IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

WP CMI REPRESENTATIVE LLC,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action
	:	No. 11877-VCL
ROCHE DIAGNOSTICS OPERATIONS INC. AND ROCHE DIAGNOSTICS HEMATOLOGY, INC.,	:	
	:	
Defendants.	:	

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Chancery Courtroom No. 12B
New Castle County Courthouse
500 North King Street
Wilmington, Delaware
Thursday, July 14, 2016
10:00 a.m.

- - -

BEFORE: HON. J. TRAVIS LASTER, Vice Chancellor

- - -

ORAL ARGUMENT
DEFENDANTS' MOTION TO DISMISS
AND THE COURT'S RULING

CHANCERY COURT REPORTERS
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THE COURT: Welcome, everyone.

MR. FLINN: Good morning, Your Honor.

THE COURT: Mr. Flinn, good morning. How are you?

MR. FLINN: I'm doing well. Barr Flinn from Young Conaway for the plaintiff WP CMI Representative LLC.

Your Honor, Mr. Brauerman and I thought it might make sense to make some introductions first.

THE COURT: That's fine.

MR. FLINN: First I'd like to introduce you to my co-counsel, Sameer Advani from Willkie Farr & Gallagher.

THE COURT: Welcome.

MR. FLINN: He'll be making the presentation today. And you also know my colleagues, James Yoch and Julia Ripple from Young Conaway.

THE COURT: I do. Great to see you all.

MR. FLINN: Thank you, Your Honor.

THE COURT: Great.

Mr. Brauerman, how are you?

MR. BRAUERMAN: Very well, Your Honor.

And you?

THE COURT: Good.

MR. BRAUERMAN: Good morning, Your Honor. Steve Brauerman from Bayard. I'm joined at counsel table by Paul Spagnoletti --

THE COURT: Welcome.

MR. SPAGNOLETTI: Good morning, Your Honor.

MR. BRAUERMAN: -- and Carissa Pilotti of Davis Polk & Wardwell. And Your Honor knows my colleague, Sara Bussiere. In the back row, Your Honor, we have Barbara Uncovsky. Ms. Uncovsky is in-house counsel for the Roche defendants.

THE COURT: Thank you for making the trip.

MR. BRAUERMAN: To her right, Your Honor, is Meredith Manning and Brooke Kettler, both of Davis Polk & Wardwell.

THE COURT: Great.

MR. BRAUERMAN: With Your Honor's permission, Mr. Spagnoletti, who has been admitted pro hac vice, will make the argument today.

THE COURT: That's fine.

MR. SPAGNOLETTI: Good morning, Your

Honor. We are here on the Roche defendants' motion to dismiss.

Maybe just a couple of words to set the stage. This case relates to an acquisition by Roche of a medical devices company named CMI. In 2013, July, the deal closed. About $200 million was paid in consideration of the acquisition, and there were also additional earnout payments if particular milestones were achieved following the closing.

The first milestone was paid in May of 2014, after the first commercial unit was delivered to Roche by the manufacturer that was manufacturing the device. Subsequent milestones have not been met and may not be met.

Plaintiff has brought a breach of contract claim and also a claim based upon the implied covenant of good faith and fair dealing, claiming that Roche breached the agreement by virtue of the inability to achieve at least the second milestone event and maybe others.

Our motion, as the Court is I'm sure aware, is based on the principle that the plaintiffs have not adequately pled either a breach of contract claim or a claim based on the implied covenant of good

faith and fair dealing. And with the Court's permission, what I'd like to do is start with the breach of contract claim and talk about essentially the two subparts of that that the plaintiffs have alleged.

The first basic claim that plaintiffs make is that Roche violated the provision of the merger agreement that required Roche to act in good faith following the consummation of the merger and what they refer to as Section 1.12(c) of the merger agreement.

And if I might just read the relevant portion to the Court -- this is from the attachment to our moving papers -- 1.12(c), in the relevant part, says that Roche must "operate [the] business in good faith and shall not take any action (or series of actions) the primary purpose of which is to avoid achieving the Milestone Events or making any Milestone Payments ...."

There is further language later down in that same provision that requires Roche to "use commercially reasonable efforts to develop, manufacture, test, market, sell and ship Bloodhound Instruments and to achieve the Milestone Events," and

then it goes on to give some more specifics about what "commercially reasonable efforts" might mean.

Plaintiffs have alleged that Roche has violated both of those provisions, the good faith provision and the commercially reasonable efforts provision. And as we set forth in our papers, we believe that plaintiffs have simply not alleged specific facts or allegations that are sufficient to permit this case to go forward. Their allegations are summary, they're conclusory, and impermissible under Delaware law.

There are four main areas where plaintiffs make allegations, both under the good faith provision and the commercially reasonable efforts provision. They relate to the following: the throughput rate, calibrators and controls, reticulocyte staining, and the KMC agreement. KMC is the manufacturer of the instrument. And if I may, I might just go through those four and talk about both good faith and commercially reasonable efforts in each one.

With respect to the throughput rate, and just to orient the Court and all of us here, that's essentially how fast the machine operates, how

many samples it can process in an hour, plaintiff's principal allegation in this regard is that the throughput rate at the time of the closing was 49 per hour and that Roche made efforts to increase the throughput rate from 49 to 60. Plaintiff alleges that Roche's effort to improve the speed of the instrument was not in good faith and also that it was commercially unreasonable. But, again, plaintiff does so in a summary and conclusory fashion.

First of all, plaintiff makes no allegations whatsoever that anyone at Roche had a subjective intent to frustrate the achievement of a milestone or the payment of a milestone payment by virtue of increasing the throughput rate from 49 to 60.

Moreover, as I indicated when I read the language from the contract, the contract requires I think in the context of analyzing good faith that there be at least some allegation that the primary purpose of the conduct that's at issue be to undermine the achievement of a particular milestone.

Again, plaintiffs make no effort and do not allege that Roche acted in increasing the throughput rate with the primary purpose of

frustrating the achievement of a milestone.

And for those reasons, we believe that the allegations regarding the throughput rate are fatal from the perspective of a good faith claim under the contract.

