differences, if any, in what they wanted to see regarding
184 product performance as compared to a submission for a product using "old"
185 technology.]

186 **JONES:** I've heard stories about manufacturing where everybody in the whole
187 company is filling vials and putting caps on.

188 **OWEN:** Oh yes – it was sometimes an "all hands" evolution. I sat in production lines
189 on Saturdays for Jeanne Dunham, the Director of Manufacturing. Not only was the
190 additional labor needed by Manufacturing, I think that was really important to
191 confirm to the people in manufacturing that they weren't out there by themselves.

192 When they needed extra pairs of hands, people from R&D, people from Marketing,
193 everybody got on the production line and helped.

194 **JONES:** Let's back up just a little bit. When you first came down to Hybritech, what
195 convinced you to come? Did you perceive a lot of risk in doing this at the time?

196 **OWEN:** Oh yes, I knew it was a risky career move. When I joined the company,
197 literally just about the same time that I joined, we were approaching the point that
198 we couldn't make payroll. I had recently been promoted at J&J and I had just been
199 told that I was going to be moved up again, to additional responsibilities. That
200 awareness, that I was to be offered another position at J&J, actually changed the
201 timing of when I moved to Hybritech. At the time I was not anticipating that I was
202 going to make the transition, nor was Hybritech, until probably after the first of the
203 year, sometime in 1981. I actually joined Hybritech in September of '80. We (me and
204 Hybritech) were planning for me to join in January or February, and then I was made
205 aware of a pending promotion, which was to occur in the fourth quarter. I didn't want
206 to accept the promotion and then leave just two or three months later. There had
207 been a lot of turmoil within the company. We had just gotten a new President, for
208 instance, and I was to be reporting to the President. I knew that some of the people I
209 worked with would perceive an exit soon after a promotion to be because either I
210 couldn't get along with him, or I thought he wasn't going to be the person that was
211 needed in that position, or other negative inferences. I didn't want to accept the
212 promotion and then resign, given the macro circumstances at J&J, so I called
213 Hybritech, told the senior guys what the situation was. I told them that I didn't want
214 to accept the promotion, but that I didn't have any rationale to go back and say,
215 'Well, I'm not going to take this job offer.' They understood and the result was I
216 moved earlier than was initially planned from J&J to Hybritech.

217 **JONES:** And you were impressed with the company?

218 **OWEN:** Absolutely. I was highly confident that the technology was going to work.

219 **JONES:** Well, what convinced you about that?

220 **OWEN:** I could have been wrong of course. Personally, I just felt that I knew that it
221 was going to work – that was why I had pushed J&J so hard to put more resources in
222 the emerging biotech area. I thought we were, we, at the time being J&J, were making
223 a mistake not to get into this new area with both feet. I was sure it was going to work.

224 To me, Hybritech looked to be one of the more substantial of the companies getting
225 into biotech from an infrastructure, strategy, money and organizational standpoint. I
226 mean, as thin as we were in headcount, each of the people was very, very competent
227 in his or her respective area. The company had good, quality money behind it. I didn't
228 know much about venture capitalists at the time, but I could tell that it was a better
229 grade of venture capitalist than the Acme Venture Club, which was where a lot of
230 early biotechnology pure plays were being funded. Of course, I might have been
231 wrong.

232 **JONES:** Did any of the venture capitalists get involved in recruiting you?

233 **OWEN:** I think not in the sense that you're asking the question, although keep in
234 mind the reason that I ended up moving from Genentech to Hybritech was because it
235 was the same venture capital guys. But, it wasn't like Brook Byers or one of the other
236 Kleiner, Perkins, Caufield and Byers people personally interviewed me at that time. In
237 fact, I don't think I met Brook personally until after I had made the decision to accept
238 Hybritech's offer. Certainly I knew that he had the respect of not only the Hybritech
239 management, but he also had the respect of the Genentech people, which is where I
240 started my conversation, so I had no cautions about the funding group.

241 **JONES:** Well, as the company started to grow and began to put products on the
242 market, were you involved in recruiting, bringing people in?

