# West Pharmaceutical Services Inc – CDMO, Proprietary Products & Rubber Business – 12 November 2020

## Disclaimer



**Specialist:** Bob Hargesheimer (BH)
**Title:** Former VP, Global Strategic Operations at West Pharmaceutical Services Inc
**Moderator:** Arelis Agosto (AA), Third Bridge Sector Analyst

**Agenda:**

1. West Pharmaceutical Services' (NYSE: WST) competitive strengths and weaknesses, and impact of COVID-19
2. Effects of vaccines development and need for syringes, vials and other products
3. West Pharmaceutical's business segments – CDMO, Proprietary Products and rubber
4. Growth outlook – impact of the political climate, and potential supply chain challenges in plastic, elastomer or aluminium

## Contents

# West Pharmaceutical Services Inc – CDMO, Proprietary Products & Rubber Business

Transcription begins at 00:00:05 of the recorded material

**AA:** Welcome to Third Bridge's Forum's Interview entitled West Pharmaceutical Services Inc – CDMO, Proprietary Products & Rubber Business. I am Lis Agosto and I'll be facilitating today's Interview with Bob Hargesheimer, former VP of Global Strategic Operations at West Pharmaceutical Services.

Bob, before we start today's Interview please state I agree or I disagree to the following statement. You understand the definition of material non-public information and agree not to disclose any such information, or any other information, which is confidential, during this Interview.

**BH:** I agree.

**AA:** Could you begin with a brief introduction to your background?

**BH:** My name is Bob Hargesheimer. I am retired now but had a 20-plus year career with West that spanned both functions like sales, finance, operations, as well as the divisions, contract, manufacturing, the baseline rubber business etc. I have experience across what they refer to as the core business, the rubber business, as well as the various segments over the years, the contract manufacturing, both as it exists now, and as it existed previously back in the 90s. A very, very broad background in their business.

[00:01:44]

**Q:** Can you highlight any trends or recent developments in the drug packaging industry and how they relate to West Pharmaceutical Services?

**BH:** I think the biggest advent of the last 20 years in the packaging industry has been the advent of biologics. That is the single biggest driver for what you've seen here that's impacting West, as well as their competitive set. It's the requirements for biologics, the protein-based drugs, the large molecules, and that is impacting, not just the packaging, but the delivery of those products. Small molecules, generally subcutaneous, generally one shot, fairly simple from an administrative perspective. In many cases a lot of drugs in small molecules can start out as an injectable and then the science advances well enough for it to be transferred over to an oral platform, which is what the drug companies would prefer. Biologics, because they're protein based, very, very difficult to transfer over to an oral route of administration. Biologic drugs have driven the market, they've driven the demand for high-end packaging, and they're going to stay injectable for a long, long time. If there is one trend in there that has impacted the industry, that is it. The other piece of the puzzle is really the regulatory environment. The quality standards keep going up and up, and as the detection science continues to improve you find more in your product, whether it be particulate or trace elements, or etc, that the regulatory environment doesn't want associated with the primary packaging. So, the quality standards have grown remarkably since the 90s and those two trends will continue.

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**Q:** How has West Pharma's overall business model and positioning trended in the last 1-2 years? How does it maintain its positioning across the markets it operates in?

**BH:** The environment really hasn't changed, and you have to understand how the industry works. In West's case their primary role is to deal in what we used to refer to as the highly-regulated markets, and those would be North America, Western Europe, and in some spots in Asia. It's really the regulatory bodies there. These packaging components, when they are submitted to those regulatory bodies, and for instance we'll use the FDA as an example. They are filed with the drug product and they become part of the drug file there, so it's very hard for the pharmaceutical customer to change that product. In order to do so they have to reopen the NDA, the New Drug Application, and they are loathe to do so for two reasons. (1) Because of the cost involved. They have to re-run all of their stability trials. (2) If they reopen it on a major change like a change in packaging format or a change in stopper product, it opens up the rest of the NDA for question by the FDA, and the FDA can go back in there and take a look at things, and things change over time. Views change over time. They are loathe to do that. Once you are approved on a product the odds are extraordinarily high that you're going to be the packaging components for that product for its entire life cycle. That's really the baseline of West's business there. The secret to their business model has been to (inaudible 07.19) pursue the new drug products and get filed with them. Then you're on them until the product's no longer sold. So, the positioning really hasn't changed. Their business model hasn't changed, in 20 years.