It's also worth spending a moment and focusing a little bit on some of the other allegations plaintiffs make in this regard. What they say in their complaint is that prior to the closing, CMI had the intention of going to market and going to FDA approval with a throughput rate of 49. Well, it's interesting, if that's true, and we'll assume it's true for purposes of today, but it's completely irrelevant. What CMI's premerger intentions were vis-a-vis the throughput rate has no bearing whatsoever on either whether Roche acted in good faith following the merger or whether Roche acted commercially reasonably following the merger.

Section 1.12(c) of the agreement, a little bit later on in the section that I quoted earlier, actually addresses this. And it says "... all decisions regarding the business and operations of the Surviving Company, including decisions which may directly or indirectly affect the

amounts of any Milestone Payment, shall be made by the Surviving Company in its sole discretion ...."

There is no obligation in this contract that Roche has to operate its business with the sole purpose of achieving a milestone event or making a milestone payment. Roche is entitled to consider a host of factors. It's entitled to consider cost, profitability, competitive advantage, its own brand, among other things.

And the notion that Roche had an obligation to comply with CMI's premerger intention to seek FDA approval with an instrument that was operating at 49 samples per hour instead of 60 is just wrong, and it's inconsistent with the language of the agreement.

Plaintiffs also allege, as I mention, that the increase of a throughput rate from 49 to 60 also had the effect of breaching the commercially reasonable efforts provision of Section 1.12(c). Again, that is just simply not the case, and plaintiffs have not pled specifically and identified sufficiently the facts that would support that type of claim.

Most notably, plaintiffs concede in

paragraphs 21 and 22 of their own complaint that the speed of the instrument is an important factor. It's important commercially. And while they make other allegations in other parts of their complaint that 49 was adequate, there is no doubt that they make allegations as well that speed is an important commercial consideration.

Under these circumstances, all plaintiffs have alleged with respect to throughput is that Roche was acting in a manner that was entirely consistent with its own legitimate business interests and that Roche was attempting to improve the instrument that it had acquired. These are simply just not sufficient allegations to allow this case to get to discovery.

I'll turn now to the second area where plaintiffs allege that Roche breached these two parts of the agreement, in the area of the calibrators and controls. And again, let me just spend a moment talking about what that means and what this is.

These allegations are based upon and focused on a May 2013 letter that CMI received from the FDA prior to the closing of the merger. And what the letter said was that the company's intent or

expectation that they would use a certain type of co-calibration system with a different machine was not going to be sufficient for purposes of the FDA clinical trials.

And again -- I had to learn this recently -- what that essentially means is that the company was anticipating that it was going to calibrate the Bloodhound Instrument by looking at what another instrument that was in the market already yielded with respect to a particular blood sample. So the other instrument, the competitor instrument, for example, would have been the so-called "truth," and they would calibrate the Bloodhound Instrument based upon the truth yielded by the competitor instrument.

What the FDA was saying in the letter was that that could not be done for purposes of the clinical trial and that what CMI and later Roche had to do was to go to its third-party vendor, a company named Streck, and have Streck essentially invent a synthetic blood sample that could be used to calibrate this new highly customized and state-of-the-art Bloodhound Instrument. That's a big undertaking.

Now, I appreciate that there's a lot of facts here and I know we can't get into the facts,

but the plaintiff's essential allegation here is that Roche acted in bad faith and, again, commercially unreasonably by not moving quickly enough, essentially, to get Streck, this third party, to produce the synthetic blood sample for purposes of the calibrators and controls.

Once again, no allegations that anyone at Roche dragged their feet with the intent, for example, of trying to frustrate a particular milestone event. No allegation that the primary purpose of any delay associated with the calibrators was, again, to frustrate a milestone event. And, indeed, what Roche was simply doing, and I think any reasonable read of the complaint reveals this, is trying to make sure that the instrument is correct, accurate, and safe vis-a-vis the FDA before clinical trials begin. There is no reasonable inference that can be drawn from any of the allegations in the complaint that Roche did anything other than that.

The third area that the complaint focuses on is something called the reticulocyte stain. And, again, just a moment on that. That's essentially a process by which the sample, the blood sample, is stained with a particular solution in order to

highlight reticulocytes. Reticulocytes are immature blood cells. Plaintiff's allegation is that Roche made improvements to the reticulocyte staining process, again, in a way that breached their duty of good faith and breached their obligation to engage in commercially reasonable efforts.

Again, their allegations in this regard are summary, they're conclusory, and they just simply don't support the claim that plaintiffs have attempted to bring here. Again, I guess for purposes of this argument, I have to assume the complaint is correct and the allegations are true. What the plaintiffs say is that the staining was "satisfactory" at the time that the closing occurred. The staining was actually not working, but for purposes of this argument, the staining was satisfactory.

Roche is perfectly entitled under the provisions of the merger agreement to try to improve what is a satisfactory element of its product, assuming it's satisfactory at all.

Again, like the throughput rate, Roche had the sole discretion to try to improve the product and to make it as competitive and consistent with the Roche brand as possible. And the allegations don't

articulate, again, any specificity that Roche did anything vis-a-vis the reticulocyte staining that was in bad faith or with the purpose of trying to avoid paying a milestone.

Lastly, plaintiffs make allegations with respect to the so-called KMC agreement. KMC is the entity that has been manufacturing the Bloodhound Instrument for CMI and then Roche.

Essentially, plaintiffs' allegation with respect to the KMC agreement is that the agreement to manufacture should have been signed promptly after the close in July of 2013. The agreement was not, in fact, signed until December of 2013.

Again, plaintiffs take the position that this supports some sort of inference that Roche acted in bad faith or that Roche acted unreasonably from a commercial perspective. And what they say is that this several-month delay set off a cascade of other unspecified delays.

Again, this is just simply not the stuff bad faith is made of. They make no allegation about what Roche could have done to try to secure the signing of the KMC agreement sooner or why the

several-month delay that it took to actually get the final agreement in place had any specific impact on any of this timing.

So for all these reasons, Your Honor, we believe that the -- and as set forth in our papers -- that the complaint is just simply inadequate when it comes to good faith, when it comes to commercially reasonable efforts, and what plaintiffs are really trying to do here is to create a new provision and put that into the highly negotiated merger agreement.

And what that provision is is a provision that says that Roche is not allowed to do anything unless it is designed specifically to reach a particular milestone and pay a milestone payment to plaintiffs. That's just not what the agreement provides. It's not what it requires. And I think the allegations are clear that they cannot support an inference that Roche did anything that is contrary to the requirements of the agreement.