243 **OWEN:** Oh yes. It's hard to recall the details at this point. I don't know how many
244 people a month we were interviewing but it was a relatively large number for our size,
245 and the approach was to have several people interview each candidate. I had an
246 opportunity to meet and interview our first CFO, Jim Jungwirth, for instance, and
247 many R&D candidates, manufacturing people, and of course, marketing staff. There
248 were three or four or five of us who were routinely involved in the interview circuit. It
249 helped the person making the hire to get a better impression of the candidate. It was
250 sort of a screening and first impression comparison objective among alternate
251 potential candidates. We'd often go to dinner with candidates. I must have gone to
252 dinner twice a week, some weeks, with job candidates. One time it would be
253 somebody from R&D who would ask, 'Would meet with so and so,' and the next time
254 it would be someone from manufacturing who would make the same request. And
255 you know, I'd do the same thing. I would have a candidate coming in for a marketing
256 position and I might call Russ Saunders in R&D and ask him to please meet with the

257 person, just to help me get a perspective by getting Russ' impressions of the person.
258 We didn't have a personnel department or a human resources department so it was a
259 group effort to obtain the most perspective you could from what was often an
260 expensive interview visit – because many – probably most – of these people were
261 being flown in from somewhere else. The employment base in San Diego, at that
262 time, was very thin for experienced biotech or industry resources – keep in mind we
263 were the first biotech company in town.

264 **JONES:** During this whole time, the early years, do you remember particular growing
265 pains, particular problems that cropped up that had to be dealt with? I assume the
266 problem with meeting the payroll was a one-time thing, and that other than that
267 there were no serious financial crises.

268 **OWEN:** Well, that financial crunch wasn't visible to anyone outside the company,
269 because the checks showed up on time. If you were paying attention, you knew that
270 we had gotten really squeezed in our bank account and that there was some personal
271 money being shuffled around to keep things running, but no one was running around
272 with his or her hair on fire. I think we were each probably most aware, on a daily
273 basis, that we were making consecutive decisions that were going to be critically
274 important regarding achieving our long-term strategic objectives. And, we knew we
275 were having to make the decisions with not very much information. That noted, we
276 had a group of people each of whom were recruited, selected and hired because, to
277 the best of our judgment, these were the best resources that we could get out of the
278 industry or from the given academic specialty. We were pretty conscious, pretty
279 aware of consciously trying to get people from different companies in particular, so
280 that we were getting the advantages of learning how a given problem was solved by
281 that group, or how it had been done in that company. So, if you get to work with a
282 group of people, each of whom has had above average success in his or her prior
283 environment, compared to both the people that they were working with and with
284 whom they were competing with for resources, then you gain a lot of expertise from a
285 lot of difference companies. One result was that there was a lot of pushing and
286 shoving among us to get to an endpoint, because each person had his own, or her
287 own, ideas about how it should be done. However, there was an absolute minimum of
288 the petty, in-house politics sort of stuff. I think we were really fortunate in that way. I
289 don't remember the politics and in-fighting you see too often in companies ever
290 being a problem at Hybritech in those early days.

291 **JONES:** You were in sort of the first wave, I guess, in 1980, the first wave of
292 management. Did things start to change when the second wave came in, David Hale
293 and Tim Wollaeger, you know, a year or two later?

294 **OWEN:** Well, things were changing, I don't know if it was because of the wave, or
295 because the organization was both growing in size, with respect to head count, and
296 was just progressing in other ways. We were getting larger in all ways. I'm sure there
297 are social scientists who have described what happens as head count increases.

298 **JONES:** Probably not very well.

299 **OWEN:** From my experience, I'd suggest that there seems to be sort of an
300 organizational personality, a sort of ethnic makeup of a growing company. It's one
301 entity and has that personality when you're about forty or fifty or sixty people, and
302 then the entity's "personality" changes at a couple of hundred people. I think it
303 changes again at about five hundred people, and I don't know where the next tipping
304 point is relative to organizational size, maybe it's a thousand or fifteen hundred
305 employees – maybe it's at eight hundred employees – probably the lower number. In
306 any case, it's not a continuum. The "personality" of a company seems to sort of
307 change by notches, at least that's my perception. It starts to modulate and change at
308 the notches as it hits certain levels which I'd associate with headcount, but there may
309 be a better marker driving the changes. It may be that when you get to a thousand
310 employees that it doesn't change again after that, I think the initial "personality",
311 which I've now seen in three or four different new companies, is a result of the fact
312 that when you're small and dynamic, everybody's wearing a lot of different hats.
313 Everyone is doing a lot of things and no one has time for the petty stuff. There are not
314 enough people to do what needs to be done. I think that is the reason that there is a
315 minimum, if any, in-house politics in those situations. There is also no place to hide –
316 if you aren't helping to pull the wagon, it's obvious who isn't pulling. There is so
317 much more to do than there are people to do it that nobody gives a rat's ass if you
318 pick up a ball that might be considered to be in their court. If you do something that
319 might otherwise have been deemed to have been in their area, they may very well not
320 care because they didn't have time to do it anyway. So, if you want to do it, have at it.
321 Whereas, if you're in AT&T or General Motors and you pick up a ball that is in
322 somebody else's court, they're probably going to get territorial. If somebody had an
323 idea for a product positioning statement or an advertising concept and came to me
324 and said, 'Here, we ought to do this,' your response was not likely to be to ignore