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**Q:** How is the pandemic impacting the drug packaging industry? What is West Pharma's opportunity to capitalise on this?

**BH:** Everybody would love to quantify the COVID impact, and I would too. It's a bit difficult because there are a couple of different factors going on here. Let's talk about the COVID direct related supply. Those would be stoppers, seals, components, perhaps pre-filled syringes directly for vaccine and therapeutic use. So, remdesivir, etc, all those kinds of products you've heard about. That's one piece of the puzzle there. It's very easy to do the maths, and let me just do it for illustrative purposes. You've got 330 million people in the US, you're going to need at least 330 million doses, and that's with a one-step vaccine. Some products may require a two-step vaccine, similar to, say, Shingrix, the shingles vaccine. You can do the maths there and say at some point you're going to be up around well over one billion individual pieces of components over time. That's probably going to play out over 2-3 years, there. That's one component of it. The other component is pre-ordering by customers because they know that, even if they don't have a vaccine, there's going to be a great demand for vaccine production coming up, so they're trying to stockpile what they need. So, the industrial capacity is freeing up, and they've got the products they need to keep their products moving in the marketplace. People are still getting sick with other ailments at the same rate that they did before COVID so the baseline demand is still there.

We've seen over the years this pre-ordering phenomenon. These products that West sells and their competitor base, are a very small percentage of the pharma companies' total cost of goods, so they're willing to stockpile to make sure that their filling lines can run when they need them to. As far as putting on hard-and-fast numbers here, it's very difficult. You can estimate. If you look at West's Q3 results, up almost 20%, 18% YoY. That is significant, and I would venture a guess that probably at last half of that is, in some form or fashion, COVID related.

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**Q:** The pandemic has been a significant tailwind for West Pharma. How significant has it been for its peers? Has West Pharma's positioning adapted more than its peers?

**BH:** West, their positioning hasn't changed relative to their competitive base. West has always maintained a larger, more robust manufacturing footprint than its competitive base. They've just got more plants in more parts of the world with more capacity than anybody else that sells the same kinds of products. Their competitive base really is pretty limited. There are only two other legitimate players in that line there, and that is Datwyler and Aptar, and both have much smaller market shares than West. I had not looked at Aptar's or Datwyler's public statements but I assume they're undergoing some of the same phenomenon that West is because their customers are pre-ordering as well.

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**Q:** What are the benefits of having a broad portfolio? How does the breadth of West Pharma's portfolio compare to its peers? What is West Pharma's cross selling ability, given its breadth of offering?

**BH:** If you look at their product portfolio it really isn't that broad. It's really focused on two primary segments. The first being, they term it proprietary, but the proprietary in their language also includes the devices. If you really break it down and look at it hard you've got the rubber business and then you've got the plastics business, which includes some proprietary devices like the SelfDose, the inter-dose, etc. It's really not a terribly broad product portfolio. The rubber business is an adjunct to the overall delivery market. When I say an adjunct, for injectable drugs there's a need for elastomer components, either on top of vial or on top of the cartridge that goes into, say, a pump-type product. So, the delivery business was really envisioned in the early 2000s as an extension of the rubber business, and understanding the rubber business is kind of the core of the whole thing. They've added some technologies along the way, but they're long lead time. The delivery mechanisms are becoming more automated, they're trying to stay out of a clinical setting, whenever possible, so there is promise to the delivery business but it's going to take a while to take off. It's long lead time adoptions, but in the West mindset it fits in well with the growth in biologics because it does provide much more dosing flexibility. Some of the biologics, you want to avoid a bolus effect. You don't want to give a 5ml or a 10ml shot all at once.