I'll just spend a moment, if I may, on the implied covenant claim. I think our papers are clear that what plaintiffs have done is just add a duplicative claim that's entirely duplicative of the

good faith contract claim and the commercially reasonable efforts claim. Courts in Delaware only allow implied covenant of good faith claims to go forward under circumstances where there is a gap or an ambiguity in the contract. There is no such gap or ambiguity in this particular case. The contract is clear in terms of what it requires. And, again, plaintiffs are simply attempting to insert a new provision that they couldn't negotiate three years ago when they entered into this deal.

Unless the Court has any questions, I'll sit down.

THE COURT: Thank you.

MR. SPAGNOLETTI: Thank you.

MR. ADVANI: Good morning, Your Honor. Sameer Advani from Willkie Farr for the plaintiff WP CMI Representative.

Your Honor, before I begin with my arguments in opposition, just having heard what defense counsel just said in his statements, I thought it might be helpful if I could clarify what the bases are for plaintiff's breach of contract claim. Because I think you heard a lot from him this morning and it's in their briefs as well about the primary purpose

prong of the milestone provisions, which talk about the obligation Roche has to not take actions the primary purpose of which is to avoid the milestones.

Now, no doubt that's in there. That is one of the obligations. But it is not one, importantly, that we have asserted. I think, as you would have seen from our briefs, we said that at the time we filed the complaint, we did not believe we had the facts to support that breach, although we reserved the right if the case continues in discovery to come back and seek leave to amend. But the bottom line is it's not relevant for purposes of this motion. And so to the extent there were arguments as to that, I don't think they have any bearing on the outcome.

Separately, counsel pointed out the obligation to use good faith to operate the business, which is also in Section 1.12. Now, that is something that we have included in our complaint for the breach of contract claim. But as Your Honor might have noticed, it's not an issue that the parties engaged on very much in the briefing.

And although we noted in our opposition brief we think that there is a basis to allege a breach of the good faith obligation, candidly

speaking, Your Honor, we acknowledge that if you don't conclude that we have stated a claim for breach of the commercially reasonable efforts provision, you're likely not going to find that we breached -- we alleged a claim for the breach of good faith.

And so on that basis, I think what I'm saying is the outcome of this motion is not going to turn on the good faith prong; and, frankly, we would be content if Your Honor wants to treat those as dismissed for the purposes of this motion, although we would ask that it be done without prejudice. So if, in discovery, evidence turns up, you know, more that we can use to support it, we, again, would come back and seek leave to pursue it.

So unless Your Honor doesn't want me to, I'm going to focus on the commercially reasonable efforts prong of the agreement in discussing the motion and why it should not be granted.

Obviously, Your Honor has read the briefs and the complaint, and I don't want to spend too much time on the facts, although I would want to point out just two issues that I think provide a helpful context for the dispute today, one of which is that before the parties signed the agreement in 2013,

some three years ago, there was a lot of work that went into this machine. It was not some start-up product, some prototype that was just getting off the ground with an uncertain path to regulatory approval or commercialization. Quite the opposite.

As we allege in the complaint, and this is talked about around paragraph 24, hundreds of thousands of dollars -- I'm sorry -- millions of dollars and hundreds of thousands of hours went into the testing and the development of the instrument. A lot of work was done with market research going out into the market, talking to people in the hematology industry to understand what their needs were, what they would be interested in purchasing. There was work done with the FDA starting back in 2011: meetings, in-person meetings, exchanges with the FDA, about regulatory approval.

And all of that meant that by the time we get to the spring of 2013, when the parties are signing this agreement, you know, we have a unit, an instrument, that's perfectly positioned for the defendants after closing to finish up the remaining steps and take it to market. So that's point one.

Point two I think I'd like to point

out -- and, again, this is in the complaint -- is that Roche did a lot of work on this. This wasn't some expedited deal that was signed in a week. There was almost eight weeks of diligence, with a whole contingent of Roche personnel, including very senior personnel in the Roche Diagnostics hierarchy, who came down and engaged in diligence on a whole spectrum of issues, including things like the throughput rate, what the instrument was capable of doing.

So, certainly, although there's arguments in their papers and in the record of them being surprised by the throughput rate after, I don't think that that matches what we've alleged in the complaint. And they were very aware of these specifications and capabilities.

And, frankly, in the negotiations, Roche even built in provisions to protect that. And one of them that I think counsel referenced was the first commercial unit, which is the first of the milestones, which was met. And the definition of that is that the instrument -- they accepted delivery of an instrument that met the final specifications, their final technical package, all of the quality requirements, and all of the requirements of the

European Union's CE mark certification. And they acknowledged delivery of that not right after closing but several months later, almost a year later, in May of 2014. So these were all issues that were discussed and built into the contract.

Coming now then to the commercially reasonable efforts, which I think is really where the meat of the dispute is, if we look at the language -- and I know, you know, Mr. Spagnoletti took you to that language right now. It's on page 12 and 13 of the agreement. I think it is important to focus on what that that provision says, because it requires Roche to use commercially reasonable efforts to develop, manufacture, test, market, sell, ship the Bloodhound Instruments, and to achieve the milestone events. So, really, what you have is two obligations that are tied to the commercially reasonableness standard.

Now, while they acknowledge that those words are in the contract --

THE COURT: There's seven obligations.

MR. ADVANI: I'm sorry, Your Honor?

THE COURT: I get seven obligations.

MR. ADVANI: Over the course of 1.12(c)?

THE COURT: Yeah. They've got to use commercially reasonable efforts to develop the Bloodhound Instruments, they've got to use commercially reasonable efforts to manufacture the Bloodhound Instruments, they've got to use commercially reasonable efforts to test the Bloodhound Instruments, they've got to use commercially reasonable efforts to market the Bloodhound Instruments, they've got to use commercially reasonable efforts to sell the Bloodhound Instruments, they've got to use commercially reasonable efforts to ship the Bloodhound Instruments, and they've got to use commercially reasonable efforts to achieve the milestone events.

MR. ADVANI: That's a fair observation, Your Honor, and that's right. And we're focusing, really, on that last one, the one that says they have to use the commercially reasonable efforts to achieve the milestone events. And, as I said, they've acknowledged that those words are in there, but their arguments all but render that last part redundant. Because the basic theme of their argument is that they were, you know, free to take efforts to develop and launch the product. And developing and

launching it was part and parcel -- these are their words -- of achieving the milestone events. As long as they take commercially reasonable efforts to develop and launch it, they have not violated any obligation.