325 them. Often you realized the suggestion they made was something you should have
326 been thinking about last week – but you hadn't. Likewise, if you found a new package
327 or saw a new approach to something relevant to our world, the idea could be for use
328 in R&D or on the packaging line, if you told a person in R&D, they weren't going to
329 look at you like, 'Oh, you think you're going to do R&D?' The response was much
330 more likely to be, 'Oh, who's got it? How much does it cost?' If the R&D person had a
331 problem to solve regarding buffers, you may have just made the job easier – so
332 territoriality was rarely a problem. I think that the smaller the entity, the more the
333 "personality" is collegial rather than territorial. It's just how things go, because each
334 person is so busy, and there's so much going on, and it's exciting and it's also a lot of
335 fun – you just don't worry about the small stuff. At a headcount of a couple of
336 hundred people, I think that it's about two hundred, maybe less than that, it begins
337 to start to change. Actually Brook Byers at Kleiner Perkins would be a good resource
338 to ask about company personalities because he's worked with so many small
339 companies that have been successful and have then grown to large head counts,
340 going through these growth stages.

341 **JONES:** He's seen a lot of different examples.

342 **OWEN:** Well, yes. He and I have talked about it a little at various times, and he's both
343 more articulate than I am and he's seen a lot of companies go through "personality"
344 transition points. Tom Perkins, actually, might be an even better resource for that
345 question. At this point in time everybody talks about Brook as having been our key
346 senior management resource, and while that is true and he certainly deserves that
347 credit, in fact Brook wasn't our first Board Chair, it was Tom Perkins at the outset of
348 the company. Tom's had even more extensive experience with small, rapidly growing
349 companies. I think as an element of company personality, when you're twenty or
350 forty people comprising the company, nobody is that far from the senior person, in
351 our case that was of course Ted Greene. You're not very far from the President. He
352 isn't a picture on the wall in a meeting room – you actually know him. It doesn't
353 matter if you are at the back door receiving supplies or in a lab washing glassware,
354 you know the President. He knows you. He knows your name, for whom you work
355 and your job responsibility. There's a closeness from that standpoint in the small
356 group. At a couple of hundred people, you can't have that closeness anymore. You
357 start to need a hierarchy, a management infrastructure. One person can't effectively
358 manage everyone in the building. Most agree that one supervisor can effectively
359 supervise eight or ten people, twelve, maybe. That person has to report to someone

360 who also can't manage more than eight or ten people. You start getting a hierarchy. I
361 don't think you can put it off beyond a hundred people or so – at most a couple of
362 hundred people. If you do so, then you start to see a situation where you have
363 somebody at the top who is trying to micromanage everything and everyone. They
364 end making decisions for the person in the warehouse in the back of the building. A
365 person's supervisor may say, 'We're going to use a blue one,' and then the person he's
366 talking to, who may be the lowest guy on the totem pole, says, 'No. I talked to Ted
367 yesterday afternoon. We're going to use a red one.' And that's when the system starts
368 to come apart. So, at a couple of hundred people or so, you have to have a structured
369 supervisory structure in place and we began to see that need at Hybritech. By the
370 time you get to about five hundred, there starts to be some real distance between the
371 most senior level person and the people moving boxes in the back. They no longer
372 have the proximity and the access to that senior person. Mechanically, you just can't
373 do it that way anymore – and that can be very painful to those early employees who
374 have lost that former direct contact they had routinely with the President of the
375 company. It's a cost of growing.

376 **JONES:** What were the numbers at Hybritech when different facilities started to be
377 opened, when, for instance, manufacturing moved over to Miramar?

378 **OWEN:** I'm not sure I can answer that but I can help you find someone who can
379 accurately give you those details.

380 **JONES:** It's not real important.

381 **OWEN:** I could guess, but it would be just guesses.

382 **JONES:** Well, in the beginning there was this real sense of teamwork, a spirit of
383 teamwork, everybody pulling together. How much do you think everybody having a
384 piece of the company contributed to that?