You want to introduce that into the patient over a time period, or you can do that with a programmable pump, the mini patch pumps there. So, that opens up design and it just provides a lot more flexibility to the pharmaceutical customer. Is there cross selling? Yes, but they have to like your device. They may use you for the elastomer products contained within the device and, fact is, given your market share for West, you probably will be involved, but you have to have a device that works for the drug and the customer. They've gotten their first approval for Unidose, it's out there in the market, it's being demonstrated, so I would expect the next approvals to be easier, again because the pharma customers are very conservative. They rarely like to be first in something. More than likely they want to be second or third and you have a proven track record as far as market. Cross selling is a small piece of the puzzle.

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**Q:** Has pricing increased recently? Do you expect significant YoY pricing increases?

**BH:** Pricing is always a difficult piece of the puzzle because there's a natural tension between the customers and West. The customers know that, ultimately, West has them over the barrel and can implement price increases any time they want for any amount they want, and that, because of the regulatory restrictions, they're stuck. West, on the other hand, knows that for its long-term health, it has to keep their price increases moderate and acceptable because, again, the West business model was built upon being on that next new approved drug, and they want that business, to lock it up for future. If I look at their Q3 results, they call out very little of the sales growth and price increases. Obviously, their 2020 price increases were relatively modest. Again, with the customers, most of these you've got 3-5 year contracts with and they come up on a rolling basis across customers. So, your YoY pricing power is somewhat limited. But over a span of 3-5 years you can implement what you need to do. Most of the customer contracts have inflaters and deflators in them relative to raw material cost, and those were really a function of the 2008 raw material shocks that went through the industry. West will be compensated for any oil shocks, and it's usually oil-based because their entire product line, the base product, is butyl rubber, and that's highly dependent upon the oil market.

There is pricing power. West usually takes advantage of the pricing power when they introduce a new feature to the product, and add features to it. That's why you see the margins on the high-value products being so much more than the standard products. There's going to be a natural pricing ladder that occurs because customers are moving up that ladder for high-value products. I don't know what the numbers are now but I know that there's been a significant increase in what they call the Westar product lines over the last 20 years, and that's really just a high end washing process. Then, customers may go on to having product washed and sterilised, may go on to having products washed, sterilised, vision inspected, so there's a whole range there where the pricing is significant, and the increases in the pricing. But they're adding features at the same time, so that's really what's driven West's margin expansion over the last 10, 15 years.

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**Q:** Do you expect customers to have more choice after the pandemic than before it, given the demand influx? How do you think this will impact pricing?

**BH:** I see zero ability to shop around more because I don't think the regulatory environment will allow it. Over the course of the last 20 years there have been trials by various pharma manufacturers, both Chinese, Indian, etc, to break into the US market. To my knowledge they've been unsuccessful, except on the very, very fringes of it, again, because the regulatory barriers. It would be very difficult for a customer to shop around for a lower priced option for one of their current drugs, and their new approvals, quite honestly, the reliability of West and/or Aptar or Datwyler, to deliver, they're making a long-term commitment when they pick a particular packaging vendor and they want to stick with somebody who delivers the quality they want, when they want it, has the capacity, and has the financial strength to stay in business. It would be a significant event that would have to drive somebody away. I do not see the regulatory bodies loosening up their standards at all. I don't see any ability to shop around post-COVID.

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**Q:** How does West Pharma's quality compare to its peers?

**BH:** The competitors essentially had products out the same as West. If you really look down and understand what the technologies are, they really are the same. Aptar and Datwyler deliver the same level of quality that West does for their customers and their products. They have to because we're all operating to the same standards. The difference is that West, although they haven't always been number one to introduce a product to the market, in some cases Aptar and/or Datwyler has introduced a feature to the market sooner than West has, West has been very good over the last 20 years. When they announce it to the market they've got more manufacturing behind it, more manufacturing history. They've run bigger trials, they've put in capacity to be able to handle demand. If you're a customer and you're saying, "Okay. Datwyler, you have one million pieces of your capacity of a product with a specific feature to it. That's great. I only need 700,000, but that doesn't leave a lot of room." Or, West, "You've got five million pieces capacity for this particular feature. If this product takes off I know I've got capacity behind me." That's been a significant advantage of West is, quite honestly, over the years, their size and their manufacturing breadth, and their ability to make the customers comfortable that, under almost any circumstances, they're able to deliver. As far as the quality standards, etc, everybody's operating to the same levels, because they have to. They're shipping to the same customers.