And they try and bolster that with this notion, which is also in Section 1.12, that they, after closing, have sole discretion -- and I agree, that's what the agreement says -- to make decisions about the business post-closing. And they only say that's subject to the requirement that they don't take actions for the primary purpose of avoiding a milestone.

And I just don't think that's right, because under their reading of the contract, what it would mean is that they could do pretty much whatever they wanted after closing to develop and launch it, as long as they didn't take anything for the primary purpose of avoiding a milestone and regardless of the impact it would have on achieving the milestones. And that can't be right, because it would be, basically, if they happen to hit a milestone, it would be a lucky break for the sellers. And I don't think that's what my clients negotiated. It's just not a reasonable

reading, and it would also render that last provision meaningless. And I think we all know the case law says you don't interpret contracts that way.

It must mean something, and it must constrain Roche's post-closing conduct in some way over and above the obligations to use commercially reasonable efforts to ship, sell, market an instrument. It has to have some meaning.

And from here, I think we have some guidance from Vice Chancellor Glasscock's recent decision in the Williams-ETE merger, which we sent Your Honor a letter on Tuesday on. And I think at page 16 of the opinion, dealing there in that case with an obligation to use commercially reasonable efforts to procure a law firm's tax opinion -- I think Your Honor is familiar with the case -- here's what he said.

"I find that, by agreeing to make 'commercially reasonable efforts' to achieve the 721 Opinion" -- that's the tax opinion -- "the Partnership necessarily submitted itself to an objective standard - that is, it bound itself to do those things objectively reasonable to produce the desired 721 Opinion, in the context of the agreement reached by

the parties."

And so what we say is that this language means, in the context of our agreement, that they must take into account the milestones when making decisions post-closing. They can't ignore those deadlines, for example, by taking an action that's not necessary for the purpose of achieving the milestone and actions that result in the milestone deadline being missed. That's really the key to it.

And while we're on this, what we're not saying -- and these are some of the arguments that I think defendants' briefs have tried to impute on plaintiff -- we're not saying any milestone is guaranteed. We've never said that. We understand that they may not occur. We're not saying that any delay means that defendants have breached the milestone or that there is a blanket ban -- I think that's one of their words -- on any action that could cause a delay.

I'll just give an example. If there is a directive from the FDA that says that the machine has to have a throughput rate of, pick a number, 100 samples per hour, and they take reasonable steps after closing to try and meet that and they don't meet it in

time for the deadline, I don't think we'd be here. But what we can't have is a situation where they take unnecessary steps. And I'll get to that in a minute when we go through the four items.

We're also not saying that Roche can't make any changes after closing. The agreement specifically says they can, and we don't dispute that. The question is what type of changes and how we do them. And we're certainly not saying that they only have to take -- and this is something that came up in the opening submissions. We're not saying that the contract obliges them to only take actions that reach the milestones. That's not what it says.

Before I get into the actual facts, I do also want to pick up on one big-picture point that I think is a theme that runs through their papers, and it's this idea that defendants are aligned with plaintiff because they're incentivized to get this to market, so, really, there is no disconnect. And I think, frankly, Your Honor, if that were the case, there would really be no need for Section 1.12(c).

As Your Honor knows, having dealt with these kinds of earnout provisions in other cases, they're put in there specifically because the parties

aren't aligned. And they function as sort of almost an accountability mechanism for the selling shareholders who are now long gone. They have zero control, zero visibility. It's their way of making sure and protecting their interests as to the contingent component of the deal price.

So now we come to the facts. What we say the obligation to use commercially reasonable efforts to achieve the milestone events means in this context -- and I'll go through it using the second milestone, the FDA approval milestone, and through the specific conduct. So we get to throughput rate. And the real point here, I think, is that -- and I don't think I heard Mr. Spagnoletti even touch on this -- is the necessity of what they did.

Here's what we've alleged, if you look at the facts. Paragraphs 34 and 52, we alleged that the throughput rate was something that was extensively discussed by the parties during the diligence phase. There were no surprises here. Those discussions formed the basis of the milestone schedules, among other things, but that was certainly part of it.

And we're not saying that to the extent CMI had an intention to take it to market at

that rate, that binds Roche, but it does form the basis for the schedule that the parties jointly agreed to in the agreement.

Now, there is also -- and we allege this in paragraph 52 -- there is no requirement in the agreement that the machine had to reach 60 per hour before you seek FDA approval. It's just not there. And, frankly, and this is also in the same paragraph, increasing the throughput rate would not impact FDA approval, so the work you did on it to increase it was not necessary. That is a fact that we allege, and that's not something I heard dealt with in the opening submission or, frankly, in their briefs.

And, therefore, Roche's actions to increase it, which, again, the record supports, resulted in the delay of pushing back the clinical trials, the FDA clinical trials, by a year, into August 2014 at the earliest, just mere months before the deadline was going to arrive.

So taking all these allegations together, and as you have to take them as true for purposes of the motion, they didn't use commercially reasonable efforts to meet the milestone because they made unnecessary changes that resulted in the delay.

Now, to the extent there are little references in the brief about the fact that this additional work was necessary -- and I'm quoting here -- maximizing the chances of obtaining FDA approval, or it was done to ensure that the FDA requirements were met, suggesting that they were necessary, that's not what we've alleged. And to get there and to make that argument, they'd have to dispute and contradict us. And I think that's something that would, frankly, have to wait for discovery.

Before moving on, there is one other point that was raised today, and it's also in the briefs, about they have alleged or they claim that the complaint acknowledges that the speed was something that was going to be very important to customers, and we've therefore conceded that point.

Your Honor, I would just direct Your Honor to pages 26 and 27 of our opposition where we put in context the allegations about what the speed meant. And, frankly, there's plenty of allegations in there about the market research, the extensive market research that was done to show that speed was not among the characteristics that future customers would

value.

Moving on, then, to my favorite word, "reticulocyte." There's been a lot of practice to get that right. The complaint alleges -- and let's go through the facts that have been alleged -- that at the time of closing, the unit was able to measure it. And this is not a question of speed or anything like that. It's can it measure reticulocyte concentrations and blood samples in the machine, in the stain. And we said it could.