385 **OWEN:** I think there was a point at which everyone owning stock became important
386 but maybe not at the time you might assume. Ted was superb about being sensitive
387 to that. He made sure that everybody was in the stock option program, and that it
388 was an option program that didn't cost you anything at the time of joining. I'm not
389 sure that as many people as you might think thought about value at the time they got
390 the option. Probably not as many as you might think. They did after the fact, when all
391 of a sudden there was obvious value, realize it but early on, the process was really

392 driven by Ted. He made sure that every clerical person, every dishwasher, secretary,
393 the receptionist, everybody was in the stock option program. In the first couple of
394 years, it was sort of a moot point if you were in or not. You also have to keep in mind
395 the average age of Hybritech employees in those early years was 28, I think. Twenty-
396 eight year old people don't think so much about retirement issues or personal capital
397 acquisition. So, yes, while everybody was involved in the stock option program, it was
398 only later that it became important to a lot of employees. It was also valuable to the
399 company "personality" that everyone knew that no one had been left out. But as
400 much of a surprise as it may be, many of the people that joined the company were
401 just out of school as science undergraduates or with grad degrees. They wanted to
402 work in a lab and Hybritech was a good place to do that. It was fun and it was
403 interesting. If you gave them stock, they'd take the job. If you didn't give them stock,
404 I suspect most of them would still have taken the job as long as the salary was
405 competitive. It is kind of circular argument about how important it was but honestly,
406 I don't think it was very important to many employees at the beginning. It may have
407 become more important when you got to that couple of hundred employee level. It
408 was also important when people began to realize that nobody had been left out, and
409 that we were all in this together. They could have been left out. A lot of companies do
410 that – still.

411 **JONES:** When did you make the transition from marketing to business development
412 and the licensing, that kind of stuff? Was this before or after ICON?

413 **OWEN:** It was kind of about the same time that ICON begin to emerge. What
414 became ICON was just coming into existence as an R&D project.

415 **JONES:** Well then, let's talk about ICON. Can you tell me about the circumstances
416 surrounding that? I saw that your name is one the patent?

417 **OWEN:** Well, you'll hear a lot of stories and get a lot of input about ICON, where it
418 came from, what it was, and the further you get away from Hybritech, the more
419 people you'll find who will tell you they were closely involved and take credit for it.
420 I've come across people who take credit for ICON in some fashion, or for the
421 marketing of ICON, that I'd never heard of – much less met. The way the product
422 format (later called ICON) came into being started pretty simply. I was in one of the
423 labs one day – and I can tell you all of this, but I'm not sure how much of this...

424 **JONES:** I'm looking for mundane details.

425 **OWEN:** I mean, I'm not sure that some of this you may get to write down, because
426 there are still some intellectual property squabbles going on about ICON.

427 **JONES:** Oh, sure, well you can review all of that.

428 **OWEN:** I was in the lab, one of Russ Saunders' development labs. One of the research
429 scientists, Gunars Valkirs, who is a biophysicist by training, he's now at Biosite and
430 one of the founders of Biosite. Gunars was literally sitting on the floor between two
431 lab benches, and I think had a piece of two by four and a hammer. He was using
432 something as a die, I think it was a piece of half-inch water pipe. Anyway, Gunars was
433 using his die to cut out round pieces of gauze or nylon from a roll of stock, using his
434 "die cutter." I asked him, 'Gunars, what the hell are you doing?' He explained what he
435 was doing, which involved making a filtration-based immunoassay format as one
436 element to accomplish a research objective he had for the given project. He was
437 working on a pretty remote application but it was a very interesting idea and I said,
438 'Could you do that with something that somebody cared something about?' And he
439 said, 'Like what?' And I said, 'Like HCG.' And, only a few days later, literally days
440 later, using antibody, conjugated HCG antibody and buffer components we already
441 had, Gunars put together an HCG assay using his approach – HCG was used the
442 hormone to determine pregnancy in the lab. He demonstrated that, using his
443 method, in about a fifteen minute time frame he could deliver a very sensitive
444 pregnancy test result that using other methods was taking about two hours to get
445 that same sensitivity level. I almost went through the roof with excitement. This was
446 a very crude first iteration of the assay. I think Gunars was using a 12x75 test tube as
447 the holder for the various reagent components. The test tube had the bottom cut out
448 of it, so it was just a plastic column with his active section on top and he used
449 cigarettes filters that he broke off cigarettes as his adsorbent material. He jammed the
450 cigarette filter up in the tube from the bottom as the absorbent for the test specimen
451 liquid and any excess reagents. At J&J, early on there I had managed the product
452 group that included pregnancy testing products. J&J had been the innovator and had
453 introduced the first immunologic pregnancy test. Before the J&J lab test, the
454 pregnancy test method was a biological test using live frogs – which were kept in a
455 tray in the lab refrigerator. I knew the history of the pregnancy testing market, its
456 transitions, competitive characteristics, etc., really, really well. I almost jumped out of
457 my skin when I saw what Gunars had accomplished. I immediately started lobbying
458 for us to develop that test format, initially for pregnancy testing. There was
459 discussion about the opportunities and the development project really started almost