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**Q:** Have there been shifts in the injectables customer base that you think are important to understand?

**BH:** Again, the shift in the customer base, the injectable market, is being driven by biologics. I won't say small molecule is dead. There is certainly a lot of science that's been focused towards it, but primarily it's been the biologics that are driving it, and that's the key expansion there in the entirety of the injectable market space. Following the biologics is certainly what West does. They've done it very well over the years and will continue to do so. I think they've got some advantages over Aptar on the R&D side on that front with the ownership of Daikyo Seiko, where some of the technology comes from, but most specifically their FluroTec technology, is all driven out of Daikyo. That is the premier elastomer coating for biologics, and the last I saw West was on 19 of the top 20 biologics globally, because they've got the positioning and they've got the products that deliver on that front.

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**Q:** West Pharma highlighted its automation and digital technology efforts in its most recent earnings call – it is clearly investing significantly in that area. What is your assessment of its tech strategy? What else in its strategy do you expect to materialise in the near future?

**BH:** I don't know. Everybody has had to upgrade their systems and harden their systems as well. I think in some cases it's an overdue investment. I'm trying to recall here but I believe somewhere around 2010-2012 they installed SAT, which was a major overhaul and investment for the company. I know they still have strides to make in making that efficient and really get a payoff from that. There's a lot that can be done on the factory floor as far as automation and they need to make those investments, especially on the factory floor. Right now it's a fairly high labour content and part of the problem with people in a manufacturing environment like this is people are naturally dirty. We're dirty creatures. We track a lot of things into a sterile environment with us, no matter what kind of precautions you take. Automating that and being able to keep those manufacturing environments as clean as possible is always a help, and those kinds of investments need to be made. They've been made significantly since 2000 and earlier but there's still a lot that can be done.

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**Q:** The FDA [Food and Drug Administration] cleared a West Pharma 20mm Vial2Bag for launch in October 2020. How significant is this? Do you expect an uptick in interest for any of its products? You mention that competitors have largely similar portfolios.

**BH:** I forget whether it was the 20mm or the Vial2Bag, but that got pulled off the market due to manufacturing problems a couple of years ago and it's taken them some time to reassure the FDA that they've got a solid product. Although it's a nice little product, nice niche in the marketplace, I would not expect to see a significant earnings uptick on that. It's certainly additive but it's not going to be a key driver. The market's just not big enough. That product is driven out of the acquisition of Medimop back in, I want to say, 2005. It's a reconstitution technology. Handy in the hospitals, the people who used it liked it. It was painful to take it off the market, I know for West a couple of years ago, but I would not see a significant uptick either short term or even in the long term, just because the mass is not there to drive the numbers.

**AA**: Do you expect a significant uptick in interest for any products?

**BH:** If we take COVID out of the equation, the smart dose, I think, is a nice product. How big it's ultimately going to be, it's very hard to tell. They do have their first approval for that. I think it's been marketed for probably about seven or eight years now. I think the next three years will be the telling tale for how successful that product will be. The reason I say that, it's usually between seven and 10 years is the adoption cycle. I know that working with clients, other than the one approval they have, but, to the best of my knowledge, it hasn't been approved for any other follow-on products. That's going to be told over time and the jury is still out on that one. SelfDose, the autoinjector, again, it's a nice product, but there are other players out there in the market who have a much more significant market share, and track record, with autoinjectors. Ypsomed, SHL, etc. That one's a little bit easier as far as adoption goes because the customer has the flexibility to either trial it as a combination product or as a separate medical device. Again, that's been on the market for a while and, to the best of my knowledge, hasn't received approval yet. So, I think the next 3-5 years are really going to be able tell for those other products. For the core product lines, in the rubber I see the current products that they have just continuing to grow. I see customers taking their existing products and adding features to them.