And the functionality was something that was known to Roche. It was something that was required for purposes of the CE mark that they got in Europe earlier in 2013. And all that information relating to the CE mark process was shared with Roche. They accepted delivery about a year after closing of the first commercial unit which met the various specifications, including the specifications for a CE mark. That's the definition of a first commercial unit.

So the additional work that they undertook to finalize the stain basically resulted -- and, again, it's in the record that it resulted in a delay. And the reports that are attached to our

papers make that very clear. And, in short, there was no need for there to be additional work.

Now, again, Mr. Spagnoletti made the comment that he thought that there was need for the work. It wasn't ready to go. But he accepts that he needs to take our allegations as true. But the fact of the matter is, by undertaking that work, notwithstanding the delays that it caused, is just another example of a breach of the commercially reasonable efforts provision.

And then, once again, to the extent that they're suggesting that the work was -- failing to take that work would have created an increased risk of FDA failure, and I think this is in the opening brief they make that point, that directly contradicts our allegation that the work was not necessary. The machine could do this. And, therefore, undertaking it and the resulting delays is what makes it commercially unreasonable.

The third point deals with the calibrators and controls. And this is slightly different than the first two that I discussed. Here, the issue is resolving development issues that may impact the FDA process but doing so in a timely

manner. That's what really is at issue here. And let me explain by recapping again the quick facts that are in the complaint.

There was a letter from the FDA that came in on May 30th, I believe, 2013, so very soon after signing but just before closing, saying that the unit had to have fully developed calibrators and controls, which, as counsel explained, is commercially available calibrators, instead of using an alternative method.

Roche got the letter the same day. It was shared with them. There were discussions. And even before the letter came in, CMI, as it was then called, had been working with Streck, which is one of the leading manufacturers of these kinds of controls and calibrator testing peripherals, about developing the commercially available set.

And here's the key allegation, which, again, I didn't hear come up in its submissions to date. We've alleged that Streck told CMI that they believe these issues, the issues that were raised in the FDA letter about having fully available calibrators and controls, could be accomplished by August 2013, just a couple of months down the road.

So it might cause a delay in the timeline but not a major delay at all. And yet we have reports from Roche saying that because of this issue, the timeline for the clinical trials was kicked, by about a year, to August 2014.

So in this context, it is not commercially reasonable to push back the timeline for clinical trials by a year, to August 2014, when we have alleged facts saying that the party who was going to assist us in resolving this, Streck, has said we can be done by August 2013.

And there is an argument that came up just in the reply -- we haven't really had a chance to address it, and I'll address it now -- that we've raised a new argument that -- there is a reference to issues with Streck. And I guess, just to clarify, there are no other issues. We're talking about the same thing, the issue that was raised in the FDA letter. There is no other sort of unspecified issues with Streck.

Finally, we come to the KMC contract. And as was explained, KMC is the company that was going to manufacture the unit. And the issue here was getting a production agreement with them, which is

necessarily a gating issue, a threshold issue, before you could start production.

And the facts here are that even before signing, there had been a lot of work with CMI and KMC, working on a production agreement. And the contract actually acknowledges and contemplates that to the extent the production agreement was not signed before closing, there is this express obligation on the part of Roche to use commercially reasonable efforts to promptly finalize and sign a definitive agreement. And that's also in Section 1.12(c).

And so what we have here is another obligation with a timing requirement to do something promptly. Yet notwithstanding that obligation, we learned that the agreement was not signed until December of 2013, six months earlier.

Now, defendants have taken the position and said, So what? There was work going on in the meantime. It's a delay with no consequence. But we look at the reports. I mean, they actually say they needed to have the final instrument from Streck before clinical trials could begin.

So if you think about it this way, the deal closed on July 1 of 2013. The FDA deadline is

December 1 of 2014. You have 17 months to finalize the instrument, run the clinical trial process, put together a submission, get it in, get the approval. If you eat up six months of that, more than a third of that period, on a gating issue, which is negotiating a production agreement with a company that's going to make it, that's necessarily going to have an impact on your ability to meet it.

And the reason we say it's unnecessary is this: It's not like Roche was starting with a blank page on July 1 and having to pick up a pen and draft an agreement. They were given something where the parties had already agreed on the key terms and had an agreement in principle. And that's why it's unreasonable for them to have taken that long and then have that sort of create the delays which caused the deadline to be missed.

Finally, just very quickly, as I mentioned earlier, Your Honor, I used, through these examples, the FDA milestone, and there is a suggestion in the reply brief that we have -- in a complaint, we alleged that the acts that Roche undertook post-closing also had an impact on the third and fourth milestones, which, as Your Honor sees from the

agreement, are sales milestones, one for domestic sales and one for non-U.S. sales within the calendar year 2016. And I think this argument can be dealt with pretty quickly.

We didn't waive those claims. I mean, Your Honor, the fact that they took these actions and missed the deadline for FDA approval -- and, frankly, I don't think FDA approval has even been achieved to date, and we're well into 2016. I think it's pretty clear that that same conduct will violate the obligation to achieve the two sales milestones that are tied to sales in 2016. And we allege that, in fact, in the complaint, at paragraph 67.

And, frankly, I think the reply brief that they put in actually acknowledges the interplay between these. And I think, on page 13, I believe they make the argument that the second, third and fourth milestones are all directly linked together. And they're part and parcel -- again, their words -- of the efforts to achieve the milestones.

So I think there is no need for us to allege a whole set of different facts. There might be other facts that are relevant to this, and discovery will maybe tell us those, but for now, the allegations

in the complaint support a breach of the obligation as to the third and fourth milestones.

And so, finally, last but not least, we get to the implied covenant claim. And, here, I think, really, the point is, Your Honor, I think it's pretty clear from the complaint that we pled this in the alternative.

By that, I mean if Your Honor concludes that the agreement does address this conduct -- I don't think we have an implied covenant claim -- I would agree with that. But the fact of the matter is -- and, frankly, we have taken the position that the commercially reasonable efforts provision does address and, frankly, prohibit the conduct that was taken.

I believe plaintiffs have made the same argument in their papers too, that there is -- that the provision does govern it. But, of course, what we think and what they think is not as important as what you think. And until you make that determination as to whether it's covered, I think it's premature to rule that the implied covenant can't stand as an alternative claim.