460 immediately. It wasn't a funded research project at first, more a "bootleg" R&D
461 project, but it started. Another piece of relevant history, prior to my time in the Navy
462 I had worked for Celanese Fibers Corporation, which is now a part of Hoechst, but at
463 the time was an independent synthetic fibers production company, I'm an engineer
464 by training, and I had I worked as an industrial engineer in one of the Celanese
465 production facilities, where among other things we had made a synthetic fiber called
466 "cigarette filter tow" which was the raw material used to make cigarette filters. So,
467 when I saw what Gunars was doing, I learned he still had a lot of questions about
468 what materials to use as various components to comprise what became the ICON
469 device. Where could we get the right absorbents, what choices were available, etc.?
470 This was a foreign area to us – no one had used that format for an immunoassay and
471 none of the basic questions about materials had been investigated. So, when we
472 started looking at those sorts of questions, I knew from my Celanese experience that
473 we could buy a fifty-five gallon drum of filter tow if we wanted it, we didn't have to
474 break the ends off of cigarettes. I called a couple of guys at Celanese, and got from
475 them other references to other guys elsewhere making similar materials and we
476 began to get some good perspective on our available choices. My suggestions were
477 very early regarding materials – Gunars and his team figured out what was needed –
478 we never used any of the Celanese materials and moved quickly to other, better
479 materials than the stuff from which cigarette filters were made. Anyway, we started
480 the process of getting a broader look at what the bits and pieces were that we would
481 need. It was a fun time and in a very short period of time, Gunars and company had a
482 prototype product. I may be wrong on this, but I think that it was within about five or
483 six months after I had first asked Gunars what he was doing to us having a very, very
484 nicely functional prototype assay. In another six months or so we were ready to file
485 with the FDA and in another six or eight months, maybe it was a year, we had a forty
486 percent market share of the pregnancy testing business in the U.S. And, as
487 importantly, we had those sales at a dollar a test price premium to the pricing of the
488 old format pregnancy tests. The price for the old format tests was only a dollar,
489 sometimes even less, so we were really priced much higher than any other rapid test
490 on the market. Customers loved it. ICON probably represents as significant a
491 procedural transition for a test in the clinical lab as had occurred in immunoassays.
492 The TANDEM transition was probably more important from an R&D innovation
493 perspective, and TANDEM also provided the basic immunology tools required for the
494 ICON innovation, but as to day-to-day use in the lab, customers will probably tell you
495 the ICON was just as important to them. Back to your original question, I moved to

496 be the VP of business development prior to the launch of ICON, although I was still
497 going to ICON project team meetings as a marketing resource, even after I was
498 running business development. Kim Blickenstaff, who's now the CEO at Biosite
499 (Gunars is there, as well) became the key marketing person for ICON and deserves
500 credit for getting it on the market and its market success. Kim had moved from
501 Hybritech's finance group into marketing. He picked up the marketing reigns first as
502 the project manager, then the marketing manager. David Hale had joined Hybritech
503 by that point in time and was Executive V/P. I think David got tired of me beating on
504 his door every other day telling him that ICON this was going to be the most
505 important thing we did in the market that next year. It was.

506 **JONES:** Did you have to work to convince David Hale and others?

507 **OWEN:** I think it wasn't so much that David didn't hear me or that he disagreed, or
508 that Ted or Tom Adams didn't hear me or disagreed. There was just so much going
509 on already in R&D. Everyone's plate was already full – and this was to be a major new
510 development obligation if we took it on. There were a lot of alligators already in the
511 pond. We had products on the market at that point and we had to support them and
512 keep them working. We couldn't just stop support of the in-process products, and the
513 ones already on the market, to work on ICON. But at any rate, somewhere along the
514 line, we made enough noise that Tim Wollaeger, who was by then our CFO, was
515 made the senior project team leader in order to get this new format developed and
516 out the door. Somewhere along the way I think David told me it had become
517 apparent that it was obvious we were going to do it anyway, so he might as well make
518 it an official and "load" the research project. Tim picked up the reigns and very
519 effectively managed the project process. Kim Blickenstaff started looking at the
520 format from the perspective of, OK, we know we can do this, so what else can we do
521 with it? By that time, I had moved to business development full time and was less and
522 less involved with ICON. I was doing technology licensing, both in and out, for our
523 innovations and/or for new inventions/innovations we wanted to bring in house.

524 **JONES:** Did you license the ICON assay?