I see those product lines continue to expand. If you look at it in the West world, with the high-value products, that will continue to be growing as far as their total sales. Right now, on the last, I think I saw per their presentation through 2018, a 10% increase. It's now what they term "high-value products" are now in excess of 50% of their total product portfolio and I see that growing over time. So, I think that's going to be the key driver rather than absolute volumes, as far as unit volumes.

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**Q:** West Pharma noted impressive margin expansion in its last earnings call. Do you expect this to continue? What further steps do you expect the firm to take for this to happen?

**BH:** I think that they had some pretty significant margin expansion, but that's driven off of operating leverage and volume primarily, so their margins will continue to grow in the short term here as they continue to pump that volume through the existing operations space. Post-COVID, when all the world starts to settle down again and their volume growth settles down, I think you get back to the normal operations bump-and-grind of looking to see cost savings in your facilities. They're very successful with that over the years. I think their last results over the course of, certainly, this year, have been remarkable, but it's been because of that operating leverage. I think that's a fairly short-term phenomenon. By short term I mean that we could be in a COVID environment for the next 18-24 months, but I would expect it to settle back down to maybe 50 basis points per year that you're able to streamline your operations, rather than the, what did they see last quarter, 250 basis points? That's operating leverage, pure and simple.

[00:40:55]

**Q:** You mentioned West Pharma's competitive positioning may not shift post-pandemic, but how do you expect its demand to trend? How might the company's COVID-19 work have shifted its demand expectations?

**BH:** If I were management right now I would be very nervous about how do I talk to the investor community post-COVID, because you've seen this inventory surge with your customers that is both COVID related and non-COVID related, and how do you talk to the investment community when your growth rates all of a sudden start declining markedly? There could very well be a point where you see a decline in net sales, YoY or QoQ and, again, that's just driven by the inventory phenomenon in the customer base. West has experienced that in the past. Seen it go through with various different product lines, when there are capacity constraints customers start ordering ahead. If you look at the business over a pretty long-term basis and take COVID out of it, it's a mid-to-high single-digit growth business, and it delivers that very reliably. You get some bumps along the road through extraneous factors that may drive it up or down over time, but looking at it over a very long-term horizon there really is a mid-single-digit growth business. They've obviously experienced a lot more growth than that over the last couple of quarters, some of that is mix related, the drive to high-volume products. Some of that is volume related. I think their most recent quarter, most of it, quite honestly, has probably been delivered by volume rather than mix. I would be very nervous if I were management right now about how do I talk to my investor base and make them comfortable that the business is still solid when the numbers have settled down to a much more normal basis.

**AA:** Can you share any commentary on the proportion of West Pharma's business segments you expect demand to shift in post-pandemic?

**BH:** No, I don't see any significant change there because, quite honestly, the world fundamentally, once we take COVID out of it, and even in the COVID environment, the world hasn't changed. People are still getting sick at a regular basis. I do not have a good feel whether vaccines will become more popular than they have been. There's a non-vaccine segment of the population out there, whether they will be more open to it in a post-COVID world or not, I don't know. If you look at the actual numbers and the number of products, I don't see any real shift out there other than the trends that are going on right now, and we've spoken about biologics being the key trend there. I think it's going to settle back into the framework that it always has, and certainly vaccines will be a part of it, but the therapeutics drive most of the volume.

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**Q:** You highlighted some concerns around there being strong long-term post-pandemic demand. What are your M&A expectations? Could it shore up some capacity?

**BH:** I don't see any M&A in terms of the rubber business because of anti-trust. That's been looked at over the years time and time again. I don't see any avenues to be able to capture more market share now through anti-trust. They would have to be the acquisition at the Datwyler portfolio and/or the Aptar portfolio, the old Stelmi business. I don't see anybody allowing that on an anti-trust basis, so they have very limited options there. There is ability, because of the breadth of it, in the device area, but you'd have to pick a segment out in the devices because it's such a broad concept of where do you place your bets in that industry? Historically, West has placed its bet on some new technology that's relatively nascent, that they could develop and nurture along. That feels, quite honestly, in the device side, it's so broad. I think they need to make an acquisition for future growth. I would foresee it to be on the device side of the spectrum, but what they're thinking about, who knows?