And that is why this case is very

different from the Fortis case before Chancellor Bouchard, because in that case, the breach of contract claim -- they didn't make the motion to dismiss the breach of contract claim. The defendants agreed that that was a viable claim. So the only issue for the Court, then, was what to do with this implied covenant claim. And the fact of the matter is, over there -- and the Court used the word "mimic" just because I think the plaintiffs argued the exact same conduct.

What we have here -- and there are other cases that they've cited that I think have the similar problem. I think in the Haney case, which is the most recent case they cited, in their reply brief, a 2016 decision, the issue there was that the plaintiff didn't plead the claim as an alternative. And so that's not what we're doing here. And I think that makes a significant difference in the outcome.

The gap is the other issue. And I know Your Honor, in your El Paso decision, lays out some of the analytical tests where you have to first establish that there is a gap, and if so, whether it needs to be filled and, finally, how you fill it. And I just want to spend a couple of minutes walking through that.

I think the gap that needs to be filled here, Your Honor, if you conclude that the agreement doesn't address this issue, is the defendants cannot elect to make modifications that are not required to achieve the milestones and that have the effect of precluding or preventing the achievement of the milestones before the expiry of the deadline.

And on this, I disagree when defendants say that that's just a pure mirror image or a mimic. It would be different if we said they're breaching the implied covenant by failing to take commercially reasonable efforts. I get that. I would agree with them. But that's not what we have here. And this is why I think a lot of the cases they've cited are distinguishable.

For example, in the Matthew case, the issue was whether they need to attend board meetings. Well, the operating agreement said that "thou shalt attend board meetings." So you don't really have that gap that we have here.

Should the gap be filled? Yes. I don't think there's any suggestion that the parties discussed and thought about whether or not Roche could make elective changes that would roll past the

deadline and decided, no, let's just leave it silent on that key issue. It would be an entirely unreasonable inference.

And the last step is how would you fill the gap? And, again, I think we readily accept, Your Honor, that we can't ask the Court to imply an obligation that contradicts or is inconsistent with an express term of the contract. We've got to be faithful to the purpose of the contract. I fully accept that.

But the gap-filler that we are asking the Court to imply here -- we're not looking to add something that's different or new. We're implying an obligation, and this is -- it vindicates the expectations that we had in signing that milestone -- signing an agreement that had the milestone provisions.

And, frankly, this is actually one of the scenarios I think that the implied covenant is really meant to operate in. And I go back to the Supreme Court's Dunlap decision where they basically, I think, set out one of the key uses of the covenant, which is you have a breaching party that breaches the implied covenant when the conduct frustrates an

overarching purpose of the contract by taking advantage -- and this is where the language comes from -- taking advantage of their position to control the implementation of the agreement's terms. And that's what we have here. We're not in the picture anymore. They're in that position.

This is the type of contract where we think there is room for an implied covenant if Your Honor rules that the contract doesn't cover it.

Unless Your Honor has any questions, those are my submissions.

THE COURT: No. Thank you. Reply?

MR. SPAGNOLETTI: Thank you, Your Honor. I'll be brief.

I just want to address a couple of aspects of the argument relating to commercially reasonable efforts and whether or not there is this element of the contract that requires Roche not to do anything that was not necessary for the achievement of a particular milestone event. Again, respectfully, that's just not what the contract says.

As the Court pointed out a few moments ago, there are actually seven different things that Roche has to do in the context of commercially

reasonable efforts, only one of which is to make efforts that were reasonable to achieve milestone events. It also must develop, manufacture, test, market, sell, and ship the instruments in a commercially reasonable way.

And there are certainly circumstances, as there are in this particular case, where those various obligations could come into some tension.

It might be reasonable from a commercial perspective to try to increase your throughput rate before you actually seek FDA approval, because if you wait until after you seek FDA approval, you might have to do your clinical trials all over again because you have a different instrument.

It might be commercially reasonable in the manufacture of your instrument to actually fix your reticulocyte staining problem or to improve your reticulocyte staining problem from what it is, satisfactory, even if that might mean delaying a particular milestone, because you have an overriding commercial interest in doing that.

The provision in 1.12(c), importantly, goes on to say, in the part at the bottom of page 12 to the top of page 13, that the commercially

reasonable efforts must take into account "all reasonably relevant factors, including, as applicable, stage of development (including, without limitation, the availability of reliability data) or product life, anticipated development cost, operating cost and timelines, the nature of the product, actual or anticipated regulatory approval process, end-user needs, the nature and extent of market exclusivity" -- I'll skip the parenthetical -- "cost and likelihood of obtaining regulatory approval, the setting in which it is expected to be used, competitiveness of the marketplace, other product candidates, actual or projected profitability ...."

This is what Roche is being judged against. There is nothing in that section that says that there's a necessity requirement; that in order for Roche to act commercially reasonably, it must do something that is necessary to achieve a particular milestone event.

It has a host of interests, as any company does, in being commercially profitable, in putting out a good product, in making sure that its brand is not tarnished. And this contract, as it's drafted, protects Roche's right to do that in its sole

discretion.

There are obviously, as I mentioned a moment ago, a number of instances where a party might decide, reasonably, rationally, from a commercial perspective, to wait a little bit, to not rush off and try to get FDA approval, to not rush a product, a health product that tests people's blood, to the market unless it's absolutely sure that it's working properly and that it's going to be competitive. Roche has the right to do that here.

What we're saying in our briefs is not that plaintiffs have to show that the primary purpose of Roche's conduct was to frustrate a milestone event in the context of the commercially reasonable efforts clause. We're not reading that into "commercially reasonable efforts." But what we are saying is that when it comes to plaintiffs' allegations, they actually have to say something about why what Roche did was unreasonable; and they haven't.

When it comes to throughput rate, what is unreasonable about making your instrument faster, especially in circumstances where they acknowledge speed is important?

When it comes to reticulocyte

staining, what is unreasonable about improving the staining process so that it's not merely "satisfactory"?

When it comes to responding to a concern by the FDA about the calibrators and controls that needed to essentially be invented for purposes of the calibration system, what is it that's unreasonable about it taking a few months longer to deal with that?

What could Roche have done that they didn't do? What should Streck have done that it didn't do? There is nothing in the complaint. It's a void when it comes to these things.

There is no reference to other commercial products that Roche has that are comparable. There is no reference to industry standards. The complaint says nothing other than there's been a delay, we didn't get paid, so therefore it's unreasonable.