525 **OWEN:** Well, we didn't license it for other lab-based human health care applications.
526 We did license the format to a company called Agritech Systems, which is now
527 IDEXX, a veterinary products company, limited to vet market applications. Agritech
528 started about the time we started, but with a different market focus. David Shaw was

529 the President and Irwin Workman ran R&D. Irwin was out of Abbott. They licensed
530 the ICON format for veterinary applications, and they did very well with it. We got
531 real close to a licensing agreement with TAMBrands for the ICON format for what
532 would have been probably the first over the counter pregnancy test. We ended up not
533 doing a deal with them. They instead bought a small company in Boston, I think, and
534 went in another direction to get a pregnancy test. We later did a license with Unilever
535 ("Lever Brothers") for use of some of our antibody technology in an over-the-counter
536 pregnancy test that they marketed. In business development I continued to be
537 concerned with ICON licensing opportunities but there were a lot of other things, as
538 well. We were still in-licensing monoclonal antibodies (cell lines) from academic
539 investigators, for instance. We were acquiring technologies that we needed, as well as
540 out licensing our own inventions and innovations. It was at about that time I started
541 making fairly regular trips to China. China has some huge medical facilities that
542 specialize in particular diseases and pathologies and exist on a scale just not seen
543 elsewhere. Different cities were organized with different responsibilities for research
544 and treatment of certain cancers and/or infectious diseases for instance. I think the
545 city of Wuhan was responsible for hepatitis research, for instance. Shanghai may have
546 had a breast cancer focus. Shenyang had another solid tumor cancer focus, maybe
547 prostate cancer. The result was that you could identify cities in China where there
548 were one-thousand bed cancer hospitals, one thousand patient beds and every
549 patient had the particular cancer type. Every patient with the subject pathology. We
550 don't have very many one thousand bed hospitals in the United States to begin with –
551 and none that specialize in a single disease or pathology. So, China represented a rich
552 resource with respect to research and clinical activities of interest to us and, of
553 course, represented a very large, rapidly growing potential market opportunity.

554 **JONES:** Did much ever come of that, did you make deals with the Chinese?

555 **OWEN:** No, we had identified some very interesting opportunities and had good
556 discussions underway but those discussions got serious about the same time that Eli
557 Lilly began to talk seriously with Hybritech, initially about a proprietary research
558 project for them and then later, about acquiring the company. In fact, the last trip I
559 made to China, maybe not the last one, but one of the last ones, the Hybritech/Lilly
560 discussions were far enough along that I actually spent time in Beijing with the Lilly's
561 guy in China, an Expat who lived full time in Beijing. I didn't know he was there
562 during my initial trips, and didn't talk with him my first few visits. I think it was my
563 next to last visit when we met, and by the last visit we were spending more and more

564 time together. And then, the Lilly acquisition occurred. I left Hybritech soon after
565 that. Opportunities for Hybritech in China were not nearly as interesting to Lilly as
566 were the China opportunities to Hybritech. I think the China focus lost attention and
567 I don't think a deal was done, or more correctly, if so, I didn't make a deal. Ron
568 Taylor, who was V/P Operations, picked up the China discussions, as I recall.

569 **JONES:** Did you know about the Lilly sale before it happened? How close were you to
570 those negotiations and what was going on there? Well, maybe I should ask you first,
571 what other significant licensing deals did you make? Do any stand out as particularly
572 important to the company at the time?

573 **OWEN:** Well, Howard Birndorf, who was my predecessor in business development,
574 started the process of licensing the raw materials that we used for PSA, Prostate
575 Specific Antigen, the basis for PSA testing that has become routine prostate screening
576 for men of fifty years of age or older. The basic purified PSA material, needed to make
577 antibody, was first purified and identified by an investigator at Roswell Park, in New
578 York. Howard initiated that contact and passed it off to me and I completed the
579 agreement. There were several licenses with academic researchers done for either key
580 purified materials, such as PSA, or for a cell line making a monoclonal antibody (or
581 several monoclonals) that were of interest for either a potential imaging agent or for
582 an in vitro diagnostic product. I remember one of the licenses that seemed to take
583 forever, was for materials that came out of the Ludwig Institute in Germany. We also
584 had very interesting negotiations with Roche toward a cross-licensing agreement for
585 technology for which Roche had patents issued in Europe but not the U.S., and
586 Hybritech had similar inventions patented in the U.S., but not in Europe. Those were
587 very interesting negotiations.

588 **JONES:** What were the problems there? These were research institutes?

589 **OWEN:** Yes, primarily research coming from academic institutions. It's been a long
590 time. There was chelating technology out of the University of California, Davis, I
591 think. There was conjugation and chelation technology that Hybritech developed
592 further and then we later licensed to IDEC, which became an important basis for the
593 original founding of IDEC. We did a development agreement for reagent
594 development with a diagnostic instruments company in Japan, Tosoh. We of course
595 did several "research and development" partnerships with various large

596 pharmaceutical companies – those all prior to the Lilly acquisition, of course. We did
597 a product distribution deal in Japan with Mitsubishi.