[00:48:09]

**Q:** What do you expect to be the biggest COVID-19-related challenge or hurdle for West Pharma? How do you think that some of those positions have addressed those hurdles?

**BH:** It all depends on what sort of hurdle you consider, or what you consider a hurdle. I still believe the franchise, with the base business, the rubber business, is rock solid, as long as they keep the quality and the delivery up, keep the customers happy, I don't see any real hurdles in that environment. Managing through a post-COVID world, I think there are going to be more than a couple of healthcare companies trying to do that, Pfizer being one. I expect them to get their emergency authorisation and start shipping, their results do certainly reflect that, and it's just going to be a fact of life that quite a few people are going to have to deal with. I don't see any real hurdles other than a swamp at some point here in the future, over the course of the 18-24 months, in volumes, but the base business is truly rock solid. Again, because of the FDA requirements, they're not going to lose any business. They may have a sales dip for two or three quarters, but they should settle back into historical rate right after that.

[00:50:31]

**Q:** Can you unpack West Pharmaceutical Services' regulatory considerations, highlighting any expected changes and whether its physicians think it is poised to withstand or react to those?

**BH:** In the regulatory landscape there will not be a revolution, it's always evolution, and it's just a continuing improvement of standards. I referred to earlier as the increase in testing equipment, well if you look over the last 20 years, the ability of the testing equipment to identify things that you don't think are on your product, that's improved markedly. Back in the early 90s when I started with West, there were always particular requirements on the product, but they were always visible particles, so you shouldn't be able to see anything on the product. Right now, they're up dealing in the micron level particulate, because they've got the ability to detect it, and so it's just going to be a continuation of those kinds of activities there, and customers are going to want the best for the product. That environment, I think, plays very well to West because, again, it's got the wherewithal to react to those market trends and the financial resources to either modify their plants to meet those regulatory requirements, or the ability to go out and to create new standards within the industry, which is fundamentally what it did way back in the late 90s with the Westar.

It established a washing criteria that, quite honestly, the FDA adopted and said, "This is how we would like to see things in the future." That's why you're seeing the expansion of the Westar product lines over the last 20-plus years. So, they're well positioned to take advantage of that, as well as their good relationships with the regulatory bodies. They've worked hard and established a lot of trust with the regulatory bodies, that West will do their homework and just put the science behind what they do.

[00:53:41]

**Q:** Would you like to mention any other key considerations for evaluating West Pharma or the broader drug packaging industry?

**BH:** Let's talk about West as a piece of the puzzle. One of their large franchises, within the rubber business, is the insulin business, do a lot of work for Novo, Lilly, Sanofi, the big three insulin producers. One issue that they're going to have to deal with, coming up here, is the advent of medical devices, insulin pumps, what amount to artificial pancreases that take the place of the pancreas. That's certainly one trend they're going to have to work through and deal with as that insulin business changes over time. That's going to be a slow change, but it's certainly one of the issues they're going to deal with. With respect to immediate threats, I don't see any short-term threats, and by short I mean 5-10 year threats, again, because the regulatory environment and the pharmaceutical customers tend to very conservative and change happens slowly in the pharma business. I certainly don't see the threats outweighing the opportunities. Unless there's a delivery breakthrough in the biologic term that lets pharmaceutical customers convert a protein-based drug, a large molecule drug, into an oral dosage form, which I have not seen anything that anybody's been successful on that front. That would be the only potential threat to them, even shortly beyond that five- and ten-year horizon. I think their challenge in a post-COVID world is going to be generating the kind of growth that they've exhibited to date, and where do they go from there? That's why the M&A picture, what other technologies are they acquiring, is going to become critical for them to maintain that growth level.

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**AA:** Given all of this, if there's nothing else on your end it seems like a good place for us to conclude. So, at this point, let me just finish by saying thank you so much, Bob, for your input and insights today. We definitely very much appreciate it, and thank you, clients, for joining Third Bridge Forum's Interview. Thanks so much.

**BH:** Take care.

Transcription ends at 00:56:56 of the recorded material