And when it comes to the KMC agreement, it's the same point. What is unreasonable about it taking a little while longer to negotiate a final agreement with your manufacturer? Especially under circumstances where there's no allegation that the delay in negotiating the agreement actually had

any impact specifically on the development of the Bloodhound Instrument and the production of the Bloodhound Instrument.

What we're talking about is papering up the deal. We're not talking about whether KMC was actually doing the work that they needed to be done. It was doing work for years before this.

So for all these reasons, Your Honor, quite frankly, this notion that Roche has an obligation not to do anything that is not necessary for the achievement of a milestone is wrong. It's inconsistent with the plain language of the agreement. And for that reason, the case should be dismissed.

THE COURT: All right. We're going to take a recess until 11:00. I'm going to come back and give you my answer.

MR. ADVANI: Your Honor, may I just address that point very briefly?

THE COURT: No.

(A brief recess was taken.) ^

THE COURT: Welcome back, everyone. Thank you for your very helpful briefing and your presentations this morning. It's allowed me to have a view as to this matter that I'm going to give you now.

The bottom line up front is that I'm going to deny the motion to dismiss as to Count I and I'm going to grant the motion to dismiss as to Count II.

Count I is the breach of contract claim. It may be helpful for you all going forward to have my reading of the provision, not because there's any value to my insight, but because you're stuck with me as your decision-maker at this level. So here's my reading.

When I look at Subsection (c) of 1.12, I see a multi-facetted provision. It enumerates two main obligations under Romanette (i) and Romanette (ii). Romanette (i) actually has two parts. The surviving company and the parent are obligated under the first part to cause the surviving company to operate its business in good faith. You could stop that obligation right there. That's an obligation.

Then there is an "and." We're now getting to the second obligation that is part of Romanette (i). Under this part of the obligation, "The Surviving Company shall ... not take any action (or series of actions) the primary purpose of which is to avoid achieving the Milestone Events or making any

Milestone Payments to the Securityholders as provided in this Agreement ...."

So Romanette (i), I think, has those two subparts. They're separate obligations. The operating in good faith concept is Part 1(a). The primary purpose part is Part 1(b). I don't think they overlap or extend to different parts of the agreement or anything like that. It might be difficult to envision the type of conduct that would implicate the latter without implicating the former, but there you have it. That's how it was drafted.

Part 1 is, as has been pointed out, largely subjective. So in Part 1(a), you have the obligation to operate the business in good faith. Under Delaware law, that's a subjective standard. The second obligation under Romanette (i) is to not take action, to refrain from action, that has a primary purpose. The primary purpose is, again, subjective.

Now let's shift away from Romanette (i)(a), which, as counsel indicated this morning, is actually not what they're relying on. It's all well and good to talk about it. They may come back and amend to rely on it, but they're not relying on it now. Let's now look at Romanette (ii).

Romanette (ii) is objective. Romanette (ii) says "the Parent shall, and shall cause the Surviving Company ...." To do what? To "use commercially reasonable efforts." The inclusion of the word "reasonable" makes that an objective standard. We also have the good Vice Chancellor Glasscock's recent learning on that same point.

What are you obligated to do in that objectively commercially reasonable way? Well, you're obligated to do those seven things that come after it. What is part of using commercially reasonable efforts to do those things? Part of using those commercially reasonable efforts to do those things is to do the things that follow the prepositional phrase "including." So you have to dedicate sufficient resources and efforts.

This also is an objectively measured item. "Dedicating sufficient resources and efforts" that are what? That are "consistent with the Parent's customary practices" for doing the ensuing things. What that means is a Court is going to look at parent's customary practices and measure what you did in terms of devoting resources and efforts in this case against your customary practices.

Now, it is true that whether you have devoted sufficient resources and efforts that are consistent with your customary practices has to take into account all reasonably relevant factors, but there's that word again: "reasonably." It's objective.

At the end of this lengthy sentence on page 13 is a proviso. The proviso introduces a concept of sole discretion, but the proviso has important introductory language. The proviso qualifies the objective requirements that I've just identified, but it says that it does so "subject to compliance with the foregoing by Parent and the Surviving Corporation."

What that means is as long as you have met the objectively measured standards in Romanette (ii), then once you are operating within those objectively measured standards, which I think one could fairly say are not tight -- they're going to be broad; it's a reasonableness standard -- within that, then any decisions regarding the business and operation of the surviving company, including decisions which may directly or indirectly affect the amounts of any milestone, can be made by the surviving

company in its sole discretion.

Note that this language is linked to a disclaimer of fiduciary or other duties. I don't think those would apply anyway in an arm's-length agreement, but I think that what the drafters were getting at here is that as long as you work within that standard of objectively measured reasonableness, you get the ability to make the decision.

So to give you a really simple example, let's assume that Roche is trying to decide who they're going to hire to put in charge of the Bloodhound project. Roche has three eminently qualified people to choose from who are all able to do everything that needs to be done to achieve this project in a commercially reasonable manner, such that hiring any one of these people would be consistent with parent's customary practices.

Let's say it's Joe, Susie and Bill. There's no breach if you choose Joe. There's no breach if you choose Susie. There's no breach if you choose Bill. Why? Because choosing any one of them is within the commercially reasonable, objectively measured standard, so you have sole discretion to do it.

Now let's say Laster applies. Laster doesn't know jack about Bloodhound. It would be commercially unreasonable to put Laster in charge of this project. You could not rely on your sole discretion to choose Laster, because it would be objectively commercially unreasonable and not consistent with parent's past practices to hire me to run this project.

And then there's the kicker at the end, which is the additional KMC Systems' negotiating provision.

With that backdrop, let's talk about the allegations. I think as to all four of the items, the complaint sufficiently alleges facts which, when read in a manner favorable to the plaintiff, could give rise or do give rise to an inference that what was done falls outside the scope of commercially reasonable efforts. That doesn't mean that I'm going to find that it did. It means that one possible interpretation of the facts is that it did. And at this stage, 12(b)(6), the plaintiff gets the benefit of that inference.

So let's think about the throughput example as an illustration of this. "Parent shall,

and shall cause the Surviving Company to, use commercially reasonable efforts to" do seven things, one of which is achieving the milestone events.