598 **JONES:** What about the Lilly sale, how close were you to those negotiations? Did you
599 know what was going on?

600 **OWEN:** I knew we were in negotiations and I was one of the "resource" people
601 included in the "diligence" discussions by Lilly, as that company kicked the Hybritech
602 tires and gathered information. The Lilly transaction (actually it was called a merger,
603 not an acquisition) was kind of like what I mentioned regarding ICON. You can find a
604 lot of people who insert themselves into that transaction, as if they were critical to it.
605 Every rooster that crows takes credit for the sunrise. There are a lot of roosters
606 around trying to take credit for the Lilly deal. Ted was the person who did that Lilly
607 deal, in my opinion if you want a singular name. Anyone else who pretends to have
608 driven it or kept it alive or kept it at the table may have an enthusiastic memory.
609 Certainly a lot of people were involved and had something to do with the transaction
610 coming to fruition, but Ted was the driver. Tim Wollaeger was also involved in a very
611 important way. David Hale, as well. Dennis Carlo. Larry Respass, Hybritech's General
612 Counsel, and outside counsel, a fellow named Tom Sparks, were both very important
613 to the process and to getting to the successful transaction. But I think that the person
614 who really deserves the most credit for the structure, the arrangement, and getting to
615 the end point, was Ted. There was a lot of discussion, and some disagreement on the
616 Hybritech side, internally, I don't know how many people will tell you about this.

617 **JONES:** In management, or at the Board level?

618 **OWEN:** Yes and yes, opinions about whether we should do the deal, was it too soon?
619 Were we still growing too fast in value to do a deal "now"? The reality was that
620 Hybritech was going to need more cash from 'outside' at that point in time. Our rate
621 of growth, and rate of growth of revenues from sales, as rapidly as it was increasing –
622 was not as fast as our expense growth. We were beginning to move forward rapidly in
623 some in vivo diagnostic imaging agents and potential therapeutic applications. Those
624 projects and associated clinical investigations were going to suck up money faster
625 than the rising sales could support. It was clear that we had to have more money. We
626 were at a point where we had to do another financing in some fashion or we had to
627 be acquired. There were some individuals, both management and Board level, who
628 were not so sure that we should sell to Lilly at that time because they felt that the

629 value was only going to go higher. The value that was being discussed initially was
630 less than they felt would be the future opportunity. And, the value that Lilly paid was
631 not the amount being discussed at the time.

632 **JONES:** It was lower?

633 **OWEN:** Yes, it was less. And again, Ted (with Tim's assistance) was primarily the
634 person who got the number up, in my opinion. There were activities on a parallel
635 track for me, personally, at that same point in time. David Hale was diligently trying
636 to get me to move to Europe to move into responsibility for Hybritech's European
637 operations. There was a perception that the European operations might benefit from
638 more close management than was occurring. David asked me to go and I was very
639 seriously considering it. I went over there a couple of times with that anticipation
640 that I was going to relocate to Hybritech Europe, which was located in Belgium. My
641 wife went with me, we looked at places to live, and we looked at schools for our kids.
642 This must have been happening in '85, maybe as late as early '86. As I thought about
643 Europe, and as Lilly discussions continued, it became more and more evident to me
644 that there was a probability that Lilly might buy us. And, there were a couple of
645 things relative to the European operation about which David and I couldn't get in
646 sync. We weren't in full agreement in how certain authority and associated
647 responsibility issues would be sorted out.

648 **JONES:** With the guys that were already there?

649 **OWEN:** That was part of it, but there were just a lot of issues. It's tough for an
650 expatriate to go into those kinds of situations. I had a really good friend who was a
651 very senior person at 3M. He was in my wedding, I had known him for a long, long
652 time and at the time he ran the European operations for 3M, also located in Belgium.
653 So, I spent a lot of time with him, and I felt I had a really good handle on how the
654 dynamics were going to work for someone arriving from the U.S. I was trying to get
655 some things in place regarding authority and responsibility that I thought would be
656 the best way to manage the dynamics. We were neophytes at that sort of stuff at
657 Hybritech. We were neophytes and I felt that I had gotten some very good insight
658 from people with relevant experience in similar situations. Each of people I knew in
659 similar settings, including the 3M friend and some friends from years earlier at J&J,
660 people with "on the ground" international experience, said, 'Yeah, this is what is
661 going to happen.' The gist of the opinions were that one had to immediately deal with