It may be true that bumping up the throughput on this thing makes it a better product, but the obligation isn't to use commercially reasonable efforts to make the best possible product. There's a floor in that you have to use commercially reasonable efforts to develop, manufacture, test, market, sell, and ship, but then you also have to try to achieve the milestone events.

I'll give you another simple example as to why increasing the quality of a product might nevertheless result in a problem for achieving a milestone payment.

Let's say you are building an addition on your house. You have an agreement with the builder. This is going to be an addition. It's going to be a den, a rec room, that type of thing. And you know contractors sometimes don't work as fast as homeowners might like, so you say, "You know what? If you get this thing done by June 30th, I'll give you a bonus." That bonus is analogous to a milestone payment.

Now let's say you come back to the contractor and you say, "You know what? We still want the rec room, but we've decided that it would be really great for the resale value of our home if this had geothermal heat in it because people really like geothermal these days."

The contractor looks at you and says, "I can't get that done by June 30. Our deal was if I got the original thing done by June 30, I get this bonus. I'll do this for you, but we've got to make some arrangements about my bonus, because if I take this on, I'm being deprived of my bonus."

Now, in an arm's-length negotiation like that, everyone would see that issue because the person who is adversely affected by the change would raise it. Here, you have a situation where the surviving company is in charge of the whole process, and WP is in the position analogous to the contractor but without doing any of the work.

Might it ultimately be a better rec room? Sure. It might be a much better rec room. It might be the world's greatest rec room. Is it a problem for the bonus and the milestone payment? Yeah, it's a problem for the bonus and the milestone

payment.

So the fact that it may ultimately be a better Bloodhound doesn't mean that increasing the throughput might not constitute a breach of the obligation to use commercially reasonable efforts to achieve the milestone event.

One of the arguments that's made to blunt that inference is the idea that everybody's interests are aligned in making this a successful product. That is a blissfully naive and Panglossian assessment. People are not aligned as to timing. There are specific timing obligations that trigger returns for one side that actually result in -- not zero-sum if it theoretically could benefit on down the road, but it's value-shifting as between the parties.

So incentives aren't aligned. They're certainly not aligned to the point where it defeats the reasonable inference that when you do something that wasn't originally contemplated and which has the effect of causing the milestone not to be hit, that it's reasonably conceivable that the change was not using commercially reasonable efforts to achieve the milestone event.

I don't know what the ultimate answer

is as to any of these four, but I can tell you that one interpretation of each of these four is that it's consistent with a failure to use commercially reasonable efforts to achieve the milestone events. And that's all we're doing today.

So in terms of Count I, the motion to dismiss is denied. You all may win at a later phase of the case, "you all" being the Rocheians, but we're not there yet.

Now let's get to Count II, which is the implied covenant of good faith and fair dealing. This is pled in the alternative as a fallback. I think it's supposed to generally be a fallback. This is a repeated situation where people plead the express provision and then they plead the implied covenant as a fallback.

My realistic assessment of what I am actually doing when I rule on these types of things is making a probabilistic guess as to how likely it is that the implied covenant is going to come into play so as to save you the hassle of briefing it and litigating it and doing all these other things.

What I have here are two sophisticated parties. What I have here is a 1.12(c) that is at the

fully worked end of the spectrum in terms of these post-closing obligations. What I have here is a section that has both subjective and objective components. If there's one thing I am confident about, it's that I don't know a lot, and I certainly don't know how the case is going to unfold. And so saying this is hubristic, but it seems to me highly unlikely that the implied covenant is going to come into play, given the subjective and objective components and the explicit standards that are here.

Is it theoretically possible, in a universe where virtually anything is, that there might eventually be shown to be a gap, and the gap might be one where, if we put ourselves back in the original negotiating position of the Warburgers talking to the Rocheians and identifying this issue, that everyone would look at each other and say, in substance, "Well, of course you can't do that. We don't even need to talk about that. Of course you can't do that." And that's really what the implied covenant asks. Is that theoretically possible? Yeah, I guess it's theoretically possible. But I personally view it as sufficiently unlikely that I don't think at this stage that it is reasonably conceivable.

So I am going to dismiss Count II. As I say, I'm doing so because of the nature of this agreement, the sophisticated parties involved, and the type of the provision that I'm looking at in terms of 1.12(c). I personally don't think it's a bright-line rule where the implied covenant is always out or the implied covenant is always in. I think we're doing the best we can. At least I'm doing the best I can.

So there you have it. I will go downstairs and enter an order to this effect that dismisses Count II and denies the motion to dismiss as to Count I.

I'll tell you what you all already know. Why don't you get some smart person from Warburg together with some smart person from Roche and have them sit down in a room and talk about this. I say this at the expense of the lawyers in the room. I think it's great that lawyers make a good living. I particularly think it's great that Delaware lawyers make a good living. But this is one where men and women of business should be able to come together and essentially work out a repricing.

Maybe Bloodhound hasn't worked out as well as people thought. Maybe Roche really does have

ways to make it better. I don't know. But I would bet that with some open discussions, maybe a work-product-privileged set of white papers on each side, and a meeting by sufficiently high-level people who can assess the risk-adjusted value of the litigation, net of fees and costs and including distraction, people can come out of this with an answer. Otherwise, I'll see you again.

On that point, and to give the men and women of business an incentive, assuming you all want to do it, to get together sooner rather than later, let's get a schedule and get this done. So how about nine months to a year? That's on the faster side. But why don't you all talk about it. I don't think it needs to be expedited in the sense of "expedited," because it's money, but I also think it would be helpful to everyone if this is not a mañana issue that we just leave to the lawyers to keep kicking down the road until, eventually, someone says, "Well, let's deal with it."

MR. FLINN: Understood.

THE COURT: Thank you all for your time. We stand in recess.

(Court adjourned at 11:26 a.m.)

CERTIFICATE

I, JEANNE CAHILL, RDR, CRR, Official Court Reporter for the Court of Chancery of the State of Delaware, do hereby certify that the foregoing pages numbered 3 through 60 contain a true and correct transcription of the proceedings as stenographically reported by me at the hearing in the above cause before the Vice Chancellor of the State of Delaware, on the date therein indicated.

IN WITNESS WHEREOF I have hereunto set my hand at Wilmington, Delaware, this 15th day of July, 2016.

/s/ Jeanne Cahill

Jeanne Cahill, RDR, CRR
Official Chancery Court Reporter
Registered Diplomate Reporter
Certified Realtime Reporter