662 certain issues or you would never get them sorted out – and, you'll be miserable in
663 the job. It was going to be difficult to take some of the actions that I thought needed
664 to be taken. As importantly, I realized that Lilly was probably going to acquire
665 Hybritech. I would exit prior to the sale and then really not know anyone running the
666 company when it was time for me to come home. I was concerned that I would go
667 from having been one of the early people at Hybritech to a standing outside,
668 knocking on the door, saying, 'Hello? I've been three years or five years, can I come
669 home?' And somebody on the other side of the door was likely to say, 'Cole who?'
670 And I decided I'm not going to run that risk so I decided I wasn't going to go. I
671 remember sitting at dinner with David and his wife, Linda, and my wife, Lynn, and
672 finally turning to Linda, and saying, 'Please, tell your husband that we are not going
673 to move to Belgium. It's not going to happen,' after he had closed me two or three
674 times that night to take the job – and this was the second or third go around on the
675 issue. David is nothing if not persistent – It's why he has been so successful. But, I was
676 concerned that you are either in Rome, or you're not, and Belgium was not Rome. San
677 Diego was at the time, and as it turned out, San Diego was about to not be Rome
678 anymore, Indianapolis was going to be. And that was, in fact, a big reason that I left
679 Hybritech. I was the only Vice-President that did not sign a non-compete
680 employment agreement. I knew that I was not going to stay as a Lilly employee. I had
681 been involved in acquiring companies for J&J and had seen this movie from the other
682 side of the table. I thought that Hybritech was a great acquisition for Lilly, and that
683 Lilly was a great group to be acquiring us, I didn't have any problems at all with the
684 transaction. However, I also knew that I would end up sending the goldenrod copy to
685 someone in Indianapolis to ask them if it was OK for me to do something that I'd
686 been doing on my own authority for the last five years and so I said, 'I'm not going to
687 stay.' And, I think I was the first person that exited after the acquisition – I know I
688 was the first V/P level person to resign.

689 **JONES:** And that's when the Owen & Associates opportunity came up?

690 **OWEN:** Yes.

691 **JONES:** Well, maybe we can talk about that another time?

692 **OWEN:** OK.

693 **JONES:** You were also involved in the formation of Immune Response, is that right?

694 **OWEN:** Yes, when it began, Immune Response was another phone line at my office.

695 **JONES:** OK, I'd like to talk to you about that.

696 **OWEN:** So was Cortex Pharmaceuticals, which came out of UC Irvine and was
697 located up in Orange County.

698 **JONES:** Cortex? OK, I wondered why Cortex was on this list and what the connection
699 was.

700 **OWEN:** There's a custom formulation and packaging operation in town that really
701 came out of Hybritech, by the way, called Bioserv. Do you know that company?

702 **JONES:** Yeah, I've been over to talk to Jeanne Dunham at Bioserv.

703 **OWEN:** Do you know about BioStruct?

704 **JONES:** No.

705 **OWEN:** It's the facility that builds more labs and biotech facilities, certainly in this
706 area, maybe in Southern California, than any other construction company. It was
707 started by the fellow who was the lead carpenter and who outfitted the interiors of
708 each of the Hybritech facilities and built all the lab benches.

709 **JONES:** What was his name?

710 **OWEN:** Bruce Birch, you'll see his trucks all over Mira Mesa and Sorrento Valley.

711 **JONES:** And this ad agency company is?

712 **OWEN:** Mentus is a large "high tech" ad agency here in San Diego. The founder, Guy
713 Iannuzzi, was sort of a successful graphic artist when he relocated to San Diego. He
714 was one of the early outside resources for Hybritech with respect to graphics services.
715 He provided most of the graphics we needed for our slides [at the time, prior to
716 PowerPoint] and later he did most of our early journal adverts and product
717 brochures. He later founded Mentus. They must have fifty people now. Now, Mentus
718 probably does the promotional work for many companies and the annual reports for
719 probably thirty companies. Mentus has become a large operation.

720 **JONES:** Have you consulted for a lot of ex-Hybritech people as they started up their
721 companies?

722 **OWEN:** Yes, fortunately, but I've also worked with a lot of companies that were not
723 founded by ex-Hybritech employees, as well as working for larger, well-established
724 companies.

END INTERVIEW

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The San Diego Technology Archive (SDTA), an initiative of the UC San Diego Library, documents the history, formation, and evolution of the companies that formed the San Diego region's high-tech cluster, beginning in 1965. The SDTA captures the vision, strategic thinking, and recollections of key technology and business founders, entrepreneurs, academics, venture capitalists, early employees, and service providers, many of whom figured prominently in the development of San Diego's dynamic technology cluster. As these individuals articulate and comment on their contributions, innovations, and entrepreneurial trajectories, a rich living history emerges about the extraordinarily synergistic academic and commercial collaborations that distinguish the San Diego technology community.